



# Vaccine Buying Pools: Is More Protectionism the Best Route?

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Dean Baker

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**Center for Economic and Policy Research**

1611 Connecticut Avenue, NW, Suite 400

Washington, D.C. 20009

202-293-5380

[www.cepr.net](http://www.cepr.net)

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## **About the Author**

Dean Baker is co-Director at the Center for Economic and Policy Research in Washington, DC. This paper was prepared for the conference “Making New Technologies Work for Human Development,” which was sponsored by the Rockefeller Foundation and the United Nations Development Program, in Tarrytown, NY, from May 31 - June 2, 2001.

## Executive Summary

Patents are a form of protectionism: they prevent the free exchange of products between consenting individuals. Calling patents intellectual property "rights" does not change their logical status as a form of protectionism. Undoubtedly members of medieval guilds (the origin of patents) believed that they had an exclusive right to practice their craft. However, no serious economist would allow the moral perceptions of guild members to alter their assessment of guild restrictions as protectionist. Similarly, the desire of many participants in policy debates to treat patents as a property right cannot change the underlying economic issues. Characterizing patents as a form of protectionism is not just a question of semantics. Economists have developed an extensive body of research on the consequences of protectionism.

The Kremer-Sachs (KS) proposal is an effort to create a government/NGO funded agency which would commit itself in advance to large-scale purchases of vaccines against specific diseases (Kremer 2000(a); Kremer 2000(b); Sachs 1999). The intention is to create a market for vaccines against diseases that primarily afflict people in developing nations, in order to provide an incentive for the pharmaceutical industry to conduct research. In principle, the proposal would replicate the sort of incentive structure that the current patent system creates for research into vaccines (or drugs) against diseases that afflict people in developed nations. KS put this system forward as an alternative to a "push" system that would rely on directly funded research.

To seriously evaluate any proposal that relies on, and extends, patent protection, as does the KS proposal for establishing vaccine buying pools for developing nations, it is necessary to draw on the economic literature on the inefficiencies of protectionism. The following discussion will briefly note some of the well-known problems of protectionism as they apply to patents in general, and how they would be relevant to the KS proposal. It will then discuss ways in which the buying pool arrangements proposed by KS can create additional sources of waste and inefficiency. Finally, it will briefly discuss an alternative mechanism for promoting research.

## Inefficiencies of Patents in General

In addition to the inefficiencies that result from the unusual buying arrangements established in the KS proposal, the system would have all of the inefficiencies that are associated with medical patents in general. These inefficiencies can be grouped into two categories, static inefficiencies, which are the predictable outcome of a gap between price and marginal cost, and dynamic inefficiencies, which can be expected to lead to waste in the research and development process.

The most obvious static inefficiency is simply the distortion that results from forcing consumers, either as individuals or nations, to pay a price that is several hundred or even several thousand percent above the marginal production cost. The money in the buying pool shifts this expense to the donors for the vaccines that are actually purchased through the pool, but the buying nations would be forced to pay patent protected prices for purchases of vaccines which are not obtained with purchasing pool funds. At the least, this will mean paying several times more than the cost of production, and perhaps paying prices that are ten or twenty times higher than the cost of production. In many instances, people or nations will be forced to go without vaccines, even though they were willing to pay the cost of actually producing them. In such instances, patents will be directly denying people access to vaccines.

The large gap between marginal cost and the price of a patent protected products inevitably will lead to enforcement problems for developing nations. Even governments that are committed to respecting patent protections will find it very costly to do so, since the potential gains from evading the patents are so large. The nature of the problem is exactly the same as that created by any other trade barrier, except the distortions created by tariffs and most other trade restrictions rarely raise prices by more than 30-40 percent. Patents on vaccines or drugs raise the price by several hundred or thousand percent.

The large gap between price and marginal cost virtually guarantees that some unlicensed versions of vaccines will be produced. Their quality will be hard to monitor, and it is less likely that these unlicensed versions will be administered under proper conditions than if they were being produced in a fully legal manner.

There will also be the same sort of dynamic inefficiencies associated with the research stimulated by vaccine buying pools as are created by patents in general. Some amount of research will inevitably be wasted in copycat efforts. There will incentives to keep research findings secret, which will slow progress in the development of new vaccines, and there will be incentives to misrepresent or conceal research findings which reflect poorly on a firm's vaccine (see e.g. Bodenheimer, 2000).

### **Problems that are Unique to the KS System**

There are three types of problems that the KS proposal would create, which would not exist in a system of directly supported research:

- i) it risks diverting a large percentage of scarce research resources into fruitless areas of research;
- ii) it will do little, if anything, to promote an indigenous research capacity within developing nations; and
- iii) it will allow considerable opportunities for gaming by pharmaceutical companies and government officials in developing nations.

These problems are discussed in turn below.

### **Diverting Resources Down Dead Ends**

The risk of diverting resources down a fruitless path are intrinsic to the rules established under the KS proposal. Under this system, a significant amount of resources would be promised to support the purchase of vaccines against specific diseases, which meet some well defined guidelines. Kremer is quite explicit that these guarantees should be almost impossible to retract and, in principle, should be legally binding.

This creates a problem, because it is impossible to know in advance what areas of research will prove most fruitful. As a result, committing funds to combating a disease where it may not be possible to develop an effective vaccine can lead to vast amount of resources being wasted. While none of the fund's money is actually spent if a vaccine is not developed, there are a limited number of researchers with expertise in the diseases that afflict developing nations. If a buying pool is established for the wrong one, it will guarantee that many of these researchers are pulled away from lines of research that are potentially far more productive. Furthermore, it is unlikely that donors will be willing to commit additional funds to combat other diseases as long as there is a possibility that a breakthrough may force them to honor obligations under a previous commitment.

To see this point more clearly, imagine that malaria is selected as one of the diseases for which funding is committed. For whatever reason, suppose that it turns out to be very difficult to develop an effective vaccine for combating malaria. If some amount of preliminary research were conducted down standard paths, it may be possible for scientists to recognize that further research is not likely to bear fruit.<sup>1</sup> However under the KS system, this recognition would not prevent additional research from taking place. A legally binding guarantee would mean that there would still be far greater incentives for pursuing research

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<sup>1</sup> It is worth noting that the KS system, like any system of patent supported research, will make it more difficult for the scientific community to make such an assessment, since it encourages keeping research findings secret. Therefore, several different companies may pursue the same mistaken path, because there is no incentive for firms to share their research findings with potential competitors.

into a vaccine against malaria, even with a small probability of success, than research into developing vaccines against one of the diseases not selected to be covered under the system. Since KS propose that the guaranteed vaccine price actually rise through time in order to provide larger incentives, this could lead researchers to pursue a dead end almost indefinitely.

The problem is even more serious when it is recognized that the specificity of the guarantee can even misdirect research against one of the diseases that is designated within the buying pool. Suppose that research into malaria indicates that an effective vaccine may be difficult to produce but that some combination of pesticides, effective sanitation, and nutritional factors can substantially reduce both the incidence and the severity of the disease. Researchers would have no incentive to pursue these alternative paths.<sup>2</sup> The incentive created by the system is exclusively for developing a vaccine. Insofar as corporations respond to this incentive, they will pull researchers away from other potentially promising paths.

There is no simple way that this problem can be addressed within the KS system, since it is crucial that the goal be well-defined in advance in order for the purchasing pool guarantee to be seen as credible by the industry. Furthermore, a clause that allowed for a redefinition of the goals based on preliminary research findings would create a huge legal morass, if the guarantees are legally binding. For example, a company that spent \$50 million researching a Malaria vaccine would have a compelling legal case, if the guarantee was switched after 15 years to some other disease or broadened to any form of prevention/treatment of malaria.

In principle, it would be desirable to continually redefine the research agenda based on ongoing research findings. This can be done in a push system where findings are shared quickly and are fully public. It is all but impossible under the KS system, where the goals must effectively be written in stone far in advance, and the system provides large incentives for keeping interim research results secret.

### **Failure to Promote an Indigenous Research Capacity**

The KS proposal is clearly designed to provide incentives for the existing pharmaceutical industry to research diseases in developing nations. It is not intended to build up a research capacity within these nations themselves. This is an important drawback relative to a system which may do more to develop indigenous research capacities within developing nations.

First, it is relatively easy to see that the KS system is designed with the intention of providing incentives to the existing industry. The discussion focuses on making the purchasing guarantees credible to the industry, for example by including former industry representatives on the board which oversees the administration of the program. It also suggests excluding representatives of the WHO, and other international agencies, who are viewed with suspicion by the industry.

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<sup>2</sup> Again, the incentives for secrecy under the patent system will also slow the recognition that these alternative routes may be the most promising avenues for further research.

Even if there were no effort to stack the deck, the existing industry would inevitable enjoy an enormous advantage against upstarts in developing nations. The most obvious advantage is the extensive research structures that the existing industry already has in place. This will give established firms a huge advantage over any research efforts that might be pursued in developing nations. An even more important advantage may be the resources to effectively pursue legal claims to patents on research findings. The legal expenses on patent disputes often run into many million of dollars. Few firms, or teams of researchers, in developing nations would be in a position to pay these expenses. The recognition of the difficulty in protecting their patent rights is likely to discourage them from even trying to compete with the existing industry.

Some might dismiss the concern for building up an indigenous research capacity as a secondary issue -- after all, there are lives at stake and it is important to develop effective vaccines as quickly as possible, regardless of who does the research. This attitude is shortsighted. First, at best, the KS proposal will develop vaccines for a significant subset of the diseases that afflict people in developing nations. It does nothing to combat diseases not designated as part of the pool, or to find treatments other than vaccines. This means that, even in the most optimistic scenario, there will be a vast pool of unmet health problems in developing nations. In other words, people will still be dying, even if the KS proposal is successful.

If the resources committed to these buying pools could be used in a way that also helped develop research capacities in developing nations, then it is reasonable to believe that this expertise could be directed towards other health problems as well. Researchers and health care professionals are more likely to be interested in combating diseases that afflict their family and friends than people in distant nations.<sup>3</sup> If the developing nations cannot count on the charity of the developed nations indefinitely, then it will be advantageous for them to have their own network of researchers to address their health problems.

It is also important to note that, as a practical matter, indigenous teams of researchers may be more effective than researchers from the industrialized nations. This is not just for the obvious reason, that they are likely to have a more thorough knowledge of people's lifestyles and health condition, but perhaps more importantly, they may get greater cooperation from the populations at risk. In many developing nations the legacy of colonialism has created considerable suspicion towards people from the developed nations. In some cases, the basis of this suspicion includes drug research of questionable ethics. The reluctance of the population to cooperate with researchers can seriously impede progress by either making it more difficult to find subjects for clinical trials, or by not reporting honestly to researchers. For this reason, it would be desirable to have researchers who enjoy the confidence of the population they are trying to serve.

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<sup>3</sup> Kremer at one point argues for the need for a pull program like the KS proposal to develop vaccines because researchers are likely to have "intellectual interests that orient them to fundamental science" rather than testing effective vaccines (Kremer, 2000a, p 26). It is not easy to know what determines intellectual interests, but saving the lives of family and friends may have an effect.

## Gaming the System

Any time that the price of goods exceeds their marginal cost of production, as is true with any patented product, there will be opportunities for buyers and sellers to both gain by violating the rules. However, since much of the payment for vaccines comes from a third party in the KS system, there are even more opportunities for gaming the system. Also, since the payments under the system come from a peculiar mixture of market and administrative price setting, manipulating the system is likely to prove more profitable than effective research.

The most obvious way to game the system is to have a side payment from a pharmaceutical company to government officials to encourage them to buy their vaccine, rather than buying a competitor's vaccine, or saving their purchase pool money for a vaccine yet to be developed. Since the purchasing pool will provide a sum of money that could be several times larger than the country's expenditure on the vaccine, there is potentially a large pot that could be shared by the vaccine manufacturer and developing nations. This could take the form of straight corruption, where the officials personally profit, or it could take the form of side payments to the government, or a price reduction on some other drug being sold by the same company. While the last two outcomes could benefit people in developing nations, it would still mean that money was being wasted by the pool and/or the best vaccine was not being used. Kremer notes this possibility but argues that a combination of anti-bribery laws, whistleblower procedures, and the active involvement of civil society groups could limit the problem (Kremer, 2000b, pp 20-21). Economists usually place little confidence in these sorts of safeguards, and instead try to ensure that the structures in place do not create incentives for this type of corruption.

The other obvious mechanism for gaming the system is putting forth misleading findings about the effectiveness of a vaccine. KS propose that the price for a vaccine be set based on its effectiveness and usefulness, or that bonuses be given for vaccines that exceed certain standards. This mechanism of price setting will provide firms with large incentives to provide misleading, if not inaccurate, research findings to the board that controls the pool. For example, if different clinical studies showed a range of effectiveness of a vaccine, the manufacturer would have a strong incentive to only report the studies showing the highest rate of effectiveness. While this sort of incentive already exists with research findings, it is likely to be more serious under the KS system. Once a vaccine is found to meet a standard warranting a high price or bonus, it may prove very difficult legally and politically to take back money that already had been paid out, even if subsequent research shows it to be less effective than originally reported. Furthermore, insofar as such matters are placed at the discretion of the board controlling the fund, there will be an enormous incentive for manufacturers to try to influence their decisions through bribes or other mechanisms.

### Alternatives to the KS System -- An Expanded Push Mechanism

The discussion of push mechanisms in Kremer (2000a) is far too dismissive of this alternative. It draws extensively on the failure to develop an effective vaccine against malaria. It would have been easy to draw on a long record of achievements in research directly supported by government or NGO funding. The most obvious example for this discussion would have been the development of the polio vaccine in the early fifties, which was supported by a charity in the United States. There is a long track record of important research breakthroughs in work that has been supported by the NIH in the U.S.. This has included not just primary research, but in some cases, actually carrying drugs through the clinical testing stage.

Virtually no one involved in this debate disputes the importance of primary research being supported by government agencies or NGOs. The insistence on the need for a pull mechanism, in the form of patents, depends on a distinction between the character of work involved in basic research and the work involved in the development and clinical testing of drugs or vaccines. Note that it is not sufficient to assert that private industry will do the latter type of research, but not the more basic research, because the payoffs are too distant and diffuse. This fact only means that the granting of patent monopolies can provide an alternative to directly funded research, it does not mean that this alternative is preferable to directly funded research.

If governments in developed nations, as well as NGOs, were prepared to commit funding to producing vaccines, it is likely that it would be far better spent in an expanded push mechanism. (It is worth noting that even Kremer [2000a] sees a need for more funding of basic research in this area.) As Kremer points out, there are problems of potential conflicts of interest and corruption in push systems, but there is no reason to believe that these problems are greater than what they would be under the KS system. Usually these problems can be seen as proportionate to the rents involved, and the KS system will allow rents to patent holders that are far larger than any of the rents that could be gained by individuals under the push system.

Also, if the involvement of groups from civil society can limit corruption in the KS system, it surely could do so at least as effectively in a push system. Agencies and individuals receiving governmental or quasi governmental funds under a push system would face far more stringent disclosure requirements than private firms operating under the KS system. In fact, the existence of extensive disclosure requirements is one of the reasons why it is relatively easy to find instances of corruption or nepotism in publicly supported research. It is far less likely that similar practices would ever be made public in the private sector.

There are several principles that could be followed under an expanded push mechanism to try to maximize the efficiency of research spending and minimize the extent of corruption. For example, it would probably be best to set up competing structures at several phases of the development process. For example, different agencies or divisions could be given the responsibility for supporting research designed to develop vaccines against a particular disease or set of diseases. An agency that fell behind would be likely to face reorganization, while one that shot forward could provide an important example to be emulated. Within each agency or division, grants would be best given for limited time periods subject to

renewal based on the accomplishments of the research team, basically the procedure currently in place at NIH. Unlike the research supported under the KS system, with an expanded push mechanism, the results would be widely and quickly disseminated, allowing researchers to benefit from the failures or successes of competing teams.

It would also be possible to try to target some amount of the push spending towards researchers within developing countries. An important goal of this spending would be to build an effective research capability in these countries. Undoubtedly some of this money would be wasted. It will always be more risky to support relatively inexperienced research teams in developing nations than established researchers at elite universities, but the potential payoffs are quite large. If the system can help establish important research centers in developing nations, the gains will be long lasting.

It is also important to note that it is possible to establish significant monetary incentives for especially important research breakthroughs in the context of an expanded system of government/NGO supported research. Large cash prizes, which also carry considerable prestige, such as the Nobel Prize, or the John Bates Clark award in economics, are likely to provide substantial incentives to researchers. The sums of money that are being discussed in the context of the KS proposal could support numerous prizes of varying size, in addition to paying for research that would be directly funded.

Since the vaccines, drugs, and other output of a push system would all be placed in the public domain, they would be produced and sold in a competitive market. Their price would be equal to their marginal cost of production, which would mean in most cases they would be affordable to all but the poorest nations. Allowing the drugs to be sold in a competitive market also eliminates virtually all the incentives to use bribes or misleading information to promote the sale of inappropriate or harmful drugs and vaccines. For all the reasons that economists generally value competitive markets, it would be desirable to have them in the production of drugs and vaccines as well.

There is one final point worth noting about the relative superiority of an expanded push system over the KS proposal. While a portion of the funding for the pool envisioned by KS will come from foundations or private individuals, it is also expected that a portion will be provided by governments in wealthy nations. There clearly is public support within the developed nations for some amount of aid of this type, but the money that the public is willing to commit will always be limited. Under the KS system, the public's support for a funding pool would always have to be motivated almost entirely by charitable concerns, since there would never be direct paybacks from the resulting research. It would be impossible to distinguish the research stimulated by the vaccine buying pools from any other research. Therefore, if any of this research had benefits for people in the industrialized nations – for example an effective vaccine against AIDS -- it would be difficult to attribute the benefits to the money contributed to the buying pool.

However, under a push system, the spin-off benefits from the resulting research would be directly visible. In the case of an effective AIDS vaccine, if this were the result of research funding through an expanded push mechanism, the patent for the vaccine would be placed in the public domain so that the vaccine would be available at a minimal cost. In this situation, the benefits from research supported via this mechanism would be readily

apparent to the public, which should increase its willingness to support funding in the future. In other words, the public in wealthy nations is likely to be more supportive of funding for research into diseases that primarily afflict people in developing nations, if they believe that they stand to benefit as well from such research, as opposed to the situation that would exist under the KS system, where any benefits for taxpayers in the developed nations would be extremely limited, and difficult to recognize in any case.

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