

Bird Flu Fears: Is There a Better Way to Develop Drugs?

BY DEAN BAKER

In the late Middle Ages, the Bubonic Plague killed tens of millions of people. According to some public health experts, there could be a similar loss of life today from possible mutations of the Avian Flu virus. While the state of medical knowledge has advanced enormously since the late Middle Ages, Avian Flu poses such risks in part because the legal system surrounding the development and distribution of medicine is still mired in the Middle Ages. Government-granted patent monopolies have limited the ability to produce and stockpile large quantities of the drugs deemed most effective in treating the Avian Flu. As a result, the United States, and much of the world, are poorly prepared to deal with a possible outbreak of the flu, and millions could die unnecessarily as a result.

The basic issue here is relatively simple. In order to provide the private sector with incentives to develop new drugs, the government grants patent monopolies. These patent monopolies (which originated in the medieval guild system) allow firms to sell drugs at prices far above their competitive market price. As a result of patent protection, drugs that might have sold for \$15 or \$20 per prescription in a competitive market can be sold for prices as high as \$500 or even a \$1,000 per prescription.

This is exactly the problem the world faces in dealing with the Avian Flu virus. The patent for Tamiflu, the drug deemed most effective in treating Avian Flu, is held by Roche, a Swiss pharmaceutical company. Roche wants to maintain control over its patent for Tamiflu in order to earn as much money as possible from the drug. This means charging a price that is far above the cost of production, and also restricting supply, since Roche has limited manufacturing capacities.

In the absence of patent protection, any manufacturer in the world would be free to produce Tamiflu, if they could learn how to reverse engineer the drug.¹ If the patent protection were removed, or the production was subject to a compulsory license, then the amount of the drug available in the United States and around the world could be hugely increased in a short period of time.

Center for Economic and Policy Research
1611 Connecticut Ave, NW
Suite 400
Washington, DC 20009
tel: 202-293-5380
fax: 202-588-1356
www.cepr.net

¹ Apparently, the reverse engineering is not too difficult. Cipla, a major Indian drug manufacturer meets the highest quality standard, claims that it was able to master the engineering process in two weeks (“[Indian Company to Make Generic Version of Flu Drug Tamiflu](#),” *New York Times*, 10-14-05)

Dean Baker is Co-Director of the Center for Economic and Policy Research.

However, Roche and the pharmaceutical industry are prepared to fight to protect the patent monopoly on Tamiflu. They argue that if Roche is forced to license production of Tamiflu, then it will reduce the incentive to research new drugs. The industry claims that there will be less incentive to develop drugs if companies know that the government may occasionally require them to license their drugs to other manufacturers, rather than allowing them to reap the full benefits of a patent monopoly.

There is some truth in the industry's argument. Anything that reduces its expectations of future profits will reduce the incentive to undertake new research. If the industry believes that it will lose patent monopolies anytime a serious health emergency arises, then it will expect lower future profits than in a situation in which it believes that patent monopolies will be fully enforced regardless of how many lives are at stake. But, this is not a reason for sacrificing lives to patent protection. Rather, it is a reason for asking why the United States is still relying on a relic of the feudal guild system to support drug development in the 21st century.

Patent protection is one way to finance prescription drug research. It is not the only way, and it may not be the best way. The key question for health policy is whether the drug patent system is a more efficient way to provide incentives for developing new drugs, as compared with alternatives such as direct public funding or various types of prize mechanisms.

The Problem With Patent Monopolies

Patent monopolies on drugs create distortions in the same way that trade tariffs, quotas, or any other form of government intervention does. The main difference is that the price distortions are much larger in the case of patent monopolies on drugs – tariffs rarely raise the price of goods by more than 15-20 percent. Also, the opportunities to exploit monopoly profits are increased by the large amount of asymmetric information in the prescription drug industry. Specifically, the drug's manufacturer knows much more about a drug's effects than either the patient or the doctors prescribing the drug. There is also a problem associated with the fact that most drugs are paid for by third parties (either private insurers or the government) which makes the market far more complicated and introduces a large political component. The discussion below briefly outlines the economic and health problems that result from patent monopolies.

1) High Drug Prices

The point of patent monopolies is to allow drug companies to charge prices that are far above the competitive market price in order to earn back the cost of research. A simple way of estimating the cost of a drug patent is to look at the difference between the price of generic drugs and the price of brand drugs. The average generic prescription drug sells for approximately 30 percent of the price of an average brand prescription drug.² This measure is very inexact since many brand drugs manufacturers

² This is based on estimates from the National Association of Chain Drug Stores, cited in Blue Cross Blue Shield of Michigan and Blue Care Network, 2003, "[The Price Difference is Huge.](#)"

make discounts available that are probably not captured in this calculation. On the other side, some generic drugs enter the market with a six-month period of exclusivity as the sole generic producer of a brand drug. This period of market exclusivity would push up the price of generic drugs above the competitive market price.

While it would be desirable to have a more precise number, it is reasonable to assume that drug prices would fall by close to 70 percent if they were sold in a competitive market. The Centers for Medicare and Medicaid Services (CMS) estimate that the United States will spend \$224 billion on prescription drugs in 2005.³ A 70 percent price reduction would imply savings of more than \$150 billion. CMS projects that prescription drug expenditures will rise to \$520 billion by 2014, implying savings of \$360 billion in that year if drugs were sold in a competitive market. CMS projects that the public sector will spend \$240 billion on prescription drugs in 2014, implying that the combined savings to federal, state, and local governments from having drugs sold in a competitive market could be in the neighborhood of \$170 billion in the year 2014. By contrast, the industry claims that it carried through a worldwide total of \$49 billion of research in 2004, approximately \$41 billion of which was in the United States.

2) Copycat Research

Drug companies direct research in order to maximize profits, not to maximize the benefits to public health. One result of patent monopolies is that drug research often intends to gain a portion of the monopoly profits earned by another company by making a drug that essentially duplicates the function of an existing drug, rather than finding a cure for a disease that cannot be treated. For example, Schering Plough's large profits on Claritin provided a substantial incentive for other companies to develop comparable allergy drugs. While it is desirable to have more than one drug to treat any specific disease (patients react differently to the same drug), in most cases the second, third, or fourth version of a cholesterol-lowering drug will be of much less medical value than the first drug to treat a different disease.

In a world where drug companies enjoy patent monopolies, copycat drugs can be beneficial because they provide an element of competition, thereby lowering the price of the drug. However, much of this research into copycat drugs would be wasteful in a world without patent monopolies. According to data from the pharmaceutical industry, approximately two-thirds of its research spending (\$27 billion of the \$41 billion it spent on research in 2004) was devoted to copycat drugs.⁴ This implies that just \$14 billion of the research that the industry conducted in the United States was devoted to developing breakthrough drugs.

³ Center for Medicare and Medicaid Services, 2005, "[National Health Care Expenditures Projections 2004-2014](#)", table 11.

⁴ This calculation is based on the FDA's assessment that 70 percent of new drug approvals are not qualitative improvements over existing drugs and a study from the pharmaceutical industry indicating that duplicative drugs cost 90 percent as much to research as breakthrough drugs (see Baker, D. 2004. "[Financing Prescription Drug Research: What Are the Issues?](#)").

3) Excessive Marketing

Monopoly profits provide a large incentive to firms to market their patent-protected drugs. The industry's data show that it hires more people to market its drugs than to perform research. This marketing takes the form of ads on television and radio directed toward patients. The industry also employs an army of marketers who go directly to doctors' offices to persuade them to prescribe its drugs. Marketing efforts have also led to such practices as paying prominent researchers to sign their names to articles promoting drugs, company-paid conferences for doctors at resort locations that have the appearances of kickbacks, and in some cases outright kickbacks to doctors for prescribing specific drugs. These are exactly the sort of abuses that economic theory predicts would result from patent monopolies.

4) Concealing or Misrepresenting Research Findings

There is a regular stream of news articles about instances in which a drug company concealed research findings showing that its drug was either not as effective as claimed or might even be harmful. The most recent example that received substantial public attention was Vioxx, where it seems that Merck attempted to conceal evidence that the drug could prove harmful to people with heart problems. Patent monopolies on drugs provide a large incentive to conceal or falsify negative research findings. While stiff regulation and harsh penalties may limit the extent to which firms can succeed in misrepresenting their research, it is difficult for the government to effectively counteract the negative incentives that patent monopolies create.

5) Secrecy in Research

Science advances most rapidly in an atmosphere of openness, in which research results can be published as quickly as practical and can be discussed freely among researchers. The incentives created by patent-financed research work to promote secrecy. A company that has funded research to develop a specific drug has little incentive to make available any information beyond what is needed to obtain the patent, gain the Food and Drug Administration's (FDA) approval for the drug, and to promote the drug. The fact that much information is kept secret undoubtedly leads to a large amount of wasteful research. In many cases, drug companies may replicate research that other companies have already discovered to be unproductive. As a result, patent-supported research is likely to be far less efficient than research that is fully public.

6) Corruption in the Assessment of Drug Effectiveness and Safety

The patent system provides large incentives for the industry to attempt to influence regulatory bodies in their assessment of drug safety and effectiveness. A very large percentage of the researchers who have the expertise to assess the effectiveness of any specific drug have often received payments

(usually consulting fees) from the firms that are attempting to market the drug. As a result, the FDA is rarely in a situation where it can assemble a panel of disinterested experts to assess the safety and effectiveness of a new drug.

Patent monopolies also give the industry an incentive to spend large amounts of money lobbying politicians to shape the direction of legislation or regulatory practices. For example, drug companies have often conducted major lobbying campaigns to ensure that Medicaid will pay for a specific drug rather than lower cost alternatives.

7) Promotion of Counterfeit Drugs

Whenever government intervention leads to a large divergence between price and marginal cost, there is a strong incentive for counterfeiters to enter a market, taking advantage of this gap. This has happened to some extent with prescription drugs and it is likely to be a growing problem in the years ahead as the gap between price and marginal cost grows larger. Counterfeit drugs vary in quality – in some cases they may be as good as the brand drug – but patients cannot be sure of the quality when they use an unauthorized version of a drug. However, just as the government cannot eliminate cocaine or heroin, if the profits from counterfeiting drugs are large enough, it will not be able to prevent the production and distribution of counterfeit production of prescription drugs either.

Alternatives to Patent Financing: The Free Market Drug Act

There are many potential alternative mechanisms for supporting prescription drug research and a full range should be considered.⁵ This discussion focuses on one particular method, which is laid out in the Free Market Drug Act [FMDA].⁶ This bill proposes increasing public funding for bio-medical research by an amount approximately equal to what the industry currently spends on research (approximately \$30 billion a year). However, the additional funding, unlike the \$30 billion that currently goes to the National Institutes of Health, would be used to actually develop drugs and bring them through the FDA approval process. All the patents generated through this research would be placed in the public domain so that the drugs could be sold in a competitive market. All the research findings that resulted from this support would also be made fully public so that other researchers could benefit from it.

The proposal calls for creating a new structure of government-sponsored corporations that would maintain a strong element of competition. It would also establish a prize fund to reward extraordinary achievements by individual researchers or groups of researchers.

⁵ Other alternatives include a prize system, where patent holders are paid a sum depending on the importance of their breakthrough and an auction system in which the government pays a price for patents depending on how much private actors would have been willing to pay. In both cases, the patents would then be placed in the public domain so that the drugs could be produced as generics (see Baker, D. 2004. “[Financing Prescription Drug Research: What Are the Issues?](#)”).

⁶ The Free Market Drug Act was introduced in Congress in 2004 by Ohio Representative Dennis Kucinich.

The FMDA would create competition by establishing 10 distinct government-sponsored companies, each of which would be granted approximately \$3 billion a year to finance the research and development of new drugs. These companies could either undertake the research themselves or, like the pharmaceutical industry, contract out with university based researchers for most of their work. They could even contract out with private pharmaceutical companies. At periodic intervals (e.g. 10 years), a commission of public health experts and research scientists would evaluate the output of each corporation. The two least efficient would be eliminated and two new ones would be created in their place. This should ensure that inefficient companies do not gain an indefinite claim on public funds.

The FMDA would also establish a prize fund of approximately \$1 billion a year. This money would be used to provide prizes (similar to the Nobel Prize), in addition to researchers' normal salaries, to reward extraordinary innovations or discoveries. This would ensure that researchers would have a strong monetary incentive to work for major breakthroughs and also increase the probability that those whose work did make substantial contributions to the advancement of medicine or public health would be rewarded. As with the current system, there is no guarantee that the people who make the most important contributions will be rewarded for their efforts, but such a prize system would increase the probability that they will be.

Conclusion

It is critical that the public determine if the most effective way to provide incentives for developing new drugs is the current drug patent system, and to explore potential alternatives. The system of direct public funding laid out in the FMDA is just one alternative to patent-supported prescription drug research. There are other mechanisms that could also accomplish the task. However, the key point is that the country should as a matter of public policy decide the best mechanism for financing research. It cannot continue to accept patent-financed research, with all of its known inefficiencies and flaws, simply because it worked in the Middle Ages. People should not die because of patents.