## A KILLED VIRUS VACCINE FOR HIV/AIDS VIDEO TRANSCRIPT

18-minute version May 16, 2011

BURTON

DORMAN: We've not tested the most obvious way to make a vaccine for

HIV/AIDS.

TITLE: A Killed Virus Vaccine for HIV/AIDS

SUBTITLE: BURTON P. DORMAN, Ph.D.

Co-Founder and President, AGRI and Acrogen, Inc.

DORMAN: Here we are, almost thirty years and sixty-plus million infections

into the pandemic, and we've never tried a classical vaccine, which arguably from day one was the most direct, the most

obvious, and the most likely route to a vaccine.

SUBTITLE: ZILOSE LYONS

Infectious Disease Prevention Advocate

LYONS: In countries like Zambia the people who are affected are the

people at the prime of their life. The most creative, most productive, most to contribute. For my sister who died, there are many other people's sisters who died also. Think about the

prevention of that.

SUBTITLE: MARCUS A. CONANT, M.D.

HIV/AIDS Treatment Specialist

CONANT: It's a societal issue. Society has got to say: "we want to stop

this disease."

SUBTITLE: DONALD P. FRANCIS, M.D., D. Sc.

Global Health / Infectious Disease Scientist

FRANCIS: The killed virus approach is one of oldest in vaccinology and

we still use a lot of it now.

SUBTITLE: HAYNES W. Sheppard, Ph.D.

Public Health Laboratory Specialist

SHEPPARD: Killed virus vaccines have been effective in the past. In

addition to that, we know that there are several animal retroviruses guite similar to HIV for which KV vaccines have

been made and are effective in those animals.

SUBTITLE: DONALD KENNEDY, Ph.D.

Stanford University, Science Magazine, U.S. F.D.A.

KENNEDY: It's worked before, that's number one. Number two, nobody's

doing it at all, despite the fact that it's worked before. And three, you could make a real difference if this succeeded.

DORMAN: It would take only a few years, it would cost only a few million

dollars, and it could save millions of lives.

LYONS: Let's test something that works. Let's get testing. Can we test

everything? Can we test the old technology and see if it

works?

CONANT: You know, if this does work, this will change the history of the

world.

TITLE: Black screen

FRANCIS: My involvement in HIV started from the beginning of the AIDS

epidemic, in '81, when I was at the Centers for Disease Control

in Atlanta.

CONANT: The next thing you knew I had the largest private AIDS clinic in

the country. I've been doing clinical trials now since 1963. Forty

years. That's a long time.

KENNEDY: At one time I was Commissioner of the Food and Drug

Administration, here in the United States. I came back to

Stanford, I served as president for a dozen years, and after that I became editor of Science magazine, which is the journal of the American Association for the Advancement of Science.

DORMAN: In 1979 I started a biotech company, and the public health

people knew about our work with killed virus vaccines, and

asked if we could help with the AIDS vaccine issue.

SHEPPARD: I've been working on HIV and AIDS for about twenty-five years

now. I started in 1987. And, uh, still working on it.

TITLE: Why is a vaccine needed?

FRANCIS: There is no way to describe the worldwide epidemic of AIDS

but horrific.

LYONS:

When you get sick from it, it is serious, you're sick, you suffer, you die a horrible, slow, devastating death, so it's not an easy death, it's a painful death. There is no family, in Zambia that can claim that they haven't been affected by HIV. Every single household, every single family over there has been affected in one way or another. Either because they have a relative, a friend, a friend of a friend.... But everybody – everybody – has been affected in my country.

FRANCIS:

The only way we're going to stop the AIDS epidemic is with a vaccine. That's true of so many bacterial and viral diseases. You can have therapies and do your best but in reality it's prevention that stops it.

CONANT:

You've never treated a disease out of existence. We didn't treat smallpox out of existence, we came up with a vaccine to eliminate the virus. Doctors working in their clinics cannot eliminate diseases.

FRANCIS:

So a vaccine is absolutely key, where you give the vaccine, and then it's prevented in hopefully a high proportion of cases, it's prevented, and eventually the disease disappears because there is no place for it to go.

TITLE: What is a killed-virus vaccine?

CONANT: Burt Dorman for years has been advocating: why don't we look

at, essentially what Salk did with polio? Let's look at a killed virus vaccine. Let's take the virus, let's kill it, so that it can't infect people. We did that with hepatitis. You took the virus from people who had the disease. You kill the virus. And then you inoculated people. They made antibodies against the virus,

and protected people from transmission of the disease.

SHEPPARD: The rabies vaccine is a killed virus vaccine, the flu vaccine is a

killed virus vaccine, and many others.

TITLE: Which vaccine methods have been tried so far?

SHEPPARD: What the biomedical establishment has been doing for the last

thirty years is trying to develop, an HIV vaccine based on

modern, genetic engineering approaches.

FRANCIS It's not surprising that you'd see a temptation to move ahead

with high tech stuff. The consensus comes out relatively quickly that we're looking for modern technology—people don't look

back to things like killed [virus vaccine] that's old technology. Instead let's move ahead with things like molecular biology.

SHEPPARD: Unfortunately, in the case of HIV, all of the best approaches

that are known today for genetically engineering a vaccine

have not worked.

CONANT: They will tell you, "we have to go back to the drawing board.

We don't know how to do it at this point." Well, we may not know how to do it at this point, but we do know how vaccines were developed in the past. So why don't we try that, first, while we're trying to come up with some new, innovative idea?

KENNEDY: There isn't any group of supported, funded scientists who are

trying to do what Jonas Salk did with the polio vaccine, namely to work with killed viruses. Why can't people understand that there was a lesson there and that it probably ought to be tried

again? But it hasn't been.

TITLE: How is it possible that a killed-virus vaccine has not been

tested for HIV?

SHEPPARD: Some people say: "If this is really such a good idea, why is it

that the biomedical establishment in this country hasn't really worked on this for the past twenty-five or thirty years despite the failure of a number of other approaches? There must be

something wrong with this."

FRANCIS: I wouldn't say that just because you have a lot of smart people

working on a project that all bases are going to be touched. Because sometimes you have to have a view that is a little broader than today's modern molecular biology review. Sometimes we can't do these kinds of things and we need to

have a broader approach.

DORMAN: You will encounter all kinds of reasons from very intelligent

scientists that our classical approach may not work or it may

not work well enough.

CONANT: I like to call this "erroneous consensus." Many experts, based

only on logic, not on testing, said, "oh, that's not gonna work." In science, you never know whether something works or not until you get in the laboratory, and you see does it really work,

or not.

DORMAN: It has not been adequately tested, and every review panel that

has looked at the question has reached that conclusion. And yes it's true that it might not work but if we had any approach

that was guaranteed to work that's the only thing anyone would need to be doing. We have no approach in that category. But we have this approach—the classical killed virus vaccine approach – that has worked in the past for many viral diseases. Polio and influenza and rabies and hepatitis. And which has worked for animal diseases closely related to HIV in cats and in horses and in monkeys. So it deserves to be tested -- for humans.

TITLE: What's the quickest route to a vaccine?

SHEPPARD: Perhaps some day basic science will find a brand new way to

make vaccines that's dramatically better than anything that's been done before. But that sort of research effort is something that could take many, many decades. We don't have that kind

of time.

CONANT: Could it possibly work? As opposed to: "maybe but we ought

to try this first." Because right now, there's no other first. There's nothing out there. All the experts agree we have nothing at this point that looks even halfway promising.

FRANCIS: We had this somewhat surprising result with our vaccine where

we got thirty percent protection, which had never been seen before in a huge trial in Thailand. And so that kind of opens a chink in the possibility of a vaccine, but it's still going to be decades of work to try to figure out what happened and then try to fill it so that it's a highly effective vaccine. So it's a slow process, and clearly is not one that has the immediate end in

sight, for sure.

DORMAN: A classical vaccine is a very well known undertaking. If we

could develop and prove a vaccine within six years in another three or four years we could deploy it globally. So I think it's entirely reasonable to assume that a killed-virus vaccine could be deployed by the year 2020. And I think the odds of that are

pretty reasonable. It's a pretty good bet.

CONANT: You've got a world out there with – what, now – approaching

forty million infected people? The cheapest, fastest vaccine

you can get out there is clearly what we need.

LYONS: It does matter, we can't sit back and wait. It's very urgent. It's

not something that you can wait for this many years, for five, ten. Let's get it together now, if we can, please let's do it.

TITLE: What about cost?

KENNEDY: The cost of present research directions at NIH it's very

substantial. And at the moment nothing is being spent on the

other, the alternative.

SHEPPARD: Compared to the billion dollars a year that's currently

being spent on HIV vaccine development, the money required to determine whether a killed-virus vaccine has some promise in the clinic would probably cost twenty-five to fifty million dollars. So you can see that as a percentage of the money that's being spent currently on HIV vaccine development, a killed-virus vaccine effort would be almost a drop in the bucket by comparison.

DORMAN: If you can accelerate the time to a vaccine by four days,

the project pays for itself. And we might accelerate the time to a vaccine by forty years. So it's a pretty good

return on investment.

CONANT: Now of course it's going to cost money to test it. It's

going to cost millions of dollars to test it. But it costs money to treat these patients – close to thirty thousand dollars a year to take care of these patients. And we have in this country 1.1 million infected people. Now, not all of them are on treatment — but they eventually will be. And a few million dollars to test Burt Dorman's idea... would seem like a reasonable investment.

TITLE: Who might fund a killed-virus vaccine?

DORMAN: I have many colleagues, both in this country and abroad, who

have reached the conclusion that we will never, ever obtain support for classical vaccine development from the usual funding entities like NIH or Gates or IAVI or any other.

Because their commitment seems to be irrevocable to trying to

invent something better than we've had in the past.

CONANT: If you're going to fund ideas that have been discarded but not

tested, you should go to private donors who have the

resources to put up a few million dollars — which is really not a lot of money — to test an old idea and find out does it work, and what it can teach us that will help us build on that to

develop a vaccine.

FRANCIS: It's the people that are willing to take different chances and

step out of the mainstream consensus that are more likely to

succeed on many things, HIV vaccine included. So if you stick with the consensus of the day it's usually wrong.

CONANT:

Someone who comes to me and says, you know, "other people tell me this won't work," my advice would be, ask them why they're saying that. Why are they saying that will not work? Do they have scientific evidence that says that, or is this just a presumption? You will not know whether it works or does not work until you take it into the lab.

**KENNEDY**:

There is an opportunity to do this but nobody is funding it to support the work. You have to consider whether this is a reasonable situation, or whether you would like to do something about it to change matters.

LYONS:

What is my agenda as the funder, right? Is my agenda to fund only so-called novel technologies, or just any technology? Fund everything that has a promise for working. Why not fund something that has the potential to work out? That would be my criteria.

FRANCIS:

It does take some guts to go up against the established research community and say, "Let's try something different." But you watch – that consensus can change very, very rapidly. And finally when you see a positive result, suddenly everyone's on your side. So I would follow your instincts and go with them, and then let everyone else line up with you later when you have success.

CONANT:

It's going to have to be someone who does not just listen to the general consensus and say "I'm gonna go along with the crowd." Almost a contrarian, who says, "I don't care what the expert says. I'm going to follow my instincts to say this idea should be tried."

TITLE: What's Next?

CONANT: Killed-virus vaccine has been has been tested for years. We

know how to do that. We know we *can* do that. And if it does work, you've got a world out there with, what now, approaching forty million infected people? The cheapest, fastest vaccine

you can get out there is clearly what we need.

SHEPPARD: The need is so great. And it's clear to all of us that the

only ultimate solution to the HIV pandemic is an effective

vaccine.

KENNEDY: I think there's a moral imperative because people are dying all

over the place, and suffering terrible deficits in their quality of life all over the world. And not to try an approach that might

work seems to me to be... unconscionable.

FRANCIS: Given the importance of HIV and the misery that the HIV

epidemic is causing, limiting the number of approaches that should be taken to develop a preventive vaccine is nonsense. If you kind of take the standard ideas, and in this case a killed vaccine...pretty good bet that something good may come out of

it.

SHEPPARD: We really should try every possible approach that has worked

in the past. And killed-virus vaccine is one approach that's worked in the past that hasn't been tried. Almost every other approach that has worked in the past has been tried very seriously with a large amount of funding, with the exception of

killed-virus.

CONANT: And all I'm saying is, with nothing out here to look forward to,

let's go back to the beginning and start again. Take what we know we can do fairly quickly, safely, test it in people, see if it's effective. We want to eliminate this organism from the face of

the earth, so that we don't have to deal with this.

LYONS: That would be wonderful. I think that would be a great world

where many men and women and children, no longer have to

face AIDS.

DORMAN: We would urge anyone interested in stopping the pandemic

sooner rather than later to give a serious hearing to this idea. Because there's no guarantee, but it could potentially stop the pandemic well before someone invents a better way to do it.

LYONS: I would just be happy for the lucky souls who will have the

opportunity to have this vaccine. I would be sad about the people who were caught, people like my sister. I would feel bad that it didn't come sooner, but I would be more ecstatic that

it came. If it came.

TITLE: www.KILLEDHIV.org