

A Ton of Prevention: How the FDA Threatens Vaccine Supplies

by Arthur E. Foulkes

After two troubled years, the supply of flu vaccine was plentiful in 2002. But toward the end of November, after nearly all flu shots had been given, one of the three companies making injectable vaccine said it was dropping out of the business, raising immediate concerns of greater scarcity in the future.

The news was especially disturbing for older Americans and others for whom the flu can lead to serious complications, including death. The Centers for Disease Control and Prevention (CDC) estimates some 20,000 Americans, mostly over 65, die annually from flu-related illness.

When I first heard about the vaccine scarcities of 2000 and 2001, I wondered why this was happening. After all, I never hear about short supplies of McDonald's hamburgers or Coca-Cola. Even more complex goods, such as computers or televisions, are always in stock. Why, of all things, flu vaccine?

Media accounts of the problem in 2000 named two causes. First, they said, several vaccine makers were having problems growing one of the three virus strains mandated by the Food and Drug Administration (FDA) to be included in that year's vaccine. The

vaccine is different each year because the flu bug circulating changes. Each dose of vaccine contains three virus strains that are designed to best combat the year's expected virus.

Second, they reported, "manufacturing difficulties" occurred at two of the four vaccine companies. Apparently, these two companies stopped production in mid-season to comply (or attempt to comply) with FDA regulations.

I quickly noticed both causes had one thing in common: the FDA. This made me suspicious. Could it be that the agency notorious in economic literature for preventing, obstructing, and delaying drug development, was having a similar effect on vaccines?¹ I believe the answer is yes. (The vaccine scarcities in 2001 owed much to the anthrax scare when politicians and others urged people to get shots to prevent anthrax false alarms.)

The FDA has the legal authority to determine which three flu virus strains are to be included in each year's vaccine. Until the FDA decides on the "proper" mix of strains, vaccine makers have their hands tied. If the FDA is slow reaching its decision, vaccine producers are immediately on a tight schedule—it normally takes six to eight months to manufacture flu vaccine. As it happens, the FDA was slower reaching its decision in

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2000 than usual. It did not determine the three acceptable strains until April. This, even though the World Health Organization had recommended complementary strains in February and European health officials had made their recommendations in March.

More important, the FDA also contributed to the 2000 scarcity through a set of regulatory guidelines known as Current Good Manufacturing Practice (CGMP) regulations. These rules allow the FDA to dictate even minor details of vaccine making (such as record keeping, lighting, and labeling) and force manufacturers to constantly invest in the “latest, greatest technology” to keep up with FDA-determined industry standards.² Worse, the FDA can change CGMP standards without warning. This seems to have happened in 2000.

“The FDA didn’t communicate very clearly that they were changing the rules of the game,” said economist and industry-observer David Webster. Two vaccine makers were “caught unaware” he said—namely Parkedale Pharmaceuticals and Wyeth Pharmaceuticals. “The FDA presented a decision to them, which was to completely upgrade or leave the business.”³

Out of Business

Parkedale took the latter option and left the business on the eve of flu-shot season, 2000. In doing so, the company wrote off some \$51 million in losses and took 15 percent of the expected flu-vaccine supply with it.⁴ Wyeth, on the other hand, halted production only temporarily then resumed (after paying a \$30 million fine to the federal government and agreeing to stepped-up FDA inspections). But by then it was several weeks behind schedule. (Wyeth had both biological problems and FDA problems, making it the last major vaccine producer to ship all its vaccine—several weeks later than usual.)

Two years later, Wyeth joined Parkedale in leaving the injectable flu-vaccine business. The company manufactured 20 million doses of the vaccine in 2002, but near the end of the season it still had not sold over 25

percent of its product.⁵ A company spokesman said Wyeth was quitting partly to focus (with partner MedImmune) on its revolutionary nasal spray flu vaccine, known as FluMist, which has still not received FDA approval, despite several years of development and testing. (The FDA rejected FluMist for sale in the United States in 2001 and again in 2002, saying it could not be sure the medicine was safe for children in combination with other vaccines.⁶)

The FDA has not merely disrupted influenza vaccine supplies, but those of many other vaccines as well. An “already serious shortage” of tetanus vaccine was made worse after Wyeth left that market two months after the FDA found quality-control problems at two of its plants in October 2000.⁷ In 2001, FDA inspectors brought about a one-month shutdown at a Merck and Co. plant resulting in a temporary shortage of vaccine for measles, mumps, chicken pox, and hepatitis.⁸ In a classic example of the FDA’s making questionable risk/benefit analyses on behalf of Americans, the agency shut down a plant making a life-saving hemophilia vaccine. This move led to a temporary aggravated scarcity that put hemophilia patients at risk even though the FDA acknowledged that the vaccine produced at the plant was safe.⁹ And finally, in March 2002, *Infectious Disease News* listed the FDA’s CGMPs as the specific cause of five vaccine shortages, including MMR (measles, mumps, rubella), hib, varicella, and hepatitis B.¹⁰

The FDA plays a major role in hampering vaccine production and innovation. Len Lavenda of Aventis Pasteur, the largest U.S. flu-vaccine company, said in an August 14, 2002, telephone interview with me that the FDA is in the forefront of any innovation decisions his company makes. Because the innovations require FDA approval, which is costly and time consuming, his company makes only those changes deemed “absolutely necessary.”

Despite that role (or because of it), vaccine and drug company officials are reluctant to speak out publicly about their federal overlords. Three of the four flu-vaccine makers I

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contacted for this article would not return phone calls. Another company, Merck, simply rules out any comment on its relations with the FDA.¹¹

With its decision to drop out of the injectable flu-vaccine business, Wyeth may have decided to take the offense against the FDA by increasing pressure on the agency to approve FluMist. This may work. As political scientist Daniel Carpenter has shown, the FDA is not above being swayed by public opinion or political considerations. “The case of AIDS offers a lucid example. When ACT-UP protesters, dismayed that the FDA might delay approval of lifesaving therapies, demonstrated at agency headquarters in 1988, they embarrassed the agency and prompted a *sharp change in policy on AIDS drugs.*”¹²

This strategy, if that’s indeed what it is, may also backfire. As one industry observer told TheStreet.com, Wyeth’s decision “is going to raise some eyebrows.”¹³

FDA Damage

The economic literature showing the damage done to Americans’ health by the FDA is impressive.¹⁴ While this work focuses primarily on prescription and other drugs, vaccines are clearly not immune. The best solution for Americans’ health and freedom is to do away with the FDA altogether. Drug and vaccine companies would find it to their interest to have their products privately certified and inspected—without a bureaucratic agency holding the authority to make life-and-death decisions for the entire population.

As economist David R. Henderson points out in *The Joy of Freedom*: “The FDA may have some expertise when it comes to drug safety and efficacy, but on the only issue that matters—your tradeoffs between various

risks—you are the expert, and the FDA’s scientists are rank amateurs.”¹⁵

But would private drug and vaccine inspectors face an insurmountable conflict of interest? After all, they would be seeking business contracts from the very companies they would be certifying. It is of course possible that some certification companies would be fraudulent. But the market would soon distinguish between poor certifiers and top certifiers. The best certification companies would have a strong incentive to perform honestly and maintain a clean reputation—their very existence would depend on it.

Indeed the free market offers many examples of for-profit certification companies that guard their reputations closely. For instance, motorcycle helmets are required to meet a certain level of quality by the U.S. Department of Transportation. These helmets are fine for some people, but those seeking the really top-quality helmets look for a certification from a private company, Snell, which only certifies helmets that meet tougher quality standards. The threat of bankruptcy provides a strong incentive for Snell to maintain its reputation for strict standards and impartiality.

In 2000, critics said the free market was unable to guarantee flu vaccine to the most needy people and led to “price gouging.” (The American Medical Association led the charge against “price gouging” and called on Congress to investigate flu-vaccine distribution problems. It also asked Congress to develop a “mechanism” to guarantee better vaccine distribution in the event of another shortage.¹⁶) Some flu-vaccine prices clearly did rise dramatically. Vaccine ordered in June sold for under \$3 per dose. By November the average price had risen to \$7, but some vaccine sold to last-minute purchasers was going for \$12 or more.¹⁷

But these problems were symptoms of bad public policy, not “market failure.” Naturally the price of a commodity will rise when, other things remaining unchanged, supply drops dramatically. This is an important signal for new entrepreneurs to enter the market. Yet if FDA regulations continue to drive more and more companies out of the vaccine business, scarcities will remain a threat. If the agency can further impose unexpected and never-ending costs, entrepreneur-producers will naturally look to other investment possibilities. As even one FDA official recently noted, costs imposed by the agency have helped lead to “a decreased interest in making vaccines.”¹⁸

Not surprisingly, most proposed solutions to the flu and other vaccine-supply problems have called for a larger government role. One idea, proposed by U.S. Representative Peter DeFazio, would give the federal government the power to declare a public-health emergency (according to its own judgment) and seize vaccine supplies.¹⁹ While manufacturers would be reimbursed, distributors (who must shoulder large investments in specially designed shipping and storage equipment) would be left without the ability to cover their capital costs. In other words, even in years of high demand (such as a bad flu season or more FDA-caused shortages) distributors would suffer losses after the government took over vaccine distribution. On the other hand, in years when supplies were high, demand low, or both, distributors would again face losses or tiny profits because of natural market forces. The prospect for above “normal” profits would disappear. Soon entrepreneur-producers would take productive resources out of the flu-vaccine distribution business altogether.

It’s not hard to see how this would lead to more supply and distribution problems—opening the door for *even more* government intervention and possibly the eventual nationalization of the flu-vaccine distribu-

tion business. It would be far better to free vaccine companies to determine their own virus-strain combinations (if the FDA gets it wrong, everyone suffers), eliminate CGMP regulations, and allow uninhibited innovation. Perhaps then vaccine shortages would be as unheard of as shortages for hamburgers and Coca-Cola. □

1. For an excellent summary see Daniel B. Klein, “Economists Against the FDA,” *Ideas on Liberty*, September 2000. For a good look at the political culture of the FDA, which contributes to these problems considerably, see Paul J. Quirk, “Food and Drug Administration,” in *The Politics of Regulation*, ed. James Q. Wilson (New York: Basic Books, 1980), pp. 217–18. Also see Henry I. Miller, “First Do No Harm,” *Hoover Digest*, 2000, no. 4.

2. Jess Kilby, “Nobody is Immune,” *Portland Phoenix*, March 2002.

3. Author interview with David Webster, July 1, 2002.

4. “FDA Halts Parkedale Flu Vaccine, 204 Layoffs Result,” *Crain’s Detroit Business*, November 27, 2000, and Kenneth Chang, “Flu Shot Delays Reported for Many Who Are at Risk,” *New York Times*, November 7, 2000.

5. Linda A. Johnson, “Wyeth Stops Making Flu and Pneumonia Vaccines,” *Newsday.com* (AP), November 19, 2002, www.newsday.com/news/local/wire/ny-bc-nj—wyeth-vaccines/1119nov19,0,6425028.story.

6. “Panel Rejects Nasal Flu Vaccine,” *MSNBC.com* (AP), July 27, 2002, www.msnbc.com/news/606077.asp.

7. Kilby.

8. Sabin Russell, “Critical Vaccines Run Low; Tetanus Shots Rationed; Congress Probes Shortages,” *San Francisco Chronicle*, February 10, 2002.

9. *Ibid.*

10. “How to Shore Up Nation’s Vaccine Supply,” *Infectious Disease News*, March 2002, www.infectiousdiseaseneews.com/200203/vaccine.asp.

11. Russell. Further see David Henderson’s *The Joy of Freedom* (New York: Financial Times Prentice Hall, 2002), p. 280, for a good account of how company executives fear making FDA officials upset, especially when a new drug is up for approval.

12. Daniel P. Carpenter, “Groups, the Media, and Agency Waiting Costs: The Political Economy of FDA Drug Approval,” Department of Political Science, University of Michigan, June 2001, www-personal.umich.edu/~dancarp/fdaproject.html; italics added.

13. Adam Feuerstein, “Flu Vaccine Shift Smells Sweet to Wyeth,” *TheStreet.com*, Nov. 19, 2002, www.thestreet.com/_tsclsii/tech/adamfeuerstein/10055071.html

14. See Klein, and Quirk, pp. 217–18. Also, Miller, and Henderson, pp. 276–80.

15. Henderson, p. 277.

16. See Stephanie Stapleton, “Flu Vaccine: Enough to Go Around?” *American Medical News*, January 1–8, 2001.

17. Government Accounting Office (GAO) report, *Flu Vaccine: Supply Problems Heighten Need to Ensure Access for High-Risk People*, May 2001, GAO-01-624.

18. Kathryn Zoon, director of the Center for Biologics Evaluation and Research at the FDA, quoted in “Government, Industry Discuss Strategies for Preventing Vaccine Shortages,” *Reuters Medical News*, February 11, 2002.

19. See H.R. 910, introduced March 7, 2001.