

Pharmaceutical lobbying and pandemic stockpiling of Tamiflu: a qualitative study of arguments and tactics

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ABSTRACT

Background Little is known about how pharmaceutical companies lobby authorities or experts regarding procurement or the use of vaccines and antivirals. This paper investigates how members of Denmark's pandemic planning committee experienced lobbying efforts by Roche, manufacturer of Tamiflu, the antiviral that was stockpiled before the 2009 A(H1N1) pandemic.

Methods Analysis of interviews with six of seven members of the Danish core pandemic committee, supplemented with documentary analysis. We sought to identify (1) arguments and (2) tactics used in lobbying, and to characterize interviewees' views on the impact of (3) lobbying and (4) scientific evidence on the decision to stockpile Tamiflu.

Results Roche lobbied directly (in its own name) and through a seemingly independent third party. Roche used two arguments: (1) the procurement agreement had to be signed quickly because the drug would be delivered on a first-come, first-served basis and (2) Denmark was especially vulnerable to an influenza crisis because it had smaller Tamiflu stocks than other countries. Most interviewees suspected that lobbying had an impact on Tamiflu procurement.

Conclusions Our study highlights risks posed by pharmaceutical lobbying. Arguments and tactics deployed by Roche are likely to be repeated whenever many countries are negotiating drug procurements in a monopolistic market.

Keywords communicable diseases, economics, finance and industry, government and Law

Introduction

Previous research has documented and criticized a range of lobbying tactics and arguments used by tobacco, alcohol and food industries to persuade decision-makers to create or stall legislation and policy.^{1–5} Pharmaceutical companies have also long been criticized for lobbying to promote drugs that provide limited clinical gains,⁶ are not cost-effective,⁷ or have cheaper alternatives.⁸ Little is known, however, about how pharmaceutical companies lobby authorities or experts responsible for recommending procurement or deployment of 'public health drugs' like vaccines and antivirals. Nevertheless, companies do engage in high-level lobbying to secure lucrative deals with countries or subnational entities, as confirmed by research showing how companies lobby policymakers in the USA by mobilizing legislators and physician organizations and conducting direct-to-consumer marketing in order to influence vaccine

policymaking.⁹ Efforts by industry to influence procurement and use of public health drugs are problematic due to the high health and financial stakes and the associated risk that commercial interests will bias decisions.^{9,10} Furthermore, should public perception be that commercial pressures underpin decisions, trust in public health institutions and policies could be undermined.¹¹ However, despite the influence that the pharmaceutical industry may exert on community health and trust, public health researchers have seldom addressed this type of lobbying, its consequences, or appropriate responses.⁹

A particularly relevant case in point is the global stockpiling of the antiviral Tamiflu (oseltamivir) prior to the 2009 A(H1N1) influenza pandemic. By 2009, a total of 95 governments had reportedly purchased or ordered Tamiflu to

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cover an estimated 350 million people.¹² Tamiflu generated total sales in excess of \$18bn, roughly half of which could be attributed to pandemic stockpiling. Claims by Roche, the manufacturer of Tamiflu, that the drug reduces hospitalizations and serious complications of flu were a key factor underlying stockpiling decisions.¹² However, in the scientific¹³ and public¹⁴ debates that took place in the aftermath of the pandemic, critics accused governments and public institutions of having allowed themselves to be misled by the drug manufacturer into stockpiling a drug with limited efficacy. In particular, criticism was fierce after the Cochrane collaboration in 2014 published meta-analyses of all Tamiflu clinical trials showing that Tamiflu shortened the duration of influenza symptoms by less than a day if treatment is begun in time (i.e. within 48 h), but that the evidence of reduction in hospitalizations and viral transmission was limited; and although Tamiflu did prevent some disease when used for post-exposure prophylaxis, the authors questioned the rationale for stockpiling the drug.¹³ Adding fuel to the fire, investigative journalists had exposed that key WHO pandemic guidance were authored by experts who had received payment for other work from Roche, and that conflicts of interest had remained undisclosed by the WHO.¹⁵

However, despite repeated accusations of commercial bias^{13,16} and undue pressure,^{15,17} conspicuously little is known about the corporate tactics and arguments at the national level that preceded procurement deals and deployment of Tamiflu. The present paper begins to address this gap by investigating how the members of Denmark's core group of experts who developed the country's pandemic plan experienced Roche's lobbying.

Unlike its Nordic neighbours, Denmark pursued a more restrictive vaccination strategy during the 2009 pandemic, based on risk group coverage rather than universal coverage.¹⁸ However, despite this more conservative approach, like the rest of the Nordics, Denmark stockpiled Tamiflu, but predominantly in bulk powder form for reconstitution into oral suspension, rather than as capsules, in order to reduce price and prolong shelf-life.¹⁹ In total, Denmark purchased sufficient Tamiflu powder to cover 6% of the population prophylactically, or 19% for treatment of infection. Yet, like many other countries, Denmark used little Tamiflu during the 2009 pandemic,²⁰ which begs the question of why Tamiflu was stockpiled in the first place.

Methods

We conducted an interview study with Danish informants who had exceptional insight into high-level decision-making before and during the 2009 pandemic. Formally, Denmark's

pandemic planning was the responsibility of the National Board of Health (the Danish Health Authority), but in close collaboration with the Ministry of Interior and Health and the State Serum Institute (SSI), which is responsible for Denmark's preparedness against infectious diseases.²¹ In 2003, the Ministry of Interior and Health appointed a permanent advisory committee for pandemic preparedness under the umbrella of the National Board of Health comprising 22 representatives from various societal, public health and healthcare-related areas. Within this larger group, a 'core group' of seven was tasked with developing the pandemic preparedness plan, and in effect this smaller group stewarded the country's pandemic response.²¹

We sought to interview all seven members of this core group, but one declined. We also sought to interview representatives of Roche Denmark, but the company declined to participate. To obtain additional background data, we also interviewed two members of the larger pandemic group who appeared repeatedly in media reports on the pandemic, and one recognized local expert in pandemic response who was not involved in the country's pandemic planning. Between November 2015 and January 2016, one investigator (A.V.) conducted semi-structured interviews in English face-to-face ($n = 6$) or by telephone ($n = 2$), lasting 45–60 min, and based on an interview guide (Web Appendix 1). Interviews were audio recorded and transcribed. One interview was conducted by e-mail. All interviewees were briefed on the broad goal of the research and informed that their statements would be anonymised, and they provided both written and verbal informed consent to participate. The interviews focused broadly on Denmark's pandemic planning and response, with some questions about pharmaceutical lobbying and Tamiflu stockpiling. In a few cases, informants were contacted by e-mail after the interview to clarify certain responses. Where relevant, the information provided was crosschecked and supplemented with official reports and other documents. The Ethical Review Board in Lund, Sweden decided that ethical vetting was not required for the study (no. 2015/624).

Our analysis of transcripts from the six interviews with the core group members applied an inductive, constant comparative approach, broadly in line with the principles of grounded theory.²² Based on previous research on industry lobbying,¹ we sought to identify alleged 'arguments' and 'tactics' used by Roche. In addition, we sought to characterize interviewee opinions on the impact of lobbying and of scientific evidence on the decision to stockpile Tamiflu. To this end, all transcripts were read and re-read by both authors; relevant themes were identified and coded across all six interviews. Initial descriptive codes were organized into hierarchies, and

relationships between codes in different parts of the hierarchy were identified. Finally, interview quotes were selected to illustrate the specific themes that emerged.

Results

Lobbying tactics and arguments

Our analysis of key informant interviews, supplemented with analysis of official reports and other documents, revealed two tactics and two arguments used by the company. Two informants who were especially knowledgeable in the procurement process highlighted how—following Denmark's decision to stockpile antivirals—Roche directly (i.e. in its own name) lobbied the political and public health leadership (Tactic 1), urging them to swiftly sign the procurement agreement. Roche did so in a letter in August 2004 addressed to the Director General of the Board of Health (with copy to the Minister of Interior and Health), claiming that the drug would be delivered on a 'first-come, first-served basis',²³ implying that should the agreement remain unsigned by a stipulated date, the company could not guarantee significant quantities in the near future, since precedence would be given to countries that acted more swiftly (Argument 1).

'It was a huge pressure...Roche wrote a letter, as far as I remember either to the Danish Board of Health or the Ministry, saying that they were of course willing, within their limits, to be of use: they could offer some [quantities of the drug] but people would have to take it very seriously. They could make a special offer for time being—I've forgotten the English word for it—to be on the top of those who could queue up for buying substantial amounts of it. But "please hurry up, because the scenario may be absolutely changed in 2 weeks' time"'. (Informant 1)

Additionally, Roche was alleged to have promoted Tamiflu by saying that Denmark was at heightened risk in the event of a major influenza outbreak because it had smaller Tamiflu stocks than other countries (Argument 2). One informant described how Roche 'toured' nearby countries in the years before the pandemic, including Denmark, repeating this argument to ratchet up volumes of Tamiflu stockpiles.

'By "touring" I mean—they did the same thing in neighbouring countries—I had the impression that after one country had bought a certain amount, they used it [as an argument] to push other countries and vice versa, and they would lobby this by all means...I remember at one stage they flagged that Norway had stocked up and so

should we, and later that Norway had purchased more than Denmark so we should buy more too.' (Informant 2)

Several interviews referred to this type of reasoning as exemplified in a consultancy report issued on behalf of Roche by the Danish Health Institute (DSI) in September 2007.²⁴ Remarkably, the DSI was established by the public sector to conduct independent research and to advise the healthcare sector. This report argued that Denmark was ill-prepared for a pandemic mainly because its Tamiflu stockpile covered only 19% of the population, while Norway, England and France could cover 30, 25 and 23%, respectively.

The DSI report shows how Roche tried to influence discussions via a third party (Tactic 2). Relatedly, some members of the core group suspected that certain doctors who argued strongly in favour of stockpiling were acting on behalf of the company.

'There was great pressure from many colleagues in the medical field to buy more antivirals, but I think it was a kind of lobbyism from the industry...I was called several times and had to talk to a lot of senior doctors in infectious disease, for example about the quantity [of the stockpile].' (Informant 4)

According to another informant, those colleagues not only approached the pandemic group but also 'tried to raise political support in the Danish Parliament for procuring Tamiflu on a national and grand-scale.' (Informant 1)

Impact of lobbying and of scientific evidence on Tamiflu stockpiling

One informant suggested that the core group was already aware of Roche's role and motives, for which reason the DSI report was rendered ineffectual: 'I remember someone said if it's Roche we couldn't care less. I mean, they sold the drug and we didn't listen to them...' (Informant 3)

Consistent with the idea that DSI report was ineffectual, when a Social Democratic Party MP suggested that the Ministry of Interior and Health summon the political parties to discuss Denmark's pandemic preparedness 'in light of the scathing criticism' in the report, this was rejected because the National Board of Health had assessed the report to be of low quality.²⁵

Nevertheless, almost all core pandemic group members suspected that lobbying by Roche had some effect on the amount of Tamiflu purchased or how quickly the agreement was signed (see Theme 1 in Web Appendix 2 for quotes). As one informant put it:

‘...perhaps Roche was quite successful in convincing governments to stockpile oseltamivir...although it is not something we have discussed much within the group, my feeling is that they indeed were successful in their lobbying efforts and that many governments, including our own, bought too much Tamiflu or bulk oseltamivir.’ (Informant 5)

With reference to attempts by Roche to seal the deal quickly, based on the argument that Tamiflu would be delivered on a first-come, first-served basis, another informant commented, ‘...the Board of Health and the Ministry ended up buying under this pressure.’ (Informant 1)

Furthermore, in retrospect the general view was that Roche successfully sold a product that the core group considered to be of limited and uncertain therapeutic benefit (see Theme 2 in Web Appendix 2 for quotes), for example:

‘None of us actually had high expectations for Tamiflu, you know, knowing well that it could maybe decrease the duration of disease by 1–2 days. It could maybe, at the time we didn’t have any good data, possibly prevent spread of infection and that is how we hoped it could work.’ (Informant 2)

Indeed, one informant went so far as to say that Tamiflu was bought without robust evidence to support widespread use:

‘No, I can be absolutely honest with you, there was of course no scientific basis. What we did was to go through a lot of material. I remember having spent quite a long time going through old reports just to calculate what had happened in previous epidemics, just to have an idea of the likely number of people to be hospitalized...That was as close as we got to evidence: old evidence and guessed estimations about the impact on what we thought would be likely and useful, and then we were of course taken by this train which was called Tamiflu.’ (Informant 1)

Discussion

Main finding of this study

Roche promoted Tamiflu using two arguments: that the procurement deal had to be signed quickly because the drug would be delivered on a first-come, first-served basis, and that Denmark was at heightened risk in the event of a major influenza outbreak because it had a smaller Tamiflu stockpile than other countries. One informant pointed to how Roche

‘toured’ Denmark and neighbouring countries to ratchet up the volume of Tamiflu stockpiles. Interestingly, and in line with this allegation, in March 2005 Roche sent an official letter²⁶ directly to the Swedish Minister of Health and Social Affairs (and copies to the Director Generals of the National Board of Health and Welfare and the Crisis Management Agency) that exactly repeated these two arguments: Roche (1) lamented the ‘drawn-out procurement processes’, citing the risk in compromising Sweden’s ability to secure the stipulated doses of Tamiflu and (2) argued ‘It is unfortunate that Sweden’s ambitions to protect its population is significantly smaller than other comparable countries.’ Notably, as in the DSI report, the ‘comparable countries’ to which Roche referred included only countries with higher levels of coverage, such as Norway (30%) and Finland (25%), but not Denmark, even though it is also a neighbour.

Furthermore, Roche practised tactics that included both lobbying through direct contact and lobbying through a seemingly independent third party, i.e. the DSI. In addition, some interviewees suspected third party lobbying via colleagues. The DSI was established by the public sector to conduct independent research, yet it still agreed to act on behalf of the company—quite a disturbing finding.

Ultimately, it is difficult to gauge the impact of Roche’s lobbying. However, most members of the core group suspected that Roche’s tactics and arguments did have an effect, and several were retrospectively critical of Denmark’s anti-viral procurement and deployment strategy.

What is already known on this topic

There is a growing body of research showing how the tobacco, beverage and food industries influence public health-related legislation and policies through lobbying.^{1–3,5} Studies on pharmaceutical lobbying to date have revealed important parallels, especially the use of endorsements expressed by third parties such as patient organizations and medical experts.^{9,27–30} A number of studies also show how pharmaceutical companies and trade associations engage in high-level political lobbying and foster alliances with groups both inside and outside the state apparatus to influence the policies, laws and regulations relevant to pharmaceutical markets.^{31–34}

What this study adds

To the best of our knowledge, this is the first systematic investigation of pharmaceutical lobbying in relation to the 2009 pandemic, despite lingering concerns.^{16,17} As such, our study contributes to emerging research highlighting the need to critically evaluate industry lobbying at key points along

the trajectories of public health drugs, e.g. procurement and stockpiling (this study), deployment strategies and legislation,⁹ and pricing and reimbursement,²⁷ given the potential detrimental impact on public health. Baekkeskov argues that the presence of experts within the leadership of public health agencies that respond to pandemics ensures that in countries like Denmark, cutting-edge science and epidemiology exert greater influence over policy than do commercial interests.³⁵ Yet, in the case of Tamiflu, the idea that science can be divorced from commercial pressures to dominate policy is problematic considering the recognized biases in, and low quality and limited transparency of, clinical trials, and as suggested here, the influence of lobbying efforts that precede procurement deals. Other factors that could have contributed to Roche's success was the sense of urgency that existed at the time and the optimistic statements on Tamiflu efficacy made by prominent public health bodies despite the poor evidence base.^{36,37}

Ozieranski and King urge researchers of pharmaceutical lobbying to consider universal as well as country-specific lobbying since companies' arguments and tactics are carefully calibrated to fit local circumstances.²⁸ Nonetheless, in the context of pandemic stockpiling, the arguments and tactics deployed by Roche are likely to repeat themselves whenever many countries negotiate procurement of medical countermeasures in a monopolistic market. As countries are now in the process of renewing their antiviral contracts—and in the absence of joint procurements—we believe there is a need to increase awareness of Roche's past lobbying in the event of more of the same when negotiating renewal contracts. From this perspective it is lamentable that Denmark did not evaluate its antiviral strategy (see Web Appendix 2; Quote from Informant 5) despite interviewees' concerns about the nature and impact of lobbying and the limited evidence base for pandemic stockpiling.

Related to this, pandemic planning committee members should be encouraged to ventilate any concerns they might have about industry lobbying or other perceived pressures or sources of bias. To this end, we suggest that inclusion of members in committees that are knowledgeable in lobbying and health ethics could improve preparedness against industry lobbying and help identify and manage real or perceived conflict of interest situations. Another measure that could reduce the risk of undue industry influences is better cooperation and information sharing between countries. In the present case, several respondents lamented the lack of a joint Nordic evaluation after the pandemic (not shown). Cooperation and information sharing may help ensure that efficacy evidence garnered since the 2009 pandemic inform discussions on stockpile renewal and mitigate the effect of

manufacturers 'touring' countries to ratchet up the volume of stockpiles.

Limitations of this study

Because our study is largely based on interviews conducted several years after the pandemic, it is open to recall bias and selective reporting. On the other hand, the passage of time may have allowed interviewees to speak more freely. Furthermore, our typology of lobbying tactics and arguments is likely to be incomplete since it is based on information provided by company outsiders and official documents. Previous research has shown that first-hand employee testimonies and company-internal documentation are required to reveal the full range of practices.^{38–40}

Supplementary data

Supplementary data are available at the *Journal of Public Health* online.

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