Developing an AIDS Vaccine: 
A Global Public Good

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An Interview with Priya Bindra
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Seth Berkley, President, Chief Executive Officer and Founder of IAVI, is a medical doctor specializing in infectious disease epidemiology and international health. Prior to founding the International AIDS Vaccine Initiative (IAVI), Dr. Berkley was Associate Director of the Health Sciences Division at the Rockefeller Foundation. He is Adjunct Professor of Public Health at Columbia University, and Adjunct Professor of Medicine at Brown University.

Brown Journal of World Affairs: Could you describe the founding of the International AIDS Vaccine Initiative (IAVI) and how you see its role in combating AIDS?

Seth Berkley: Discussions about forming the IAVI was started in the early 1990s at a time when a worldwide effort to develop an AIDS vaccine had really hit its nadir. Taking a historical view, in 1981 the disease appeared, and in 1984 they figured out it was a virus. In response, everybody said, “We have to have a vaccine; it’s the only way to control a virus.” The activist community replied, “My god, people are sick, people are dying, we need drugs!” Scientists said, “We don’t know how to make drugs.” The activist community replied, “We don’t care, invest money, learn how to do it.”

In a way the activist community deserves the Noble Prize for having led this effort. On the vaccine side, what happened was, less and less of the public money was going towards producing a vaccine. It was shifting away. In a way the anti-Noble Prize goes to the public sector for not keeping on this. For the corporate sector, the science was difficult, it was clear that the public spending was decreasing on AIDS vaccines and it was also clear that the disease was mostly now in the developing world. There-
fore, the market was not going to be as profitable. In addition, vaccines themselves are not as profitable as drugs are, given what you can charge for them. Lastly, AIDS was a very controversial disease. From a company perspective, therefore, it was not a particularly good place to invest shareholder resources. You had this strange position where neither public nor private resources were driving vaccine development forward.

In response to these conditions, IAVI was formed with the goal of revitalizing the AIDS vaccine effort. After all, only with an AIDS vaccine, will we be able to ultimately end the epidemic. It is, therefore, a critical global priority and the challenge really was how best to do it. IAVI was born after a series of meetings that looked at whether there was a problem, which there was. We also asked whether science suggested that a solution was possible, and scientists got together and said in fact it is possible, it was just that we were going about it in the wrong way. And then there were a set of meetings on how to structure the organization, what it should look like, how to finance it, what to do about intellectual property, etc. IAVI was established in the beginning of 1996.

Journal: How do you see the work of the vaccine initiative as related to the work done by other global health initiatives, such as UNAIDS, the World Health Organization (WHO), and the Global Fund to Fight AIDS, TB and Malaria?

Berkley: If you ask the important question, “Who is responsible for the development of an international public good that affects the whole world?” then the answer is nobody. In other words, it is not an individual country and it’s not the WHO (who do not really make products). It is not the World Bank, who do not do this type of thing. There is no other real UN body. It’s not a company’s job to make something that would be used in Malawi. So there was not an organization. The challenge was then to create an institution that would bring together all the critical players where the public and private sectors could move this forward.

The Director of UNAIDS is on our board and has been from the beginning. We are working with the current Executive Director of the Global Fund (who was also on our board for eight years), and we work closely with the WHO. However, this really is a niche; it is a new area that the IAVI is filling. If you look at the Global Fund, it is doing no work on AIDS vaccines. Similarly, neither the vaccine fund nor Global Alliance of Vaccines and Immunizations, are working on AIDS vaccines. AIDS vaccines are outside everyone’s mandate.

Journal: Given that historically vaccine research has taken place at institutions in the developed world, should developing countries take a larger role in both the search and implementation of the vaccine?
Berkley: Historically, most vaccines have been developed in the North. They have been released at high prices and have then trickled down to the developing countries ten, fifteen, or twenty years later. The problem, of course, is that the practice of developing vaccines only in the North is not right for any vaccine, especially for one combatting HIV. The challenge here is to start off with a strategy that says, “We want to have simultaneous availability of a vaccine in the North and the South.” Not that it will be immediately available in every location, but there is no reason why we should not be at least initiating bringing it out in the North and South at the same time. To do that means that one would need to include the developing world as serious partners if you are to get it out at a quick pace. There are, however, other benefits as well. If your only goal was to make a vaccine as soon as possible, given that the epidemic is mostly in the developing world, you would go there anyway to do your testing. The challenge is to do that in a way that accelerates the access to the developing world as part of that goal.

Journal: In the past two years, we have seen clinical trials of potential vaccines take place. How far would you say we are from developing a viable vaccine?

Berkley: The shocking thing is that in the 22-year history of AIDS there has only been one trial to see if a vaccine works. That was just completed and of course it did not show efficacy. One of the challenges will be getting vaccines that look promising into clinical trials as soon as possible and accelerating every aspect of their development and testing. To achieve this, we need to accelerate what we are doing, or we will take an awfully long time to get there. On the other hand, even if we did everything right, ran all the trials, and put the right resources into it, you cannot guarantee that you are going to succeed in any immediate time frame. But given everything we know, we would think that by the end of the decade, we would have multiple promising products that had been tested.

Journal: What are the most significant current political and economic obstacles to developing an effective vaccine?

Berkley: The most significant obstacle is solving the scientific challenges. In terms of political and economic obstacles the single most important thing is the issue of short-term versus long-term. Currently, the world is very focused on the short-term emergency and rightfully so. We have people dying everyday, we have 15,000 new infections a day, and the world’s focus is on what they can do now. The challenge is to get people to also focus on the long-term goal because had they done that ten years ago we might have had a vaccine by now. But if we do not focus on it now, in ten years we are...
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still not going to have it. The challenge is to get people to focus on the long-term and short-term simultaneously and not in competition. You need to do both of those simultaneously. That should be our number one priority; number two is on the economic side. First, we want the economic push for the vaccine to be insulated from the ups and downs that occur due to short-term funding. Second, you want it to be global. You do not want funding to come from just one country or one area because if you make it global, then you get the involvement of many different countries and many different groups in trying to push forward this agenda, which is critical. Finally, the other large obstacle is that there is not a constituency. In other words, if you are sick with a disease then you become your own constituency to argue for improved treatment. The problem for an AIDS vaccine is that the constituency will be adolescents in the future. Often people undervalue prevention and in fact heavily discount their personal risk of contracting the diseases. So you do not have advocates for AIDS vaccines the same way you do for other concerns and that, of course, affects the funding and political weight that its given.

Journal: What is your view on the recent Bush AIDS Initiative, given that much of this money will go towards treatment and prevention programs rather than vaccine development?

Berkley: The fact that AIDS is now being seen as the global problem that it really is, as the greatest epidemic since the 14th century is fabulous. Over the last few years, there has been more money and more interest put into this area by organizations including the Global Fund, the Bush Initiative, and the World Bank, and I am delighted to see it. However, as mentioned earlier, I think there also needs to be a long-term view. We need to make sure that you not only fund short-term initiatives but long-term ones. Certainly, I would like to see more funding going into vaccines but the money that is coming forward to meet today’s needs is absolutely critical and I am delighted to see it.

Journal: The IAVI has had a two-pronged goal of both developing a vaccine and ensuring its distribution in developing countries. How can current systems structuring drug access in the developing world be improved?

Berkley: The challenge is that there are really two separate issues. One is pricing or availability and the second is the distribution and delivery of the product. Where we make mistakes is that we forget about the second. For example, the current six vaccines together cost about a dollar. The delivery system for those vaccines costs between 18 to 35 dollars depending upon the country and labor costs in that country. In this particu-
lar case, the delivery is massively more costly than the vaccines. We do not expect that to be the case in AIDS vaccines which are expected to be substantially more expensive than the existing vaccines. But there still will be very substantial costs in getting these vaccines out to adolescents, IV drug users, truck drivers; groups we normally do not reach with our immunization campaigns. One has to set up those types of systems with a structure that enables them to get a vaccine out to people. Also, if we build systems to get current prevention strategies out, they may very well be useful for vaccines as well, although it also may be different. Treatment for AIDS is going to go to people slightly older and people who have already been infected. To use vaccines most effectively we want to go to people before they get a chance to get infected so it is going to be slightly different.

Journal: You have mentioned that industry has a critical role to play in AIDS vaccine development. What is your view on the potential for public-private partnerships in the fight against AIDS?

Berkley: It is absolutely critical that the expertise in industry be part of the effort. We are fooling ourselves if we think we can do this without having their help. Now whether the work is done in those companies in situ, or whether some of those types of people are hired into other efforts or in the best circumstances, a combination of efforts where you bring the skills that each has to work together, any of those can succeed. But it is absolutely critical to have industry engaged in development. They have over the years built the capacity, the experience, and collected the talent and they need to be part of this. In an ideal world, the public sector would accelerate some ideas, and as soon as they became promising, industries would pick them up and run with them. They would handle all of the late stage work, and manufacturing and all of that. If that does not occur, then we have to figure out what the alternatives are. Do we take a smaller company and make it into a big company? Do we work with contract manufacturers? Do we work with developing country manufacturers? Any one of those would still require the expertise that exists in today’s large vaccine companies.

Journal: How can collaboration be structured to avoid potential conflicts of interest?

Berkley: The challenge, first of all, is that you need to put incentives in place. Companies are not going to do it unless there are incentives. Secondly, it turns out that the markets we are so concerned about are the markets that the companies are not going to be thinking about as their primary markets. The company is not saying, “Gee, I am going to run out and try to serve Malawi as my primary market.” On the other hand, if one does serve Malawi, they want to make sure that it doesn’t hurt their bottom line.
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in New York or in Rome or Tokyo. The challenge is to create a system that allows differential pricing for different parts of the world. It should be one that allows companies to be clear that they will be able to make money in their for-profit markets and not be hurt by working in the rest of the world. There are several possible options for structuring this separation. Whether it is truly differential pricing or whether we have different groups manufacturing vaccines for the south and north, or whether it be differences in distribution patterns, it’s a matter of working that out ahead of time.

Journal: What is your position on the current debate over the production of generic anti-retroviral drugs?

Berkley: The tough issue here is that we have to do everything we can to ensure that everybody who needs medicines and vaccines has access to them. On the other hand, we do not want to destroy the engine that is doing research and design and creating these products. That is the fine line we have to walk. I am all for having generic anti-viral drugs as long as it does not hurt the industry’s interest in investing new money in R&D for new drugs. If it becomes clear to industry that any drug it develops is immediately going to become generic and influence pricing in their own markets, they will stop putting research into new products and then the world is in trouble. In the end industry has a responsibility to deal with these different groups in the world who cannot afford it. We in the public sector also have a role to play. It really is the combination of all of that creates the system and we have to do it with a clear goal in mind and working together.

Journal: What are the prospects of the AIDS epidemic being resolved with tools currently available?

Berkley: Existing prevention tools can slow down the epidemic and control it in subsets of populations. It is thus critical we get existing tools to all those who need them without delay. However, we have not been able to end the epidemic in any population with these current tools. Given that AIDS vaccines are not an immediate possibility, it is easy to not make them a priority now, yet that is the greatest mistake we can make. We clearly need new tools and the world has to make sure we do everything we can to move them as fast as possible while we are dealing with today’s emergency. That is the challenge for society.