

Congress of the United States
Washington, DC 20515

May 19, 2006

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

During the week of May 22, the World Health Assembly (WHA) will meet in Geneva to debate the World Health Organization's (WHO) Executive Board Draft resolution EB117 R13, with a bracketed title of "[Global framework on] essential health research and development."

At present, consumers in the United States are the major source of financing for global R&D on new medicines, both because they pay the highest prices in the world for patented medicines, and because through taxes they pay more for public sector medical R&D than all other countries combined. It is in our national interest to share more equitably the costs of new drug development.

Around the world, policymakers and health officials share a common interest in encouraging greater investments in research and development (R&D) on innovative medicines, especially those to treat or cure pandemic diseases or neglected diseases that afflict developing countries. There is also a common interest in promoting a fairer distribution of the burden for paying for new drug R&D.

There have been a number of different approaches recommended for advancing the dual goals of increasing global research on new drugs and of fairly sharing the R&D burden. Some have called for liberalization of parallel trade in medicines (also called reimportation) between the U.S., Canada, Europe and other nations as a market-based approach to minimizing pricing differentials among high-income countries. While this approach could help equalize the R&D burden, it is unclear whether it would increase global R&D outlays.

Another approach has been to call for the elimination of so-called price controls and reference pricing in high income countries, on the grounds that forcing consumers in other countries to pay more for medicines would create revenues that could be channeled into R&D spending. Another approach is the U.S. government's practice of including extensive intellectual property provisions in bilateral trade agreements, on the argument that such measures will lead to more R&D investment. In both these cases, it is not clear that additional revenues raised through these policies would necessarily be invested into R&D, and further, that such R&D would be directed at priority research of special concern in other, especially developing, countries.

The Honorable Michael Leavitt
Page 2

The WHO Executive Board's resolution suggests a different model for a more equitable sharing of medical R&D costs, which seeks not only an overall increase in R&D outlays, but a method of focusing research on priority public health concerns.

At the moment there is ongoing debate about what a global R&D framework might look like. Some governments and public health experts have called for a broad WHO treaty on medical R&D, which would obligate countries to support essential R&D at a certain proportion of national income, and create a mechanism to identify and support special priority R&D, such as for avian flu, malaria or AIDS. Others have suggested creating "best practice" norms, and greater coordination on support for priority R&D projects, particularly in the area of neglected diseases. All parties to these discussions correctly recognize the importance of both public and private sector investments, and the legitimacy of a number of different tools to stimulate investments in R&D, including intellectual property rights.

The growing global interest in a new international agreement on medical R&D has received endorsements by several leading medical researchers, non-government public health, development and consumer rights organizations and other experts.

These discussions on a global R&D framework are important, and should be given serious consideration and debate. The initiative before the WHA does not bind the United States or any other party to an outcome. It merely provides the opportunity for a dialogue on how to best reconcile the needs of supporting innovation in a world where governments will also protect their consumers from high drug prices. If the U.S. government wants its concerns about the global R&D burden to be taken seriously by our trading partners, it should allow a full and fair debate on the global R&D framework at the World Health Organization.

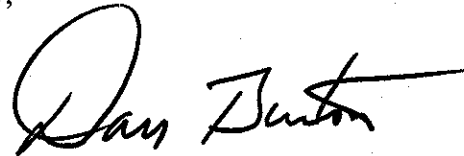
The WHA proposal to discuss new ways to addressing the global sharing of R&D costs is timely and important, and should be supported by the United States government.

Thank you in advance for your consideration of our request.

Sincerely,



Tom Allen
Member of Congress

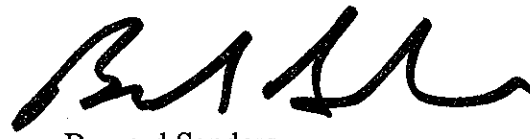


Dan Burton
Member of Congress

The Honorable Michael Leavitt
Page 3



Lloyd Doggett
Member of Congress



Bernard Sanders
Member of Congress



Dennis Kucinich
Member of Congress

cc: The Honorable Susan Schwab, United States Trade Representative-designate