Once regulatory approval has been granted, the next stage in the life of a new medicine is usually taking the product to market. This is the point at which companies can begin to recoup the financial investment made in developing the new medicine. Yet even then significant commercial risks remain. The fact that a new medicine has been granted regulatory approval does not necessarily mean that it will become a commercial success. Licensure and adoption of a new medicine are not one and the same thing. This chapter therefore explores what happened to Tamiflu after it secured its marketing approvals and entered the marketplace. Would Tamiflu finally become the new blockbuster drug that Roche was hoping?

It would not—at least not initially. Once Tamiflu entered the marketplace, it quickly encountered a number of obstacles that prevented it from becoming the desired commercial success. Most countries ban direct-to-consumer marketing, making it very difficult for Roche to raise awareness of its new product among the potential customer base for Tamiflu. Some governments in key pharmaceutical markets also set up new institutions charged with scrutinizing novel medicines on cost-benefit grounds. Medicines would not just have to demonstrate that they are safe and effective; they would also have to represent good value for the money. All the while, parallel attempts by Roche to persuade governments to purchase Tamiflu for pandemic preparedness purposes largely fell on deaf ears during these early years. Several years after it obtained regulatory approval, the overall commercial performance of Tamiflu was proving quite disappointing for the company—especially when measured against the high initial expectations. Tamiflu was not likely to become a blockbuster product after all.
This unfavorable commercial picture only began to change in 2003. That year witnessed the unexpected reemergence of lethal human infections with highly pathogenic avian influenza viruses (H5N1) in Hong Kong. As deadly human infections with the H5N1 "bird flu" virus began to spread to other countries and eventually also moved closer to the borders of several high-income countries, government interest in Tamiflu suddenly peaked. With international concern about an imminent flu pandemic now skyrocketing, Tamiflu’s first—and fairly unsuccessful—commercial life as an antiviral medication for seasonal flu faded into the background, as the antiviral rapidly transitioned into its second (and much more prosperous) life as the world’s most prominent medical countermeasure against the looming pandemic flu threat. In a complete reversal of Tamiflu’s commercial fortunes, there was suddenly a massive explosion in global demand for the drug—with governments, corporations, and individuals all clamoring to acquire scarce international supplies of the antiviral as the first line of defense against pandemic flu.

This sudden reversal in the global demand for Tamiflu reveals two further challenges surrounding medical countermeasures more generally. First, governments also have to carefully gauge their demand for such products to ensure that they have access to the right number of the right medical countermeasures at the right time in order to protect their populations. It may not be feasible for governments to simply wait until an emergency has occurred before trying to obtain them. That is because such medical countermeasures may need to be administered very rapidly, because governments may require a larger volume of such medical countermeasures than normal supply chains can quickly deliver, and because those existing supply chains may themselves become disrupted during an emergency. Again, the security context within which medical countermeasures would be used begins to complicate matters considerably.

In the case of Tamiflu, many governments have tried to address this challenge by creating new emergency stockpiles of the antiviral. Yet simply having warehouses stacked full of such medical countermeasures would also be fairly pointless without a parallel logistical strategy for rapidly distributing them to the population in the event they are urgently needed. Even once a pharmaceutical stockpile has been set up, governments must still give further thought to exactly how those medical countermeasures would then be distributed to individuals in a very short period of time—and
possibly in a context where normal distribution channels have become disrupted because of the outbreak of a pandemic. In addition to the demand management challenge, there is thus also a second logistical challenge that emerges at this stage about how governments would go about mass distributing such stockpiled medical countermeasures to the population when a future emergency transpires.

These two additional challenges, moreover, again also show that developing an effective medical countermeasure capability is ultimately not just a narrow question of how governments can encourage pharmaceutical companies to develop a few new products. Governments will also need to do much more than that if they wish to secure their populations pharmaceutically. They will need to further ensure that they would have access to the right number of medical countermeasures at the right time. They will also need to put into place systems for quickly distributing them to the population during a future emergency.

Tamiflu on the Tightrope: Struggling for a Viable Commercial Market

Once regulatory approval for Tamiflu was secured, Roche still faced a number of hurdles before it could begin to make a profit from its new product. The biggest of these challenges was to figure out how the company would raise awareness about its new antiviral product among patients. After all, if doctors and patients did not know that this new product for treating the flu even existed, they could hardly prescribe and purchase it. What is more, people were generally not accustomed to going to their doctor to treat the flu. Popular wisdom dictated that adults who were otherwise healthy should stay at home, drink plenty of fluids, and rest in bed. Yet if Tamiflu were to work as intended, patients would have to begin treatment during the early onset of the illness. All of this meant that for Tamiflu to become a commercial success, Roche would first have to do nothing short of changing people’s flu-related behavior and get them to actively seek out their doctors at the earliest signs of flu. Mathias Dick, product manager for Roche Pharma Switzerland at the time, succinctly summarized the challenge in the following terms: “For seventy years we had been telling people that the best thing to do for influenza was to stay in bed . . . yet now we had to convince them to go to see their doctor” (Schneider 2001). Provoking such behavior
change was going to prove especially challenging in the world’s major pharmaceutical markets.

The Ban on Direct-to-Consumer Marketing

The first hurdle that Roche confronted in turning Tamiflu into a commercial success was that the advertisement of medicines is heavily regulated in many of the world’s pharmaceutical markets. That problem is illustrated very well by the case of Switzerland, where Tamiflu had received the world’s first regulatory approval. Swiss law stipulated that new medicines would need to be prescription-only for the first five years after licensing. On top of that, the country also operated a ban on direct-to-consumer marketing for prescription medicines. How would Roche raise awareness of the drug among patients and doctors within the Swiss regulatory environment? Various ideas were floated and tried. Mathias Dick’s team at Roche first developed credit card–sized leaflets explaining the difference between influenza and a common cold. The cards also provided a telephone number for queries and an Internet address. More than five million of the cards were distributed in Switzerland alone (Schneider 2001).

In parallel, Roche also developed a new poster campaign with messages along the lines of: “What do you know about influenza? Find out about it. Now. www.Tamiflu.ch” (Schneider 2001). The design of the new poster campaign was clever in that it did not explicitly mention the drug by name, but the name was clearly embedded in the website domain name: www.Tamiflu.ch (Baumgartner 2000). Roche’s team also developed an informational campaign tour of 12 Swiss cities to make doctors and pharmacists aware of the new drug. The company even flew some Swiss journalists to a press conference in London, which provided them with background information on the health and economic threat posed by flu and how Tamiflu worked (Schneider 2001).

Unsurprisingly, perhaps, the Swiss authorities were not entirely pleased with all of those activities. In their opinion, some of the campaigns fell afoul of the relevant regulations. They therefore prohibited Roche from using the Tamiflu name in the Internet address that formed part of its advertisements, and eventually the domain name was changed to www.roche-grippe.ch (Baumgartner 2000). In this kind of regulatory context Roche was clearly going to struggle to turn Tamiflu into a significant commercial success.
Reflecting on the outlook at the time, and given that the success of the drug requires patients to change their flu behavior by rapidly going to their doctors, Roche’s marketing team suspected it would take at least five to ten years for the drug to establish itself in the market (Schneider 2001).

The kinds of regulatory constraints Roche encountered in Switzerland would also feature in other European markets. Direct-to-consumer advertising of prescription medicines is prohibited throughout the European Union. In fact, direct-to-consumer marketing of prescription medicines is banned in most countries around the world—with the notable exceptions of the United States and New Zealand. Even in those two countries, where it was made legal in the late 1990s, the practice is controversial, and in both countries there have also been subsequent attempts to change the legislation in a way that would introduce a moratorium on advertising newly approved drugs (Magrini and Font 2007). In the United States, such advertising also remains subject to regulation by the Food and Drug Administration. From a strictly commercial point of view, the bans on direct-to-consumer marketing thus posed a significant hurdle to a more widespread promotion and adoption of Tamiflu.

That said, the United States was clearly one of the few countries in the world where Roche could unleash its full marketing prowess in a more unrestrained manner. Glaxo Wellcome was already heavily promoting its rival product Relenza there, even recruiting the celebrity Wayne Knight from the popular sitcom *Seinfeld* to play the role of an obnoxious houseguest called “influenza” (West 2000: 122). To quickly make up ground, Roche worked with the specialist company Edelman New York (West 2000: 120). The US marketing campaign for Tamiflu would begin on 15 November 1999—only three weeks after the FDA had approved Tamiflu—and would include both television and print ads (West 2000: 120). All would feature a toll-free number, 1-800-I-GOT-FLU, and a website address, www.Tamiflu.com (West 2000: 121).

The campaign’s most creative idea, however, was undoubtedly the use of the Tamiflu van. This van, or truck, featured a live actor on display in a glass-enclosed, fully furnished apartment (roughly 9 feet by 20 feet) mounted on the back of a truck. In plain view, the actor would get out of bed in his pajamas and undertake a number of mundane activities, such as eating breakfast and reading the newspaper. He would then go watch TV, work, play video games, and so forth, all inside this glass apartment without
paying any attention to the bystanders who could clearly see everything he was doing. The punch line—printed across the side of the truck—was “One person in this town who can probably feel safe from the flu . . . For the rest of us flu sufferers, there’s Tamiflu.” The tour made its way through America’s 71 largest flu markets using a total of 8 such mobile apartments (Bittar 2001).

As the creative marketing campaign began to bear fruit, Tamiflu went on to dominate the antiviral flu market, securing a 58 percent market share in the United States and achieving $41 million in sales from November 1999 through to April 2000, compared to Relenza’s at $20 million (Bittar 2001). Coming to market second rather than first had not been such a disadvantage after all. One influenza scientist interviewed for this book recalls that the timing of the peak flu season around the Christmas vacation that year may also have played a role. Glaxo Wellcome had apparently shut down its computers because of fears about the millennium bug—meaning that they could not ship Relenza from France where it was being produced (but Relenza also later developed some issues with side effects) (Influenza Scientist 2014). In either case, the commercial situation with Tamiflu in the United States very much marked the exception rather than the rule—especially when compared with the wider international picture.

A Fourth Hurdle? NICE and the Rise of Cost-Benefit Analysis

Roche (and Glaxo) also faced another hurdle in trying to turn their new neuraminidase inhibitors into blockbuster products. In some of the world’s key pharmaceutical markets, governments were in the process of setting up new institutions to further scrutinize new medicines on cost-benefit grounds. Many governments continue to be faced with spiraling health-care costs and have to make difficult decisions about how to allocate limited public resources. Because neuraminidase inhibitors seemed to reduce the duration of symptoms by “only” around one day, Relenza and Tamiflu were often considered to be borderline drugs in terms of their cost-effectiveness. Going back once more to Roche’s home market, for example, Swiss health insurance funds were generally not willing to reimburse the costs of these new medicines and were demanding price reductions of 20 percent. They felt that the utility, effectiveness, and public health benefits did not justify the price and also that at those prices it would make more sense to just keep vaccinating (Schlatter 1999).
The battle between governments and pharmaceutical companies over cost-effectiveness came to a particularly dramatic head in the United Kingdom. There, the licensing of Relenza coincided with the creation of the new National Institute for Clinical Excellence (NICE). NICE is charged with advising the UK National Health Service on the clinical and cost effectiveness of drugs. The very first drug appraisal that the new organization ever carried out was on Relenza. In discussions with NICE, it was agreed that Relenza should be subject to a fast-track assessment prior to the 1999–2000 influenza season. Glaxo Wellcome accordingly made its Relenza submission to NICE on 1 September 1999. Everyone realized that the outcome would be crucial for all sides—for the company in terms of the future market for Relenza, as well as for NICE in terms of establishing itself as a credible new institution.

After conducting its review, NICE arrived at the one conclusion that the pharmaceutical companies had probably feared most. It advised that “health professionals should not prescribe zanamivir (Relenza) during the 1999/2000 influenza season” (NICE 1999: 2). NICE had sent a clear signal that cost-benefit analysis would become much more critical for governments moving forward and that pharmaceutical products that did not meet its threshold would henceforth have a much harder time.

Market analysts quickly pointed to the decision’s wider commercial significance. According to Nigel Barnes, analyst at the wealth management firm Merrill Lynch, “If you look at the UK [which accounts for 6 percent of global drugs sales] in isolation, this decision would probably have minimal impact. . . . But it could have ramifications elsewhere, particularly in Europe where healthcare expenditure is under even greater focus” (quoted in Pilling 1999). From the commercial side, there was particular concern that NICE’s decision could influence regulators in Japan, where a similar approval process was under way. Japan was the world’s second biggest drug market at the time (Pilling 1999).

If Glaxo was shocked by this decision, so too was the wider UK-based pharmaceutical industry. The industry upset caused by the decision was so great, in fact, that the British Pharma Group—made up at the time of AstraZeneca, Glaxo Wellcome, and SmithKline Beecham—took the unusual step of writing a letter directly to the British prime minister, Tony Blair. The letter claimed that the companies were “appalled at the recommendation” and pointed to the “potentially devastating consequences for the future of
the British-based pharmaceutical industry.” The letter also expressed concern that NICE was now effectively operating as a “fourth hurdle” for new medicines: “Much damage has already been done by the signals sent out by NICE’s recommendations on Relenza,” it asserted, and “the landmark ruling on Relenza makes it crystal clear that our worst fears were fully justified” (McKillop 1999). NICE would not succumb to such political pressure by the industry, however. When it issued further guidance the following year (in November 2000), it again found that “for otherwise healthy adults with influenza, the use of zanamivir is not recommended” (NICE 2000: 1). By 2004 Glaxo would have only sold around £4 million worth of the drug (Jack 2006).

If the NICE assessments did not go well for Glaxo’s Relenza (zanamivir), Tamiflu (oseltamivir) did not fare much better a couple of years later. NICE issued recommendations on oseltamivir in February and September 2003—looking separately at the questions of treatment and prophylactic use. The first only recommended use in “at risk” adults and children presenting with influenza-like illness and who could start therapy within 48 hours of the onset of symptoms (NICE 2003b: 1–2). The second did not recommend oseltamivir for seasonal prophylaxis of influenza but recommended postexposure prophylaxis for certain “at-risk” groups aged over 13 who were exposed to someone with influenza-like illness, who could begin prophylaxis within 48 hours, and who were not protected by a vaccine (NICE 2003a: 4).

In either case, greater government emphasis on cost-benefit considerations began to form a second “hurdle” to the widespread adoption of these new antiviral drugs—especially given the claimed reduction in symptom duration of around one day. The commercial developers of neuraminidase inhibitors were now effectively faced with a dual challenge. Even though they had developed a new drug and obtained regulatory approval, in most markets they could not advertise widely for their new product, and new agencies like NICE that were increasingly looking at cost-benefit issues were not recommending widespread adoption of the new medicine. Things were not going well. As one report in the PharmaTimes from 2003 noted, “Despite the fanfare hailing these products, they have not been the hoped-for success both firms had anticipated and Tamiflu generated just 97 million Swiss francs in 2001 (the last figures available) despite being made available in more than 40 countries around the world following
concerns over their cost-effectiveness” (PharmaTimes 2003). It was becoming increasingly clear that neuraminidase inhibitors were unlikely to become the blockbuster products that the companies had initially hoped for.

Falling on Deaf Ears: Government Reluctance to Create Pandemic Stockpiles

With efforts on seasonal flu running into difficulties, Roche still had one last option left in its playbook to turn around Tamiflu’s commercial fortunes. Given the dual nature of the flu challenge, the company could instead try to push the antiviral for pandemic flu. Thus, Roche also began to approach governments to see if they would be interested in acquiring the drug as part of their pandemic preparedness planning. Sales made directly to governments for such pandemic preparedness purposes would not require direct-to-consumer marketing. Nor would they be subject to the same kinds of cost-effectiveness evaluations increasingly conducted for seasonal use. Indeed, health security threats and pandemic flu (rather than seasonal flu) were generally seen to be beyond the remit of organizations like NICE. Given the large number of governments in Europe (and around the world), as well as the need to create sizable stockpiles to cover a significant proportion of the populations, pandemic preparedness could form a very different route toward commercial success for Roche to pursue.

However, most governments at the time did not take Roche’s early attempts to warn about the specter of a renewed pandemic very seriously. In fact, they proved remarkably recalcitrant in not placing stockpiling orders during those early years. According to David Reddy, Roche’s influenza pandemic team leader at the time, Roche was discussing pandemic preparedness plans with various governments, but, he said, “Our awareness campaigns had fallen on deaf ears. The threat was perceived as too elusive. The few orders that did come in were nothing we could not cope with” (quoted in Samii and van Wassenhove 2008: 1). Even though WHO was by this time recommending that governments make pandemic preparedness plans, and Roche was trying to convince governments to stockpile Tamiflu, most governments still had no pandemic preparedness plans in place (Samii and van Wassenhove 2008: 6). One former Roche employee even recalled, “I remember how some regulators almost ridiculed us and laughed
at us saying a pandemic—what’s that?—that’s never going to happen” (Bergstrom 2013).

One country where Roche’s argument about the need for government stockpiling strategy gained at least some traction was the United States. US preparations for a possible pandemic had begun to gather pace in August 1997. That year the CDC conducted an outbreak investigation on avian influenza (H5N1) infections occurring in poultry and humans in Hong Kong. It was the first time such infections had been detected in human beings, and a significant proportion of them proved lethal. In this context of escalating pandemic fears, the US government awarded a small contract to AmeriSource/McKesson at the end of 2003. The contract was for $10.6 million to acquire 238,000 treatment courses of Tamiflu using funds from the Strategic National Stockpile (US Senate 2005: 20). In 2004 this was followed with another contract with Roche for $74 million to acquire 2.1 million treatment courses of Tamiflu, again using Strategic National Stockpile funds (US Senate 2005: 20).

That said, even the US Tamiflu stockpile was still quite small and would not make a huge difference to the overall profitability of the drug. Internationally, it also very much marked the exception rather than the rule. The overall commercial picture for Tamiflu therefore continued to look quite bleak by this point, and it did not seem likely that pandemic preparedness arguments would be able to offset the poor commercial performance of Tamiflu for seasonal flu. As Roche’s Franz Humer, who had initially acquired the drug for Roche from Gilead, explained in an interview for the Financial Times at the time, “Our forecasts were more optimistic initially. . . . We had thought that doctors would prescribe and governments reimburse” (quoted in Jack 2006). By and large that assumption proved incorrect, with the notable exception of Japan, which agreed to reimburse health services for Tamiflu (Jack 2006). With low prescription figures, Tamiflu was not even on the list of the 20 most sold Roche medicines by 2003 (Vetterli 2009).

By this stage, then, Tamiflu was fast becoming a commercial flop—notwithstanding all of the investment Roche had put into acquiring the molecule from Gilead, developing it, setting up mass manufacturing facilities, carrying out the clinical trials necessary for regulatory approval, marketing it, and so forth. The whole Tamiflu experience was fast turning into
a salutary reminder that acquiring regulatory approval alone is no guarantee of commercial success, and of just how careful pharmaceutical companies need to be in deciding which medicines to take forward. Even where there is a fairly clearly defined commercial market, there is still no certainty that commercial success will ensue. So Tamiflu’s first life as a fairly conventional pharmaceutical product aimed at the seasonal flu market slowly started to fade into the background.

**Tipping Point: Tamiflu as the First Line of Defense**

The international picture around Tamiflu suddenly changed very dramatically through an unexpected turn of events in 2003. That year saw the surfacing of new reports about a type of highly pathogenic avian influenza—H5N1—sporadically infecting humans in Asia. The authorities in Hong Kong had first encountered such human infections with the H5N1 virus in 1997 but quickly took measures at the time to contain the initial outbreak—including the culling of many birds. The measures appeared successful, and things went quiet for several years. In 2003, however, human cases of lethal infection with H5N1 reemerged in the city. Further clusters were then also detected in Vietnam in February and March 2004. Those cases were particularly significant because human-to-human transmission could not be immediately ruled out, raising significant international concern about the possible onset of a new pandemic (WHO 2011a).

Over time, further human infections with the H5N1 virus were registered in other Asian countries and started moving closer to the borders of Europe. The advent of such lethal new cases of human infections with H5N1 in Asia, in conjunction with an H7N7 influenza outbreak in the Netherlands that caused a human fatality, would mark a crucial turning point in the history of Tamiflu. Suddenly the possibility of a new flu pandemic seemed much more palpable to politicians, and governments could see that they were likely to come under much more political pressure to ensure that they would be prepared for the possibility that these outbreaks could turn into a wider pandemic. What would governments do to protect their populations in that eventuality, and would they have taken the necessary precautions to ensure that they had access to antiviral medications and vaccines?

To make matters worse, a number of governments had recently appeared quite unprepared in the face of other unexpected crises. They would thus be
keen to avoid a politically damaging repeat. In the United States, for instance, President George W. Bush’s administration was still reeling from its botched handling of Hurricane Katrina and needed to better prepare for catastrophic events with a small probability but a high impact (Schulz 2005). French president Jacques Chirac similarly wanted to avoid a repetition of the political fallout from the excessive deaths of elderly people that had recently been caused by summer heat waves. In the United Kingdom the experience of a foot-and-mouth disease debacle still lingered (Jack 2009). With the spread of H5N1, all eyes would now be on governments once more to gauge how capable they would be at handling the next crisis—and it looked like that next crisis might well be a flu pandemic (Caduff 2015). In this context, the interests and priorities of many governments changed as they suddenly felt popular and political pressure not to be unprepared (Lakoff 2018).

Precisely that political realization ushered in Tamiflu’s second life as a prominent medical countermeasure against pandemic flu. Moving forward, government considerations around the drug would be governed less by strict cost-benefit considerations and more by security logics and political imperatives that now moved into the foreground. Shifting out of the context of seasonal flu and into that of pandemic flu fundamentally transformed the financial arithmetic around Tamiflu. Given that a pandemic posed a potentially much more serious and disruptive economic threat than seasonal flu, even modest clinical benefits would be seen as desirable, especially when aggregated at population level. Rather than assessing the drug economically on strict cost-benefit grounds, the political logic now morphed into one of taking out “insurance” against the possibility of a potentially catastrophic threat. As one senior policy maker working on influenza in Europe explains, “The problem that comes with pandemics is that you are looking much more for an insurance policy approach than you are for value for money” (European Influenza Expert 2012). The threat of a pandemic was beginning to shift the government calculus toward using public funds to purchase significant quantities of Tamiflu, and the prospect of large-scale government stockpiles of Tamiflu began to open up politically. Government demand for Tamiflu began to rise sharply as a result. It rose so sharply, in fact, that there was now effectively an international run on the drug—with government demand rapidly outstripping what the commercial supply chains could generate.
Guidance issued by the World Health Organization in 2005 played a crucial role in this political process. WHO guidance was that some drugs available for the treatment and prevention of influenza could also be effective in treating the illnesses caused by avian influenza (WHO 2005: 48–51). While acknowledging several constraints, the guidance found that “antiviral drugs have important roles to play, both now and at the start of a pandemic” (WHO 2005: 49). Antivirals would be particularly crucial during the early phases of a pandemic, because vaccines will not yet be available at that stage: “Under pandemic conditions, their [antivirals’] importance is elevated during the first wave of infection when vaccines—unquestionably the most useful medical tool for reducing morbidity and mortality—are not yet available. In the absence of vaccines, antiviral drugs will be the only medical intervention for providing both protection against disease and therapeutic benefit in persons who are ill” (WHO 2005: 49). As the only medical intervention available in the early phases of a flu pandemic, antivirals would effectively come to constitute the first line of defense—at least for those countries that could secure access to them.

Yet how could governments ensure that they would have sufficient Tamiflu available to protect their populations? Governments would need access to sufficiently large quantities of the antiviral to cover significant proportions of their populations. They would also need to administer them very quickly to their citizens, because these pharmaceutical interventions had to be taken early on in the course of infection. Yet usage of the antiviral for seasonal flu was very low in most countries. This meant that existing supply chains were unlikely to be able to satisfy this surge of demand during such a pandemic (Nguyen-Van-Tam 2015). Nor could governments simply try to buy more stocks once a pandemic occurred, because many countries around the world would then all be chasing scarce global supplies of Tamiflu at the same time. There could thus be no guarantee that sufficient quantities of Tamiflu would actually be available in the global marketplace to fulfil a government order during a pandemic. If a government wanted to be prepared, special arrangements would have to be made. WHO accordingly advised governments that “stockpiling drugs in advance is presently the only way to ensure that sufficient supplies are available at the start of a pandemic” (WHO 2005: 51). Many governments decided to follow that advice and began to build such stockpiles to ensure that they would indeed have
the right medical countermeasure available in the right quantities and at the right time.

How large should those new government stockpiles be? That question generated a lot uncertainty among influenza experts. Although WHO guidance did not provide a specific figure, its estimate that such a pandemic could affect around 25 percent of the population proved to be a widely adopted reference point for many pandemic preparedness planners (Jack 2006). In general terms, and reflecting on the European experience in particular, one senior European policy maker working on influenza described the process of deciding appropriate levels of stockpiling in the following terms: governments “would seek advice but eventually the decision is a central one, a political one”—not least because “we have to say, Look, there isn’t an answer for that because it so much depends on the virus and the new virus that is emerging.” (European Influenza Expert 2012).

By and large, countries that decided to build Tamiflu stockpiles wanted to be able to cover a significant proportion of their population. So the first and foremost effect of shifting to a health security logic was to stimulate a rapid global rise in demand for Tamiflu as governments clamored to create pharmaceutical stockpiles for their populations.

Stockpiling Frenzy: H5N1 and the Pandemic of Preparedness Planning

Which governments were first out of the gate in what was quickly becoming a global race to stockpile Tamiflu? The first countries to stockpile tended to be high-income countries that were either in close geographic proximity to some of the human cases of H5N1 reported in Asia or that had already suffered earlier formative experiences with other infectious disease outbreaks. The Australian government, for example, began to build up a stockpile of antivirals as early as February 2004. In April 2004 it then placed a Tamiflu order to treat nearly 20 percent of the Australian population. According to Tony Abbott, then minister for health and aging, their order “virtually cornered the world anti-viral market for 12 months” (Abbott 2005).

Canada was another country to build an early stockpile. It announced a government purchase of Tamiflu in February 2005 to treat nearly one million people (Jack 2006). Canada’s decision was likely linked to its earlier experiences with SARS in 2003, which had led to 438 suspected cases and 44
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deaths (Jack 2006). Canada thus had relatively recent and firsthand experience with the impact of a new infectious disease outbreak, with WHO even issuing travel adversaries for people traveling to Canada at the time. Together with the United States and Australia, Canada formed part of the first wave of governments moving toward a policy of creating government stockpiles of Tamiflu.

Although the US government had begun stockpiling Tamiflu as early as 2003 within the context of its Strategic National Stockpile, it had initially only acquired relatively small quantities. As late as 2005 Roche would still have to remind the US Congress that US stockpiling efforts were lagging considerably behind those of other countries around the world. Roche warned Congress that “other nations are currently well ahead of the United States in Tamiflu stockpiling; and . . . the U.S. has to make commitments now to ensure a timely and adequate supply of Tamiflu” (US Congress 2005). The US government did begin to signal such a considerable change in its stockpiling ambitions later that year, as Secretary of Health and Human Services Michael Leavitt indicated his intention to build a much more sizable stockpile to Congress:

I’d like to make an important point. Anti-virals are an important part of a comprehensive plan, but anti-virals are not the equivalent of preparation. There is no certainty of their effectiveness on any particular virus. There is no capacity to change the anti-viral if the virus adapts. There are distribution dilemmas. Nevertheless, it’s a very important part of a comprehensive plan, and the plan does call for us to build a stockpile of 20 million courses. The vendors have represented to us that those could be delivered by the fourth quarter of 2006, and we could build our collective stockpiles to 81 million by the summer of 2007. Again, that’s a date vendors are able to meet. (quoted in US Senate 2005)

That would allow for enough drugs to cover 25 percent of the US population (more than 75 million people), leaving another 6 million courses to contain any initial US outbreak (US Senate 2005).

The US stockpile was notable not only because of its large size (especially in absolute terms); it also stood out because the US government wanted the entire Tamiflu supply chain to be established within the territorial borders of the United States. The government was concerned that, in the event of a global pandemic, international distribution systems might encounter severe disruption. Given a global shortage of supply, moreover, other countries
might also nationalize existing stock or production facilities. According to Secretary Leavitt, part of the rationale for the sizable US government order was thus to “enable manufacturers to make significant expansion in its U.S.-based manufacturing capacity—thereby positioning itself to meet future demands much more readily than currently is possible” and thus also helping the United States meet its longer-term pandemic preparedness and health security objectives (US Senate 2005: 11). Roche duly complied with the request, and the United States ended up building one of the world’s largest stockpiles of Tamiflu.

It is more difficult to obtain reliable information about stockpiling in Europe. That is because Roche will not release information about government orders, insisting that it is up to those governments to disclose their orders if they so choose (Roche 2012: 9). However, it appears from several sources that 2005 marked the turning point for government stockpiling efforts in Europe as well. William Burns, head of Roche’s pharmaceuticals division, pointed out in October 2005 that “following four ducks (that died) in Romania last weekend, Europe went mad. I don’t think you’ll find a single pack (of Tamiflu) in Paris. And this is not because we’ve had an influenza outbreak” (quoted in S. Turner 2005). The dead birds found at Europe’s borders began to focus minds and would even begin to cause a run on Tamiflu in several countries. Roche’s David Reddy observed at the time how “in one country we sold within a week the amount that we would normally sell in an entire year! We had to give priority to government orders as well as ensure treatment of people during the regular influenza season” (quoted in Samii and van Wassenhove 2008: 7).

Additional information about European stockpiling activities can be gleaned from a 2005 review of European pandemic plans conducted on the basis of information in the public domain at the time. It found that 20 countries in Europe had developed an antiviral-drug strategy (Mounier-Jack and Coker 2006: 1408). The study also found that 13 countries had publicly acknowledged stockpiling but that provision for individual countries varied greatly—ranging from 2% to 53% population coverage (Mounier-Jack and Coker 2006: 1410). A similar review of the situation undertaken only one year later (in 2006) pointed to a further increase in the stockpiling trend in Europe. Focusing on European national strategic plans for pandemic preparedness published before the end of September 2006, this study found that of the 29 plans it surveyed, “most plans stated an intention to stockpile
antiviral drugs, with 14 noting that a stockpile had been secured” (Mounier-Jack et al. 2007). The study was supported by a grant from Hoffmann-La Roche, the manufacturer of Tamiflu.

Several public health experts interviewed for this book noted how such studies generated some unease in European policy-making circles. Indeed, the studies were perceived as exerting an unhelpful form of pressure on governments to explain how they had set their stockpiling levels—especially when some other governments appeared to have set higher targets. Several interview subjects also expressed the view that industry had been quite aggressive in pushing antivirals and that there was also peer pressure involved (e.g., Tegnell 2012). One senior European influenza policy maker working on influenza even pointed to the slightly awkward way in which these kinds of studies were carried out. After all, Roche would have known pretty accurately from its own order books which governments in Europe were stockpiling and at what levels, but because of the confidentiality clauses in the contracts, the company could not reveal this information. To get around that constraint, Roche essentially paid somebody to use the Internet to determine what levels could be reported based on public statements (European Influenza Expert 2012). “Personally,” one policy maker recalls, “I was a bit unhappy about creating a culture of competitiveness in between the countries as to who’s got the biggest useless stockpile because they couldn’t deliver it” (European Influenza Expert 2012). Governments at the time would certainly have been looking over their shoulders to see what other countries were doing.

In retrospect, then, perhaps the most striking aspect about this competitive race to stockpile is that most European countries tried to go it alone rather than joining together. Given the many different European Union member countries that were simultaneously trying to obtain stockpiles, they could conceivably have taken a more coordinated EU-wide approach. In that way, the governments could also have presented a more united negotiating position vis-à-vis Roche. Speaking in 2007, the EU commissioner for public health at the time, Markos Kyprianou, indicated that he had made stockpiling one of his personal priorities. He certainly saw scope for a European stockpile that would not so much replace those of member states but could at least serve as an emergency stockpile for strategic use. The project never got off the ground, however, because of the absence of an appropriate EU competency in this area and a lack of support
from some member states (Trakatellis 2007: 25). This stood in marked contrast to other regional groupings, most notably in Southeast Asia, where it was agreed to establish a regional stockpile (Trakatellis 2007: 25), with an antiviral stockpile of 500,000 courses to be held in Singapore (Ghosh and Soeriaatmadja 2006).

In either case, government stockpiling of Tamiflu would become a widespread international phenomenon over the coming years. By 2009 a total of 95 governments around the world had purchased or ordered pandemic Tamiflu stockpiles according to Roche. The company later also reported that it had supplied governments around the world with 350 million treatment courses (3.5 billion doses) of Tamiflu between 2004 and 2009 (Reddy 2010: ii35). Tamiflu was now effectively enjoying a second life as a medical countermeasure and first line of defense against the pandemic flu threat. In a complete reversal of its commercial fortunes, the pandemic threat meant that there was suddenly huge global demand for Tamiflu, and governments seeking to stockpile the antiviral for their populations now formed a significant chunk of that global demand.

**Donald Rumsfeld and the Pentagon Stockpile**

Many of those new Tamiflu stockpiles were aimed at the civilian population. Yet some governments also wanted to set up additional stockpiles for particular subgroups to ensure that core elements of the state would be properly protected and could continue to function during a pandemic. One particularly colorful chapter in the history of Tamiflu thus relates to the attempt by the US Department of Defense to create a Tamiflu stockpile specifically for the US military. The attempt generated a number of media headlines because of the close role that the secretary of defense at the time, Donald Rumsfeld, had previously played in Gilead Sciences—the company that invented the drug, owned its patent, and still received royalties on worldwide sales from Roche.

John Stanton, working at the time for the Washington, DC–based political news group Roll Call, researched the likely impact of the 2005 pandemic concerns on Donald Rumsfeld’s financial fortunes at the time. Prior to being sworn in as secretary of defense, Rumsfeld had received a generous send-off from his colleagues at Gilead Sciences. John C. Martin, president and chief executive officer of Gilead, said at the time that “Don Rumsfeld’s insight and contributions over the last twelve years have been invaluable as
Gilead has evolved from a promising biotech company into the worldwide biopharmaceutical corporation it is today” (Business Wire 2001). But what would happen with Rumsfeld’s financial links to the company once he became secretary of defense? Upon taking up his new political office, Rumsfeld was not required to liquidate his extensive stock holdings in Gilead Sciences because the company was not a defense contractor (AFP 2005). Federal disclosure documents submitted by Rumsfeld at the time indicated the he had holdings in Gilead Sciences of approximately $5 million to $25 million (Schwartz 2005a).

In characteristic style, Rumsfeld was deeply dissatisfied with the entire process of having to submit such financial disclosure documents. In a letter to the Office of Government Ethics, he complained at the time that the forms were “excessively complex and confusing” (AP 2002) and said of the forms that “they’re so complex that no human being, college educated or not, can understand them” (quoted in Washington Post 2002). Rumsfeld was also unhappy about the fact that he had incurred more than $60,000 in accountant’s fees just to fill out the forms (which he claimed he did not have time to complete himself) (AP 2002). The forms revealed assets worth between $53 million and $175 million at the time (Washington Post 2002) and indicated that Rumsfeld also had to sell between $20.5 million and $91.2 million in assets and investments as part of the process of becoming secretary of defense (AP 2002).

Following Rumsfeld’s complaint, the director of the Office of Government Ethics at the time, Amy Comstock, dutifully responded. She acknowledged that the form was confusing and indicated plans to create simpler forms for the future. However, she also reminded Rumsfeld that public disclosure performs a “vital role” in preventing conflicts of interest from arising (Washington Post 2002). To this day, Rumsfeld continues to complain about the complexity of the tax code and that, despite employing accountants, he is not sure whether he is paying the correct amount of taxes (Forbes 2014). In either case, Comstock’s warning about potential conflicts of interest would prove prescient when the issue later surfaced in relation to the decision by the Pentagon to create a Tamiflu stockpile.

It is likely that the value of Rumsfeld’s Gilead shares appreciated significantly because of the rise of international pandemic concerns about H5N1. Rumsfeld reportedly sold some of those shares in 2004, generating $5 million in capital gains according to his financial disclosure report (Lean
and Owen 2006). The following year, in 2005, amid rising pandemic fears, the value of Gilead stock prices increased further, from $35 to $47 per share, with *Fortune* magazine reporting that Rumsfeld would have made at least $1 million dollars on his Gilead stock (Schwartz 2005b). John Stanton has calculated that the rise in Gilead stock from the end of 2004 to the end of 2005 would have meant that the value of Rumsfeld’s personal holding would have increased by between $2.8 million and $13.77 million—figures that do not include Gilead shares that Rumsfeld may have previously transferred into a foundation and a trust that he controls or any investments in Gilead made by investment companies that Rumsfeld cofounded and maintains a financial interest in (Stanton 2005).

Given his continuing financial interests in Gilead Sciences, Rumsfeld’s role in the decision-making process around building a Tamiflu stockpile for the Department of Defense also attracted media scrutiny. The Pentagon placed an order for $58 million worth of Tamiflu to protect US troops around the world in July 2005 (Schwartz 2005a; AFP 2005)—a decision that could present a conflict of interest given Rumsfeld’s role as secretary of defense. The issue was subsequently raised in a press conference on 1 November 2005. During the press conference Rumsfeld reportedly responded that—following consultation with the Senate Ethics Committee, Department of Justice attorneys, and an attorney specializing in private securities—he had decided to maintain control of his stock but to not participate in any decision that might affect Gilead (Stanton 2005).

Rumsfeld said at the time: “I did consider every option and went to all of these people for advice, and finally made a decision that it would be a problem were I to sell it in the current situation” (quoted in AFP 2005). That was also the message put out by Gilead Sciences, a representative of which pointed out at the time: “Secretary Rumsfeld has no relationship with Gilead Sciences, Inc beyond his investments in the company. When he became Secretary of Defense in January 2001, divestiture of his investment in Gilead was not required by the Senate Armed Services Committee, the Office of Government Ethics, or the Department of Defense Standards of Conduct Office. Upon taking office, he recused himself from participating in any particular matter when the matter would directly and predictably affect his financial interest in Gilead Science” (quoted in Lean and Owen 2006). According to a spokesperson, this arrangement was also communicated to Department of Defense employees by Defense General Counsel William
Haynes in a letter on 27 October 2005. The letter reminded staff that Rumsfeld could not participate personally or substantially in any matter (including the prevention and treatment of flu) that could directly and predictably affect his financial interest in Gilead (AFP 2005).

Stanton also points out, however, that this letter was issued only after the Department of Defense had already decided to stockpile the medication (Stanton 2005). What is more, the memo stated that Rumsfeld could continue to deal with wider issues surrounding avian flu—including the issue of possible quarantines and the use of US troops: “The secretary may participate personally and substantially as these matters will not directly and predictably affect Gilead” (quoted in AFP 2005). As Stanton argues, “The Oct. 27 recusal also paints a much narrower picture of the types of decisions Rumsfeld will stay away from than the generic ‘recusal’ he has cited in public statements. According to the letter, Rumsfeld’s recusal only applies to ‘matters concerning avian flu dealing with the development and acquisition by the government of vaccines and/or treatments,’ since those decisions ‘may directly and predictably affect Gilead’” (Stanton 2005). Even after letter was sent, in other words, Rumsfeld would still be able to be involved in decisions, which—even if they were not so explicitly conflictual—could still conceivably have an indirectly beneficial impact on the company’s fortunes (Stanton 2005). In either case, the creation of such specialist stockpiles for the armed forces shows that governments were not just interested in stockpiling Tamiflu to protect the civilian population; they were also becoming concerned about how the core institutions of the state would continue to function in the case of a pandemic.

Corporate Stockpiling: Developing the Business Continuity Market

Nor was such pharmaceutical stockpiling confined to governments. Many large corporations, too, wanted to create Tamiflu stockpiles as part of their business continuity plans to ensure economic damage is kept to a minimum during a pandemic. In the United States, government plans for pandemic flu actively assumed that the private sector would play a central role in pandemic preparedness planning. According to the then deputy secretary of health and human services Tevi Troy, “Stockpiling of antivirals is an essential act of preparedness for a potential flu pandemic, but it is one that is a shared responsibility that extends across all levels of government and all
segments of society” (quoted in Business Wire 2008). He urged industry in particular to make a contribution to national efforts: “Planning efforts by business and private industry . . . comprise a fundamental part of our nation’s efforts to ensure community resilience in a public health emergency. We encourage government, private industry and individuals to take action to prepare” (quoted in Business Wire 2008).

As the manufacturer of Tamiflu, Roche led the way by creating its own business continuity plan for pandemic flu. The plan aimed to ensure that during a pandemic Roche’s business activities would not increase infection risk for employees or third parties, that employees had been issued Tamiflu prior to a pandemic materializing, and that company sites did not pose a danger for employees. Roche also wanted to be sure that it could continue manufacturing and distribution of lifesaving medicines in a pandemic and that the company could rapidly return to business. As part of the plan, all Roche employees and their close family contacts in the same household would receive Tamiflu, local laws and regulations permitting.

Beyond addressing its own business continuity needs, the Roche program also had a broader signaling function for other large corporations. Roche representatives thus made presentations about their own preparedness activities to wider business audiences, in which they would then ask the audience to also consider how well their businesses, in turn, would also cope in a pandemic—reminding them of their role in ensuring the welfare of their employees (R. Turner 2006). Roche proactively contacted other Fortune 500 companies about business continuity planning as part of this new marketing effort. As CEO and president of Hoffmann-La Roche, Inc., George Abercrombie recalled at the time: “It is the first time I have ever engaged a business in a dialogue over a prescription medicine” (Fox 2007). Yet there was clearly a market for such a program. Roche claims it received enquiries from more than 800 US-based companies and orders from more than 300 companies by June 2008 (Business Wire 2008). The high-level concern that many other businesses also had about the pandemic flu threat could also be seen very clearly in Davos in 2006, where the threat of a pandemic was now identified as a major global risk (WEF 2006).

In order to deal with such business continuity issues in the corporate sector, Roche also introduced a flexible “reserve” program in June 2008. In return for an annual charge, corporations could—as part of this new program—maintain access to their own corporate stockpile of Tamiflu for
use during a pandemic: “The Roche Antiviral Protection Program (RAPP) holds one course of Tamiflu in its inventory for an annual reserve fee (which is low relative to the purchase price of the drug). The holder of a RAPP contract has the right to buy a single course at the regular price with delivery within 24–48 h. Thus, rather than immediately purchasing at the regular price to stockpile on its own, an organization can purchase the right to buy and thereby ensure supply” (Harrington and Hsu 2010: 438). While some companies preferred to predistribute Tamiflu directly to their employees, this scheme was designed to expand the market to those who were interested in having a Tamiflu capability but wanted different and more flexible planning options.

Yet this wider move to expand into corporate stockpiling would also touch upon a range of complex legal and regulatory sensitivities. In some cases, creating such corporate stockpiles required working with governments to alter legislation. One of the potential issues to emerge here was that this effectively constituted a way of marketing Tamiflu directly to businesses without going through doctors and other medical professionals. This even led to an employee allegation in May 2010 that Roche was putting sales staff under illegal pressure to sell Tamiflu to business continuity managers who were not doctors, a charge denied by Roche. The employee further alleged that he was asked to establish a special unit in 2006 for selling Tamiflu to companies and in the process discovered that there were no proper controls to ensure that sales staff only spoke to health-care professionals (Jack 2010). In either case, those corporate efforts show very clearly that stockpiling efforts were not confined to governments but spanned across many large companies as well.

**Personal Stockpiling and Internet Sales**

Many anxious individuals even tried to build up their own personal stockpiles of Tamiflu at home, especially as the pandemic flu threat received heightened media attention. In the age of the Internet, citizens who were concerned about the pandemic flu threat could easily seek out information about this antiviral on their own accord. Rather than relying on the government to protect them, they could simply try to secure their own supplies of the antiviral medicine (Ortiz et al. 2008). The extent to which citizens were trying to obtain information about Tamiflu, and perhaps even trying to
acquire the drug over the Internet, can be gleaned by looking at Google Trends data.

Google Trends analyzes a sample of searches performed on the popular commercial search engine and then computes how many searches are being performed for a particular term relative to the number of searches done over time. These results are displayed in the search volume index. Although this only provides a rough approximation because of the use of data sampling methods and multiple approximations, it clearly shows the enormously increased Internet activity surrounding Tamiflu during recent pandemic scares. The search volume index for “Tamiflu” reveals two distinct and large spikes: one during the international fears of an imminent H5N1 pandemic in 2005 and a later one during the H1N1 pandemic that began to spread in April 2009. Those peaks coincide with periods of intense media reporting (Google Trends 2013). Although not conclusive, such data strongly suggest that many citizens wanted more information about and actively sought access to Tamiflu during those two pandemic scares.

There is also other evidence revealing the considerable lengths to which some citizens would go in trying to secure their own supplies of Tamiflu. During the H5N1 bird flu pandemic scare, for example, the popular Internet auction site eBay had to withdraw sales of Tamiflu through its website after prices reached more than £100 for a treatment course—more than three times its usual prescription price (Reuters 2005). Roche Canada had to cease distribution of Tamiflu to pharmacies in that country following concerns about citizens stockpiling the drug for personal use because of fears about H5N1, even though the government was also creating a national stockpile (Spurgeon 2005). During the subsequent H1N1 swine flu pandemic in April 2009, and despite UK government reassurances that the national stockpile was sufficiently large, online pharmacists again reported very dramatic increases in demand for Tamiflu as people tried to create personal stockpiles; in some cases demand was reportedly up by around 1,000 percent (Swaine and Smith 2009). Faced with the imminent threat of a pandemic, many citizens were actively seeking information about and demanding access to available pharmaceutical defenses.

The desperation of some people to secure their own personal Tamiflu supplies is further revealed by the way in which illegally operating groups even sought to profit from the sale of counterfeit Tamiflu. For example, four
dozen shipments (51 packages) of counterfeit Tamiflu were seized by US federal customs officials at a post office in South San Francisco in November 2005 (Walsh 2005). The pills, marked “generic Tamiflu,” had been ordered over the Internet and were shipped from China. Nor was this a one-off occurrence. The FDA would later also discover other sales of fraudulent Tamiflu. In June 2010 it had to issue a warning to consumers over a potentially harmful product called “Generic Tamiflu” that was being sold over the Internet by an online retailer claiming to be an online drug store. The product did not in fact contain oseltamivir but cloxacillin, an antibiotic substance (FDA 2010a). In the end, the emergence of pandemic fears about H5N1 had provoked a global stockpiling frenzy over Tamiflu spanning governments, corporations, and individuals alike, all now desperately clamoring to acquire the antiviral as the first line of defense.

Tamiflu's pivotal transition during this period of its life shows just how rapidly the introduction of security logics can alter the way a pharmaceutical product is perceived. Prior to the concerns about pandemic flu, the drug was largely viewed as a borderline drug—with a fairly limited role to play in the management of seasonal flu. With political fears now escalating about the pandemic flu threat, however, the economic calculations around the drug changed dramatically, and public demand for the product was radically transformed in many parts of the world. Tamiflu's early years of struggling for commercial viability now seemed like a distant memory, and the drug was fast becoming a lucrative source of income for Roche (and to a smaller extent also for Gilead Sciences). Tamiflu had become, in the words of Andrew Jack, the first “virtual” blockbuster medicine, “earning ten digit revenues to treat a virus that did not yet exist” (Jack 2009). Within a short period of time, the shift to a context of health security and pandemic preparedness had completely reversed the commercial outlook for Tamiflu.

This pivotal reversal in Tamiflu's fortunes also reveals two additional challenges that governments confront more generally when trying to build effective medical countermeasure capabilities. First, they have to accurately gauge and plan their demand for such medical countermeasures. Any new medical countermeasure would remain fairly useless if it is not available in sufficient quantities during a future emergency. To develop an effective medical countermeasure capability, governments thus need to have access to the right medical countermeasures in the right quantities at the right
time. When it comes to many common diseases that are managed within the context of more routine health-care provision, this demand for pharmaceutical products remains fairly consistent, or the fluctuations in demand can at least be forecast with reasonable confidence. Demand for medical countermeasures, by contrast, can oscillate wildly and rapidly over time—in line with events unfolding on the ground, media coverage, political developments, and so forth. All of this means that demand for medical countermeasures is much more difficult to gauge properly, and governments will face difficult choices. In the face of their electorates, they must appear prepared during an emergency. At the same time, they must not be seen as wasting precious public resources on expensive medical countermeasures that might never be used and that will also eventually expire. Governments must therefore perform a difficult balancing act.

What is more, too much uncertainty about government demand for medical countermeasures might also further deter commercial developers of such products. From Roche’s perspective, it appeared one day that nobody was interested in acquiring Tamiflu as a medical countermeasure, and the company was trying largely in vain to persuade governments to stockpile Tamiflu. The next day there was a new outbreak, and demand for the product suddenly mushroomed out of control as governments clamored to stockpile the drug. At that point, demand increased so rapidly around the world that Roche was unsure whether it would be able to adequately meet the spike in demand. From the commercial perspective, such high volatility around the demand for medical countermeasures only complicates matters further. Indeed, prospective commercial developers of medical countermeasures will likely struggle to forecast demand for medical countermeasures with the degree of certainty that would be required for their business models. As one industry analyst explains, “You have an uncertain regulatory path to approval, the government determining procurement volumes, and the government reserving the right to change its mind. That makes it all kind of scary” (quoted in Wizemann et al. 2010: 127–128). On both sides of the public-private equation, the unpredictability of demand for medical countermeasures thus generates a fifth challenge, demand forecasting. The most prominent way that many governments have tried to manage this challenge so far is by building new pharmaceutical stockpiles.

The fact that so many countries around the world did end up building sizable Tamiflu stockpiles also points to a possible strategy for improving
the wider prospects for commercial medical countermeasure development in the future. If a new medical countermeasure could be simultaneously sold to many different governments around the world, then it might become possible for companies to achieve a higher volume of sales and thus improve their chances for achieving a sound commercial return on their investment. Roche’s overall revenues achieved from Tamiflu stockpiling are difficult to calculate with accuracy, because most of the government contracts are confidential. But there can be little doubt that sales ran into billions. According to calculations by the Bureau of Investigative Journalism, for instance, worldwide orders for Tamiflu by 2010 exceeded $10 billion since 2004 (BIJ 2010b). Four years later, oseltamivir had reportedly generated cumulative sales exceeding $18 billion since the drug was commercially launched in 1999, around half of which was driven by government and commercial stockpiles (Abbasi 2014; Jack 2014). Even such ballpark figures should be substantial enough to form the basis of a viable business case for developing new medical countermeasures—provided enough countries decide to stockpile the product in sufficient volumes. Pooling of international resources could thus be one possible way forward in terms of building greater commercial demand for medical countermeasures in the future.

Yet we have also seen during this stage of Tamiflu’s life that even stockpiling such medical countermeasure is not sufficient in and of itself. In fact, those expensive stockpiles will remain fairly useless if there is no way of rapidly, reliably, and securely distributing them to the public at large during a future emergency. Simply storing medical countermeasures in warehouses does not equate to a functioning and effective medical countermeasure capability. Governments also have to be able to get the medical countermeasures directly to people who need them, and they have to be able to do so very quickly in a context where normal distribution channels may cease to function properly. To do that, governments also need to put logistical distribution systems in place for medical countermeasures.

To be effective, such logistical distribution systems must meet a number of critical requirements. They have to be able to reach all the way down to the level of the individual citizen, with the “last mile” often being the hardest part of the chain to service. Governments must be able to activate distribution systems on fairly short notice, usually requiring that plans and processes be in place well in advance of an emergency. The logistical systems also have to meet the specific requirements of pharmaceutical products,
such as maintaining a particular temperature range, humidity levels, and so forth. Finally, they have to work independently of normal pharmaceutical distribution chains, as those may become severely disrupted during an emergency.

Countries have already tried to develop a variety of models and logistical systems, some relying on the postal system, some signing advance contracts with logistics companies, some resorting to the armed forces, and some even planning to use school buses to distribute medical countermeasures in the event of an emergency. Irrespective of which option they take, logistical mass distribution emerges as a sixth key challenge surrounding medical countermeasures. Together with the issues of obtaining regulatory approval and accurately forecasting demand, it also completes the second set of challenges that comes into play after a new medical countermeasure has been developed. These additional acquisition challenges show very clearly how developing an effective medical countermeasures capability is not just a technical issue of designing new pharmaceutical products. It also entails carrying out a lot of additional planning work for governments to ensure that such products can be used effectively, such as making sure that sufficient volumes are available at the right time and that they can be quickly distributed in an emergency. Once a crisis or emergency arises and a medical countermeasure actually has to be distributed to the population, there is still a whole third set of deployment challenges that quickly comes into play.
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