This is a great crowd and I'm thrilled to be here. Welcome and thank you for coming to the third of our four Voices from the Vanguard lecture series. My name is Pat Thomas, I'm the Knight Chair in Health and Medical Journalism at Grady College. These lectures are a collaboration between my program and the UGA Center for Tropical and Emerging Global Diseases headed by Dan Colley. And we are also very grateful for the financial support from the President's Venture Fund. Dan really wanted to be here but he's in Kenya with some snails right now. He studies the schistosomiasis. If you've been here before, you know that the speakers in this lecture series are not just researchers and thinkers but people who are taking real actions that will save millions of lives around the world. Tonight you'll hear from Dr. Don Francis, one of the most important figures in the 25-year history of HIV/AIDS. He'll talk for 40 or 45 minutes or so, then take questions, and after that we invite you to join us next door in Demosthenian Hall for a reception. At the first international
AIDS meeting back in April 1985 in Atlanta, Don Francis was one of the most controversial speakers on the program. I remember because I was there. He had alienated many of his colleagues at CDC and in the government by insisting that Francis already knew enough about this dangerous virus called HTLV3 at the time, to make specific public health recommendations. At that time, Dr. Francis was on the warpath about screening donated blood to make sure people wouldn't be infected by transfusions. He was also urging gay men, who were the epicenter of the epidemic at that point, to be tested with a newly available antibody test and to have sex only with people whose antibody status matched their own. More cautious government authorities thought these recommendations were premature, even rash, and that Dr. Francis was out of line to suggest such things. So it came as no surprise soon after the meeting when I heard that he had been transferred to San Francisco where he would be an advisor to public health officials there. But he stayed true to form and he pretty much angered the gay community in that city by insisting that the popular
bath houses be shut down.<br/>
<time begin="00:03:15.58"/><clear/>In his words, they were
nothing more than<br/>
amplification systems for this virus.<br/>
<time begin="00:03:21.51"/><clear/>Now chronicling all of this,
was a man who<br/>
was in the pressrooms with me and other people<br/>
<time begin="00:03:27.64"/><clear/>at that time, Randy
Schultz,<br/>
<time begin="00:03:30.16"/><clear/>the San Francisco Chronicle's
only openly gay<br/>
reporter -- probably not its only gay reporter,<br/>
<time begin="00:03:37.55"/><clear/>but openly gay was pretty
rare at that time.<br/>
<time begin="00:03:40.92"/><clear/>So in 1987 Randy published
his<br/>
seminal book, And the Band Played On.<br/>
<time begin="00:03:46.53"/><clear/>This is still the most
influential<br/>
book ever written about HIV/AIDS.<br/>
<time begin="00:03:49.84"/><clear/>And the hero of that story,
as many of<br/>
you know if you've ever read the book<br/>
<time begin="00:03:55.03"/><clear/>or seen the movie, was Don
Francis.<br/>
<time begin="00:03:58.91"/><clear/>Now Francis left CDC in 1992
and<br/>
got to a large biotech company south<br/>
<time begin="00:04:04.02"/><clear/>of San Francisco called
Genentech.<br/>
<time begin="00:04:05.85"/><clear/>And there he became the
clinical leader of<br/>
the company's pioneering efforts to develop<br/>
<time begin="00:04:11.58"/><clear/>and test a vaccine to prevent
HIV infection.<br/>
<time begin="00:04:15.83"/><clear/>The company abandoned
this<br/>
effort however, in mid 1994,<br/>
<time begin="00:04:20.42"/><clear/>after the federal government
pulled back from<br/>
an earlier commitment to test this vaccine<br/>
<time begin="00:04:27.90"/><clear/>on another one in trials
whether they really worked or didn't work.<br/>
<time begin="00:04:33.13"/><clear/>Now companies were leaving
this field, there<br/>
Francis was a lot of depression about the prospects for an HIV vaccine, but Don Francis was not a person to ever take no for answer. So he teamed up with some of the scientists who had invented this vaccine and he started a company called VaxGen, a spin-off determined to organize and carry out a clinical trial that would answer the question, do we have a vaccine to prevent AIDS or don't we? In January 1997, I began researching a book about the quest for an AIDS vaccine, and within the first two months, I lived in Boston at the time, I had interviewed about 30 people on the east coast. Now nearly every one of those people wanted to talk to me about Don Francis' crazy idea of starting VaxGen. And people told me that he was delusional, living in a dream world if he thought he could raise the $18 million that Genentech wanted upfront in order to free up their patent protections on the vaccine. Now in March, I headed west to do some interviews on the west coast, and in Seattle, I think the first people that I talked to there said, "You know what, Don Francis and his partners have raised that money." Well I thought this probably can't be true.
March 26, 1997

on a rainy day when I had horrible laryngitis and he was on a lunch break from an advisory board meeting to the UC regents I believe it was. And I was stunned when we sat down to talk and he told me, "No, we didn't just raise $18 million, we raised $27 million to launch this trial, and we did it by talking to small groups of rich people in little conference rooms, in Four Seasons, in Ritz-Carlton, and a Holiday Inn somewhere in south Florida." Now I came away thinking that no one should ever count this guy out, ever. The VaxGen trial began in June 1998 in the United States and Thailand, and on February 24, 2003, its final results were announced, and disappointingly, the vaccine showed no overall ability to protect healthy people against infection. But Don Francis was not finished. Tonight, he'll continue the story picking up where I left off I think, with a talk entitled Deadly Imbalance: Social versus Medical Value of Preventive Vaccines. And here's Don Francis. [Applause] Thank you, Pat, very much. Can everyone hear? What I thought I would do, more than was to broaden this story.
Francis.txt

<time begin="00:07:39.03"/>about vaccines in general and really highlight<br/>
the confusion that we have as societies<br/>
<time begin="00:07:48.01"/>in general, and the confusion being broader in<br/>
who actually speaks for the society at large,<br/>
<time begin="00:07:56.70"/>both the U.S. society, but equally important to<br/>
world society in terms of developing, of making,<br/>
<time begin="00:08:03.92"/>adding the social value if you will, to vaccines<br/>
in general for not only the United States<br/>
<time begin="00:08:09.50"/>but the world as a whole since<br/>
these are incredibly valuable tools.<br/>
<time begin="00:08:17.27"/>And it's a bit of a sad story to be honest,<br/>
HIV vaccine being only a small piece of it,<br/>
<time begin="00:08:23.14"/>how with absence of the social value, one has<br/>
real trouble in stimulating the private sector,<br/>
<time begin="00:08:30.53"/>the mixed vaccines, to actually make<br/>
them and see the progress that we've seen<br/>
<time begin="00:08:35.28"/>over the years for infectious disease control.<br/>
<time begin="00:08:39.50"/>So with that let me start,<nolabel>
and there's really<br/>
two points I want to make about vaccines.<br/>
<time begin="00:08:46.27"/>Vaccines, as you know, you give to an<br/>
individual before they're infected,<br/>
<time begin="00:08:50.67"/>to prevent the disease occurrence<br/>
in yourself later<br/>
<time begin="00:08:55.53"/>after your immune system has recognized the<br/>
pseudo infection that the vaccine gives you.<br/>
<time begin="00:09:00.58"/>Hopefully without disease you get immunity and<br/>
therefore your body thinks its been exposed<br/>
<time begin="00:09:06.77"/>to the disease and you don't<br/>
get in the future in your life.<br/>
<time begin="00:09:10.26"/>So the clear public health goal of vaccine is<br/>
to decrease or eliminate the disease in question<br/>
Francis.txt
<time begin="00:09:17.31"/>to which the vaccine is targeted.<br/>
<time begin="00:09:20.17"/>And realize everyone in this room has<br/>
received probably close to a dozen vaccines<br/>
<time begin="00:09:24.23"/>in your childhood, and we don't see multiple diseases because of that.<br/>But what I want to add here, and this is the important theme of this talk,<br/>is not only decrease or eliminate disease, but in the shortest possible time.<br/>
That is, we should be able to apply our scientific technology to make the vaccine<br/>in the shortest time possible, and then ultimately apply the vaccine to eliminate the disease.<br/>
And here is where on both of these how we break down to be honest.<br/>So what I want to do is talk about this example of the delay that has occurred in looking at past vaccines, and try to explore why we see this delay in both from the time of discovery of the organism, to making the vaccine, and importantly from the time the vaccine is made to the time the disease is eliminated.<br/>And that's why really in my mind I use the term lack of social value, that is we do not give value to vaccines. Even though we don't suffer from these diseases, we don't look ahead in the future to give the social value which will stimulate
Francis.txt
the production of new vaccines in the future.<br/>
And in that, I will look extensively<br/>
at the roles of both, the private sector<br/>
which traditionally has made vaccines, and the<br/>social value there is a return on investment.<br/>
And the public health people who generally make<br/>the recommendations and deliver those vaccines,<br/>and how we end up with a lack of coordination,<br/>if you will; a lack of social value,<br/>if you will, given by public health to vaccine development<br/>that inhibits industry for making it.<br/>And then because of this lack of value given to it,<br/>I want to talk about why industry would make these decisions and be able<br/>to cost the vaccine development, how<br/>much it costs to make any drug now.<br/>And ultimately then if you're going to invest<br/>in it, this is what you have to invest,<br/>and then deal with the costs on the other side of the risk benefit that is what it costs you<br/>by delaying the development and<br/>ultimately the delivery of the vaccine.<br/>This is all kind of a downer and I admit it.<br/>This is not a good example of our society, as<br/>I think recently we've had many measurements<br/>of the lack of our social wisdom,<br/>but this is just one of them.<br/>But I'm going to put in here at the end a positive note how especially<br/>when the money comes from
Bill and Melinda Gates Foundation,

how there are changes especially in the less developed parts of the world that have stimulated a change.

So I don't want to send you all out with frowns and gray faces. We just say we have some real holes in our society and hopefully we're fixing those holes much like the holes in a road.

Now let's look at this, this is the occurrence of multiple diseases in the United States, this is diphtheria, the measles, polio, and ultimately see AIDS coming up, which carries on item for item at this point.

And I want to really stress the left-hand side of this slide, which is this remarkable decline in diseases that my parents, your grandparents, had as routine -- I think in my mother's aunts, at least of her family, all but one of them got diphtheria and about half of them died. So it was incredibly common that everyone in the United States got these diseases and the reason they declined primarily were vaccines, and so they’ve had a tremendous effect.

And I want to take some examples of these diseases and show how the good news is good, that is that we eliminated the disease; the sad thing is that once we had the tools to eliminate this disease, we didn't do it as fast as we could.
And the first one I want to deal with is smallpox, which is a disease none of you have seen, but one of which I have either had the fortune or misfortune of dealing a great deal in my earlier days at CDC, which really infected everyone in the world. Don Hopkins at CDC wrote a book called Princes and Paupers or something like that where he outlined the effect of smallpox on especially the elite royalty of various countries. Smallpox really killed -- it infected everyone and about 40, 50 percent of people died. So you can imagine what that did to princes and paupers around the world. And so everyone had scars on their face from smallpox, and somewhere around 40 percent had died in any given family, including the elite of all countries with princes and all people with paupers. And had a huge effect on the history of the world as kings and princes and such died. And interestingly, Edward Jenner, who I think is on the next slide, made the observation that the only pretty faces in U.K. at the time were milkmaids. They're the only ones whose face did not look like it received a shotgun blast and had all these pox all
over, these holes.<br/>
But they had pox on their hands and he surmised that the teats of cows had these lesions also, and that they remember getting these raised lesions on their hand that produced a hole in their hand, but they never then got smallpox on their face. And so he surmised that if you touched the puss from one of the cows and giving that to people may protect from smallpox, and this is actually the picture, a rendition of a picture where he took a child and actually vaccinated them with the cow pox virus, and then exposed this child to smallpox and the child did not come down with it. So this was one of the earliest vaccines ever initiated, and it actually ended up being the tool that we ultimately used for the eradication of smallpox around the world. And this is looking at the number of countries with smallpox from 1967 to 1977, and you can see that there was a concerted effort of the world to actually end smallpox in their own countries, and then this was actually the beginning of the WHO program that then began vaccinating kids all around the world. And what we did then was search for cases in different parts of the world and then vaccinate
And so that was good news, we ultimately eliminated smallpox in the world, and no one actually is using the smallpox vaccine anymore because the only hosts for smallpox are humans, which is wonderful. If you stop it in humans -- it doesn't come out of an animal's feces, and so we're able to stop the use of the smallpox vaccine because of some toxicities associated with it and that there was no disease. So the good news is that we eliminated smallpox. Oh, now I'm stuck, and they're gone. Because it will not go backwards I'm told.

But the good news was -- and I'll show you on a subsequent slide -- was that we eliminated smallpox, the problem was this was a delay of literally decades, if not centuries, from the discovery of the vaccine and the proof that it actually would prevent disease until the actual eliminating disease in the late 70s. So there's a huge delay that occurred, and therefore literally millions and millions of people around the world died needlessly. And so there was this God awful delay that occurred and I went off to Africa and India.

For the better part of what
three years chasing smallpox, and it's a horrible disease, still killing about 30 percent and scarring and really decimating families. But it was -- oh, look at that, thank you. [ Laughter ]

That it was a huge time delay -- since I can't go backwards, I'll show you on a subsequent slide. So there was good news and bad news on smallpox, also good news and bad news on polio. Polio, a disease that when I was a child, there was no polio vaccine. And this is a picture of Rancho Los Amigos in southern California of the iron lungs, the severe part of polio, it would affect the lower limbs and go all the way up and ultimately get your respiratory nerves and then the respiratory paralysis. And so these were the earliest of respirators, these people cannot breathe because polio has paralyzed their respiratory nerves, and therefore a vacuum process just like a respirator with a tube, has to be instilled, and so there were literally just rooms and rooms. And I remember there was one hospital in San Francisco that I would drive by the kids, and you'd see through the door, and see through the glass these people on these respirators. And I did my pediatric training at LA County.
Hospital and we had all of these stored in the back and occasionally used them for Guillain-Barre and the like. So it was just like a horrible disease. And interestingly, in contrast to HIV that there was a great political pull and push to do something about polio. And unfortunately, the president of the United States at the age of 39, well before he was elected was paralyzed with polio and was in a wheelchair throughout his presidency, although I think this is one of the few pictures of him in the wheelchair, you'll always see him standing against something or with someone, and he would never show in public that he was totally paralyzed and in a wheelchair or crutches. But this is Franklin Delano Roosevelt, and then he started from Warm Springs, Georgia, the March of Dimes equivalence called infantile paralysis program at the time, where you'd go to Warm Springs and elsewhere to get therapy for your polio and also raise money for vaccine development. It helps to be president of the United States when it comes to developing programs for any disease and to be afflicted with the disease or personally affected with it.
things, we haven't
seen that with the current administrations,

I don't know which one you would wish for.

I just got back from India a while ago,
I'm going back again in a couple of weeks.

This is polio continuing in India, this young man was at a house where the child had polio,
but there's a massive immunization program going on in the world right now to try to eliminate polio.

And how do we do that?

This is Jonas Salk as a young man who had the clever idea just growing up a bunch of polio virus and killing it with chemicals and using that as the vaccine for polio.

And you see here the -- I probably have to read some of this, but this is 1985 and now 2009,
this is the progress towards polio eradication that now -- remember in that last slide,

Jonas Salk discovered the vaccine in 1955, this 1985, and in 1988 the world health assembly makes a resolution to eradicate polio in the world.

1989, this has not been easy, he continued to do that.

This was the original target date for eradication and we still have a few countries now with polio, unfortunately we've had a big setback with the Muslim countries
North Africa, especially in Nigeria, where they thought this was some family planning program. Well, I can stop immunizing and then Hajj followers marching across North Africa to Mecca, spread the disease all the way to Mecca and then beyond all the way to Indonesia, so we had to clean that back up. And India continues, a little bit in Afghanistan, but hopefully we'll be able to eradicate polio in the next few years.

This is the issue with India, in cases massive amounts and then the program begins. These are the mass immunization days all across India, which is a huge effort as you might imagine, and we still have these few leftover cases, about 16 in [inaudible] and 16 in Bihar last year. So they continue to dribble on and it's a little tougher than smallpox because you have to literally immunize every kid. Here's now the slide that if I don't punch the button again, this is smallpox here, the vaccine became quote commercially available some time after the 1900s. It was eradicated in northern Europe and the United States between 1930 and 1953, with the delay of 30 to 50 years between the vaccine to eradication.
Francis.txt
<time begin="00:23:03.94"/>that the worldwide eradication occurred in<br/>
1977, and so you end up with half a century<br/>
<time begin="00:23:14.13"/>or three-quarters of century from<br/>
the time the vaccine is available, to the time it was eradicated around the world.<br/>
<time begin="00:23:20.29"/>And you saw that slide just back there with all the polio cases from India,<br/>
<time begin="00:23:24.66"/>you can imagine what decades of polio do to the little kids that you saw walking<br/>
on a stick in the previous slide.<br/>
<time begin="00:23:32.06"/>Just drive along the streets in northern India, you see case after case of polio,<br/>
<time begin="00:23:38.06"/>but really it's tough enough to be a child or a young adult in India, but you can imagine being one with either one leg or no legs functioning at all.<br/>
<time begin="00:23:47.45"/>And polio, where the vaccine in 55 took a 36 year delay to eradicating in north America and Europe, and it looks if we're lucky, to be able to eradicate it in 50 years in the rest of the world.<br/>
<time begin="00:24:03.01"/>Now let's take the last disease, this is hepatitis B infection.<br/>
<time begin="00:24:11.31"/>Hepatitis B is another virus spread by sex or blood sharing much like HIV,<br/>
<time begin="00:24:16.65"/>but produces some pretty terrible diseases.<br/>
<time begin="00:24:20.90"/>Here this is just the outline of it with 60 to 90 days from the time you get infected to the time you turn yellow and you get jaundice, you know, infrequently as a child
and maybe a third or so of the individuals actually turn yellow and you can tell. So it's a relatively mild disease with very little mortality when it comes to the acute case of hepatitis that all of you would be fearful of. But this is the real challenge, that the chronic infection that occurs literally years after the people become carriers of the virus and then develop cirrhosis or cancer of the liver, somewhere in the neighborhood of 30, 40 years after infection. And that is a huge mortality when you talk about 15 to 25 percent of the individuals are going to die of their chronic disease, really what I would call the modern disease like HIV that has a long incubation period from the time of the infection to the time of the actual manifestation of disease and death. Well let's look at this, here's again a wonderful vaccine, this is the first recombinant vaccine where we didn't have to grow up virus, but it was done by a private sector company, Merck, who figured out a way to inactivate the virus. This is cases in the United States '78 to '95, it was licensed here, we finally started screening pregnant women and vaccination of babies here.
And then infant immunization now in 1991, this is ten years, in the United States, ten years from the discovery of the vaccine until it was actually recommended and then adolescent catch up another three years after that. So a remarkable time from a very effective vaccine that literally can eliminate the hepatitis B virus infection with little problem, and yet this huge delay from the time that it was licensed and to the time it was used, and that's in the United States of America. This is the rest of the world with the -- ah. [Laughter] Okay, that was the rest of the world with the -- oh, thank you -- I've got two buttons here and I can't, you know, all these years of education and I can't figure out which button to push in order to go forward or backward, so I apologize. But -- ooh, I did it even twice, going back, Gee whiz, I keep going back, I must have hit about -- there we go. Now I'll try to be better, thank you. And the places in massive need of hepatitis B infections were 60, 70 percent of the population infected with hepatitis B virus, is central Africa, and this means that no
vaccine program exists there at all. So it took us years to even apply it in a county like the United States and now what 30 years almost after the invention of the vaccine, it is still not used in parts of the world where it is needed the most. So why do we have these delays? Why do you have major disease occurrence causing horrible situations and tools necessary to develop them, or indeed an interest, a virus that we know causes it, and we could make a vaccine, but we haven't even made the vaccine yet? And I think it's relatively straightforward, now that I've been in the government in the private sector, both making and using these kinds of product, I think I can give some sort of approved overall view that you find the virus, you need to figure out what part of the virus immune system is directed towards, make candidate vaccines, use them in animals and see if they work, and then once you've developed the vaccine in humans, actually apply that vaccine. It's simple, no? You figure out what the virus is, figure out what the immune response is, figure out how to make a vaccine safely, try it in animals and then humans, and then public health takes
it and gives
it to the people and the disease goes away.
Really remarkably straightforward,
this is not complex politics
in reality, this is simple science.
And it's all driven by social value, that is what the people
in this room think is important will be done
because people will ultimately drive this
through either political pressure or funding or something else.
So that's the process and I say social value is the key here to drive it.
Let's now start from that and work our way down.
Who makes vaccines?
Where is the expertise -- so starting down this pathway that actually will develop them?
And it really is in two places; one is places like this, the discovery of the agent,
the figuring out what the immune response is, what the immunology is, what would be the logical vaccine, and then private pharmaceutical companies take that on.
Now it's important for you folks in university to realize that universities by and large do not make these products.
Many times the government thinks if they dump more money throughout NIH it will come to universities and will make vaccines.
But I think there's an
Page 21
important split between university academic research and actual product development, this is a wonderful report by McKinsey and Company, of the World Bank, and let me read this because I think this is really worthwhile. The public sector institutions involved in vaccine R&D are primarily focused on basic science knowledge diffusion, rather than single-mindedly solving applied development problems to ensure large scale consistent production. That's an important sentence, complex, but universities are discovery pieces and they do research and discover, whereas industry is really, someone complained, that it's so highly focused. But now that I've been in industry it's wonderful, this is a product, you move it along, see if it works, and if it works make lots of it, sell it and make money. The incentives in the public sector reinforce this knowledge focus and are generally inconsistent with efficient production of commodities. Let me put that into very simple terms. If you're in a university, your output is knowledge. The measurement of that output really are the manuscripts that you publish in journals.
If you're industry, you're out for the product, and the measurement of the success of that product is how much money you make from that product. Very divergent, although complimentary in terms of making vaccines actual goals, and what the key message here is don't expect universities to make vaccines. That's not their output and they may want to get the IP for it and move it on, but somebody else has to develop it, and that somebody else has to have the skills for actual development versus research. So here again, is the scientific discovering university, some sort of industry or something like making development or then you actually drive it. And it's the lack of social value that really kills this one here in the middle in terms of taking university discoveries and moving them onwards. Why do I say that? Because I think there's low social value given to vaccines by both industry and moving them onwards. Why do I say that? Because I think there's low social value given to vaccines by both industry and making development. We used to have a dozen pharmaceutical in the industry developing vaccines in this country, and we're down now to just a
And unfortunately, they're not valued by society, but really the pull factor here to making a market for it because we're very reticent about using vaccines and it takes that long for us to take a vaccine and actually deliver it to the people.

Now why is that important? Industry thinks of the profits they make per year per investment. And if they're going to put a big investment, and I'll get into that, into a product, they want the return on that investment fast. And you say these ugly industrial people. Guys, I guarantee you that you and your families have money in these industries in some sort of a portfolio that someone has that is gaining money for your future, investment in pharmaceutical industry. And their goal is to increase the value of that portfolio and make good drugs. It is not to save the world from vaccines. So don't blame the pharmaceutical industry. Their goal is to make your portfolio better and indeed hopefully make the health better, but following social value of what we will pay for. And my conclusion here is that it's
better not to make vaccines if you're in the pharmaceutical industry as I'll get into in a second. So the public health role here is very interesting. As a public health doctor, I consider myself a public doctor, and as a career person at CDC in Atlanta, I was giving value to vaccines, I think they're wonderful things and we've got to go out there and deliver them. So we recognize the value of vaccines, but we're always talking about how they have to cost a nickel. Almost always. Pharmaceutical industry is ugly, they try to charge 2, 3 dollars or 5 dollars for these things, and so they're ugly, so let's just go head and get it down to a couple of dollars. And then there's very little political value to say that either through taxation or through other society paying for these things, that they should come through with the money necessary to deliver. Now look at this, this is a very interesting graph for [inaudible] in WHO that looks at vaccines from different parts the world. This is divided in the industrialized countries here and developing countries here. And this is the population, this is the disease burden that follows the population that most
of the disease burden is in the developing world.

And now let's look at the vaccine market.
The vaccine market is 82 percent of the $6 billion vaccine market is in the industrialized world.

And 90 percent of the investment in vaccine development comes from the industrialized world.

To make money on this 82 percent of the market that really only accounts for about 10, 15 percent of the disease.

There's a real imbalance here that you have all the disease in the developing world and all the profit on this side of the ocean, and therefore vaccines will be developed if at all for here.

This just looks at the cost of the vaccines.

When I said we'd try to drive the cost down, look at what is paid for example here, with measles vaccine in the low-income countries, 14 cents per dose.

It costs you a dollar to put it in a bottle.

So the industry is losing money because it's just grinding down and grinding down the price of these things so the WHO and UNICEF, your holiday cards can buy it.

And even the high-income countries, you only spend 15 bucks per dose.

Now next time you go to McDonald's
you'll spend $15, the people who complain that $15 is too much for a vaccine that will prevent all of these diseases. So this is a WHO statement, let me just summarize it, that the low or uncertain demand for vaccines and the lack of return on these vaccines and the continued hammering of industry to get the vaccine down drives industry out of the vaccine business. And I want you all in the next few minutes to put yourself on the board of directors of a company that has to make a decision if you're going to invest in the research for a vaccine versus you're going to invest in another drug to increase erections. [Laughter] Let me hold on a second, my telephone is going to ring in a little. Let me shut it off. Now let me just deal with you sitting on this board and you are being asked to invest in this stuff and see how much it cost actually of your money from your company. This is just one example of the flu vaccine recently licensed a couple years ago in the United States where there is public information on it, but the RND for the vaccine costs $145 million and then the manufacturing $200 million, so a total of $345 million to take one vaccine from the bench in the discovery of academic research to
actually<br/>
making the vaccine<br/>through the development
process<br/>
and available to the market.<br/>
So what it costs to bring a
vaccine to<br/>market, everyone will agree it costs somewhere<br/>
between 200 and $500 million
in 12<br/>to 15 from the time that you bring it<br/>
into a company and then you get it out.<br/>
To be honest, this is what it costs to develop a drug, a vaccine,<br/>
or any other drug in the<br/>pharmaceutical industry.<br/>It's a very expensive process
with lots of work.<br/>You start with your initial
discovery and<br/>then you get into animals and then you get<br/>into humans and face three trials and you've<br>got thousands of people, and it costs this kind<br/>of money in order to do that's just a fact of life.<br/>
So if you're going to make a vaccine --<br/>let's say that this side of the room comes<br/>to the board of directors of the<br/>company, you guys are at top of the board<br/>of directors, and you guys are the scientists.<br/>And they come to you and they say, "We would<br/>like to make a vaccine for the disease X,"<br/>and this is our plan for it
and this<br/>is how much money it's going to cost."<br/>This side of the group comes
to<br/>the board of directors and says,
We have a drug for erections, or whatever you want, we have our development plan and we want to develop this because we think this is an important drug that we'd like to develop. And you guys at the top are going to have to make the decision. Well look here, this is the total revenue in billions of dollars per year for a few drugs that I just chose. This all ten vaccines that we market in the United States, it sits up there at about $6 billion. This is the market for the less developed countries that make $1 billion. These are two drugs, one to lower cholesterol and the other to decrease heartburn. Some of you in this room probably take these drugs. Good drugs. Important drugs. But this side of the room wants to develop another one of these, and this side wants to develop a vaccine. You guys on the board of directors have really only one choice. You look at the potential this is divided into a dozen different lines, so nothing comes above $2 billion here. You make a choice. I'd rather have you guys develop your erection drug or something, and you guys lose and you
guys win.<br/>
And that's not an ethical issue.<br/>
We pay money for these drugs and we don't pay money for the vaccines that make it a significant market.<br/>
So this lack of social value ends up really being very expensive.<br/>
You end up without the social value and lack of political leadership. They interact, so you end up having continued disease occurrence in the long run. And these are the costs; continued disease occurs, which is terrible as I showed you on polio and these huge delays.<br/>
And equally important in a public health sense, the increased infected pool, that the longer you delay the control of a disease, the more people get infected, the more source of infection for others, and you end up having more disease more difficult to control in the future. So it compounds itself with time. And then lastly, you end up with a very limited market for vaccine, little social demand for it, and therefore less industry incentive to make vaccines, which causes more delay in the vaccines and the whole thing perpetuates itself for the future.
That's the end of the downer part of the talk.

It is indeed a very discouraging -- after someone like myself who's actually been out there eradicating diseases and see the potential we have in biotechnology to make vaccines, it's a shame that we are not better able to adjust those social values so that we come some sort of more equal especially for the less developed parts of the world.

And generally this is divided to two parts.

Push, that is you push the development of a product through an industry; and pull, that you pull the product through industrial development by increasing the price and increasing the purchase.

And both of these have been recently in place for the last, almost a decade now, especially as a result of the Bill and Melinda Gates Foundation. But there's quite a few, if you go back in history interestingly as I mentioned before, at the bottom of this slide you see that the March of Dimes is the one that really drove the development of polio vaccine with Jonas Salk and Albert Sabin being the ones who developed the vaccine. But before that, the
Rockefeller Foundation developed a yellow fever vaccine, and before that Institut Pasteur in Paris had developed several of the vaccines that we use still today in childhood vaccines. But now it is really adjusting again, and it's very nice to see, especially for the less developed parts of the world, you see all of these various vaccine development public/private partnerships, very much like the Rockefeller and the March of Dimes where we have vaccines for tuberculosis, malaria. This is us working on HIV and other hookworm vaccine initiatives that you heard from here, International AIDS Vaccine Initiative in New York, the Malaria Vaccine Initiative in Dengue, Pneumococcal, Rotavirus, and South African AIDS Vaccine Initiative. Most of it funded by the Bill and Melinda Gates Foundation, but also from other sources. And then we have what we've really seen also I think stimulated primarily by the Bill and Melinda Gates Foundation, the setting of the global fund and like huge amounts of money to actually pull vaccines in, especially for the less developed parts of the world. That is setting up a market.
Francis.txt

where they'd put literally now billions of dollars into the purchase and delivery of vaccines in the less developed parts of the world. So there is a market if somebody wants to develop it, either the not-for-profit institutions I showed you on the previous slide, or a for profit sector, that there is more of a market for these vaccines. So in summary, I think that vaccine development is expensive, there's 200 to 500 million dollars. It's slow, it takes really a decade or more. The skills necessary to develop vaccines rest primarily with the private sector, hopefully that's getting more into the not-for-profit now. And the same costs and effort pharmaceutical companies can develop therapeutic products that are far more profit than the vaccine. Public health leaders are cheap and unwilling to pay reasonable prices for valuable vaccines. I say that as someone who did that and indeed espoused that. The lack of social value given to vaccines makes them unattractive products for the pharmaceutical industry to develop, and vaccines, once they're out, are often applied slowly and so the return on the investment is even compounded. But there are positive
changes,<br/>
<time begin="00:44:56.59"/>the public/private vaccine
development<br/>
partnerships having pharmaceutical<br/>
<time begin="00:44:59.75"/>development expertise are
being<br/>
established, that was the list I showed you.<br/>
<time begin="00:45:03.49"/>Funding is being provided
most notably<br/>
by the Bill and Melinda Gates Foundation,<br/>
<time begin="00:45:07.38"/>and foundation support
is<br/>
driving public health authorities<br/>
<time begin="00:45:10.24"/>to deliver existing
vaccines<br/>
through the pull process.<br/>
<time begin="00:45:14.23"/>So in summary, I think we
have gone through<br/>
an evolution here where in the past we relied<br/>
<time begin="00:45:21.25"/>on foundations and
social<br/>
efforts to make vaccines,<br/>
<time begin="00:45:25.74"/>recognizing there were
terrible diseases out<br/>
there, and we had some skills to make them,<br/>
<time begin="00:45:30.21"/>and then we really let
the<br/>
private sector do this<br/>
<time begin="00:45:32.44"/>without recognizing the
private sector didn't<br/>
have much enthusiasm as time has gone on,<br/>
<time begin="00:45:37.61"/>and the tremendous
biotechnological revolution<br/>
<time begin="00:45:40.61"/>that has occurred is being
directed<br/>
towards very profitable products for cancer<br/>
<time begin="00:45:44.85"/>and other diseases that are
very<br/>
important, however, it leaves a huge void<br/>
<time begin="00:45:49.30"/>in the vaccine, especially
for the third world.<br/>
<time begin="00:45:52.22"/>And I think we're seeing some
positive<br/>
movement, especially stimulated out of Seattle<br/>
<time begin="00:45:57.45"/>with the Bill and Melinda
Gates Foundation<br/>
to actually try to readjust that both from development of vaccines and the actual purchase of vaccines for the third world. With that I will stop and we can deal with some questions. Thank you. [Applause] [Music]