

IN MEMORIAM

Beth Waters Finston

AVAC dedicates this year's Report to Beth Waters Finston, a dear friend and trusted advisor.

Beth spent a lifetime as a tireless advocate against infectious diseases. Her passion was advocacy for vaccines to prevent and treat diseases throughout the world. More than a decade ago, she was a powerful ally for the idea that a core strategy to end the AIDS epidemic is to develop a safe, effective and affordable AIDS vaccine.

She was untiring in her efforts, traveling the world to lend her intensity and expertise to companies, governmental committees and non-governmental organizations. Beth was a wise counselor, a creative problem-solver, and a relentless optimist, never ceasing to push the AIDS vaccine agenda forward, despite the scientific and political challenges.

Beth understood the power of advocacy and community engagement to push the field forward and provided visionary guidance in the formation and strategy of AVAC. She remained a close advisor and confidant to the organization's founders and directors throughout its history.

Beth was a founding member of the advisory board of the Vaccine Education Center of the Children's Hospital of Philadelphia and a member of the HIV Vaccine Communications Steering Group of the National Institute of Allergy and Infectious Disease.

A reporter for publications including the Philadelphia Bulletin, Boston Magazine and the Boston Herald in the early years of her career, Beth was a Senior Managing Director of Ogilvy Public Relations before co-founding Cooney/Waters Group, a health care public relations and public affairs company in New York City.

She continues to inspire AIDS vaccine advocacy, and she will be remembered for her dedication to conquering infectious diseases through education, sound public policy and vaccine advocacy.

LETTER FROM THE BOARD PRESIDENT AND EXECUTIVE DIRECTOR

AIDS at 25, HAART at 10, AIDS vaccines at 20+, AVAC at 11. This year marks a number of “anniversaries” that chart a sobering reality in the history of the epidemic.

In this year’s AVAC Report, our argument is simple: *the future is now.*

The next several years will bring a variety of scenarios that we must not encounter unprepared. Instead, the AIDS vaccine field, and the field of prevention research in general, must engage in rigorous debate, dialogue and scenario planning to anticipate the issues that the next few years will bring, and ensure that a wide range of stakeholders is informed and empowered to make decisions to compete against the virus.

Why do we say this? Why now?

Because:

- The next two to five years will bring results from a variety of ongoing trials, including the Thai prime-boost trial, test-of-concept studies of adenovirus-based AIDS vaccine candidates and several microbicide efficacy trials, as well as studies of male circumcision, treatment of herpes simplex virus type 2 to prevent HIV transmission or acquisition, pre-exposure prophylaxis and the female diaphragm as strategies for AIDS prevention. Each new finding means new choices, new messages, new points of convergence and necessary collaboration among trial planners, public health program designers, and communities. The time to begin anticipating and discussing these challenges is now.
- The infusion of new funding from the US National Institutes of Health and the Bill & Melinda Gates Foundation to the Center for HIV/AIDS Vaccine Immunology (CHAVI) and the Collaboration for AIDS Vaccine Discovery (CAVD) respectively, is meant to stimulate product development at the earliest stages. The fruits of these labors—in terms of products in the pipeline—will not be seen for at least two

years, based on current working plans. There is an urgent need to map out the pathway for the future: how do we ensure that there is sufficient clinical trial capacity, human resource development and community and political will for the “long haul”? How do we ensure that these new consortia generate new ideas and cross-fertilize each other?

- The AIDS vaccine field can learn valuable lessons from other fields. Recent licensure of Gardasil™, Merck’s HPV vaccine, provides the opportunity to explore issues of trial participation, access, delivery and funding for a vaccine targeted at a population that is also in urgent need of an AIDS vaccine—adolescent girls. There is no perfect model for AIDS vaccine delivery; there is also no excuse for passing up the chance to collaborate on and learn from rollout of a vital public health tool for cancer protection and sexual and reproductive health.

AIDS Vaccines: The Next Frontiers is AVAC’s first contribution to the scenario planning that we think is critical to the success of the field. In this year’s report, we present four chapters, each of which begins with a future scenario that imagines the world in the coming years. Each chapter is meant to raise issues, challenge assumptions, provoke debate, and provide a foundation for future vaccine and prevention research advocacy. These chapters are:

01. AIDS Vaccine Science, Strategy and Action: The state of the field, the stakes for the future

New infusions of funding into the field are being channeled to projects that aim to tackle one or more of the goals laid out in the Scientific Strategic Plan of the Global HIV Vaccine Enterprise. Each of the new projects aspires to greater coordination and a departure from “business as usual” in the arena of academic science and product development. How can advocates assess whether these efforts at collaboration are paying off? What are the metrics of success? And what about the areas of the plan that have not been funded to date?

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| AIDS Vaccine Field | <ul style="list-style-type: none"> • Advocate for robust, comprehensive HPV vaccine delivery to adolescent girls and boys. • Develop a common language for talking to communities about test-of-concept studies and sequencing decisions. |
| Researchers | <ul style="list-style-type: none"> • Share outputs from research on neutralizing antibodies, adjuvants, mucosal immunity assays and other work in a manner that lets us understand if and how CHAVI, CAVD and other consortia are truly adding value to the field. (And don't forget to keep thinking outside of the box!) |
| Global HIV Vaccine Enterprise | <ul style="list-style-type: none"> • Reconstitute working groups on clinical trials capacity, intellectual property, manufacturing, and regulatory issues. Give these groups specific tasks to help bring these areas up to speed. • Take swift, transparent action to identify a new executive director. |
| WHO/UNAIDS | <ul style="list-style-type: none"> • Continue to develop and regularly update guidance notes on emerging prevention interventions and technologies including HPV vaccine, couples counseling, circumcision, PrEP, and more, so that countries can plan and have dialogue even before definitive results are in. • Partner with other stakeholders to convene ethical consultations on issues related to evaluation and eventual introduction of new partially effective prevention strategies. |
| AVAC | <ul style="list-style-type: none"> • Take a leadership role in developing—in consultation with multiple partners—new guidelines for “Good Community Practice”: standards that could clarify and strengthen community-researcher relationships at prevention trials worldwide. • Support and/or convene a prevention research advocacy network which addresses emerging ethical, community and trial design issues. |

* While we make many other recommendations throughout the report, AVAC feels that these nine items are of utmost importance in the next 12 months. We'll evaluate everyone—including ourselves—by progress towards these goals.

And how will all of this go forward with the continued absence of an Enterprise chief executive? We note with concern the continued “interim” nature of Enterprise leadership, and we firmly believe that inspired leadership is increasingly vital to keeping the momentum.

We also draw your attention to the illustration of the increasingly complex field on page 14. It is our attempt to understand the new cosmology of the field at large, the Enterprise and the new funding announcements.

02. Reports from the Frontlines:

Learning from last year's clinical trials

More trials, more volunteers, more reports on what works and what doesn't work in the field are needed. The past year has seen bold moves, some exciting successes, and some instructive setbacks in AIDS vaccine trials and prevention research as a whole.

There is more conversation than ever about the need to build clinical trial capacity and to ensure that communities are authentic partners in the research process. How well is this happening “on the ground” and what can we do better?

03. **The Emerging Adolescent Agenda: HPV vaccine, AIDS prevention research, and the new opportunities for reaching the young people of the world**

Two years ago, the AVAC Report 2004 examined the issue of adolescents and HIV vaccine research in its article, “The Missing Cohort.” In light of new developments, including licensure of the first HPV vaccine and steps to involve young women and men in AIDS vaccine trials, we re-visit these issues, and discuss what it will take to make these elements coalesce into an ongoing, coordinated effort to improve health and reduce disease among the world’s young women.

04. **AIDS Prevention Evolves (Again): Why we are on the verge of an era of new complexity**

Microbicides, pre-exposure prophylaxis, herpes-simplex 2 treatment, male circumcision: the list of potential prevention interventions currently under investigation is long and varied. It is our great hope that all of these show some efficacy, and that the arsenal of AIDS prevention tools expands accordingly. And if it does, this will mean new challenges for trials of AIDS vaccines, second-generation microbicides and other interventions, which may be more complicated—though no less necessary.

Why the space theme in this year’s report? Actually, it’s not the first time AVAC has had astronauts in its annual report. In our AVAC Report 1998—the second one we ever issued—photos of the moon shot were used as a fitting analogy for the search for an AIDS vaccine.

In 2006, we’re revisiting the comparison, with a new perspective born of the past years’ progress, challenges and discoveries. Our inspiration is longtime vaccine advocate Jose Esparza, who has pointed out that the search for an AIDS vaccine is a far greater challenge than sending a man to the moon. When it came down to the space race, we knew where we were; we knew where the moon was; and we knew, roughly, how to get there. It was, essentially, an engineering problem.

When it comes to an AIDS vaccine, we don’t know where the moon is—yet. But that doesn’t stop us from aiming for the heavens. As you’ll note on this year’s cover, the spacemen and rockets morph into needles and target cells in the blink of an eye. It is our hope that careful planning and execution of the goals laid out in this report will help transform the search for an AIDS vaccine into an engineering problem whose solution will change the world.

Sincerely,



Mike Powell
AVAC Board President



Mitchell Warren
AVAC Executive Director