FOIA Number: 2018-0758-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21090

FolderID:

Folder Title:
Issues - Vaccine Technology Act of 1999

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	3	2

The Lifesaving Vaccine Technology Act of 1999

A Vaccine Research and Development Tax Credit
Targeted at the Most Deadly Infectious Diseases in the World

Legislation to be introduced by Rep. Nancy Pelosi

When private-sector investment has failed, it all adds up to very few vaccines. We need a coordinated push from beginning to end. Unless there is vigorous investment from the private sector, vaccines won't get through the pipeline. That's why we're so slow in developing the HIV vaccines, that's why we don't have a malaria vaccine...
– Dr. Phillip K. Russell, Johns Hopkins University, School of Hygiene and Health

Vaccines are among the most powerful and cost effective disease prevention tools available, and new vaccines are needed to fight existing and emerging disease threats. Governments play a crucial role in funding the basic science of vaccine research, but it is private biotech and pharmaceutical companies that have much of the expertise to take the findings of basic research and develop them into commercially viable vaccines.

Private sector pharmaceutical manufacturers have recently begun to dedicate increased attention to vaccine research, but investment in vaccines for specific diseases is often not proportional to the death and suffering caused by these maladies. AIDS, malaria and tuberculosis together account for over 7 million deaths annually worldwide. But there are market disincentives for investment in vaccines against these major killers, and relatively few vaccines against these diseases are now in development at pharmaceuticals and biotech companies. Once vaccines are developed, they are too often not readily available to people in developing countries where infectious diseases kill millions annually.

Government has an important role to play in providing incentives to help the market work more effectively to address the biggest public health opportunities. A targeted research and development tax credit for vaccines against AIDS, malaria and TB could speed development of preventive weapons against these diseases, saving millions of lives and billions of dollars in treatment costs and productivity losses. This credit would also provide a stimulus for private sector research in areas most scientifically challenging and important to global public health. In addition, this bill provides support for an international effort to expand access to vaccines, and for use of tiered pricing as one approach to make life saving vaccines more affordable in developing countries.

Provisions of The Lifesaving Vaccine Technology Act

I. Tax Credit

Provides a tax credit for qualified research and development costs associated with research on vaccines for malaria, tuberculosis, or HIV. Investments in vaccines for other infectious diseases that cause over 1 million deaths per year would also qualify. The credit would also apply to other potential biomedical prevention interventions, such as microbicides.

The tax credit equals 30% of total annual qualified R&D investments. This is a "flat" credit on all qualifying expenditures in a given year. Like the Research and Experimentation Tax Credit (R&E Credit), this tax credit could be carried forward 15 years and backward three years. The credit would be "transferable" so that a company could use the unclaimed tax credits of a company it acquires. Smaller companies that choose not to take the credit could waive the credit and pass it on to their equity investors who finance R&D on one of the priority vaccines.

"Qualified research" is the same as in the R&E Credit and includes wages, salaries, supplies, certain time-sharing costs for use of computers, and 75% of contract research performed by research organizations. Buildings, overhead, and fringe benefits are not qualified expenses. To be claimed under the credit, R&D costs must be incurred in the United States, except for human clinical trials abroad since trials of these vaccines will be required in many countries.

Developing a Plan for Access

Companies that use the credit and develop a licensed product would be obligated to establish a good faith plan for the widest possible global access to the vaccine. Companies would *not* waive any rights to pricing, patent ownership, or proprietary information.

II. Vaccine Purchase Fund - Sense of Congress

Expresses the Sense of Congress that the President and federal agencies, including the Department of State, the Department of Health and Human Services and the Department of Treasury, should work together in support of the creation and funding of multi-lateral international efforts, such as a vaccine purchase fund, to accelerate the introduction of priority vaccines into the poorest countries in the world. Further, the bill expresses the Sense of Congress that tiered or differential pricing for vaccines, providing lowered tiered prices for the poorest countries, is one of several valid strategies to accelerate the introduction of vaccines in developing countries.

Why provide a special credit to prevent these particular diseases?

Malaria, TB, and HIV together kill over 7 million people annually and undermine social and economic development in poorer countries. Each of these diseases is potentially vaccine preventable.

Tuberculosis causes more deaths than any other infectious disease, killing 3 million people annually. One hundred thousand children die from TB each year. According to the World Health Organization (WHO), "It is estimated that between now and 2020, nearly one billion more people will be newly infected, 200 million people will get sick, and 70 million will die from TB - if control is not strengthened." In the United States, over 19,000 cases of TB are reported annually. Multi drug-resistant TB exists in the US and internationally. Current TB prevention measures, including therapy for the disease and a vaccine developed early in the century, provide incomplete control.

According to WHO, **malaria** kills 2.2 million people a year, and the disease is an important public health problem in 90 countries inhabited by 2.4 billion people – 40% of the world's population. Each year, approximately one million deaths among children under five years of age are attributed to malaria alone or in combination with other diseases. In the United States, there are over 1000 cases of malaria annually. According one malaria expert, "Conventional control measures...appear increasingly inadequate to the task: As a result of the spread of drug-resistant parasites and insecticide-resistant mosquitoes, fewer tools to control malaria exist today than did 25 years ago."[1]

UNAIDS reports that **HIV/AIDS** was responsible for 2.5 million deaths in 1998, of which over half a million were children under 15. In the United States, as many as 900,000 are living with HIV disease, and 40,000 people are newly infected every year. Each day in the world, 16,000 people are newly infected with HIV. In Zimbabwe and Botswana, as many as 25% of the adult population is HIV-infected. Behavioral prevention interventions for HIV have proven effective at reducing infection rates in the US and internationally. But many factors, including political obstacles, insufficient prevention funding, forced sexual encounters, and the difficultly of maintaining safe behavior over a lifetime, mean that a vaccine will be required for control of this worldwide epidemic.

[1]Hall, B. Fenton, et al, "Malaria Vaccine Development," in The Jordon Report: Accelerated Development of Vaccines, Division of Microbiology and Infectious Disease, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 1998, p.71

What is the US interest in international health?

A 1997 *Institute of Medicine* report states that, "Due to the ease of rapid international travel, emerging and drug-resistant infectious diseases in one country represent a threat to the health and economies of all countries...The United States should ...broaden the scope of its research and development activities to include health problems that impose the greatest burden of disease around the world, toward whose alleviation we can make important contributions."[2]

What are the disincentives for private sector investment in vaccines for these diseases?

Daunting scientific challenges and uncertainties about return on financial investment make research on vaccines for the top infectious diseases comparatively unattractive.. Malaria, TB, and HIV each present unique scientific difficulties. For example, in the case of HIV, scientists agree that a vaccine is possible, but no perfect animal model exists; recovery from infection has not been documented, the "correlates of protection" (immune responses which would protect from infection) are not known, and the virus is highly variable. The economic picture is no better. For each of these major killers, the vast majority of cases of disease – and greatest need for a vaccine – is in poorer countries that have scarce resources to purchase vaccines, even highly cost effective ones.

Faced with these realities, the CEOs of biotech and pharmaceutical companies have a difficult time justifying to their Boards of Directors a significant investment in long term developmental research toward these vaccines. Other pharmaceutical research and development opportunities, such as anti-depressants or vaccines for diseases more common in the US and Europe, present surer investments.

It is therefore no surprise that private sector investment in vaccines for these three disease has been limited. Although it is difficult to measure the exact level of private sector investment, several authoritative sources have reported a serious lack of private interest.

For example, in *The State of the World's Vaccines and Immunization*, the World Health Organization reports of HIV vaccine research, "...vaccine manufacturers are no longer falling over each other in the rush to develop an HIV vaccine. Some of the smaller biotechnology companies have already fallen by the

---

[2]Institute of Medicine, America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests, National Academy Press, Washington, D.C., 1997, pgs. 1 and 5

wayside, unable to sustain the long term investment needed to tackle the scientific obstacles involved. And of the few major vaccine manufacturers that remain, most are struggling to maintain their research programmes."[3]

Of malaria vaccine research, WHO notes that, "most research is still being carried out within the public sector and not by vaccine manufacturers."[4] The National Institutes of Health (NIH) *Blueprint for Tuberculosis Vaccine Development* notes that, "Uncertainties exist within the vaccine industry as to the markets for tuberculosis vaccines, and the willingness of public and private sectors to pay for such vaccines, and possibilities for economic returns."[5]

Of the 43 vaccines listed in the Pharmaceutical Research and Manufacturers of America (PhRMA) 1998 survey of pharmaceutical company R&D, *none* were for vaccines against malaria, HIV, or TB.[6]

Doesn't it make more sense to target research funding to the National Institutes of Health?

The US National Institutes of Health is a pre-eminent world resource for scientific discovery and innovation because of its size, its peer review system, and the breadth and quality of its work, both through grants to external investigators and through its intramural labs. It also has a widely respected clinical center.

Congress has acknowledged this valuable asset to our society and economy with bi-partisan support for significant increases in NIH appropriations. The Lifesaving Vaccine Technology Act acknowledges the equally powerful asset of the American pharmaceutical and biotechnology industry. Though NIH has and does develop drugs and vaccines, it is the start-ups, the specialized companies, and the industrial giants

---

[3]Davey, Sheila, The State of the World's Vaccines and Immunization, World Health Organization, Global Programme for Vaccines and Immunization," Geneva, Switzerland, 1996, p. 132

[4]Davey, Sheila, The State of the World's Vaccines and Immunization, World Health Organization, Global Programme for Vaccines and Immunization," Geneva, Switzerland, 1996, p. 135

[5]"Blueprint for Tuberculosis Vaccine Development," Report of a Workshop held March 5-6, 1998, Rockville, MD, sponsored by the National Institute of Allergy and Infectious Disease and the National Vaccine Program Office, p. 14

[6]PhRMA, "1998 Survey: New Medicines in Development for Infectious Diseases," Pharmaceutical Research and Manufacturers of America, Washington, D.C., 1998

that control a large part of the nation's expertise and experience in developing vaccines.

Some private companies may be less inclined to work with government on a grant or contract basis than academics who depend solely on public support. Companies are justifiably protective, to maintain control of their own programs. Such autonomy stimulates diverse approaches, while the need for products that are ultimately profit-making stimulates a sense of urgency.

Competition among companies and between public and privately developed approaches is healthy at this stage of exploration and development for these vaccines. We will need to develop and test many approaches to find the ones that work best.

What are the precedents for the tax credit?

Congress has created several tax credits to spur research and development of pharmaceuticals and other products. *The Research & Experimentation Tax Credit*, enacted in 1981, offers an incentive for annual increases in R&D. The law provides a 20% tax credit on research and development expenditures over a base amount. *The Orphan Drug Act*, enacted in 1983, offers incentives for development of drugs that would not be commercially viable because they are needed by relatively few individuals. The Act provides a 50% tax credit on costs of human clinical trials and seven year marketing exclusivity period.

Even with these credits, there remain major disincentives for investment in vaccines against malaria, TB, and HIV. Existing credits are available for use on a variety of products that offer comparatively more likely and rapid returns on investment. The Lifesaving Vaccine Technology Act provides an additional credit in acknowledgment of the special need and particular disincentives for these vaccines.

Would a tax credit actually boost investment?

The Congressional Research Service (CRS) has reviewed a number of studies of the effectiveness of the R&E Credit. In a 1998 issue brief, CRS reported that studies of the credit before changes were made in 1989 "generally...agreed that it had a positive effect on private research funding." One 1992 study found that the credit stimulated about $2 billion (1982 dollars) per year in added R&D spending at a revenue cost of about $1 billion.[7] A 1997 survey by the Tufts Center for the Study of Drug Development reports that the Orphan Drug Act has been widely applauded domestically and internationally, and has served as a prototype for a similar program in Japan. The Food

[7]Guenther, Gary, "The Research and Experimentation Tax Credit," Congressional Research Service, Library of Congress, Washington, D.C., July 14, 1998, p. 8

and Drug Administration has approved 121 orphan drugs for marketing since 1983.[8]

The existing R&E credit provides an incentive for increases in investment with an "incremental" credit on annual investments over a changing base amount. The Lifesaving Vaccine Technology Act would create a "flat" 30% credit on annual qualified R&D investments in particular vaccines. The new credit offers a credit on all investment (rather than just *increased* investment) in targeted areas in an effort to encourage companies to initiate, maintain and expand programs in these crucial research areas. The credit stimulates private sector investment, by generating $7 of private investment for every $3 of credit. And by linking acceptance of the credit to a good faith plan for widespread access, the public gains increased leverage to maximize distribution of vaccines developed through the credit.

Smaller biotechs that do not yet have tax liabilities do much of the ground breaking work in vaccine development. In order to provide an incentive for investment in priority vaccines at smaller biotechs, these smaller companies (capitalized at $50 million or below) could waive the tax credit and pass it on to their investors. This "pass through" credit would be equal to 20% of the amount of equity investment used for R&D on priority vaccines.

The 30% flat credit and the 20% investor credit will be attractive to many biotechs and pharmaceuticals that have the most expertise, experience and willingness to take calculated risks that are needed to successfully research these vaccines.

What will the tax credit cost?

It is difficult to estimate the cost of the tax credit because pharmaceutical companies do not usually publish their investments in various products. As a gross estimate, if we assume there will be $100 million in research on these priority vaccines annually, the cost to the Treasury would be $20 million to $30 million each year. In fact, the larger the cost, the greater the likelihood of rapid success.

How would the credit expand access to vaccines in developing countries?

Seventeen years after the development of a safe and effective vaccine for Hepatitis B, hundreds of thousands of children in the world still do not have access to the vaccine. The WHO's Global Programme on Immunization has greatly expanded access to vaccines throughout the world, but this delivery system has been delayed by the high costs of purchasing vaccine. All the infectious diseases covered in the Lifesaving

[8] "US Orphan Drug Program: Global Reference Point," Marketletter Publications Ltd., UK, December 22, 1997

Vaccine Technology Act inflict their greatest mortality in the developing world, and often among children.

As the World Health Organization has stated, "Allowing vaccines to slowly filter down to children in the poorer countries over 10 - 20 years is neither just nor equitable."[8] The increasing use of biotechnology in the design of vaccines means that costs for the vaccines of the future are expected to be higher during their initial patent protected period than today's more traditional products.

The Pelosi legislation includes three provisions designed to maximize access to priority vaccines in developing countries.

1. *Requires companies to establish a plan for global access to the vaccine.* While this provision is non-binding, it will help governments and health authorities put public pressure on companies to work cooperatively to maximize access to vaccines.

2. *Support for multi-lateral international efforts, such as a vaccine purchase fund.* The World Bank and international public health organizations are moving towards creation of purchase funds and other approaches to expand access to vaccines. This provision directs US government agencies to play an active and supportive role in these efforts.

3. *Support for tiered or differential pricing as one of several valid strategies to accelerate the introduction of vaccines.* This provision gives Congressional support to companies that choose to expand access to vaccines by offering lower prices to poorer countries. US companies have been criticized for these pricing practices.

For more information contact
Chris Collins
Office of Representative Nancy Pelosi
202 225 4965
chris.collins@mail.house.gov

---

[9]Davey, Sheila, The State of the World's Vaccines and Immunization, World Health Organization, Global Programme for Vaccines and Immunization," Geneva, Switzerland, 1996, p. 15