

Solving the Vaccine Shortage

Market Solutions or Government Intervention?



CENTER FOR MEDICAL PROGRESS
AT THE MANHATTAN INSTITUTE

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***An Overview of Recent Shortages and the
National Vaccine Advisory Committee (NVAC)
Recommendations***

The Manufacturers' Perspective

Public Policy and Immunization

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Robert Goldberg, Ph.D.

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ROBERT GOLDBERG, Ph.D.: In a recent article, “Is There a Future for Vaccines?” that I wrote for a new journal, I talked about the poor economics of vaccine research and development, poor because of policy decisions that have turned vaccines into commodities.

Nearly a decade ago, a number of us participated in a similar conference at the American Enterprise Institute, focusing on the Clinton Administration’s Vaccines for Children Program. We discussed the impact federalizing nearly 70 percent of the vaccine market would have on the development of new vaccines, and how it would affect the availability of the pediatric vaccines recommended back then. The fact is, we raised the concern that shortages were a potential byproduct and that the Clinton plan was likely to hinder development of new vaccines in the future.

Here we are just a few years later and we are down to four vaccine manufacturers. As demand for vaccines has gone up, the number of suppliers has gone down. We have had product shortages, and we are selling some pediatric vaccines at 15 cents a dose. At the same time, the cost of manufacturing and the cost of compliance with regulation have both gone up.

We have unbelievable technology for vaccine development. Thanks to genomics, we have entered what should be a golden era. At the same time, the ability to produce vaccines in mass quantities has been thrown into question, because we have shunted the best technology into a brackish backwater of commodity production.

To solve problems of ensuring vaccine supply, some have proposed that government get into the business of producing not only the current crop of vaccines, but new vaccines yet to enter the marketplace. This will not work; it will merely compound the problems we already face.

What are the choices as we move into an era of vaccine technology that can dramatically improve the public health at a fraction of the cost of what we spend on potentially preventable diseases today? The distinguished panelists whose presentations are contained herein present compelling arguments why a market-focused government vaccine policy is the best approach to solving our vaccine shortage and improving public health.

An Overview of Recent Shortages and the National Vaccine Advisory Committee (NVAC) Recommendations

JEROME KLEIN, M.D.: I'm chairman of a working group of the National Vaccine Advisory Committee whose purpose is to identify potential causes of vaccine supply shortages, to develop a comprehensive list of strategies to address and prevent future shortages, and to enlist key stakeholders to consider the applicability, feasibility, and effectiveness of these strategies. For the past year, the working group has held discussions of these issues, including a multidisciplinary workshop in Washington in February of this year.

Concern for vaccine supply arose because of unprecedented and unanticipated shortages of a number of routinely administered vaccines beginning in 2001. These were significant, extended shortages of vaccines against eight of the eleven vaccine-preventable childhood infectious diseases, including DTaP, that is, diphtheria, tetanus toxoids and the acellular pertussis vaccine; MMR, the measles, mumps, rubella vaccine combination; varicella; and the pneumococcal conjugate vaccine. Adult tetanus and diphtheria toxoids were also in short supply.

These shortages led the authoritative medical groups—the Advisory Commission on Immunization Practices, the Academy of Pediatrics Committee on Infectious Diseases, and a similar committee of the American Academy of Family Physicians—to recommend deferral of certain immunizations and to set priorities for high-risk patients until supplies of vaccines returned to normal.

The deferrals posed an increased risk of otherwise preventable infectious diseases. The shortages were frustrating for physicians, parents, and public health officials. Pediatricians and family physicians were angry because they could not carry out their mandate to provide optimal preventive services to the children, and also because they weren't given the information they thought appropriate about why the shortages had occurred.

Why did the problem happen at this time? Was the multiplicity of shortages the result of an untimely confluence of manufacturing problems or a systemic problem in development, manufacturing, and regulation of vaccines? Why is there an apparent fragility of supply, and what can be done to strengthen it?

Disruptions in supply are likely to recur; thus, action to implement short- and long-term solutions should be considered now.

It should be pointed out that in July of this year, the shortages of DTaP and MMR were resolved, and varicella apparently will be resolved soon, leaving the pneumococcal conjugate vaccine as the only important shortage. That will likely not be resolved until the winter-spring of 2003.

The NVAC working group considered six strategies for strengthening the vaccine supply: 1) increasing financial incentives

for research, development, production, and administration; 2) streamlining regulatory processes; 3) establishing government-directed programs; 4) using vaccine stockpiles; 5) effectively managing liability issues; 6) enhancing communication and collaboration among key stakeholders.

1. Providing Incentives

Manufacturers should receive appropriate incentives to enter and remain in vaccine development and production. Companies drop out when a product no longer provides a reasonable return on investment. The need for incentives is as axiomatic to the pharmaceutical industry as it is to all profit-making organizations.

A multidisciplinary group should be convened to assess the nature of appropriate incentives. It should provide information on incentives such as tax relief for new facilities or reconstruction of old facilities to meet current good manufacturing practices, perhaps guaranteed market and price, and government contracts that reward performance, such as delivering vaccine supplies in a predictable manner.

There's also a concern about the adequacy of reimbursement to immunization providers for administration of vaccines. Recent reductions in this area constitute disincentives for physicians and other providers.

2. Streamlining Regulatory Processes

The FDA is responsible for ensuring the quality, safety and effectiveness of vaccines, their potency, purity, and availability.

The implementation of policies around good manufacturing practices should be reviewed to make sure that decisions are science-based and do not have a negative impact on supply, unless there is an issue of vaccine safety.

In addition, there should be increased support for the Center for Biologics Evaluation and Research, CBER, the agency responsible for testing and approving vaccine lots, to enhance its ability to review the scientific evidence that supports safety, efficacy and quality of vaccines. CBER is a critical component of the regulatory process.

3. Establishing Government-Directed Programs

For government-directed programs, there was consideration of a unified federal prioritization of vaccine development and distribution to assure that public health needs are met. The key word is unified, since a number of agencies have this responsibility.

There was consensus that government-owned or -operated facilities, or “GOCOs,” would not be useful for the production of routinely administered vaccines. Industry might be unable to compete with government-subsidized programs, which would lead to withdrawal of manufacturers, loss of innovation and loss of new products. GOCOs could be useful and might be critical for national defense or needs of the military, however.

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4. Using Vaccine Stockpiles

The goal of the Vaccine Stockpile Program, initiated in 1983, was to have a 6-month supply of product to meet surge demands or shortages. Currently, the vaccine stockpile includes a limited number of products: inactivated poliovirus vaccine; measles, mumps, and rubella vaccine; diphtheria and tetanus toxoids.

The vaccine stockpile is likely to be the most effective short-term solution to overcome shortages. The framework is already in place, and the program is working effectively.

Stockpiles should be enhanced, however, to include more vaccines than those currently used for routine administration and in sufficient quantities to ameliorate problems of supply and surge demands. We also need to address the limitations and challenges of the program, including varying storage temperature requirements, procedures for stockpile activation, and rotation of vaccines.

5. Strengthening the Liability Program

The vaccine liability issue has been dealt with effectively by the Vaccine Injury Compensation Program. The VICP was enacted in the late 1980s, as a collaboration of various groups, including legislators, the American Academy of Pediatrics and various parent-advocacy lobbying groups, to make sure that the children who might be injured through an adverse event in the course of administration of a routinely recommended vaccine would be quickly, easily and appropriately compensated.

Prior to the enactment of the legislation, litigation led to shortages as manufacturers left the marketplace.

Recent concerns for relaxing the burden of proof, however, have challenged the stability of the program. The NVAC working group has recommended several action points: strengthen, not just maintain, the Vaccine Injury Compensation Program; expand the number of vaccines covered; and recognize that it's the entire mix in the vial that should be considered the vaccine—that is to say, the vaccine itself is not the only active component; that preservatives and additives along with the vaccine are necessary to provide safe and effective immunization.

6. Enhancing Communication

Finally, we need better communication and collaboration among key stakeholders. The great benefit of vaccines should be communicated to the public by a national campaign. We need to counter inaccurate claims of groups that, for one reason or another, are antagonistic to immunization programs.

We need transparency of information about vaccine supply, to mitigate anger and frustration among caregivers and consumers. In addition, manufacturers should be required to provide advance notification to HHS if they intend to withdraw from the marketplace.

In conclusion, we should consider both short- and long-term solutions now, with the short-term solutions including vaccine stockpile, increased support for the research arm of the FDA, CBER, increasing the resources and the expansion of vaccines covered for the Injury Compensation Program, increased

transparency in information about supply, and, finally, a coordinated program for providing the best information about the value of vaccines to consumers and caregivers.

The long-term issues will be more complex. We need to begin that process now, including review of financial incentives, review of current good manufacturing practices, and unified federal prioritization programs for identifying vaccine needs.

The Manufacturers' Perspective

WAYNE PISANO: We are just coming off a rough 2-year period during which our nation experienced acute vaccine shortages. There has been a great deal of recent discussion as to the causes of these problems and, unfortunately, a hasty call to slap a government Band-Aid on the situation rather than fix the institutional problems that cause shortages.

As Dr. Klein noted, most of the shortages have been or shortly will be resolved.

Timetables were set by the industry to achieve these goals, and these timetables have been met. But even though the front-page shortages are over, we still must look at long-term solutions and enhancements to our vaccine supply.

Collaboration is key, and collaboration among industry, the public health community, the private provider, and government is not a new concept in vaccines. We could not have brought so many childhood diseases to near-eradication, nor could we have the high rates of immunization in our country, without such a partnership.

I'd like to provide you with some background on the vaccine industry. Currently, just four companies supply 100 percent of the childhood vaccines in this country and 90 percent of all the vaccines around the world. Not much more than two decades ago, there were a dozen companies making vaccines, most of

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which have left the market or been driven out by a variety of pressures.

Vaccine manufacturing is unique in the pharmaceutical universe. Unlike pills, vaccines require the use of biological organisms, viruses and bacteria, which will not always grow or respond on demand. Adding more people on a production line or increasing factory hours will not change this law of nature. You cannot turn on a tap and have vaccines flow out, no matter who is manufacturing them.

If vaccines are difficult and time-consuming to produce, the regulatory approval process for new and existing vaccines is equally complex and protracted, with timetables that are difficult to predict. The FDA must approve every lot of vaccine for release. Given that production schedules can run 12 months or longer, any abrupt changes in policy that can influence demand or move a company to leave the field can result, has resulted, and will result in supply interruptions.

At Aventis Pasteur, we experienced disruptions in supply of two of our vaccines—DTaP and tetanus. Each shortage was brought on by external forces that, on examination, could have been reshaped to avoid a shortage.

Last year, there was an abrupt withdrawal from the market by a tetanus manufacturer, leaving Aventis Pasteur as the only manufacturer of adult Td, DT, and tetanus toxoids. Several years earlier, we had taken a hard look at our own tetanus operation and undertook the necessary infrastructure upgrades for this essential product.

It takes us between 27 and 32 weeks to produce a purified bulk lot of tetanus vaccine. This is followed by 8 to 10 weeks of bulk lot testing, another 4 to 6 weeks of filling, packaging, and final approvals. All in all, it takes about 11 months to produce a single lot of tetanus vaccine. This is a typical vaccine production timeline.

In these circumstances, where production time lines are so long and manufacturers so few, the withdrawal of one manufacturer clearly has an incredible impact. Had a mechanism been in place where the manufacturer provided the government with some

type of confidential advance notice, this shortage largely could have been prevented or greatly reduced. Or had a stockpile program been in place, reserve supplies could have bridged the potential shortfall.

Another shortage we experienced was for DTaP vaccine. It was a vaccine already in tight supply because two manufacturers had left the marketplace. Then the government determined that thimerosal, a preservative, was to be removed from the vaccine. This seemingly simple policy change critically affected supply in several ways. First, with the change in formulation, the entire manufacturing process had to be changed and receive regulatory approval. The reformulated product had to go through a license application, with the concomitant establishment of new procedures, validation, testing, and labeling, all before getting the product into the marketplace. The net effect is that Aventis Pasteur invested approximately 2 years' development effort to replace an existing product.

Second, the way the vaccine was packaged needed to be changed. Aventis Pasteur's production facility was designed to supply multi-dose vials, the package favored by the marketplace and physicians. Without the preservative, physicians could no longer use multi-dose vials. Aventis Pasteur had to change the production to fill single-use vials. This sounds simple, but it had a major impact on supply. Each vial must be overfilled to ensure that the correct dose actually gets into the syringe. Filling schedules had to be revamped and time was lost. The overall effect of these changes was a reduction of approximately 25 percent in DTaP output.

Again, all changes could have been accommodated and the shortage avoided if policy and regulatory authorities had looked to manufacturers for a reasonable time frame for implementation. Aventis Pasteur estimated it would take 2 years to accomplish the changes without interrupting supply. Instead, the decision—made in a vacuum—was to put the introduction of thimerosal-free vaccines in the U.S. on an 18-month timeline. This effectively created a gap in supply that never needed to happen. Thimerosal in vaccines has not been shown to be harmful; continuing to use the

existing vaccines until the process changes were implemented would have minimized the shortage or prevented it entirely.

I would like to offer some potential solutions that, in part or whole, would have tremendous impact on restoring stability to the vaccine supply. These steps include some areas where I believe that government intervention will be helpful and appropriate.

1. Strengthen the Stockpile Program

Industry and Aventis Pasteur support the expanded stockpiles for use if supplies are disrupted. We support additional funding for the CDC for the establishment of stockpiles for both single- and multi-source products. In recent years, the number of vaccine stockpiles has actually decreased. This will be particularly important in the coming years as more and more combination vaccines are approved. Stockpiling single-antigen vaccines is of vital importance to ensure that, in case of unexpected shortages, the public health is still protected.

2. Provide Advance Notice When Discontinuing Product Production

We propose that manufacturers pledge to give advance notice if they voluntarily plan to cease manufacturing a vaccine. Aventis Pasteur pledges to do so should the situation ever occur. The obvious exception here is if the withdrawal is involuntary. Earlier this month, Aventis Pasteur made a public pledge to provide at least six months' notice should we for any reason discontinue manufacturing any one of our vaccines. We have urged our colleagues at the other three major manufacturers in the U.S. to make the same commitment.

3. Exchange Information With CDC

Companies have always considered supply information to be proprietary, as it provides a window into capacity and other sensitive areas. However, in a time-sensitive market such as influenza in which problems experienced by one manufacturer will have a great impact on public health, this information needs to be shared as early as possible. We propose that measures be taken to authorize the CDC to act as a confidential facilitator of critical supply information that is provided by manufacturers and to maintain this

data as proprietary and confidential, as well as to allow the CDC to use the information so that other manufacturers can fill the gap in the event of an imminent shortage.

4. Support Appropriate Government Involvement

There are two concepts that have been advanced by individuals who are less familiar with the complexities of vaccine production which we believe are absolutely the wrong path to achieving a stable vaccine supply in the U.S. The first is a national vaccine authority for adult and pediatric immunizations. This would be duplicative and expensive; it could result in an even greater fragility of supply. By setting up the government in the position of a vaccine competitor—which has been proposed in the form of a national vaccine authority—we would have created a new and potent barrier to entry for new vaccine developers and a disincentive for existing vaccine manufacturers. The vaccine industry needs to be encouraged and supported, not placed into competition with the government.

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The second concept is the establishment of the GOCO, the government-owned, corporate-operated manufacturing facility. Industry is puzzled as to why we're rushing into a GOCO when all the manufacturers are already willing to respond to the appropriate RFPs. Industry should be viewed as partners and resources, not competitors.

Let's talk about where government does have a useful and appropriate role.

We face a growing lack of parental confidence in immunization. The good news is that parents no longer fear vaccine-preventable infectious diseases. But they have also lost respect for the harm such diseases can cause. There is an urgent need to address misinformation about immunization. The government should take the leadership role in this area by supporting vaccine education efforts and emphasizing the value of vaccines through the public health authorities.

Public Policy and Immunization

HENRY MILLER, M.D.: Following recent advances in understanding of the molecular and cellular bases of immunization, and the advent of techniques like recombinant DNA technology, the present time should be the “golden age” of vaccine development. But there is scant enthusiasm for vaccine development in the drug industry. From 1967 to 1984, the number of U.S. vaccine manufacturers fell from 37 to 15, while the number of licensed vaccines declined from 380 to 88. And now, there are four manufacturers in the U.S. and only a few dozen vaccine products.

Although vaccines are widely acknowledged to have high social value, to pharmaceutical companies their economic value is low compared to other therapeutic drugs. The entire worldwide vaccine market, estimated at approximately \$6.5 billion annually, represents only about 2 percent of the global pharmaceutical market, a market roughly equal to sales of one blockbuster anti-ulcer drug.

Why have we seen vaccine development fall into such disfavor? The short answer is low return on investment and exposure to legal liability. And the reason for those factors is a flawed public policy.

For example, the U.S. Centers for Disease Control, the largest domestic purchaser of vaccines, uses its buying clout to extract deep discounts for purchases. If interference with market forces were warranted, arguably the government should be offering subsidies to enhance profitability and encourage more R&D rather than imposing what amounts to a punitive tax on vaccine manufacturers.

Another significant obstacle to vaccine development is excessive regulation. One historical example is the delay in marketing the second-generation hepatitis B vaccine, which occurred in the 1980s when I was at the FDA. The first hepatitis B vaccine had originated from the pooled plasma of patients with chronic active hepatitis. But each batch was purified and inactivated, and eventually, the FDA licensed this product in 1982. But neither patients nor physicians were very happy with the vaccine, and it was very seldom used.

In the early 1980s a promising candidate for a second-generation vaccine was produced that was genetically engineered by

recombinant DNA techniques. This vaccine was made by introducing into baker's yeast a single gene from the hepatitis virus, a gene that codes for a code protein. The yeast is grown in large vats, broken open, the code protein is purified, and that acts as the vaccine.

As you can imagine, there was great anticipation about this second-generation vaccine because no live human fluids or live virus were used in the manufacturing process. With safety (which is the primary issue in vaccines that might be contaminated with live virus) as a secondary issue here, the pivotal policy question for the FDA was the criteria for determining the efficacy of this new vaccine. The most conservative, traditional approach would be to conduct large, comprehensive clinical trials in which you look for actual prevention of hepatitis B. But you would have to do the trial in a place, such as Asia, where the disease was epidemic, and the process would be very slow, expensive and time-consuming.

At the other extreme, an alternative would be to look at surrogate endpoints that you can measure in the lab, endpoints such as seroconversion, the ability to elicit the appropriate kinds and levels of antibodies, and cellular response. This process would be much faster and much less expensive.

Still another option would have been a middle course: make seroconversion laboratory examination the primary measure of efficacy, but also do a confirmatory clinical trial, to demonstrate that the vaccine would indeed prevent the occurrence of hepatitis.

In the end, the FDA adopted the most risk-averse, conservative course: massive clinical trials in Asia involving thousands of patients, tens of millions of dollars and long delays as these Asian studies were planned, performed, and analyzed.

This decision meant a delay of years in getting that product to market. During that time more than 10,000 Americans unnecessarily contracted hepatitis B. Some of these—hundreds, probably—went on to die from the complications of hepatitis, namely cirrhosis and carcinoma of the liver, while an obviously safe vaccine was undergoing what most reasonable observers would consider to be overly comprehensive clinical trials in Asia.

It's noteworthy that during the decade following the approval of the second-generation vaccine in 1986, the incidence of hepatitis B in the United States fell by more than two-thirds.

Another current example of the FDA's general mind-set pertains to the agency's position on a vaccine to prevent meningitis C, a bacterial illness that infects thousands of persons and kills hundreds in the United States annually. At present, no conjugated vaccine against this infectious disease is approved for use in the United States, although three excellent preparations are available and widely used in Canada and Europe.

The safety and efficacy of these foreign vaccines have been demonstrated in both pre-licensing testing and in massive public health immunization programs abroad. More than 20 million doses of the vaccines have been administered. But the FDA refuses to recognize the foreign approvals, although such reciprocity of regulatory approvals has been a long-time goal of discussions among international regulators.

What can we do about this unfortunate situation? From at least two prominent quarters—the Institute of Medicine, an advisory group to the federal government, and the Gilmore Commission on Terrorism—have come recommendations for what is essentially a government takeover of vaccine production.

The Institute of Medicine has recommended a National Vaccine Authority with sweeping responsibilities, which would include market research, control of intellectual property rights, in-house R&D, and financing of clinical trials of new vaccines.

The Gilmore Commission made a similar recommendation, arguing that direct government ownership or sponsorship is the only reasonable answer, at least for vaccines against exotic diseases such as anthrax and smallpox.

These proposals to federalize vaccine production may seem in keeping with the kind of creeping governmental mandates that we've seen in the case of national or homeland security. But, historically, government manufacture of pharmaceuticals has not worked very well at all.

A good example is the National Pituitary Agency, a government program that operated from the mid-1960s to the mid-1980s under the auspices of the NIH. This program produced and distributed human growth hormone for children of short stature who lack normal amounts of the hormone.

The Agency made the drug from human pituitary glands recovered from cadavers. But the program lacked rigorous collection guidelines and purification procedures. The result was that occasionally the drug was contaminated with the slow virus that causes Creutzfeldt-Jacob disease—the human equivalent of BSE, or mad cow disease. The reason was that the glands were pooled in lots of thousands or tens of thousands; if a single gland was contaminated, the entire large batch was contaminated. As a result, several dozen recipients who received growth hormone as children subsequently died from Creutzfeldt-Jacob disease.

Had this product been made by a private manufacturer worried about competition and liability, that company likely would have updated the formulation and purification methods with state-of-the-art technology. Or a competitor would have. The FDA likely would have demanded rigorous adherence to drug-manufacturing regulations from a private manufacturer, but for a sibling agency, the FDA was less demanding.

It might seem that the recent problems with privately produced anthrax vaccine argue for more rather than less government involvement. After all, Michigan-based Bioport Corporation has had recurrent difficulties producing anthrax vaccine, ranging from poor quality control to lax record keeping. Regulators, in fact, were forced to suspend manufacturing for several years, from 1998 until January of this year.

But the rest of the story is that Bioport is not your typical pharmaceutical company. Until late 1998, it was run by the Michigan Department of Public Health. Many, if not all, of its problems stem from its days as a government-run, not a private, institution.

The GAO reports that during that period, FDA inspectors had only limited access to the plant, and the manufacturer failed to

notify the FDA promptly about important changes in its vaccine-manufacturing process.

These are lapses that the private sector would not and does not get away with. But the manufacturer in this case was able to do so partly because it had a monopoly on anthrax vaccine, no competition at all to produce it, and also it essentially had one customer: another government agency, the Pentagon.

Overall, the anthrax vaccine problems emerged not from Bioport's relatively recent incarnation as a private company, but from the period when it was run by the state.

Well, if not Uncle Sam, who should be doing R&D for vaccine development? We should be seeing—and encouraging—companies that use biotechnology and new knowledge about viruses and bacteria to make safer, more effective vaccines.

The role of the federal government should be not to take over vaccine development, but rather to craft policies that make it more attractive—or less unattractive—to the private sector.

There are several ideas for these policies. First, reciprocity of vaccine approvals between the U.S. and the European Union would significantly cut development costs and decrease time to market. Earlier appearance in the marketplace could amount to hundreds of millions of dollars of benefit to manufacturers.

Second, public sector agencies must stop using their purchasing clout to obtain heavily discounted prices for vaccines. Recently, a manufacturer's proposed price of \$58 a dose for its pneumococcal vaccine was rejected by the CDC, which demanded a discount of more than \$10 a dose. The government used its clout to gain favorable conditions and unrealistically low prices from the company.

Third, extension of the patent term for vaccines beyond that permitted for other pharmaceutical products under the Patent Term Restoration Act would be an incentive to the industry. I recognize the disadvantage of this approach to other potential manufacturers who would be excluded from the market during the period of patent extension; that is a shortcoming of this proposal.

Fourth, we should be able to use creative applications of the kinds of marketing exclusivity provisions that are embodied in the orphan drug law, which, after all, was designed to promote

development of drugs of uncertain commercial value. The key word here is “creative” because, again, we don’t want to structure market exclusivity in a way that keeps other potential manufacturers out of the business. So how can we adjust for that?

We could offer a vaccine developer a specified period of marketing exclusivity for a product of choice other than a vaccine; that is, it would be similar to emissions trading or bartering. A manufacturer could sell or transfer to another one of its own products the right to market exclusivity, which could be worth a vast amount of money in the marketplace.

Fifth, another innovation would be to decrease companies’ exposure to excessive product liability in various ways. One would be government indemnification for damages caused by side effects from FDA-approved vaccines—that is, assuming that there was no negligence or fraud involved. We already have a model for that in the Vaccine Injury Compensation Program.

Yet another innovation to reduce liability would be the establishment of a regulatory compliance defense against tort suits for damages caused by vaccines. Such a defense stipulates, in effect, that when a manufacturer has met the high bar raised by the FDA for product approval, that any mishap from use of the product would be considered to be genuinely unforeseeable. Damages would be compensated by the government, and the company would be exempt.

Sixth, the development costs of vaccines could be reduced significantly by tax credits to companies for a certain fraction of qualifying R&D.

Last, another stimulus would be health care insurers’ exemption of vaccination from plans in which the insured must pay “first dollar” health care costs, that is, a deductible, because such plans discourage the insured from paying for discretionary, preventive medical interventions, since it comes out of pocket.

In summary, then, to avoid a return of epidemics of preventable infectious diseases, we need to remove existing disincentives and create new incentives for vaccine development. I’m afraid that getting the government to do so will be like dragging a child to the doctor for a painful shot.

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