INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. TORRICELLI (for himself and Mrs. MURRAY):

S. 1716. A bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act to require local educational agencies and schools to implement integrated pest management systems to minimize the use of pesticides in schools and to provide parents, guardians, and employees with notice of the use of pesticides in schools, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. BOND (for himself, Mr. BREAUX, Mr. MCCAIN, Mr. BAUCUS, and Mrs. LINCOLN):

S. 1717. A bill to amend title XXI of the Social Security Act to provide for coverage of pregnancy-related assistance for targeted low-income pregnant women; to the Committee on Finance.

By Mr. KERRY (for himself and Mr. DURBIN):

S. 1718. A bill to amend the Internal Revenue Code of 1986 to provide a credit for medical research related to developing vaccines against widespread diseases; to the Committee on Finance.

By Mr. HUTCHINSON (for himself, Mr. SANTORUM, Mr. ABRAHAM, Mr. COVERDELL, Mr. MCCAIN, Mr. DEWINE, Mrs. HUTCHISON, and Mr. BROWNBACK):

S. 1719. A bill to provide flexibility to certain local educational agencies that develop voluntary public and private parental choice programs under title VI of the Elementary and Secondary Education Act of 1965; to the Committee on Health, Education, Labor, and Pensions.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. COVERDELL (for himself, Mr. CLELAND, Mr. BUNNING, Mr. SESSIONS, Mr. KOHL, Mr. FEINGOLD, Mr. MACK, Mr. MURKOWSKI, Mr. STEVENS, Mr. LAUTENBERG, Mr. WYDEN, Mr. DEWINE, Mr. COCHRAN, Mr. CRAIG, Mr. MCCONNELL, Mr. TORRICELLI, Mr. MCCAIN, Mr. HAGEL, Mr. BURNS, Mr. DURBIN, and Mr. SCHUMER):

S. Res. 201. A resolution congratulating Henry ''Hank'' Aaron on the 25th anniversary of breaking the Major League Baseball career home run record established by Babe Ruth and recognizing him as one of the greatest baseball players of all time; considered and agreed to.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. BOND (for himself, Mr. BREAUX, Mr. MCCAIN, and Mr. BAUCUS):

S. 1717. A bill to amend title XXI of the Social Security Act to provide for coverage of pregnancy-related assistance for targeted low-income pregnant women; to the Committee on Finance.

MOTHERS AND NEWBORNS HEALTH INSURANCE ACT OF 1999

● Mr. BOND. Mr. President, I rise today to introduce a bill that I believe is vitally important to the health care of children and pregnant women in America. The goal of this legislation is simple—to make sure more pregnant women and more children are covered by health insurance so they have access to the health care services they need to be healthy.

The need is great—on any given day, almost 12 million children and almost half a million pregnant women do not have health insurance coverage. For many of these women and children, they or their family simply can't afford insurance. Many others are actually eligible for a public program like Medicaid or CHIP, but they don't know they are eligible and are not signed up.

Lack of health insurance can lead to numerous health problems, both for children and for pregnant women. A child without health coverage is much less likely to receive the health care services that are needed to ensure the child is healthy, happy, and fully able to learn and grow. An uninsured pregnant woman is much less likely to get critical prenatal care that reduces the risk of health problems for both the woman and the child. Babies whose mothers receive no prenatal care or late prenatal care are at-risk for many health problems, including birth defects, premature births, and low birthweight.

The bill I am introducing—along with Senators BREAUX, MCCAIN, and BAUCUS—deals with this insurance problem in two ways.

First, it allows states to provide prenatal care for low-income pregnant women under the state's CHIP program if the state chooses.

Through the joint federal-state Children's Health Insurance Program, states are currently expanding the availability of health insurance for low-income children. However, federal law prevents states from using CHIP funds to provide prenatal care to low-income pregnant women over age 19, even though babies born to many low-income women become eligible for CHIP as soon as they are born.

As many as 45,000 additional women could be covered for prenatal care. There are literally billions of dollars of CHIP funds that states have not used yet, so I would hope that most states would choose this option. This provision will not impact federal CHIP expenditures because it does not change the existing federal spending caps for CHIP. Babies born to pregnant women covered by a state's CHIP program would be automatically enrolled and receive immediate coverage under CHIP themselves. It is foolish to deny prenatal care to a pregnant mother and then—only after the baby is born—provide the child with coverage under CHIP. Prenatal care can be just as important to a newborn baby as postnatal care, and the prenatal care is of course important for the mother as well.

Second, the bill will help states reach out to women and children who are eligible for—but not signed up for—Medicaid or CHIP. 358,000 pregnant women and 3 million children are estimated to be eligible for but not enrolled in Medicaid. Millions of additional children are eligible for but not yet enrolled in CHIP. When Congress passed the welfare reform bill back in 1996, we created a $500 million fund that states could tap into to make sure that all Medicaid-eligible people stayed in Medicaid. The problem is that only about 10 percent of that fund has been used, and most states are about to lose their 3-year window of opportunity to use these funds. My bill would allow states continued access to these funds by eliminating the 3-year deadline, and it would give states more flexibility to use the funds to reach out to both Medicaid and CHIP-eligible women and children.

This legislation is a smaller piece of a bill I introduced earlier this year called Healthy Kids 2000. By extracting it from the larger bill, we get a chance to show the widespread support I believe exists for these measures. I believe this is crucial legislation, and urge my colleagues to join me in support of it so that we can pass this bill.●

● Mr. BREAUX. Mr. President, I rise today to join Senator BOND in introducing the Mothers and Newborns Health Insurance Act of 1999. This is important legislation regarding our children's health.

More than 12 million women of childbearing age—one in five—lacked health insurance in 1998, according to the Census Bureau. Lack of insurance leads to bad outcomes for pregnant woman and the children. Pregnant women without health insurance face barriers to care and do not receive the medical attention they need to have healthy babies. The Mothers and Newborns Health Insurance Act could provide insurance coverage to virtually all pregnant women in the United States. Such coverage will have an enormous impact on the health of children in our nation, by ensuring pregnant women have access to prenatal care and automatically enrolling their babies in their State Children's Health Insurance Program.

In the United States, 7.6 out of 1000 babies die before their first birthday. Our nation is ranked 25th, in the world for our infant mortality rate. The statistics in my home state are even more disheartening; in Louisiana where 24.7% of childbearing age women are uninsured, there are 9.8 deaths per 1000 births. Many of these deaths are preventable, and good prenatal care is the first step to ensuring that babies see their first birthday.

The Mothers and Newborns Health Insurance Act of 1999 addresses these concerns in three ways. One, it would amend Title XXI of the Social Security Act to give states the options to use Children's Health Insurance Program (CHIP) funds for health insurance coverage of uninsured low income pregnant women. Two, it would automatically enroll newborns to CHIP eligible women in CHIP for one year. And

three, our bill would provide states additional opportunities to tap into a $500 million fund created by the 1996 welfare reform act to help expand Medicaid outreach efforts. This bill would allow the fund to be used for any Medicaid or CHIP outreach initiatives.

This Act could provide insurance coverage to 95% of currently uninsured women, by both increasing outreach efforts to pregnant women eligible for Medicaid and by giving states the option to extend CHIP coverage to low income pregnant women over the age of 18. Since the enactment of the welfare reform law, many people who are eligible for Medicaid or CHIP coverage do not realize it and remain unenrolled. It is estimated that 358,000 pregnant woman and 3 million children are eligible for but not enrolled in Medicaid. Millions of additional children are eligible for but not yet enrolled in CHIP.

This legislation has the potential to lower healthcare costs and keep our babies healthy. By removing barriers to prenatal care access and automatically enrolling babies in their State Children's Health Insurance Program, we can give our children a head start on good health. Research shows that access to appropriate prenatal care improves the outcome of pregnancy. According to the March of Dimes, prenatal care—especially among lower income women—reduces the risk of low birth weight threefold and results in decreased infant mortality rates and healthier babies. According to the Institute of Medicine, each dollar spent on prenatal care for women at high risk, saves $3.38 in medical care costs for low birth-weight babies.

This legislation is an important step to ensuring our children have bright and healthy future. I thank Senator BOND for his leadership on this bill, and I urge my colleagues to join us in supporting the Mothers and Newborns Health Insurance Act of 1999.●

By Mr. KERRY (for himself, and Mr. DURBIN):

S. 1718. A bill to amend the Internal Revenue Code of 1986 to provide a credit for medical research related to developing vaccines against widespread diseases; to the Committee on Finance.

LIFESAVING VACCINE TECHNOLOGY ACT OF 1999

Mr. KERRY. Mr. President, I rise today to introduce the Lifesaving Vaccine Technology Act of 1999 with my friend and colleague from Illinois, Senator DURBIN.

Mr. President, each year malaria, tuberculosis and AIDS kill more than 7 million people, disproportionately in the developing world. Each of these diseases is potentially preventable by vaccination.

A recent column in the Boston Globe by David Nyhan sums up the situation facing the developing world succinctly.

Tuberculosis causes more deaths than any other infectious disease, killing 3 million people annually. One hundred thousand children die from TB each year. The World Health Organization estimates 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 tuberculosis, if control is not strengthened. Tuberculosis is not just an issue for some faraway countries; in the United States, more than 19,000 cases of tuberculosis are reported annually and increasingly we are seeing drug-resistant strains of tuberculosis in this country but especially in the states of the former Soviet Union where, according to one CDC doctor, an epidemic is taking place of ''the worst situation for multidrug resistant tuberculosis ever documented in the world.'' Other areas of the world, such as central India, Bangladesh, Latvia, Congo, Uganda, Peru are also experiencing near-epidemic tuberculosis crises.

According to the World Health Organization, malaria kills more than 2 million people every year, and the disease is an important public health problem in 90 countries inhabited by almost half of the world's population. Each year, one million children under the age of five die from complications associated with malaria. Again, Mr. President, malaria is a disease we tend to associate with foreign exotic lands, and overlook the fact that in this country, more than one thousand people are stricken by malaria each year. Researchers at the National Institute of Allergies and Infectious Diseases contend that ''conventional control measures . . . appear increasingly inadequate. . . As a result of drug-resistant parasites and insecticide-resistant mosquitoes, fewer tools to control malaria exist today than did 25 years ago.''

Last year, the human immunosuppressant virus took the lives of 2.5 million, of which more than 500,000 were children under the age of 15. In the United States, almost one million are currently living with HIV-disease and 40,000 are newly infected each year. In Zimbabwe and Botswana, as many as 25 percent of the adult population is infected with HIV. In Zambia, 72 percent of households contain a child orphaned by AIDS. South Africa, which was largely isolated from HIV during its apartheid years, is now home to 10 percent of the new infections in Africa, and in the country's most populous province, KwaZulu-Natal, one-third of adults are HIV-infected. Analysts claim that India is an AIDS disaster-in-waiting: half a million people in one of India's smallest rural states (Tamil Nadu) are HIV-positive, as are fifteen percent of the women in one of India's more populous states (Maharashtra).

While AIDS is entirely preventable in this country and abroad, and while behavioral interventions for HIV have proven effective at reducing infection rates, many factors, including political obstacles, insufficient prevention funding, forced sexual encounters, and the difficulty of maintaining safe behavior over a lifetime, mean that a vaccine will be required for control of this worldwide epidemic.

And, yet, Mr. President, biotechnology and pharmaceutical companies in the United States, the home of the most innovative research and development in the world, are not working on vaccines to the world's largest killers. Market disincentives—especially the lack of a viable, cash-rich market—play against investment into these vaccines. Private-sector scientists and chief executive officers have a difficult time justifying to their boards an investment in developmental research toward these vaccines as long as other pharmaceutical research and development into products appealing to the developed world, like anti-depressants or Viagra, present more attractive investments.

This market failure and the need for incentives is shown most dramatically by last year's survey by the Pharmaceutical Research and Manufacturers of America. Of the 43 vaccine projects found to be in development by the survey not one was for HIV, malaria or tuberculosis. To find vaccines for the biggest infectious disease killers in the world, both the private and public sectors must be engaged in a bolder, more creative and dramatic way.

Mr. President, with that in mind, we are introducing the Lifesaving Vaccine Technology Act, which establishes an income tax credit for 30 percent of the qualified expenses for medical research related to the development of vaccines against widespread diseases like malaria, HIV and tuberculosis, which according to the World Health Organization, cause more than one million deaths annually.

This bill also declares that it is the sense of Congress that if the vaccine research credit is allowed to any corporation or shareholder of a corporation, the corporation should certify to the Secretary of the Treasury that, within one year after that vaccine is first licensed, the corporation will establish a good faith plan to maximize international access to high quality and affordable vaccines. In addition, the bill expresses the sense of Congress that the President and Federal agencies (including the Departments of State, Health and Human Services, and the Treasury) should work together in vigorous support of the creation and funding of a multi-lateral, international effort, such as a vaccine purchase fund, to accelerate the introduction of vaccines to which the vaccine research credit applies and of other priority vaccines into the poorest countries of the world. Lastly, the bill expresses the sense of Congress that flexible or differential pricing for vaccines, providing lowered prices for the poorest countries, is one of several valid strategies to accelerate the introduction of vaccines in developing countries.

Mr. President, this legislation has received the support of the American

Public Health Association, the Global Health Council, AIDS Action, the AIDS Policy Center for Children, Youth and Families, the International AIDS Vaccine Initiative and the AIDS Vaccine Advocacy Coalition. And, I am especially pleased that the Clinton Administration has signaled their approval of our approach. At his most recent speech before the General Assembly of the United Nations, President Clinton committed ''the United States to a concerted effort to accelerate the development and delivery of vaccines for malaria, TB, AIDS and other diseases disproportionately affecting the developing world.''

This bill is highly targeted: it will cost relatively little to implement but would have a profound impact on America's response to international public health needs. And it would complement—certainly not supplant—current federal efforts at USAID, the NIH and other federal agencies to assist developing countries and to bolster vaccine research.

Mr. President, this legislation is a companion to a bipartisan bill introduced in the other body by my friend and colleague from San Francisco, Congresswoman NANCY PELOSI, and 36 co-sponsors. Over the years, I have had the honor to work with the distinguished Congresswoman on various pieces of legislation. The nation is in her debt for her tenacity and her overwhelming sense of duty to country. Her constituents benefit daily from her leadership, and I am pleased to be associated with her again today.

I am hopeful that the positive response Congresswoman PELOSI has found in the other body is replicated in the Senate and that our colleagues join the Senator from Illinois, Senator DURBIN, and I in passing the Lifesaving Vaccine Technology Act as quickly as possible.

Mr. President, I ask unanimous consent that the Nyhan column, an article which appeared in the Albany Times-Union about the market difficulties of developing an AIDS vaccine, and a Congressional Research Service study of the bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the Boston Globe, Oct. 1, 1999]

IT'S MOSTLY BAD NEWS FOR THE POOREST PEOPLE ON THE PLANET

(By David Nyhan)

Human nature being what it is, the hawkers of news prosper more off what arouses the customer than that which accurately informs.

That's why you get more sizzle than steak, particularly when matters ''foreign'' are addressed. Pictures of a boy dragged from the earthquake's rubble or a riot squad in action are more compelling than footage of some middle-aged bureaucrat rattling on about poverty statistics. But today we're holding the sizzle and serving you teak in the form of speeches made in Washington this week before the annual meeting of the World Bank and the International Monetary Fund, two outfits that have become punching bags for a lot of people who are convinced they know what's wrong with the planet.

What is really going on here on Spaceship Earth?

Some good things: Life expectancy, on average, has gone up more in the last 40 years than in the previous 4,000. The Internet means near-universal access to information. Then there are the not-so-good trends, World Bank chief James Wolfensohn said Tuesday:

''Per-capita incomes which will stagnate or decline this year in all regions except East and South Asia. . . . with the exception of China, 100 million more people living in poverty today than a decade ago. In at least 10 countries in Africa, the scourge of AIDS has reduced life expectancy by 17 years. More than 33 million cases of AIDS in the world, of which 22 million are in Africa. Some 1.5 billion people still lacking access to safe water, and 2.4 million children who die each year of waterborne diseases. Some 125 million children still not in primary school. . . . A world where the information gap is widening. And the forests are being destroyed at the rate of an acre a second.''

These statistics are almost impossible to believe. In the time it takes to sneeze, three acres of forest are burned. And everything revolves around money. It is poverty that holds half of mankind in chains.

Next month the planet's ridership surpasses 6 billion human beings. How do they live now? Half of humanity gets along on the equivalent of $2 a day or less. Half of that half lives on less than $1 a day. When a child born today reaches the age of 25, there will be 2 billion more people fighting for air, water, food, space, roofs, jobs, schooling, roads, sewers, farmland. Only development will spare them a life of perilous poverty.

As the earthling more responsible than any single individual, perhaps even more obligated than the President of the United States, for the well-being of mankind and the development of economic structures to make mankind's future more secure, Wolfensohn asked: ''What have we learned about development?''

''We have learned that development is possible but not inevitable, that growth is essential but not sufficient to ensure poverty reduction.'' And it is essential to help poor people with local institutions, controlled by them, insulated against the corruption, both petty and grand, that turns so many cops and bureaucrats in poor countries into petty despots or grand thieves on the scale of the Baligate thieves who sacked the treasury of Indonesia and pitched the world's fourth-largest nation into anarchy.

He quoted from a massive World Bank study, ''Voice of the Poor,'' distilled from 60,000 poor people in 60 countries: ''Poverty is much more than a matter of income alone. The poor seek a sense of well-being—which is peace of mind.''

Here's the bulletin: The poor of the planet are just like us cozy Americans. What they want is what we've got. ''It is good health, community, and safety. It is choice, and freedom, as well as a steady source of income.'' He quoted the old African woman: ''to live in love without hunger''; the Eastern European survivor of communism: ''to be well is to know what will happen to me tomorrow''; the mother in Southeast Asia: ''When my child asks for something to eat, I say the rice is cooking until he falls asleep from hunger. For there is no rice.''

The day after Wolfensohn laid out the challenge, President Clinton showed up to announce cancellation of that portion of the debt owed the United States by 36 of the poorest countries that had not already been forgiven. The Pope and a number of celebrities had been agitating for debt forgiveness.

The Clinton administration had already written off about 90 percent of that debt, and this final write-off of what once totaled nearly $6 billion will encourage the campaigners of Jubilee 2000 to press other lender nations to follow suit. Clinton has been a very good President, all things considered, for the poorest people of the planet. He alluded to the high-priced lobbying that goes on in the jousting between agricultural haves to carve out more elbow room at the trough of market share: ''Because we want to fight over who sells the most food . . . are we supposed to accept the fact that nearly 40 million people a year die of hunger? That's nearly equal to the number of all the people killed in World War II.''

He had more good lines, such as ''the wealth of nations depends upon the health of nations.'' But you get the idea. We rich nations are our brother's keeper; sister's too.

[From the Albany Times Union, Mar. 14, 1999]

DRUG MAKERS STILL RELUCTANT TO INVEST IN HIV VACCINE

SCIENTIFIC UNCERTAINTY, DRUG ECONOMICS COMBINE TO DISCOURAGE EFFORTS

(By Eric Rosenberg)

WASHINGTON.—Soon after the AIDS epidemic exploded in the 1980s, Dr. Donald Burke, a senior researcher at Baltimore's Johns Hopkins University, began work on a vaccine against HIV, the virus that causes the deadly disease.

Burke made progress but knew he needed the financial backing and laboratory firepower of a pharmaceutical manufacturer in order to succeed.

''I went to all the major companies that were involved in AIDS work at the time,'' said Burke, now the director of the university's Center for Immunization Research. ''I couldn't get anybody interested and I was shocked.''

Burke's experience highlights the fact that, with a few exceptions, the pharmaceutical industry has been reluctant to commit resources toward such a goal, despite worldwide demand for a vaccine to protect against a disease that afflicts 35 million people and infects 16,000 more people daily.

According to the Pharmaceutical Research and Manufacturers of America, a trade organization that represents prescription drug makers, companies are sinking research dollars into 101 new treatments for people infected with HIV.

These include new classes of antiviral drugs to suppress the HIV virus once a person is infected; medications to fight AIDS-related diseases such as Kaposi's Sarcoma; and drugs to fend off opportunistic infections that attack when the immune system is suppressed by HIV.

Although President Clinton has made development of an AIDS vaccine a top priority and Congress has budgeted nearly $200 million this year alone for the effort, companies are investing in only 12 experimental vaccine proposals.

Nearly 20 years after the disease erupted, only one AIDS vaccine has received Food and Drug Administration approval for widespread human testing. That vaccine is under development by VaxGen, a small, 52-employee biotechnology firm, of South San Francisco, Calif.

More than 90 percent of the world's vaccines against other diseases are produced by five companies: Merck & Co., of Whitehouse Station, N.J., SmithKline Beecham and Wyeth-Lederle of Philadelphia, Pasteur Merieux Connaught of Swiftwater, Pa., and Chiron Corp. of Emeryville, Calif.

All are involved to varying degrees in AIDS vaccine research. For example,

SmithKline Beecham has only a small AIDS vaccine effort underway. ''At this point it's not one of the major efforts in our vaccine programs,'' said Richard Koenig, a SmithKline spokesman.

Pasteur, on the other hand, has aggressively pursued an experimental vaccine that is nearing government approval for a large-scale human study.

Other companies started, but then curtailed, AIDS vaccine programs. They include Bristol-Myers Squibb, British Biotech and Immuno AG.

Dr. Donald Francis, president of VaxGen and a former AIDS specialist at the federal Centers for Disease Control and Prevention, said that if VaxGen and Pasteur fail, ''There's nothing five years behind us. That's it in the AIDS vaccine field.''

Lagging science and drug economics are the two considerations underlying the modest corporate interest in AIDS vaccines.

Scientists have made strides unlocking the mysteries of how the virus operates after it infects a person. While the knowledge has been key to making new drugs that slow or halt the disease's deadly progression, it doesn't point to the discovery of a vaccine that would render a healthy person immune to HIV.

Dr. Peggy Johnston, the assistant director for AIDS vaccines at the National Institute for Allergy and Infectious Diseases, said company officials worry that not enough is known about how HIV works to warrant a large vaccine investment.

''There are enormous challenges that AIDS presents that are unparalleled compared with other viruses,'' said Johnston.

For example, HIV is proving more resilient than other viruses. Vaccines typically fend off disease by stimulating the body's production of antibodies which in turn destroy an invading virus. However, HIV appears to defend itself with a kind of sugar-based shield to fend off antibodies.

Another problem is that different strains of HIV exist in the West and in Africa and Asia. So a vaccine to protect against the North American variety might not work against other strains.

The economics of vaccines also are daunting.

The average vaccine costs about $100 million to develop. But because the scientific understanding of HIV is murky, a company could commit the resources and more than a decade of work and still fail to invent a vaccine.

In order to make a profit on vaccines, which are typically priced in the $1 to $5 per shot range, a drug maker must sell millions of inoculations. While industrialized countries could easily afford the price, much of the developing world, which is the largest potential market for an AIDS vaccine, would have difficulty.

The profitability issue is fueling a proposal by the International AIDS Vaccine Initiative (IAVI), an advocacy group based in New York, that is pressing wealthy nations to create a $1 billion AIDS vaccine purchase fund for the Third World, effectively assuring profit to a successful manufacturer.

''We think the fund would provide a very strong incentive for industry,'' said Victor Zonana, a vice president at IAVI. ''The companies would know that in addition to their markets in industrialized countries, they would have a guaranteed paying market in developing countries.''

But pharmaceutical executives believe that even with such a fund in place, a vaccine won't be as profitable as are AIDS therapeutic drugs, which are taken for the lifetime of a patient as opposed to only a few times, as are vaccines.

MEMORANDUM

CONGRESSIONAL RESEARCH SERVICE,
LIBRARY OF CONGRESS,
Washington, DC, October 6, 1999.

To: Hon. Nancy Pelosi and Hon. John Kerry; attention: Chris Collins and Ryan McCormick.

From: Gary Guenther, analyst in business taxation and finance, government and finance.

Subject: Effectiveness of the proposed tax credits for vaccine research in H.R. 1274.

Responding to your request, this memorandum assesses the likely effectiveness of the proposed tax credits for vaccine research in H.R. 1274. Effectiveness in this case signifies the likely rise in domestic investment in vaccine research and development (R&D) in response to the tax credits. This method of assessing the proposed credits' effectiveness boils down to comparing the additional vaccine R&D induced by one dollar of tax credit claimed, which is a way of analyzing the benefit-cost ratio for the credit. The proposed credits also raise the issue of whether such a subsidy can be justified on economic grounds. This issue is discussed briefly in the final section.

Two noteworthy conclusions emerge from the analysis presented here. One is that the proposed tax credits can be expected to spur increased investment in vaccine R&D by the private sector, by both increasing expected after-tax returns on this investment and improving the access of small startup firms to equity capital for investment in vaccine R&D. The second conclusion relates to the economic rationale for the proposed tax credits: they are justified on economic grounds to the extent that they attempt to correct failures in the market for vaccines that result in economically inefficient levels of domestic investment in vaccine R&D.

If you have any questions about this analysis, please call me at 7–7742.

THE ECONOMICS OF VACCINE INNOVATION

Vaccines are among the most cost-effective weapons in the arsenal of modern medicine against the spread of contagious diseases, lethal and non-lethal. By strengthening an individual's immune system to resist a wide range of infectious diseases, they offer a relatively inexpensive means of lowering a society's overall cost of medical care. While historically vaccines have been used to prevent a variety of diseases, intensive efforts are being made to develop vaccines that can treat certain diseases—mainly cancer and AIDS—after an individual contracts them.

On the whole, the development of new vaccines is a long, costly, and risky process. It typically takes 10 years and requires outlays of $100 million to bring a new vaccine from the research laboratory to the medical marketplace.[1] In addition, firms seeking to develop new vaccines face a considerable risk of failure. A 1989 study estimated that only 3 out of 10 vaccines that enter clinical trials end up being approved for general use.[2] For the most part, vaccine development passes through the same stages as the development of new therapeutic drugs: a period of basic research or discovery, followed by the filing of an investigational new drug application with the U.S. Food and Drug Administration (FDA), followed by three stages of clinical trials. Vaccine development, however, departs from the path of new drug development during the third phase of clinical trials, when a firm developing a new vaccine must file both a product license application and an establishment license application with the FDA; firms developing new therapeutic drugs only are required to file a new drug application at this stage. Once the FDA is satisfied that the vaccine is safe and effective and that the plant where it is produced meets the FDA's stringent standards for purity, cleanliness, and quality control, the vaccine can be marketed in the United States. This means that the FDA requires vaccine firms to construct and start up manufacturing facilities for new products several years before they can gain marketing approval—and thus begin to earn a return on the funds invested in their development.

The economics of vaccine innovation has important implications for the structure of the vaccine industry. High fixed costs for research, production setup, and obtaining and maintaining FDA marketing approval result in marginal vaccine production costs that are significantly below average vaccine production costs. Such a cost structure is not conducive to the existence of multiple sellers of the same vaccines. As a seller's output expands, its average costs decline; and as those costs fall, its ability to underprice its competitors and still cover its costs grows.[3] The degree of competition in the world vaccine industry seems to confirm this crucial point. Vaccine production in the United States and the rest of the world has been highly concentrated: in 1994, four firms (Institut Merieux, Merck, SmithKline Beecham, and American Cyanamid) accounted for between 65% and 80% of world sales of vaccines; and in 1993, the same four firms produced nearly all the pediatric vaccines purchased in the United States.[4]

In the United States, the federal government finances the lion's share of basic research in vaccines, where the emphasis is on understanding the fundamental mechanisms of infectious disease and the immune system. Once a vaccine research project advances to the level of applied research and development, where the emphasis is on producing and testing specific products with commercial potential, the private sector takes the lead in financing. Near the end of the development cycle for vaccines, the federal government becomes more involved again by helping fund clinical trials to test the safety and efficacy of new vaccines.[5] According to one estimate, the federal government provided $500 million (or 36%) of the $1.4 billion spent on U.S. vaccine R&D in 1995, and the private sector contributed the remaining $900 million (or 64%), with the lion's share coming from four large, established sellers of vaccines: Merck, the Wyeth-Lederle division of American Home Products, SmithKline Beecham, and the Pasteur Merieux Connaught division of Rhone Poulenc.[6]

In the past decade, the private sector has shown a vibrant interest in vaccine innovation, and investment in vaccine R&D has risen accordingly. While a number of factors have come together to spur this interest, a key driving force has been the revolutionary advances in the understanding of the molecular basis of the immune system and disease engineered by biotechnology. Recombinant technology is now being used to improve existing vaccines and to produce new ones, to design more efficient combinations of existing vaccines, and to find better ways of delivery than a shot in the arm. Moreover, most vaccine industry executives are convinced that the new vaccines developed through the application of recombinant technology will gain patent protection, unlike traditional vaccines which are derived from naturally occurring organisms and thus not eligible for patent protection. Patented vaccines tend to command much higher prices in private markets than those lacking patent protection. By one account, as of May 1998, at least 50 biotechnology firms had joined the large, established producers of vaccines

Footnotes at end of document.

in the search for new vaccines, and about 75 new vaccines were in various stages of development worldwide.[7] The economies of scale in vaccine production, however, make it unlikely that many of small startup firms now engaged in vaccine R&D will grow into large, independent producers. Although public data on vaccine R&D are sparse and not systematically collected, figures on pharmaceutical R&D reported by the Pharmaceutical Research and Manufacturers of America (PhRMA) appear to underscore the renewed interest in vaccine R&D in the pharmaceutical industry. In its latest profile of the U.S. pharmaceutical industry, PhRMA reports that domestic R&D investment in biologicals, a product class that is dominated by vaccines, rose from $274 million (or 4.7% of domestic pharmaceutical R&D) in 1989 to $716.8 million (or 5.3% of domestic pharmaceutical R&D) in 1996.

INTENDED PURPOSE OF H.R. 1274, THE LIFESAVING VACCINE TECHNOLOGY ACT OF 1999

The central aim of H.R. 1274 is to boost U.S. investment in the development of vaccines for diseases that kill large numbers of people each year, especially in developing countries. Its chief policy instrument for achieving this objective is a tax credit equal to 30% of qualified vaccine research expenses in a tax year. Under the bill, qualified vaccine research expenses are defined as a firm's in-house and contract research expenses related to the discovery and development of vaccines for malaria, tuberculosis, HIV, or any infectious disease that kills over one million persons annually, as determined by the World Health Organization. The definition of qualified research expenses under H.R. 1274 is identical to the definition of research expenses that qualify for the research and experimentation (R&E) tax credit, with one significant exception: the proposed vaccine research tax credit would apply to 75% of qualified contract research expenses, whereas the R&E tax credit applies to only 65% of such expenses—except in the case of contract research performed by certain research consortia, where 75% of the expenses qualify for the credit. Like the R&E tax credit, public or private grants for vaccine research are ineligible for the credit. In addition, any research expenses claimed for the vaccine research credit cannot also be claimed for the R&E tax credit, although qualified vaccine research expenses could be used to calculate the base amount for the R&E credit; and with the exception of expenses for human clinical testing conducted abroad, no credit is available for foreign vaccine research. H.R. 1274 also specifies that the proposed vaccine research credit would become part of the general business credit and thus subject to its limitations; any portion of the vaccine research credit that cannot be used in the tax year in which it is earned could be carried forward to a succeeding tax year, but the unused portion could not be carried back beyond the year in which the credit was enacted. Finally, like the R&E credit, qualified research expenses that are deducted under section 174 of the Internal Revenue Code (IRC) must be reduced by the amount of any vaccine research credit claimed. This requirement has important implications for the marginal effective rate of the credit, because whatever vaccine research credit is claimed in effect is taxed at a firm's marginal corporate income tax rate.

H.R. 1274 would also create a less direct tax subsidy for vaccine R&D. This subsidy is targeted at investors and is intended to make it easier for small firms involved in vaccine R&D to raise money in equity markets. Specifically, the bill would grant individuals or firms that purchase the ''qualified research stock'' of small firms undertaking or funding qualified vaccine research a tax credit equal to 20% of the amount they pay for the stock, provided two conditions are met. First, the firm whose stock is bought must use the proceeds within 18 months of the date of purchase to pay for research that qualifies for the vaccine reseach credit. Second, the firm must waive its right to claim a tax credit for the vaccine research funded by the stock purchases. Under H.R. 1274, qualified research stock is defined as any stock issued by a firm that is subject to the corporate income tax and has gross assets of $50 million or less; the stock must be issued after the date the bill is enacted and acquired ''at its original issue in exchange for money or other property (not including stock).''

LIKELY IMPACT OF H.R. 1274 ON U.S. VACCINE R&D

How are the proposed tax subsidies in H.R. 1274 likely to affect vaccine R&D? The answer hinges largely on the effect of the subsidies on two key determinants of business R&D investments: the expected after-tax rate of return on such investments and the availability and cost of capital to finance the investments.

For firms seeking to develop new or improved vaccines, the decision to invest in R&D is no different in principle from a decision to invest in any other capital asset, such as a new production facility. The key considerations are the expected after-tax returns on the proposed R&D projects, the cost of capital or funds for the projects, and the availability of funds to finance the projects. Small startup firms are more likey than large, well-established firms to have trouble funding R&D projects out of retained earnings or raising funds in debt or equity markets to finance these projects. In theory, a vaccine firm will invest in R&D projects up to the point where the expected after-tax rate of return on a possible project matches the firm's cost of capital. Projects with the largest gap between expected after-tax rates of returns and the cost of capital are likely to receive the highest priority.

H.R. 1274 can be expected to increase the level of domestic vaccine R&D by both increasing the expected after-tax rates of return on possible research projects and improving the access of smaller, newer vaccine firms to equity markets. The proposed flat 30-percent tax credit on qualified vaccine research would be one of the factors shaping the expected after-tax returns on vaccine R&D investments. Other important factors are the eventual size of the market for the vaccine, the predictability of prices and usage rates for the vaccine, expected production costs, exposure to liability suits for side effects of the vaccine, patent protection, the ease of entry into the market for the vaccine, and the cost of capital.[8] The proposed credit would increase expected after-tax rates of return. Under current tax law, firms performing vaccine R&D can claim the 20% R&E tax credit for qualified research. But because of the rules governing the use of the credit, the marginal effective rate of the credit is 6.5% or 13% on each additional dollar spent on vaccine research by firms in the 35-percent corporate tax bracket. If H.R. 1274 were enacted, the same firms could claim a tax credit for qualified research with a marginal effective rate of 19.5%; the rate would not be 30% because of the requirement that any credit claimed must be added to a firm's taxable income. All other things being equal, as a firm's marginal effective rate for the vaccine research credit goes up, the after-tax rate of return to this research rises.

In addition, vaccine firms that are constrained by a lack of funds in pursuing research opportunities could be expected to invest more in vaccine R&D if H.R. 1274 were enacted. Investors would be eligible for a flat 20% tax credit on purchases of common stock issued by small vaccine firms, provided the firms invest the proceeds from the stock purchases in qualified research within 18 months of the purchase. As a result, investors would face lower marginal tax rates on the returns to these investments than on the returns to alternative investments. This difference could lead them to invest more in small vaccine firms than they otherwise would, augmenting their available funds for R&D. Innovation is the main route of entry into the vaccine business for small firms.

How much is vaccine R&D spending likely to increase in response to the proposed credit? This is difficult to analyze in the absence of reliable estimates of the responsiveness of vaccine R&D to changes in its after-tax price. The proposed credit lowers the after-tax price of qualified R&D, and in theory vaccine firms can be expected to perform more R&D as a result. A variety of studies have estimated that in the 1980s the ''tax price elasticity of total (U.S.) R&D spending'' was unity or even higher, meaning that U.S. firms responded to a 1% decline in the after-tax price of R&D by increasing their R&D spending by 1% in that decade.[9] Assuming vaccine firms exhibit the same tax price elasticity today, a research tax credit with a marginal effective rate of 19.5% could lead to a rise of as much as 19.5% in domestic vaccine R&D spending. However, this estimate cannot be regarded as reliable and could be greatly exaggerated, because it is unlikely that the sensitivity of R&D investment to changes in its after-tax price remains constant over time and is the same for all kinds of R&D projects, and because vaccine firms would be likely to differ in their ability to use the credit in any given year.

Furthermore, there is some reason to believe that the proposed vaccine research tax credit would eventually be as cost-effective as direct spending by the federal government on vaccine R&D. A number of studies have concluded that the existing R&E tax credit yields roughly a dollar-for-dollar increase in reported R&D at the margin, but that in the early years of the credit firms were not as responsive as they were adjusting to the credit's availability.[10] In other words, these studies suggest that government spending programs and the R&E tax credit are equally effective in increasing the amount of qualified research performed in the United States.

ECONOMIC JUSTIFICATION FOR A TAX CREDIT FOR VACCINE RESEARCH

Under conventional economic theory, the use of a subsidy such as a research tax credit is justified if its ultimate aim is to correct some sort of market failure. In the case of R&D, the R&E tax credit is one way to offset the tendency of firms to underinvest in R&D because of the gap between the social and private returns to research. Economists argue that in the absence of government support for R&D, firms are likely to invest too little in R&D because they cannot appropriate all the returns to those investments. So the R&E tax credit, by lowering the after-tax cost of qualified research, is intended to spur firms to invest more in R&D than they otherwise would. Ideallly, the added R&D stimulated by the credit is enough to raise domestic R&D spending to the level commensurate with the social returns to R&D. The market failure that the R&E tax credit is attempting to remedy is underinvestment in R&D arising from the inability of firms performing R&D to capture all the profits generated by the investment.

These considerations raise the issue of whether the proposed tax credit for vaccine research in H.R. 1274 is justified on economic grounds. Is there a failure in the market for

vaccines that would warrant the adoption of such a subsidy? As was suggested earlier, there are external economic benefits from controlling the spread of infectious diseases. The cost to society of preventing an outbreak of an infectious disease tends to be much lower than the cost of treating the outbreak that might occur in the absence of immunization. This raises the possibility that private firms invest less in vaccine R&D than its potential social benefits warrant. Partly in an effort to correct for such a market failure, the federal government supports vaccine R&D through its funding of basic research in vaccines and clinical trials for new vaccines. Its research support is also intended to direct vaccine investment to address current and future public health needs. In addition, it offers two tax subsidies for R&D, namely: the R&E tax credit and the expensing of R&D costs under IRC section 174. Although these subsidies are not targeted at vaccine research but are available to all firms that perform qualified research, they benefit vaccine firms by increasing their potential aftertax rate of returns on R&D investments. The proposed vaccine research tax credit would supplant the R&D tax credit for vaccine firms, but its treatment of qualified research would be more favorable, increasing the expected profitability of vaccine F&D investment relative to other kinds of R&D investment.

Thus, an important policy issued for Congress is whether the current level of domestic vaccine R&D investment is socially desirable or efficient. And if not, would the proposed tax credit in H.R. 1274 be more efficient than added federal funding of vaccine R&D or some other policy measure (such as government grants to international agencies that purchase and distribute needed vaccines in poor countries) in raising total investment to such a level. From the perspective of economic efficiency, the R&D projects that should be promoted are those with the largest gaps between the social and private rates of return. Yet vaccine firms are likely to use any research tax credits to fund first those projects with the highest expected private rates of return. At the same time, there is no certainty that the federal government could do a better job of targeting those vaccine R&D projects with the largest spillover effects. If it is determined that domestic vaccine R&D is less than socially optimal, perhaps a combination of a targeted tax credit like the one proposed in H.R. 1274 and increased government support for basic and applied vaccine research would be more attractive than relying solely on one instrument or the other.

Another policy issue for Congress raised by the proposed tax credits in H.R. 1274 relates to the external benefits of mass immunizations. The economic benefits to a society from vaccinations far outweigh the benefits to individual consumers, who in deciding whether or not to purchase vaccines for themselves or their children tend to consider only the costs and benefits to themselves and not the potential benefits to others in the community. Even if the market for vaccines were perfectly competitive, it is unlikely that immunization levels would be socially optimal.[11] Thus government intervention in the development and distribution of vaccines is certainly justified on economic grounds. The proposed tax credits would spur the development of new vaccines, but they would not lessen any of the barriers to the achievement of universal immunization with available vaccines. Low immunization rates are due to a variety of factors, including out-of-pocket costs, parental attitudes and knowledge, access to health clinics or doctors' offices, the perceived efficacy of vaccines, and the perceived risk of contracting diseases for which vaccines exist.[12] Clearly, other policy initiatives would be needed to address these factors.

FOOTNOTES

[1] Sing, Merrile and Mary Kaye Willian. ''Supplying Vaccines.'' Supplying Vaccine: An Economic Analysis of Critical Issues. Pauly, Mark, et al., editors. Washington, D.C., IOS Press, 1996. P. 61.

[2] Grabowski, Henry G. and John M. Vernon. The Search For New Vaccines. Washington, D.C., American Enterprise Institute Press, 1997. P. 20.

[3] Pauly, Mark V. and Bridget E. Cleff. ''The Economics of Vaccine Policy: A Summary of the Issues.'' Supplying Vaccines. P. 7.

[4] Sisk, Jane E. ''The Relationship between Scientific Advances and the Research, Development, and Production of Vaccines in the United States.'' Supply Vaccines. p. 181; and FIND/SVP. The World Market for Vaccines. New York, October 1995. P. 169.

[5] Sisk, Jane E. Supplying Vaccines. P. 177.

[6] Marcuse, Edgar K., et. al. ''United States Vaccine Research: A Delicate Fabric of Public and Private Collaboration.'' Pediatrics, December 1997. P. 1017.

[7] Vaccines: Big Shots. Economist, May 9, 1998. P. 63.

[8] Sisk, Jane E. Supplying Vaccines. P. 175.

[9] Hall, Bronwyn H. and John van Reenen. How Effective Are Fiscal Incentives for R&D: A Review of the Evidence. Working Paper 7098. Cambridge, MA, National Bureau of Economic Research, April 1999. P. 21.

[10] Hall, Bronwyn H. How Effective Are Fiscal Incentives for R&D? P. 21.

[11] Holtmann, Alphonse G. ''The Economics of U.S. Immunization Policy.'' Supplying Vaccine. P. 155.

[12] Pauly, Mark V. and Bridget E. Cleff. ''The Economics of Vaccine Policy.'' Supplying Vaccine. P. 12–16.

ADDITIONAL COSPONSORS

S. 26

At the request of Mr. FEINGOLD, the name of the Senator from Iowa (Mr. HARKIN) was added as a cosponsor of S. 26, a bill entitled the ''Bipartisan Campaign Reform Act of 1999''.

S. 51

At the request of Mr. BIDEN, the name of the Senator from Delaware (Mr. ROTH) was added as a cosponsor of S. 51, a bill to reauthorize the Federal programs to prevent violence against women, and for other purposes.

S. 80

At the request of Ms. SNOWE, the name of the Senator from Iowa (Mr. GRASSLEY) was added as a cosponsor of S. 80, a bill to establish the position of Assistant United States Trade Representative for Small Business, and for other purposes.

S. 345

At the request of Mr. ALLARD, the name of the Senator from Michigan (Mr. ABRAHAM) was added as a cosponsor of S. 345, a bill to amend the Animal Welfare Act to remove the limitation that permits interstate movement of live birds, for the purpose of fighting, to States in which animal fighting is lawful.

S. 1110

At the request of Mr. LOTT, the name of the Senator from Michigan (Mr. ABRAHAM) was added as a cosponsor of S. 1110, a bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering.

S. 1264

At the request of Ms. SNOWE, the name of the Senator from South Dakota (Mr. DASCHLE) was added as a cosponsor of S. 1264, a bill to amend the Elementary and Secondary Education Act of 1965 and the National Education Statistical Act of 1994 to ensure that elementary and secondary schools prepare girls to compete in the 21st century, and for other purposes.

S. 1265

At the request of Mr. COVERDELL, the name of the Senator from South Carolina (Mr. HOLLINGS) was added as a cosponsor of S. 1265, a bill to require the Secretary of Agriculture to implement the Class I milk price structure known as Option A–1 as part of the implementation of the final rule to consolidate Federal milk marketing orders.

S. 1277

At the request of Mr. GRASSLEY, the names of the Senator from Wyoming (Mr. ENZI) and the Senator from South Carolina (Mr. THURMOND) were added as cosponsors of S. 1277, a bill to amend title XIX of the Social Security Act to establish a new prospective payment system for Federally-qualified health centers and rural health clinics.

S. 1448

At the request of Mr. HUTCHINSON, the name of the Senator from South Dakota (Mr. DASCHLE) was added as a cosponsor of S. 1448, a bill to amend the Food Security Act of 1985 to authorize the annual enrollment of land in the wetlands reserve program, to extend the program through 2005, and for other purposes.

S. 1539

At the request of Mr. DODD, the names of the Senator from Washington (Mrs. MURRAY) and the Senator from New Mexico (Mr. BINGAMAN) were added as cosponsors of S. 1539, a bill to provide for the acquisition, construction, and improvement of child care facilities or equipment, and for other purposes.

S. 1547

At the request of Mr. BURNS, the names of the Senator from Massachusetts (Mr. KERRY) and the Senator from Hawaii (Mr. AKAKA) were added as cosponsors of S. 1547, a bill to amend the Communications Act of 1934 to require the Federal Communications Commission to preserve low-power television stations that provide community broadcasting, and for other purposes.

S. 1619

At the request of Mr. DEWINE, the names of the Senator from Montana (Mr. BURNS), the Senator from Idaho, (Mr. CRAIG), and the Senator from North Carolina (Mr. HELMS) were added as cosponsors of S. 1619, a bill to amend the Trade Act of 1974 to provide for periodic revision of retaliation lists or other remedial action implemented under section 306 of such Act.

S. 1644

At the request of Mr. ABRAHAM, the name of the Senator from North Carolina (Mr. HELMS) was added as a cosponsor of S. 1644, a bill to provide additional measures for the prevention and punishment of alien smuggling, and for other purposes.