THIS WON'T HURT A BIT:

Why the vaccine crisis shows we shouldn't believe what health "planners" tell us about how to reform drug policy

JULIA WITT
BRIAN FERGUSON

AIMS COMMENTARY

December 2004

Atlantic Institute for Market Studies

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Introduction

On October 24, 2004, the op-ed page of the *New York Sunday Times* carried an opinion piece (Bartlett and Steele 2004, 11) that pretty accurately sums up the views of perhaps the majority of Americans and Canadians about the October flu debacle in the United States — it's all the market's fault. The article, by two *Time* writers, points out correctly that drug manufacturers make much more profit from products like Viagra than they do from vaccines and that, with regard to the flu vaccine shortage, "[t]he reason for the shortage is this: Preventing a flu epidemic that could kill thousands is not nearly as profitable as making pills for something like erectile dysfunction". This is partly true: the immediate reason for the shortage was contamination of the output of vaccine maker Chiron's UK plant and the UK government's subsequent refusal to permit the export of any of the plant's output to the United States. The *Time* writers then go on to say that the United States does not exercise any influence over pharmaceutical prices, which, at least as far as vaccines are concerned, is simply wrong.

Anti-market views are pretty common in this area. A *New York Times* article published a few days earlier (Grady 2004) cited experts as saying that the heart of the problem was that government was not sufficiently involved in the vaccine market. As the article put it, "The production, sale and distribution of vaccines, particularly those for flu, are handled almost entirely by pharmaceutical companies".

Canadians are generally happy to sit back and watch the United States' problems with a fair degree of complacency. We shouldn't, for a couple of reasons. First, like Americans, Canadians rely on just two producers to supply our stock of flu vaccine, one of which — fortunately not Chiron — also supplies half the US stock. Second, if Canada's federal and provincial ministers of health proceed with some of the policies they discussed at their recent meeting, Canada's pharmaceutical sector will begin to look very much like its troubled US counterpart.

Getting the Right Dose

In the United States, approximately 95 percent of the annual flu vaccine supply comes from two companies, Chiron in the UK and French-based Aventis Pasteur's US facilities, each supplying nearly half the required doses. A third manufacturer, MedImmune, produces a nasal spray flu vaccine that, because it is a live virus, is not approved for most at-risk people. Canada also obtains flu vaccine from Aventis Pasteur, but from the company's French plant, whose output is not licensed for use in the United States. Canada's second supplier, ID Biomedical, is located in Quebec and is responsible for the manufacture of 75 percent of Canada's required doses of flu vaccine.

Each year, the World Health Organization monitors flu outbreaks worldwide and recommends appropriate vaccine compositions to be used for the next flu season. In the United States, the decision about which flu virus strains to include in the vaccine is made in late January by the Vaccines and Related Biologicals Advisory Committee of the Food and Drug Administration (FDA), but production and distribution of the vaccine are largely left to the private sector. A relatively small amount is purchased by the Centers for Disease Control (CDC) and state and local health departments.

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The quantity of flu vaccine the United States requires each year is largely determined by how many doses were used the previous year. For example, about 95 million doses of vaccine were produced for the 2002–03 flu season, of which 83 million doses were used. The requirement for the 2003–04 flu season was set at about 87 million doses.

Unfortunately, flu vaccine takes a long time to manufacture — production for the October-November inoculation period starts around March. Moreover, the flu vaccine composition changes each year as new viruses travel around the world, so unused doses from the previous flu season are thrown away. It also raises the stakes for producers because there are no guarantees that their supply will be sold. Some companies have chosen to exit the vaccine business altogether — ten years ago, there were four flu vaccine manufacturers in the United States, now there are only two.

The FDA's strict guidelines are the reason US states are unable to secure flu vaccines from other countries that have a surplus.

Vaccine producers also face strict FDA regulations. Parkedale Pharmaceuticals in Rochester, Michigan, shut down its flu vaccine production facility after a long debate with the FDA that ultimately forced the company to halt its vaccine sales during the only time doses would have been in demand, wasting nearly 14 million doses. The prospect of a recurrence left the flu vaccine market with one less supplier.

Confounding these regulations is the research under way that would make the current chicken-egg method obsolete, so investing in costly FDA-required upgrades to the chicken-egg process makes less sense than exiting the market completely. The FDA's strict guidelines are also the reason US states are unable to secure flu vaccines from other countries that have a surplus. Since the FDA "cannot guarantee the safety of these vaccines", states are not allowed to import them until the agency has conducted what it considers to be adequate testing of vaccine batches.

The UK Experience

Northern Ireland was also adversely affected by the closure of Chiron, which normally supplied 80 percent of its flu vaccine. However, two factors averted a crisis there.

First, the Department of Health, Social Services and Public Safety moved quickly to secure doses from other suppliers without imposing debilitating requirements on the approval process for the new supplies.

Second, Northern Ireland's required supply of around 200,000 doses was small enough to be filled by the UK's five other suppliers of the vaccine. Chiron also supplied nearly 20 percent of the required doses in the rest of the UK, but the Department of Health quickly secures additional supplies from three of the remaining five companies, thus averting a severe shortage of flu vaccines in the UK.

The reason the UK has as many as six flu vaccine suppliers is partly because of that country's pricing mechanism for pharmaceuticals. The industry's target profit level is negotiated between the UK government (represented by the Department of Health) and the pharmaceutical sector (represented by the Association of the British Pharmaceutical Industry). The target is expressed as a level of return on capital employed, and is derived from the average level of profitability of industry in the UK in general. The scheme is meant to ensure "reasonable prices" that "promote a strong and profitable pharmaceutical industry" that will "encourage the efficient and competitive development

and supply of medicines" (ABPI and Department of Health 1999). Contrarily, in the United States, the CDC typically negotiates prices for itself and other government purchasers that are roughly half the private sector cost.[1] Unreasonable prices do not promote a strong and profitable pharmaceutical industry that will invest in expensive research and development.

Don't Blame the Market

Critics of market involvement in health care argue that, while the market is fine for providing cereals and cosmetics, it simply cannot be relied on where health care is concerned. Barlett and Steele (2004) take the view that the flu vaccine case shows "[t]he money is in the treatment — not prevention — so the market and good health care are at odds". Most health policy reformers believe that health care is simply too important to be left to the market, implying that some sort of failure on the part of the market requires direct government intervention.

It is true that the market has driven pharmaceutical companies' allocation of effort between vaccines and other products. It is not true, though, that the market has failed. The market has done exactly what it is supposed to: allocate resources toward their highest-value use or, more precisely, their highest-profit use. Firms make production decisions on the basis of market signals that have led them to shift production away from vaccines and toward other things, which reformers usually deride as "me-too" or "lifestyle" drugs.

1 For a comparison of the costs of children's vaccines to the CDC and the private sector, see website: <http://www.cdc.gov/nip/vfc/cdc_vac_price_list.htm>.

The question reformers are ducking is: why aren't those signals pointing in the other direction, toward certain vaccines? The answer, at least in the US flu vaccine case, is that government, not the market, sets the signals. The problem with the US vaccine sector isn't too little government involvement but too much.[2]

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The Great Flu Vaccine Panic

This year's flu vaccine panic in the United States is just the latest, and most dramatic, of the unintended consequences of deliberate government actions.

The story is set out in a pair of reports, one from the Institute of Medicine (IOM 2003), the other from the General Accounting Office (GAO) (United States 2002). In 1967, 26 manufacturers were licensed by the FDA to produce vaccines for the US market. By 1980, that number had declined to 17, and by 2002 there were 12. The IOM report said that the number of firms and laboratories

2 A recent *New York Times* article (Pollack 2004) gives the impression that the vaccine market is no longer unprofitable, and cites examples of new vaccines various companies have under development. It characterizes older vaccines as unprofitable by comparison with newer ones, but also mentions that the prices of vaccines covered by the Vaccines for Children program are capped without seeming to appreciate the connection between the two. The article also fails to address the shortage of suppliers in the huge US market. And while it mentions that liability concerns about a rare possible side effect have prompted Merck to run a massive clinical trial on a new vaccine, the article ignores the implications of such a trial for the cost of drug development. In fact, the article merely confirms that the market will allocate research funds toward highest-profit uses, which, thanks to government intervention and concerns about litigation, do not include the old stand-by vaccines.

producing recommended childhood vaccines for the US market had declined from eight to four between 1996 and 2002. The GAO report warned that, of the eight recommended routine childhood vaccines, five were made by a single firm. Two other vaccines were made by two firms, but only one was made by as many as three firms. It was also reported that the number of manufacturers of flu vaccine for the US market had declined from five to two over the past decade (Henderson 2004), neither of them based in the United States (Aventis Pasteur's head office is in France).

The two major players in the shrinking US vaccine industry were trial lawyers and the US government.

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Attack of the "Lawyeraptors"

The trial lawyers had a field day in the 1970s and 1980s, driving up drug prices, forcing manufacturers to build liability reserves, and putting some out of business. The California Supreme Court boasted that litigation had driven all but two manufacturers of diphtheria-tetanus-pertussis vaccine from the market and the cost of a dose of the vaccine up from 11 cents in 1982 to $11.40 in 1986 (Noah 2002). A 1974 report linking pertussis vaccine to epilepsy, though rejected by later studies, led to the filing of 800 lawsuits over the next decade and resulted in all but one US drug company abandoning production of the vaccine (Tucker 2004).

In 1998, the FDA approved a Lyme disease vaccine manufactured by SmithKlein-Beecham (now GlaxoSmithKlein). The firm removed the vaccine from the market three years later after rumours began to circulate that it was causing serious arthritis, although regulators found no evidence of adverse effects. GlaxoSmithKlein claimed it was ceasing production of the vaccine because demand had dropped off significantly, which was true — demand had fallen precipitously as the rumours spread. Despite the FDA's clean bill of health, a class action lawsuit was brought against the manufacturer. GlaxoSmithKlein settled in 2003 for just over a million dollars, small change as lawsuits go, but every penny went to the 34 lawyers and paralegals involved in the case and not one went to the vaccine's purported victims. The lawyers hailed the settlement as a victory (Shea 2003).

The Problem with Government Intervention

The US government experienced the "lawyeraptor" effect first hand in 1976, as a result of an outbreak of swine flu at Fort Dix, New Jersey. A national immunization program was recommended, but vaccine manufacturers were unwilling to participate because they were unable to get liability insurance. In response, after hearing Congressional Budget Office estimates that total damage awards would come to US$2 million, Congress decided, after suitably demonizing the insurance industry for its lack of social conscience, to provide the insurance itself. Total damage awards ultimately came to more than US$100 million (Tucker 2004).

In 1986, Congress tried to provide the manufacturers of childhood vaccines with some degree of protection by passing the *National Childhood Vaccine Injury Act*, which implemented a no-fault damage award system for children who suffered adverse consequences from vaccines, with cases determined by scientific panels. Plaintiffs were still able to opt out and go

directly to trial, however, and trial lawyers have been making use of what the IOM (2003) report refers to as "novel legal theories" to circumvent the system.

The US government's contribution to squeezing out vaccine manufacturers has two elements: keeping prices down and driving manufacturing costs up.

On the price side, despite the claim by Barlett and Steele (2004) that the government does not exert any influence over drug prices, that is certainly not true for vaccines. The GAO report itself reminds readers that, in 1993, the Clinton administration limited price increases for vaccines purchased through then-existing CDC contracts to the general rate of inflation (United States 2002). The government set a price cap on tetanus and diphtheria booster vaccine so low that manufacturers refused to sell to the CDC at that price, leaving the vaccine absent from the CDC's national stockpile.[3]

The government not only pushes vaccine prices down, it drives manufacturers' costs up.

The US government also regularly uses its purchasing clout to negotiate discounts of 40 to 50 percent off list prices (IOM 2003). Since the government is by far the largest purchaser of vaccines, these discounts can have a considerable impact on product profitability. Yet the government's efforts to restrict prices go beyond merely negotiating its own discounts. According to the IOM report, the Department of Veterans Affairs penalizes firms for increasing prices charged to nongovernment contract above the consumer price index inflation rate by reducing the price the department pays under its contract.

The FDA in the Way

The government not only pushes vaccine prices down, it drives manufacturers' costs up, through the operations of the FDA, which is responsible for ensuring the quality and safety of the US vaccine supply, a task the agency takes very seriously.

Vaccines — because of their nature and because millions of healthy people use them to avoid becoming seriously ill — are taken to warrant tougher scrutiny than other pharmaceuticals. Thus, each individual batch of vaccines intended for the US market must be inspected, and the FDA can and frequently does require upgrading of production methods when new technologies become available, even if there is no evidence of problems with the old methods. As Foulkes (2004) notes, the FDA has not hesitated to shut down production even when it acknowledges the absence of problems.

FDA requirements also discourage entry and research in the vaccine field. Before it will license a new vaccine, the FDA insists that the manufacturer construct and pass inspection of a commercial-scale production facility, and that the batches of vaccine the FDA is inspecting as part of the approval process be produced in that facility. If the vaccine fails to obtain FDA approval, the manufacturer could find itself stuck with an unused and unusable production plant. Regulatory delays also sometimes

3 It is ironic that flu vaccine has been the largest crisis in recent years, as flu was not on the 1993 list. The CDC does, however, set the reimbursement rate for flu shots under federal programs, and is quick to cry of "gouging" when prices increase.

mean that facilities are no longer state of the art by the time the vaccine comes into production, with the FDA demanding they be completely upgraded.

Clearly, such regulations bias research efforts toward safe bets — vaccines that are virtually guaranteed to obtain approval. Innovative research — say, into vaccines for hitherto neglected conditions — is effectively discouraged by the risk that the vaccine might not pass large-scale trials and that the company might be stuck with a useless plant.

The FDA's ill-judged regulatory impositions intended to prevent hypothetical problems instead created serious, real problems of vaccine shortages.

The FDA is also prone to changing requirements suddenly. A recent case involves its decision that the preservative thimerosal be removed from vaccines. Thimerosal has been used in vaccine manufacture for more than 60 years and has never been associated in clinical trials with side effects other than minor reactions involving redness and swelling at the injection site (Foulkes 2004, 39). Its presence in vaccines reduces the risk of bacterial contamination when individual doses are drawn from multidose vials (United States 2002, 16).

The substance contains small amounts of ethyl mercury, however, and rumours began to circulate that its presence was associated with autism. Despite the fact that large-scale epidemiological research had found no evidence of any such link, the FDA decided that thimerosal must be removed from all childhood vaccines sold in the United States. This proved extremely difficult in some cases. One manufacturer of diphtheria-tetanus-acellular pertussis (DTaP) vaccine simply ceased production; another had to change its packaging from multi- to single-dose form, reducing its output of the vaccine by 25 percent in the process. In addition, producers staying in the field had to take their reformulated vaccines through the whole regulatory approval process.

The thimerosal scare was a tabloid health scare with no scientific basis at the time, and researchers have consistently rejected it since, but it had the effect of reducing the number of producers of DTaP vaccine for the US market from four to two.

Furthermore, it is worth noting the situation surrounding the production of smallpox vaccine in the United States. FDA regulations, created as a result of changes to the vaccine production, now treat smallpox vaccines as a new drug with all of the increased standards associated with such a decision.[4] One can see how the FDA's decision could cause some companies to think twice before deciding whether or not to produce smallpox vaccine.

It is not unreasonable for the FDA to expect vaccines to meet certain standards of quality and safety. But the agency's approach imposes large costs on producers even when there are no problems, and forces them to absorb those costs in the short run. Some recent shortages of childhood vaccines have occurred because manufacturers could not make FDA-mandated upgrades quickly enough and had to keep their production facilities off stream for considerably longer than the FDA had expected. Thus, the FDA's ill-judged regulatory impositions intended to prevent hypothetical problems instead created serious, real problems of vaccine shortages.

The US government's pricing rules also do not allow manufacturers to pass on the increased costs of production to consumers in the form of higher prices except

4 See "A Wartime FDA", *Wall Street Journal* (Eastern Edition), November 15, 2001, p. A.26; and Bandow (2003).

in the case of a whole new vaccine. Combine a hard price ceiling with rising costs of production, and it's no wonder profit margins on vaccines are tiny compared with those on lifestyle drugs.

Conclusion

The US flu vaccine shortage is not a case of market failure. Rather, the US government is sending vaccine producers a very clear message: If you produce an important vaccine, especially one of the required childhood vaccines, you face small and diminishing profits and a high risk of lawsuits. If you are sued, do not expect the fact that you followed FDA rules to be a defence or that FDA testimony on your behalf will do you any good. On the other hand, if you produce your own competitor for Viagra, you can make as much profit as you like. Is it really any surprise (to anyone except health policy types) that the market favours lifestyle drugs?

Finally, we should warn that Canadians are getting just as prone as Americans to vilifying drug companies and complaining that they devote too much effort to developing "me-too" drugs. Somewhat ominously, federal and provincial ministers of health agreed, at their most recent meeting, to develop ways to use their combined purchasing clout to drive drug prices down. Setting aside the vanishingly small likelihood that federal and provincial ministers of health can work together on anything, the ministers should take a close look at how precisely that sort of policy has worked out in the US market for vaccines.

Like it or not — and a lot of people do not — government intervention in health care markets does more harm than good. And like it or not, government cannot guarantee supplies or access to essential medications of any kind. Ultimately, the market is the only mechanism that can ensure that valuable drugs are produced and supplied to the places where they are in demand. The failures of vaccine supply the United States has experienced regularly over the past several years illustrate, not market failure, but government failure.[5]

US vaccine supply failures illustrate, not market failure, but government failure.

5 A forthcoming AIMS paper by Brian Ferguson has a more detailed look at these issues.

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