

# SHOW US MORE THAN THE MONEY

## – OUR NEW LEGISLATIVE AGENDA

Global AIDS vaccine research is fueled in large part by NIH funding. With the approaching end of the five-year effort to double NIH funding and mounting federal deficits, pushing for continued increases at NIH remains at the top of the policy advocacy agenda. But a broad-based research effort that marshals expertise from all quarters requires more than NIH dollars. More must be done to engage industry and lay the groundwork for global vaccine delivery.

Since last fall, a coalition of advocates working on microbicides and vaccines against malaria, tuberculosis and HIV/AIDS have been meeting to map out key, shared legislative priorities. We were impressed by the comprehensive government effort to make and procure anti-bioterror products. Based on that response, we are designing model legislation that would provide many of the same incentives for development of products to prevent the three infectious diseases that collectively kill seven million people annually around the world.

For years, AVAC backed the idea of using targeted tax credits to inspire more private sector involvement in AIDS vaccine research. We thought that using the tax code would avoid a fight for more appropriations and temporarily sidestep controversial policy issues, while utilizing a tried and true incentive for the private sector. Bioterror changed all that.

We now know that if government perceives a serious and immediate threat it can relatively quickly implement a range of initiatives with no apologies.

Our new coalition proposal <http://www.avac.org/actionMemo.htm> calls for a series of legislative changes designed to spur more research in industry and the public sector, and address global access issues down the road. At this writing, our coalition is talking with legislators about these proposals and we seek support from other health advocates and industry leaders.

We are also working closely with BIO and others representing private sector concerns. We propose that the US Government:

1. **Adapt incentives for bioterror vaccine and treatment research** to encourage development of vaccines against AIDS, malaria and TB, and microbicides. *These measures include:*
  - *Expanded direct contracting for research and product development in the private sector*
  - *Public assistance with vaccine manufacturing*
  - *Non-negligent liability protection for manufacturers of licensed products (in combination with a system to provide reasonable injury compensation)*
  - *Priority regulatory consideration of products*
2. **Ensure maintenance of effort** by directing that federal research agencies sustain their research efforts on priority prevention technologies in the face of growing demands for bioterror-related research, development and testing.
3. **Create credible purchase pre-commitments to buy vaccines and microbicides for the world** by mandating that the Administration engage in collaborative efforts with other nations, international organizations and private funders to establish capacity to buy future prevention products. This must be accomplished without taking current funding away from purchase and delivery of existing treatments and vaccines. Build on the “permanent, indefinite funding authority” proposed in Project BioShield for the purchase of bioterror vaccines and treatments by adding global disease products to this purchase plan.
4. **Significantly increase the number and grant amounts of Small Business Innovation Research (SBIR) grants for priority vaccines and microbicides.** Improve the quality of the grant reviews so that people who understand product development are involved.

5. **Expand the current tax credit on contract arrangements** so that pharmaceuticals have a greater incentive to develop contracts with other research companies (e.g. biotechs) for research and development on priority vaccines and microbicides.
6. **Expand delivery of existing vaccines through increased authorization and appropriations to The Vaccine Fund.**
7. **Voice support for tiered pricing of vaccines and microbicides globally through a Sense of the Congress resolution.**
8. **Promote public sector support for R&D** by increasing funding and creating or expanding programs in priority disease areas at NIH, the Centers for Disease Control and Prevention, the United States Agency for International Development (USAID) and the Department of Defense (DOD).
9. **Accelerate regulatory consideration** of priority vaccines and microbicides by exploring legislative proposals to achieve speedier, more flexible FDA review and approval of products addressing the biggest infectious disease killers. Expand the FDA mandate to review priority products not for US use. Encourage FDA collaboration with the World Health Organization (WHO), EMEA (Europe's regulatory agency for pharmaceutical products) and resource-limited countries to provide systematic regulatory dialogue and technical assistance.

**Organizations collaborating on the legislative effort include:** AIDS Vaccine Advocacy Coalition, Alan Guttmacher Institute, Alliance for Microbicide Development, Global Campaign for Microbicides, Gay Men's Health Crisis, International AIDS Vaccine Initiative, International Partnership for Microbicides, Malaria Vaccine Initiative, and the Sequella Global Tuberculosis Foundation.

Excerpted with permission from the AIDS Vaccine Advocacy Coalition report: *How Do You Fight a Disease of Mass Destruction?*