OBAMA-BIDEN TRANSITION PROJECT

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BILL & MELINDA GATES foundation

Leadership in Global Health Research and Development

The U.S. is the world's leading innovator in health and medical science, and U.S.-supported research and development (R&D) has been critical to creating tools that fight serious global diseases. The next administration and Congress can help ensure that the U.S. remains a leader in health R&D.

The U.S. has a long tradition of investing in global health R&D:

- The National Institute of Allergy and Infectious Diseases invests 34% of a roughly $4.4 billion budget in HIV/AIDS, and another 29% for infectious diseases.
- Much of the world's private investment in R&D comes from U.S.-based sources. As of 2003, U.S. companies spent more than $17 billion on R&D, according to the National Science Foundation.
- The U.S. is also a leader in providing incentives to industry to engage in global health R&D. The U.S. recently enacted a priority review voucher, which allows companies that submit a global health technology to the FDA for review to access priority review for a product of their choosing. This is an excellent example of how U.S. innovation can provide incentives to get industry more involved in global health.

American investments in global health R&D have helped the fight against a range of diseases:

- U.S. military physicians and researchers have collaborated in the development of eight U.S.-licensed vaccines since 1934 that have had far-reaching global health benefits. This includes influenza, oral typhoid, hepatitis A and B, and several strains of meningococcus, which causes meningitis. These vaccines have saved lives worldwide.
- The world's most advanced malaria vaccine candidate, originally developed by the U.S. Walter Reed Army Institute of Research, is the first to demonstrate in clinical trials that it can protect young children living in malaria-endemic areas against infection and clinical disease caused by Plasmodium falciparum, the most deadly form of the malaria parasite.[1]
- The NIH developed components of a vaccine that can protect against rotavirus disease strains that have emerged recently in Asia and Africa. Nearly every child in the world, rich or poor, contracts rotavirus before the age of 3 – but more than 85% of rotavirus-related deaths occur in the developing world.[2]
- The advances the international community has made in HIV would not be possible without America's significant R&D investments. These investments have helped create drugs and diagnostics that are critical tools in ongoing efforts to combat the disease. Currently, 1.7 million people in Africa have access to these life-saving drugs.[3]

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[1] http://www.malariavaccine.org/files/101707/RTS_S_fact_sheet_Oct15_FINAL%20version%202.pdf

[2] http://www.path.org/projects/rotavirus_vaccine_projects.php

[3] http://www.pepfar.gov/

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U.S. investments in global health R&D have leveled off in recent years.

The Bush Administration came into office in the midst of a push to double NIH funding. It continued to promote increases for NIH through 2003, after which it sought some increases for the research and development accounts at the Departments of Defense and Energy, while the NIH budget flattened out and then declined. Consequently, NIH funding grew from $13 billion to $27 billion between 1998 and 2003, but has since lost an estimated 14% in purchasing power.

President Bush's FY 2009 budget proposes spending $147 billion for R&D across the U.S. government. More than half of this funding is for R&D in the Department of Defense; the rest of the investment goes towards other U.S. departments and agencies including, in order of budgetary importance, the NIH, DOE, NSF, USDA, DHS, VA, NIST, NOAA, and CDC.

- The Defense Department has a FY 2009 R&D budget of about $82 billion, making it the largest provider of federal R&D investments. About 80% of Defense "R&D" funding, though, goes towards the development of weapons systems rather than into research.

- The National Institutes of Health has a proposed FY 2009 budget of roughly $29 billion, making it the second largest source of U.S. R&D investments; it is also the largest source of funding for domestic and global health R&D.

The Bush Administration's largest science and R&D initiative stemmed from a report by the National Academy of Sciences entitled "Rising Above the Gathering Storm," which called for greater investment in science and math education and basic research and policy changes to promote innovation and the development, recruitment, and retention of scientists. After the report was issued, the Administration launched an "American Competitiveness Initiative," aiming to double federal research funding for the basic physical sciences through extending an R&D tax credit (for $86 billion in increased R&D over 10 years) and increasing federal R&D funding (another $50 billion over ten years). The bulk of this funding was aimed at basic research in the physical sciences and engineering, rather than the life sciences.

There is bipartisan Congressional agreement with the Administration around the need to invest in R&D; even politicians who generally oppose big government argue for federal funding of basic science research, saying that the government is essentially the sole source of this funding. In August of 2007, the Congress overwhelmingly passed and President Bush signed the "America Competes Act," to promote more federal funding of U.S. basic science and better science and math education. Congress and the Bush Administration also agreed in early October to extend the R&D tax credit for two years. Senators Specter and Harkin have led a recent push to provide another $1.2 billion to the NIH in Congressional economic stimulus/recovery packages; Nancy Pelosi has endorsed investments in innovation and science as part of the solution to current economic troubles.

Despite this consensus, appropriations for federal research and development have not been keeping pace with inflation, let alone with the aspirations of the America Competes Act. Overall, U.S. investments in R&D have been flat for the past seven years, once inflation is taken into account. At the moment, U.S. health R&D institutions -- comprised mainly of the NIH, CDC, and NSF -- are operating on straight-lined budgets under a continuing resolution, and since the NIH allocation does not include supplemental FY 2008 funding, FY 2009 funding for the NIH and health-related research is currently declining.

Preliminary and pending FY 2009 appropriations bills suggest that the U.S. Congress remains broadly interested in increasing funds to basic science and health-related R&D accounts. In the three full year FY 2009 appropriations bill that have passed (DOD, VA, and DHS), Congress provided substantial R&D

increases. Should the remaining FY 2009 appropriations bills be enacted, they would provide a modest increase in funding for the NIH, reverse the Bush Administration's proposed FY 2009 cuts to the CDC, and provide a substantial increase in NSF funding.

The next administration and Congress can help strengthen America's leadership on scientific research for global health by:

- **Quickly appointing** a high-level science adviser to energize and direct the White House's Office of Science and Technology Policy.
- **Increasing public resources for global health R&D and encourage more private sector investment with incentives targeting global health issues specifically** (like the Orphan Drug or Bioshield acts, which provide incentives for the development of drugs that are critical but likely to be unprofitable absent special tax or exclusivity rights). This will help the U.S. keep its competitive advantage in biomedical research, and attract and support the next generation of talented scientists.
- **Encouraging other donors, to sustain and increase global health R&D investments.** New technologies and tools will be core to any strategy to make a lasting difference in the health of the world's poor, and more funding and visibility should be directed to R&D activities.
- **Supporting an Advance Market Commitment (AMC) to encourage the creation and introduction of vaccines that would benefit the developing world.** By guaranteeing the size of the purchase commitment, AMCs give vaccine makers the confidence to develop new vaccines, and to build enough production capacity to satisfy global demand.

Frequently Asked Questions

Isn't the U.S. already a leader in health R&D? Why do more?

The existence of effective vaccines and treatments will be essential to any sustainable strategy to improve the health of the world's poor. The value of R&D focused on global health technologies, however, goes beyond the countries that carry the majority of the burden of disease. In a world where an influenza outbreak in a developing country can travel quickly to the U.S., the availability of effective vaccines and treatments is critical across the globe. In the case of HIV, the development of improved tools and ultimately a vaccine will benefit people the world over, including in the U.S. Further, U.S. leadership and engagement in R&D for major global diseases can benefit our economy at home, employing our scientists and researchers in both the public and private sectors to make a difference in the world.

Why is there a focus on vaccine research?

Vaccines are one of the most cost-effective tools to reduce illness and death, as well as being the most sustainable way to protect people against disease. With the introduction of wide-spread vaccination, the costs associated with once-common diseases such as measles, mumps, and polio have been averted in the U.S. for decades. Similar progress in the developing world would save significant lives and resources. However, while vaccines are very important, life-saving drugs and diagnostic tools must be a focus of R&D as well, and we must ensure these are available to those who need them most.

Has there ever been an Advance Market Commitment?

The governments of Canada, Italy, Norway, Russia, and the United Kingdom, and the Bill & Melinda Gates Foundation, in collaboration with the World Bank and GAVI have committed $1.5 billion to establish a pilot Advance Market Commitment to purchase and distribute new pneumococcal vaccines for the world's poorest children. It will be launched in early 2009.

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Pneumococcus is a bacterium that causes meningitis, pneumonia, and ear infections. It kills 1.6 million people every year, including a million children under the age of 5, according to the World Health Organization. This AMC could prevent 5.8 million childhood deaths by 2030.