Hale.txt

<time begin="00:00:00.50"/><clear/>{ music }<br/>
<time begin="00:00:33.04"/><clear/>Dan Colley: Good evening.<br/>
<time begin="00:00:33.99"/><clear/>I'm Dan Colley, the Director of the Center for Tropical and Emerging Global Diseases here at UGA.<br/>
<time begin="00:00:40.84"/><clear/>And it's truly a pleasure to welcome everyone here this evening to the first in a new lecture series,

Global Health: Voices from the Vanguard.<br/>
<time begin="00:00:53.78"/><clear/>Now Voices from the Vanguard has grown out of a collaboration between Pat Thomas, the Knight Chair in Health and Medical Journalism in the Grady College of Journalism and Mass Communication, and myself, in The Center for Tropical Emerging Global Diseases with additional support from the President's Venture Fund. And the series, however, was actually founded more broadly on what some of us perceive as a real desire by UGA to provide its students and faculty with perspectives on global issues, including global health. Now over the last several years UGA has steadily, and very positively, chosen to invest in global health related endeavors. And it has done this through the establishment of units, such as the center that I'm director of, The Center for Drug Discovery, Biomedical Health and Sciences Institute, The
Institute for Behavioral Research, The Knight Chair in Health and Medical Journalism, The College of Public Health, and multiple other programs in veterinary medicine, ecology, agriculture, and the social sciences. Now such programs have either been at UGA for a long time, or are new, but they all bear on global health. And there’s actually quite a collection of them. And the purpose of those, obviously, from the universities point of view is to enrich the milieu of the student experience here at UGA. Now as we speak, this week next, some of us are working hard to synthesize these multiple, successful, and burgeoning activities into a broadly encompassing spectrum to try and coalesce interest in global health at UGA. We’re doing this by applying through an NIH Grant mechanism called Frameworks for Global Health. So, by attending this evening’s lecture you will not only be hearing from one of global health’s purely bright stars, and I’ll leave it to Dr. Lee to elaborate on our distinguished guest in a minute. But your also being here is
For those of you who write biomedical grants, like I do, you can look at Voices from a Vanguard as preliminary data. Without preliminary data you pretty much don't get a grant these days. You can think about it if you're not in the biomedical sciences as seed money. Voices from the Vanguard is what we're using, the kind of thing we're using in this grant. So I will definitely comment on the people here, and all of those things in the grant. So I'll end simply by saying that we're gratified that each of you has made the effort to come out this evening. I'm sure you'll be fascinated by what you're going to hear, and I hope that you'll come back for the other three lectures in this series throughout the semester. Each will be quite different, because they're meant to, they're designed to try and introduce you to the ways that people, innovative people, have attacked the problems. huge challenges of global health. So thank you for coming. And with that I'll turn it over to Dr. David Lee, our Vice President for Research and Associate Provost.

Dr. David Lee: Thank you Dan, thank you for giving me the opportunity to
add an administrative welcome; administrative, but warm welcome to everybody who's here tonight. And I would like to begin by thanking Dan, and also Patricia Thomas for taking the initiative to organize, what I'm sure is going to be a very important, thought provoking, and informative lecture series. And I'm delighted to be here to help kick this off. It's a series of talks by individuals who I think are truly making a difference in the world. And I think that will be very apparent from the talk tonight. And in that vein I can think of no better way to kick off this series than with tonight's speaker, Victoria Hale, who is currently Founder, Chief Executive Officer, and Chair of the Board of Directors at the Institute of OneWorld Health. So the relatively dry facts here are that Victoria earned her PhD in pharmaceutical chemistry from UC San Francisco. And then moved to the FDA, bypassed the traditional post doctorate and went right to work at the Federal Drug Administration as a reviewer of drug applications. And spent five years doing
And I think she would say it was an important, informative experience as she gained a lot of important experience working with many drug companies, and many, many different drugs. And eventually became such an expert that she became one of the FDA’s teachers of how that process works. She then went to the other side of the street and went to work with Genentech, which some of you may know is, is one of the granddaddies of the biotechnology industry. Got started when I was a graduate student, and it’s certainly one of the most successful of the, of the biotechnology companies to this date. And I think she spent about three years there working in their neuropharmacology division. Well about three years into doing that I think she got to thinking that there had to be more. She got to thinking that there had to be more, more to a satisfying career, and perhaps her sense of wanting to do something in terms of social action, social justice, led her to take a sabbatical. And she tells me, I think I got this story straight, that after only about three months into that sabbatical she’d already begun to develop a business plan.
about what you’ll hear tonight, which is this, what has become the Institute for OneWorld Health. Over the next couple of years she actually set up a consulting company to help others with drug development, marketing, and so on. But during that time, and that was also providing valuable experience, during that time really helped this, during that time this, the plan for what she’s going to talk about tonight really germinated and developed. And was, that experience as a consultant was part of the formative period. So as a result of this thinking and this soul searching she came to the conclusion that what she wanted to do was to set up a nonprofit drug company. And to some this seems like a counter intuitive sort of thing. A nonprofit drug company that would address many of the world’s important disease problems, or another major pharmaceutical companies and government have decided not to go anywhere near. Often because there’s no major profit at the end of a long and tedious drug discovery
and marketing process.<br/>
And so she decided to pursue this challenge.<br/>
And I'm sure along the way in the early days got a lot of negative feedback from friends and colleagues who probably thought she was pretty crazy to be pursuing what, to many must have seemed like a frustrating and fruitless chorus.<br/>
Well, in fact she's proved everybody wrong; the naysayers. And over time she's gotten a lot of support from the Bill and Melinda Gates Foundation. You may know that they're interested in global diseases. She's had help from the World Health Organization. She's partnered effectively with the University of California at Berkeley. And in fact, now Major Pharma, which had looked at this whole thing skeptically from the beginning, is now looking for ways to partner with her and help her as part of their effort to convince the rest of us that they really do want to do the right thing. And so collectively with this support, this institute that Victoria has formed is developing and bringing to market, to market, drugs that will be used to treat a variety of very important global diseases, such as malaria, such as forms of diarrhea,
leishmaniasis, and others. And so this is as you'll hear, a remarkable story. And predictably Victoria has been recognized, increasingly, for her pioneering and inspiring efforts. In 2003 she was selected as a leadership foundation fellow of the International Women's Forum. In 2004 she was named to the Scientific American Fifty, which is an annual list recognizing outstanding acts of leadership in science and technology. Also in that same year she was named one of the outstanding social entrepreneurs by the Schwab Foundation for Social Entrepreneurship based in Switzerland. And in this past year, 2005, she was named the winner of the outstanding social entrepreneurs by the Schwab Foundation for Social Entrepreneurship based in Switzerland. And in this past year, she was named the winner of the outstanding social entrepreneurs by the Schwab Foundation for Social Entrepreneurship based in Switzerland. And in this past year, she was named the winner, women of the year by the Women Healthcare Executives Group. And she's also received other honors, including being asked to be an advisor to the World Health Organization. So I don't want to take any more time here, but I did want to give you the background for this remarkable story. So without further adieu, please join me in thanking Victoria for being here tonight, and being
the person to help launch this important series.\n\nVictoria we're really delighted that you're here.\n\nThank you very much.\n\n[ applause ]\n\nVictoria Hale: It's a pleasure to be here.\n\nWe've talked about this Dan, for how long?\n\nAbout a year?\n\nI think so.\n\nI'd like to begin with one little story about Dan, who was a founding scientific advisor of the Institute for OneWorld Health.\n\nI came to visit him while he was still at CDC, Director of Parasitic Diseases.\n\nAnd I said, I'm going to start a nonprofit, and I'd like your advice.\n\nI'm going to pursue parasitic diseases, and why?\n\nBecause we know the pharmaceutical industry will admit that that is not an area where we would be competing.\n\nDan had his ideas, and every advisor that I spoke to had their own ideas.\n\nAnd I asked him again, do you think it will work?\n\nAnd he said, well, I think you're on the right track, and I think you should give it your best shot.\n\nNow some advisors who I've talked to after the fact have said, you know,
I never did believe that this was going to work. I couldn't tell you that at the time, I kept it to myself. But not true for Dan. He hoped that it would work. So I can say that he was an early believer, so thank you Dan Colley.

Okay, so I have a few slides regarding a few of the diseases that we'll talk about here, and a little bit of statistics. Then we'll get into background of the pharmaceutical industry in this sector, and these diseases, and why World Health needed to exist, or a nonprofit pharmaceutical sector needed to exist. And I'll go through our lead program, in leishmaniasis. And then a bit about another program of ours, a malaria project with a university, UC Berkeley. And then I'll wind up with a zinger for you, a real challenge to you, you who are sitting here, and your friends nearby. So let's proceed. I'm gonna turn this a little bit. I have to point towards this, right?

This slide presents for you
overlapping burdens of tropical diseases, including malaria. In the darker sections are one, the darker countries are ones that have tremendous number of diseases, and inordinate burden. The hatched sections are ones, it's hard to see, where malaria is of highest incidence. Think we could dim these lights a little bit? Is that possible? This is gonna be a challenge. Great. I think I may take you up on your offer to flip the slides please, thank you. Thanks very much. Okay. So a little bit about why these diseases are important. And I know that those of you who are gathered here at 6 PM, you should be eating dinner, but thank you for coming, know that these diseases are important. And you do, you do care for them, and people with them or you wouldn't be here. These diseases are listed in order of the number of deaths that they cause globally. Individuals of all ages, so adults and children are combined here. And we see that Africa is disproportionally represented, particularly with malaria deaths and HIV. Respiratory infections and diarrheal diseases are the number one and number three killers.
And those are particularly complicated, because multiple pathogens are involved. And I propose that the world has shied away from, and scientists have been hesitant to tackle these diseases, because of the issue of multiple pathogens, and that we need to do better. And we need to learn to work together if we're going to get at the number one and number three causes of deaths in the world. And we can do it if we come together. In Asia the leading causes of death are respiratory infections, diarrheal disease, and TB. So just, you can find these data on the web. It the place that I, next slide please, educated myself growing up in the U.S. I'd say I didn't know much about what was going on elsewhere in the world. A little problem arose, for me as a pharmaceutical scientist. Once you know that certain drugs aren't being developed and they could be developed, how can you not act? Once you know, how can you continue doing what you're doing? These are, back one slide, yeah that's right. Just again a reminder that Africa, the African continent disproportionately suffers.
from deaths due to infectious diseases with Asia and the Middle East in the middle. I was surprised to see, this is data from Jeff Sachs that Europeans have half the number of deaths from infectious disease compared to the Americas. And I suppose that is all of the Americas and that's why it's different. Okay, next slide. Thanks. And why do we have these problems? Why are there disease disparities? And then why are there the consequences that no new drugs for some diseases, no new vaccines for some diseases? And that is poverty. It's the ability to pay. It really is that simple. It's unfortunate, but the good part of that is if it's simple then perhaps there is a remedy that is within reach. And that one can imagine, and that one can put forth. Next slide please. So the problem with a large part of the world living in poverty, and a small part of the world not living in poverty is that the small part of the world that has the resources gets the investment, the R and D in everything.
particular
<br/>
this slide conveys the 10
<br/>
90 gap, and R and D for health.
<br/>
And consider the last phrase on the slide.
<br/>
We all have known one person or one family in our life
<br/>
who has experienced the death of a child, and it is a horror.
<br/>
An absolute horror.
<br/>
I hope it hasn't happened to any of you in the room.
<br/>
But it's a very rare occurrence in our world, and we are blessed for that.
<br/>
And it is obvious, but I think not stated enough that 98% of the deaths of children or the deaths that occur during childhood occur in the developing world.
<br/>
just devastating. And it shouldn't happen in the year, in this new century.
<br/>
These are, this is a photo that I took of young girls in, in Bihar, state of India where we're doing our first program.
<br/>
It's a very poor state in India where we're doing our first program.
<br/>
Next slide.
<br/>
So, global health inequities, what are they about? What causes them?
<br/>
If we understand what causes them then maybe we can do something about them.
<br/>
Number one is poverty.
<br/>
We can go through the list of others.
<br/>
But basically, if you, again, are very very poor, you have different diseases.
<br/>
diseases are so different, and I'm not sure that you realize that almost all new medicines in the world if they are western medicines, and they are not traditional herbal medicine, are developed by western pharmaceutical companies. They may not be discovered by western pharmaceutical companies, they may be discovered by universities, yeah? But they are developed by western pharmaceutical companies and go through regulatory agencies. So we need some time for companies in India, okay, in Asia, in India and in China to learn to do the new drug R and D process. And maybe some of this will change, although I'll say to you that in my discussions with companies in India, their target markets are the same as pharmaceutical companies in the west. So we may maintain this problem of no new drug R and D, even though pharmaceutical companies develop the skills elsewhere in the world. Let me add as well, I believe that the world was more concerned with these diseases when colonialism was in vogue, in fashion. When European countries pulled out of its colonies, their colonies,
they pulled away their compassion, their passion and energy, and finances, and resources as well, unfortunately. If there is anything good that can come from the military, militarism that is occurring in the world, this little editorial on my part, it would be that it puts westerners back into parts of the world that we pulled out of decades or centuries ago. And I hope that turns out to be the case. Go ahead. So, the neglected diseases, the really neglected diseases are not anymore, HIV, TB, and malaria. We have a little disagreement about that in the global health sector. I have malaria here on the list. But the general consensus is, something's been going well in global health. There is quite a bit of, quite a few resources applied to HIV, TB, and malaria. That still leaves a long list of diseases, however. And diseases that affect half of the world if you're talking about nematodes or worms. Diarrheal diseases is an arena that we're moving into, and it's a tremendous market if you think about it. The top four there, the first two being enteric, then malaria, and shisto,
one of Dan's favorites.

Tremendous markets, but they don't attract industry. They just don't have the ability to pay.

Go on, next slide. Thanks. So, for malaria, just for example, deaths in Africa.

Okay, almost all deaths from malaria are in Africa. And the mortality is compounded by poor public health infrastructure, lack of access to new medicines, lack of education. But most importantly, I believe, the social, political, and economic turmoil that leads to or supports a lack of will to make a change. And I'd like to demonstrate by this slide and make one point here. We all work very hard in technology. We live in a part of the world that's very technologically oriented. We live in a part of the world that we'll have access to that technology. It will get to us. That is not true in many parts of the world.

We can work our hardest, and a miracle can happen, and we can develop a malaria vaccine. Wouldn't that, that would be a miracle at this point. But really has you know, incredible coverage. And that doesn't mean that it would save lives right away.
There are huge issues after the technology is developed. There are huge issues after regulatory approval, and they don't involve high technology.

They involve low technology. They involve going out into very rural places, and education, and working with governments, and generating a will and a force to make something happen. So malaria right across the middle, a belt around the middle. So focus on drugs now. Doctors Without Borders did a quick survey of all drugs approved in a 15-year period. About 1,400 of them, and 1% were approved for tropical diseases. 1% of new drug approvals. The catch to this is only one of them was approved for a tropical disease in humans as its first indication. So this counts second indications, etcetera. Most of these drugs were approved for veterinary disease, for agricultural purposes first. The animals before the people. It's very unfortunate. But let's turn that into an opportunity here. We can go to and work with veterinary health, animal health companies, right?
They do have these leads, and they are still in the parasitic drug business. And some of these drugs as well were approved for other indications, oncology for instance, and then came to tropical diseases. So it's very sad and obvious that you saw the list of the number of tens of millions, of hundreds of millions of people who have tropical diseases that we have these numbers, these percentages of new drug approvals. So the world has not stood by idly. And I, and my organization, and our colleagues, and friends, we're not the first to come up with a solution. The world decided about 10 years ago that there should be public private partnerships. Okay, so that's the PPP. Public always come first, as it should. The public, public sector players are the leaders in this. And public private partnerships were developed in response to this market failure. We don't like to say the word market failure when we're talking to pharmaceutical companies. If you want someone to partner with you, you don't like to, you know, rub it in. But that's really, basically what it is. These programs were generally
funded, not by private corporations, not by corporations; however, they were
generally funded by the public sector. There are about 16, I think,
that exist now that develop drugs, or vaccines, or diagnostics.
And it works reasonably well for those three big diseases, which I opened with to tell you they're not so neglected anymore.
And one of the reasons is these exact public private partnerships that have been able to bring pharmaceutical companies together with the World Health Organization, and with universities, and with various players, governments, etcetera, and make this happen. But they're not perfect. Next slide.
And these are the reasons. This is part of my strategic analysis of what was needed. So early on with public private partnerships it was pretty clear to me that you wouldn't be able to, it will work for a few diseases, but we wouldn't be able to develop a new drug for onchocerciasis. It just wouldn't happen. Leishmaniasis, we could, the list goes on. Our first choice is a good old drug that
was off patent, an old aminoglycoside. And it was a piece of low hanging fruit that really was a sure shot. It was a great first product. But it never would have worked in the existing public private partnerships, because there was no intellectual property around it. Nothing that anyone could own. A generic company anywhere in the world could make it. That's okay with us, but that's not okay with pharmaceutical companies who participate in public private partnerships. Not yet anyway. It may be in the future. The mission of these troubled private partnerships is often quite narrow, as it should be. We need to focus on, for instance, the medicines from malaria adventure. Extremely successful in bringing forward new medicines still in research stage, the newest ones, new mechanisms of action for malaria. Where do you fit a drug that is old, or off patent in that sector, in that PPP? You don't. Where do you fit a new technology to address the shortage in artemisinin that exists? Well you don't. It doesn't fit the mission. So these PPP's that exist
develop medicines have to stay narrow, except the technologies are not narrow, the beauty of technologies. And in our society, the beauty of science is that, the discoveries are as wide as we imagine they are. Are as broad and creative as we allow them to be. So we wanted to be an organization that would take on some of these more creative projects that didn't fit elsewhere. And they're dependant on philanthropy, as we've talked about. That's okay when you're in the research phase. But as these research programs are successful and move up into real drug development programs, it gets quite expensive. And our philanthropical organization, such as the Bill and Melinda Gates Foundation, are going to be able to fund the development of three antimalarials at one public private partnership. And eight diagnostics for tuberculosis at another public private partnership. And four different vaccines for another disease elsewhere. I don't think we can ask one foundation to do that. I think that they, well they've made it clear that they want other funders to participate. Next slide please. So, I'll tell you what really
inspired me first to believe that we could do this. Once you learn what's going on with global health and how many needs there are, the answer, the solution becomes, how many opportunities are there? So within our sector, who's in the pharmaceutical sector, the beauty of it is it's a wealthy sector, and there's a lot of money put into discovery. Okay so, so many more discoveries are made than can ever be developed. And much of that is what should be mined and pursued for leads for potential new medicines. I think I'll skip the rest, but basically huge untapped potential opportunities. Next slide please. So why a new player was needed? The World Health Organization does its best, but it is a small organization with very little funding. And it appeared to us, and to me, that there needed to be someone.
who could bridge the gap. Who could speak to people in global health community about what was needed. What the product would need to look like, what it would need to cost. And work with pharmaceutical companies to make that happen. So, just a reminder, one billion people live on less than a dollar a day. They need to eat, sleep, dress themselves, children have shelter. About three billion live on less than two dollars a day. So our product has to cost pennies, our drugs. So OneWorld Health was formed. With that recognition of tremendous opportunities that come from universities and academia, a very large number of extremely committed scientists. Scientists in my industry who would say to me, if you start it I'll come. You know the movie, what's it called? If you build it they will come, about the baseball team. What's it called? Field of Dreams. There you go. This is the way OneWorld Health has turned out to be. It's very cool. There are many passionate scientists who say, no I chose this field, I chose this sector.
because they wanted to help someone. And I can't remember the last time I felt that I did after a day's work. I work hard. I work hard. And my company is good to me. And you know something? I'm not ready to leave quite yet. Then in many cases I have a mortgage, I have kids, I have golden handcuffs, but I want to volunteer for you. Or you know something? I'm just up to here. I want to leave. So we have many more volunteers than we can use and wonderful opportunities to tap great employees. So we have 50, about 50 or 55 employees now. We couldn't do any of it without philanthropic investment. And almost all of that funding has come from the Bill and Melinda Gates Foundation. 140 million dollars to date, just tremendous. And we are but one small nonprofit organization in San Francisco. We will open an office in India, but we can't do this without a very large number of partners. And a lot of what I do is build, work on trust, and building relationships. People who work in this sector, and companies who come into this sector,
do not do it for business reasons. This does not make business sense to engage in any of these diseases. You're here because you want to be here. And it's about personal relationships. So it, to recognize that is very important, and it takes a lot of energy to maintain them. Across cultural barriers, age, all kinds of barriers. So, OneWorld Health is a simple experiment designed to model the successful pharmaceutical industry. Really, is it this simple? Could we just remove profit and keep everything else the same? So that's what we did. Our first project had to be successful, had to be quick, had to be inexpensive, otherwise no one would fund us further. We focused on research and development, in particular development, and we focused on drugs. We do have one vaccine in our portfolio, and that's a little bit of an experiment. We have very strategic selection of drugs. We did not want to have to develop a sales and marketing force. So choose a drug that will be distributed by others, or can be distributed by others. So you can just orchestrate
watch, that's naive isn't it? Watch that distribution happen.

It's never like that. But to approach that. And our first program is in India. We need to go to Africa and we need to go soon, but we also needed a government that was committed to a particular disease, and a reasonable amount of infrastructure. So OneWorld Health, this is our mission. New medicines for diseases of poverty. For people with diseases of poverty. We identify promising drug candidates, because lots of them sent to us. We've had some beautiful insecticides, some fantastic advanced bed nets, some incredible rehydration solution. We really try to focus on the drugs. There are lots of great technologies that have nowhere to go. And we propped up as a nonprofit health something, and when you Google us you find us. And so we have some great opportunities that we'd actually like to share. We'd like to put out publicly, rather than just say no thank you to.

Like to get, have a place for
them to go in the world, so that people know about them.

We complete animal and human clinical trials. That’s our primary work. We’re in downtown San Francisco. Picture this, we don’t have laboratories. We’re counting on you to have done the research, and for you to have taken the work as far as you can. Maybe with a company, maybe not. And then we pick it up and move it from there.

This, the work that we do truly depends on the work that comes before us. And standing on the shoulders of others, leveraging the work of others. There is plenty of quality manufacturing in the world. We do not have a factory. I think it would be a great idea to produce. To set up manufacturing facilities in the continent of Africa. Have Africans run them and make your own medicines, it’s very empowering. But at this time we use opportunities that exist in India. Tremendous manufacturing facilities. We’d like to learn more about China in the near future. And we take it all the
through regulatory approval. Our guiding principles, the first, and we got this right away with OneWorld Health in talking with big Pharma executives who passed our business plan through four retired CEO's. And we were uniformly rejected and criticized, because they thought we were going to compete. So we made that very clear.

You didn't read our target diseases? You know, can you even pronounce them? Trypanosomiasis and leishmaniasis, come on. This is not diabetes and it's not hypertension; it's not even oncology. There are western diseases that lack therapy. There are may orphan diseases that need therapy. We have been, I don't want to say tempted, because we weren't tempted, but there has been organization who have come to us in the U.S. to ask, well can you please help us with the Huntington's disease drug. We're ready to go now. We've been doing research for 30 years, or a Parkinson's disease drug. And we've said no. There needs to be a path for those, but it won't be at OneWorld Health. Do not duplicate available resources.
that's use the manufacturing in India.<br/>
<time begin="00:36:43.74"/>Focus on development, not<br/>
research.<br/>
<time begin="00:36:46.39"/>You do the research, and<br/>
we'll do the development.<br/>
<time begin="00:36:49.46"/>Be a bridge between those two<br/>
sectors that don't speak the same language or the same culture,<br/>
<time begin="00:36:54.26"/>and don't particularly like<br/>
each other, to<br/>
tell you the truth, or respect each other.<br/>
<time begin="00:37:00.16"/>Sustainability is an issue<br/>
for<br/>
any organization, any nonprofit.<br/>
<time begin="00:37:05.49"/>And I do believe that<br/>
OneWorld Health<br/>
can be partly sustainable in the future.<br/>
<time begin="00:37:09.19"/>It is important, however,<br/>
that our decision<br/>
of which drugs to develop and which diseases<br/>
to work in, not influence,<br/>
our desire to<br/>
be sustainable, not influence our decision<br/>
of which drugs to pursue<br/>
and<br/>
which diseases to work in.<br/>
<time begin="00:37:22.21"/>Because if we were only to<br/>
pursue TB, malaria, HIV, whether it's some small western market,<br/>
then those neglected, very<br/>
neglected diseases would be very neglected again.<br/>
<time begin="00:37:32.91"/>So we always will have a<br/>
mixture.<br/>
<time begin="00:37:36.32"/>And everybody has to<br/>
enjoy<br/>
their selves, or this doesn't work.<br/>
<time begin="00:37:43.76"/>Everyone has to want to be<br/>
there.<br/>
<time begin="00:37:45.27"/>And keeping that<br/>
scenario<br/>
rolling, as people change,<br/>
<time begin="00:37:48.82"/>as the project changes is<br/>
really a challenge.<br/>
<time begin="00:37:50.94"/>Keeping your, all your<br/>
partners at the table.<br/>
<time begin="00:37:53.50"/>So we focus on diseases.<br/>
<time begin="00:37:56.43"/>Oh, no this is not what I
This is what OneWorld Health has done that is, I hope, provides a take home message for you, if you care to do something like this in the future. And it is to, that we have focused on disease in new and creative ways with the technologies that we've brought in. We chose parasitic diseases where there have been, as yet, no vaccines. But drugs do save lives. We have believed in and studied old drugs and old technologies. Just because you're new doesn't mean you're better than everything else that's out there is our philosophy. We adopt high risk, high reward projects that do not go elsewhere. And I encourage you to consider that as well. But I would say that shouldn't be your first project. You should have a project that's a sure shot, that's in the bag, so to speak. And then consider these high risk, high reward programs. We work hard to provide industry with opportunity to participate. It's really wonderful. It's been a fast forward
my mind, the time in which it took for it to switch between us knocking on industry's door, and industry knocking on our door. We've said we want to partner. And they said, well we'll watch and figure out who you are. And if you can develop a drug, and then we'll decide. And now they're all coming to us, which is glorious. Then we can initiate more programs and pass them on. And find more opportunities and license them out. And get more done, advance global health and engage the industry. If we don't engage the industry then we're kidding ourselves really about what can be accomplished. So we need to work with industry. And you know something? They want to do it, they just have no idea how to do it. They haven't thought about it. So they're very different. Okay. So we like to say that we focus on the middle of this slide, the development, [unclear] technical transfer from manufacturing, and then regulatory approvals. In reality, that was the case for our first project.
But we need to back up and move forward with some of our other diseases.

My challenge as a CEO of this organization is to not have us spread too widely, rather have us do fewer projects and finish them up and do them well, then spread very broadly and be overwhelmed by the number of disciplines that we're engaged in, and the number of activities we have, or the number of projects that we have.

So this is our pipeline, a paramomycin license will be submitted, the dossier, regulatory dossier to the government of India this quarter, Q1. So we expect an answer shortly thereafter. And we hope for an approval. And that's all that I can say.

We don't know, and you really do have to wait. Having been at FDA, sometimes companies are surprised. I don't know. I would be very embarrassed if I were surprised with this one, having lead this company for some time. We have a small Chagas disease program. We have a large artemisinin program that I'll tell you about in a bit. And we have a diarrhea disease program that's coming.
we haven't announced that one yet. And a malaria vaccine. I think I have to speed this up, cause we have a little slide to show you.

Next slide.

Oh, this is visceral leish'.

Okay. Then we'll get to the video.

Our first disease visceral leishmaniasis, kala-azar.

black fever. We chose because it was perfect.

It was in a region of the world that was contained.

It is a disease that has no animal reservoir, well in this part of the world. So if you can treat people and kill sand flies then you can eliminate the disease.

Just a tremendous possibility.

The disease is in, primarily affecting India, primarily one state and spreading radially out to Bangladesh and Nepal.

Next slide.

We had Newsweek produce a five page piece.

Did you see it this summer in the health, special health addition?

Five pages on visceral leishmaniasis in Newsweek.

That's a dream come true.

This is one of the photos from the photographer.

This is one of our physicians.
in the blue plaid shirt.<br/>
<time begin="00:42:31.60"/>diagnosing VL in the field.<br/>
<time begin="00:42:33.02"/>This is another one of our sites.<br/>
The balding man is another of our investigators.<br/>
<time begin="00:42:35.87"/>Notice in the upper right that he was trained in London and Edinborough.<br/>
<time begin="00:42:38.11"/>And he came back to Bihar.<br/>
<time begin="00:42:41.80"/>All four of our investigators, "leishmaniacs," trained in the UK.<br/>
<time begin="00:42:43.99"/>And then came back to run Kala-azar clinics.<br/>
<time begin="00:42:49.53"/>One lives in Barnas, and commutes.<br/>
<time begin="00:42:51.75"/>This is me learning to palpate livers and spleens with one of our investigators.<br/>
<time begin="00:42:53.00"/>And our first drug, beautiful promolmycin. Another, an old antibiotic.<br/>
<time begin="00:42:58.75"/>I've said a lot of this already.<br/>
<time begin="00:43:04.98"/>The cost for cure will be between $10 and $20 dollars.<br/>
<time begin="00:43:09.35"/>Sounds like a lot if you think about malaria cures. If you're really cured from visceral leishmaniasis it really only happens once in your life.<br/>
<time begin="00:43:25.18"/>And present cures are between 100 and 200 dollars.<br/>
<time begin="00:43:29.27"/>And so this is a tremendous advance.<br/>
<time begin="00:43:32.37"/>To 21 day intramuscular therapy once a day. We're doing a trial soon that
will examine whether 14 days is sufficient. If we increase the dose, which would make it, by far, the shortest therapy. All the other therapies are 28 days or longer. So we are, we're very thrilled with this product. But it's not approved yet. I have to say, to emphasize. Good. This is one of our clinical sites. This is inside one of the buildings that you saw a photo of. Notice the beds have a, they're nice metal framed beds, and the floor is pretty clean. I think they did clean up a little bit before we came. But there are no mattresses on the beds, they're just cloths. The patients are packed in. Children sleep three to a bed in epidemic situations. Kala-azar is a pretty bad way to die, not that there is a good way to die. But you have basically pancytopenia. So you die of opportunistic infections, a lot like AIDS. You die of the complications of severe anemia. Or you die from hemorrhage.
It's a very bad way to go over a period of a few months. So it is an agonizing protracted suffering.

Next slide.

And we received a 30 million dollar grant. All the work that we did in the development of paromomycin was 17 million dollars. It actually cost more than that. Probably about 25, we're gonna cost this out.

We had so many volunteers we were able to do it for 17. We got a grant recently from the Bill and Melinda Gates Foundation for 30 million to figure out how to get this product out there. Remember when I said we don't do distribution? Well we don't, but somebody has to do it. And that will be the government of India.

Well, and the disease exists, because some government didn't do it's job, yes, so the government of Bihar. And we're relying most heavily on nonprofits, nonprofit organizations, and a little bit on the, on the private sector.

Man: From ABC News Headquarters in New York, this is World News Tonight.
together with TIME Magazine, is launching an unprecedented week long series, Prescription for Survival, focusing on global health issues that affect all of us. Tonight's subject, the world's worst diseases, and why most of them are ignored by major drug companies, despite the fact that they make millions of people sick. ABC's Judy Muller reports from San Francisco.>

Judy Muller: They're called neglected diseases. Parasitic illnesses that affect millions of people in poor countries, mostly in Africa and Asia. Neglected because most drug companies don't make medicines for people who cannot afford to pay.>

Man 2: These people don't represent a market, there's no return on investment there.>

Judy Muller: Black fever, almost 100% fatal, elephantiasis, more than 40 million people disfigured, river blindness, more than a quarter million blinded, sleeping sickness, also fatal, spread by the Tsi tsi fly, And the big killers, malaria and children's diarrhea.>

Institute for OneWorld Health is the nation's first not-for-profit, The Institute for OneWorld Health is the nation's first not-for-profit, pharmaceutical company.>

Judy Muller: Company
founder Victoria Hale is a corporate pharmaceutical scientist who came up with a solution, look for existing drugs that have been dropped by the big companies. Drugs that could be used to cure these neglected diseases. Her first target, black fever. Her first target, black hemorrhage and die. It's a terrible way to die. Judy Muller: Using the off-patent drug called paromomycin, and funding from the Bill and Melinda Gates Foundation, OneWorld Health has finished clinical trials in India that cured 94% of the patients. Great progress, but there are a lot of other parasites out there. Victoria Hale: The problem with infectious diseases is the bug that you are going after, it changes it mutates, it develops resistance. You have to keep developing new medicines. And it is that which is not happening. Judy Muller: Drug companies, of course, are businesses, not charities. But some are getting involved. Merck took an existing heart worm medicine for dogs, and turned it into a very effective treatment for river blindness in people. Man 3: We were lucky
enough to find something that worked, and we’ve done what we can to make it available.

Judy Muller: Even so, the diseases that afflict 90% of the world’s population, get only 10% of the health dollars. Most of those dollars go to western lifestyle problems, cholesterol, digestive problems, erectile dysfunction. Judy Muller, ABC News, San Francisco.

Victoria Hale: I am frustrated. I understand that, and I believe that the way to address it is not to go in and change this enormous system that exists. But to build a system that can work with what already exists and to make it happen. Judy Muller: And in one corner of the world, this one company is doing just that. Judy Muller, ABC News, San Francisco.

Victoria Hale: So it’s a big deal with ABC News talks about black fever. It really is. There’s a lot of good things happening. Now I’m going to wind up and get to that zinger. I told you about that challenge for you. But let me talk for a moment about social entrepreneurship. And then I actually do want to talk about one of our high risk, high reward projects. We’ve won several...
rewards
for social entrepreneurship,
and people have asked me how
do you define it?
You can Google it and find a
few definitions.
I don't want to define it, I
just want to share with you my thoughts.
So the world needs all of us.
We're all here for a reason.
You may have found your reason, and some of you may not.
If as you're wondering through the world something tugs at your heart, stop and listen.
It's important to listen.
It's important to be quiet.
We live in a noisy world where time for silence and silence itself doesn't exist.
So just a few words to contemplate for you.
Examine that world and this world, and find a significant problem.
One that means something to you, but that doesn't overwhelm you.
One that really goes, does something to you.
You're going to need that in the hard days, in the dry periods.
You're gonna need that felt reason for, to get you through.
Identify opportunities don't
Focus on the problem.<br/>
<time begin="00:50:37.82"/>Focus on the solutions.<br/>
<time begin="00:50:41.13"/>Talk to lots of people and study the work of others.<br/>
<time begin="00:50:46.24"/>There have been some pretty impressive efforts that in the end, if people had just consulted with mothers who treat babies in the developing world, you would know that that formulation will never work, or that price is never going to do it.<br/>
<time begin="00:50:50.28"/>There're lots of people in the world who've thought about what you are thinking about tangentially.<br/>
<time begin="00:50:57.90"/>Acknowledge that there will be obstacles, there will be problems. There is, there are in your laboratories every day, and there are in any work that you take on.<br/>
<time begin="00:51:00.72"/>Sometimes the problems are people in a situation where you're impacting global health situation and you want to affect change.<br/>
<time begin="00:51:05.63"/>So be aware that it isn't always an experimental problem, it can be a personal or human problem.<br/>
<time begin="00:51:12.87"/>Really it takes tremendous passion and keep that vision that you evolve over time.<br/>
<time begin="00:51:16.80"/>And then persevere.<br/>
<time begin="00:51:21.46"/>Really it takes tremendous passion and keep that vision that you evolve over time.<br/>
<time begin="00:51:24.08"/>And then persevere.<br/>
<time begin="00:51:29.51"/>So be aware that it isn't always an experimental problem, it can be a personal or human problem.<br/>
<time begin="00:51:34.53"/>Really it takes tremendous passion and keep that vision that you evolve over time.<br/>
<time begin="00:51:42.56"/>And then persevere.<br/>
<time begin="00:51:44.46"/>Really it takes tremendous passion and keep that vision that you evolve over time.<br/>
<time begin="00:51:50.12"/>And then stick with it till you finish it.<br/>
<time begin="00:51:53.53"/>when the well goes dry people say that's it.<br/>
<time begin="00:52:00.82"/>I've done all that I
And it's often just after that next mountain that you have success. That there is that oasis; that little bit of water that you need to continue, so stay with it.

Next slide.

And if you are to choose a first project, I'm gonna skip this, because it says a lot about what we do. But the last point is, it's so important to talk about the work that you do, but I learned in California from the Dotcom bust that if you talk too much you end up not getting your work done, and then your company fails, and then the whole darn sector fails.

So keep your head down early. Your first project is everything. Once you have a first success the paths and gates in life open up.

Thanks. So our high-risk project that we took on was one that is a bit different from our normal program. This isn't a drug lab producing a product here, we're addressing a global shortage, and a cost problem with artemisinin antimalarials.
So artesunate, artemuser [assumed] a little bit of arteether perhaps, through the partnership with University California Berkeley, and QB3, Quantitative Biology 3, which is Berkeley, San Francisco and Santa Cruz campuses. It is very high-risk science, extremely elegant. We plan to build a metabolic system within e coli, pick the genes out of artemisia, the plant that produces artemisinin. It's something. There are high highs and low lows when the next gene does or doesn't hit it. But we are right on course. The project is 14 months in now. We're actually ahead of milestones, so we're quite pleased with the project. Next slide. So we're working with Keasling Lab, chemical engineers at UC Berkley, and Amyris, a small biotech start up, and OneWorld Heath. So we will decide, as OneWorld Health, whether to be the producer, the fermenter, of this product in e coli. Or to engage a pharmaceutical partner and have them do it, and have them put their name on it. We'd need a substantial philanthropic
Hale.txt
donation,<br/>
<time begin="00:54:30.13"/>and cut in costs of the
product to do that.<br/>
<time begin="00:54:32.68"/>So we're still deciding.<br/>
<time begin="00:54:33.49"/>There's a lot of business
plan work that needs to<br/>
be done now in organization, and they've,<br/>
<time begin="00:54:38.29"/>we're paying some really
expensive<br/>
analysts to do that and companies.<br/>
<time begin="00:54:44.68"/>So the purpose of the
project, again<br/>
is to, it's for five, over five years,<br/>
<time begin="00:54:48.45"/>reduce the cost by five fold
we're saying,<br/>
and guarantee that there's not a shortage again<br/>
<time begin="00:54:55.81"/>of these very fine
antimalarial's.<br/>
<time begin="00:54:59.03"/>
<time begin="00:55:00.14"/>
<time begin="00:55:01.53"/>
<time begin="00:55:05.70"/>
<time begin="00:55:09.56"/>You read about preventable
diseases that we can do something about.<br/>
<time begin="00:55:12.79"/>It was a great day, by the
way, thank you.<br/>
<time begin="00:55:14.48"/>I was tired from it, which is
good.<br/>
<time begin="00:55:18.29"/>Most of these problems,
however, let's<br/>
accept it, they will not be solved<br/>
<time begin="00:55:22.33"/>by the current
corporations,<br/>
or systems, or governments.<br/>
<time begin="00:55:26.92"/>That's too bad.<br/>
<time begin="00:55:27.96"/>But it also is an
opportunity.<br/>
<time begin="00:55:29.67"/>Take those problems and
turn<br/>
them into opportunities.<br/>
<time begin="00:55:32.44"/>Be, you no see the positive
side.<br/>
We have to create the new solutions and the new paths. We can’t imagine that those who are in a situation, where something is not working, will figure out what to do. Sometimes we, sometimes you need the freshness from the outside to figure it out. So, here is the zinger for you, my challenge to you as an audience, then we’ll finish up. Who leads in global health? Does global health need a leader? I suppose would be the first question. I think that the words of Conway, what is his first name? I’ve forgotten. He’s the former president of the Rockefeller Foundation. Used a few words at a global health conference. He said, the state of global health is total anarchy. And I, if you think about it, everyone is doing their own thing, and working by themselves. And my reflection on that was, is that a problem? Is there one right way to do things? Is there one group who knows better than others? So who is leading?
I'll tell you from partnerships with the WHO, it's not. Is the Bill and Melinda Gates Foundation leading? They're told, you are leading, whether they want to or not, they're told they're leading. And they say, we don't want to lead, we want to empower, we want to fund. So we have a reluctant leader.

Is the NIH leading? Not in global health, you know CDC. Perhaps in some element of global health, in Epidemiology and some other spheres. There's a question of which continent is leading. Who cares more? Who has more schools of tropical medicine? Which government gives more money? Does that define leadership? And finally, this is it for you, is Harvard the university that leads in global health? So here's my challenge on the next slide. They certainly have the most resources, okay, get the most attention. So I have a proposal for you, for the State of Georgia, actually. I propose that Georgia has a critical mass of expertise and passion in vision and leadership. And if you got it all...
together, now that's the challenge, right?
Get everyone to come together and work together; that you'd be quite a force; quite a force to deal with.

So I challenge you to do that.

And all that you would need, you have the, you need three things to make this happen.

You need passionate people, and I, you really have them in this group.
I may not have named the alliance, the government alliance correctly in, I'm sure I'm missing a few initiatives that we've talked about today.

You have the people, very passionate, and in critical mass.

You have the technologies, okay, they exist, where you can access them.

All that you need is funding, and I have that solved here too.

Okay. What do you think about the Georgian Globalites? Isn't that good?
Or the Georgian Dozen or the Georgian Dreamers?

You have that here too.

You really, really do. And all you have to do is believe it, and go out and ask for it and make it happen.

And as I offered today at lunch, if you need a nonprofit pharmaceutical company we'll open an office in Georgia.

I don't know that you
If you decide to go to Georgia, okay and I'm passing there are lots of things you can do in global health. But I really encourage you to, can you back up one slide, really, really think about, really think about taking a leadership role. Really thinking about leaving affiliations at the door, leaving egos at the door, really thinking about leaving professional and really coming together. It's tremendous what you have. It really is. I will tell you though, to be honest, I'm working with the University of California and telling them the same thing. But I think that you're way ahead in terms of the probability of success compared to the University of California and Stanford. So, I'm available for consultation anytime, pro bono, okay? Okay. Let me wrap it up now here. Okay. So in conclusion, a nonprofit pharmaceutical company can exist and should exist, needs to exist. Nonprofit vaccine companies, they're coming along, we know of two that we really helped and they exist now. You'll hear from one of them in one of your lectures; one of the four speakers.
And we're thriving. I'll tell you honestly it's still hard. I don't, I have two sons, 13 and 7, and they balance, I have a wonderful husband that works with me too. My children give us balance in life, but I don't get home for dinner enough. So I'm not saying anywhere here that it's easy. It's hard still. And I think that anything worthwhile is hard. And that's okay. If you're in the place in life where that's what you want to do. Industry and academic scientists are very anxious. Here you are, to get going and to advance technologies, specifically for these neglected diseases. Young scientists give me hope for the future. The incredible volume, volume of passion that comes through emails and letters from young people, please may I have just two minutes of your time. I want, I'm gonna live a 100 years, because of all of these technologies that we have. A hundred more years, I going to be on this globe, okay? And it's a fricken mess, and I want to do something about it.
Please tell me what to do with my career, with my life. Just steer me toward a path and then I’ll take it, just two minutes time. And we don’t have time. We’re doing other things. So we have an email message that we send back. It doesn’t matter what path you take. There are so many opportunities. There is not one path, so so many paths. But keep that; keep that spark that you have. I said to a few of my hosts here today, right. I haven’t been on an undergraduate campus in a while, UCSF is all graduates. I spend quite a bit of time there, and I guess I’m at Berkeley when classes are going on. I don’t see the students. They look so young. Of course I’m not aging, myself. But that passion it, it truly does give me hope that whatever we begin now will be taken on and continued by future generations. I absolutely believe it. I have no doubts at all. Leadership. Leadership is desperately needed. But that passion it, it truly does give me hope that whatever we begin now will be taken on and continued by future generations. I absolutely believe it.
Don't let that be a deterrent. It just means that you may have to lead yourself at times. Keep that vision clear when you do lead.

Industry does want to participate. They don't know how. They're waiting for you to ask, convince them to make it right for them. And it's not just pharmaceutical industry; there are lots of industries. We have fantastic offers from IBM and Intel, and I don't know who else, offering what they can to advance global health. I bet you can get one from Coca Cola if you knocked on the door. Yeah? And there's plenty of money in the world. You must believe that. There truly is plenty of money.

It's our job as scientists, we don't do a good job of translating the importance of what we do, the significance of what we do. There is fear of biotechnology in Europe, and therefore [assumed] in Africa. How did that happen? It's our fault. It's our responsibility. And if we are unable to attract other families other than the Bill and Melinda Gates Foundation, although Rockefeller has been there, and
Hale.txt

<time begin="01:03:20.75"/>the Wellcome family, <br/>
which I don't think they exist any more, <br/>
<time begin="01:03:23.30"/>but were there very, very <br/>
early. <br/>
<time begin="01:03:26.09"/>If we can't invite any <br/>
other <br/>
families and convince them to be <br/>
in global health <br/>
then that's our fault. <br/>
<time begin="01:03:31.48"/>It really is. <br/>
<time begin="01:03:32.03"/>We're not trying hard <br/>
enough. <br/>
<time begin="01:03:33.50"/>Because there are many, many, <br/>
many <br/>
families who have considerable wealth. <br/>
<time begin="01:03:39.59"/>and they want to leave a <br/>
legacy in <br/>
the world, they want to leave it <br/>
in print, and they don't know <br/>
what to do. <br/>
<time begin="01:03:45.76"/>They really don't know <br/>
what <br/>
to do, and they're begging. <br/>
<time begin="01:03:48.02"/>Okay, next slide. <br/>
<time begin="01:03:53.43"/>So thank you to all of <br/>
our <br/>
partners, in particular the Bill <br/>
<time begin="01:03:56.79"/>and Melinda Gates <br/>
Foundation; <br/>
98% of our funding. <br/>
<time begin="01:04:00.07"/>I've gotten to know them very <br/>
well, and <br/>
would not be here without them. <br/>
<time begin="01:04:04.77"/>They believed in us early; <br/>
technology and in entrepreneurs. <br/>
<time begin="01:04:08.29"/>And we put that together, <br/>
that's what we're <br/>
trying to do here, put them together. <br/>
<time begin="01:04:12.02"/>And all of our partners. <br/>
<time begin="01:04:15.38"/>Next slide. <br/>
<time begin="01:04:16.68"/>Thank you, Dan and Pat, <br/>
the university, and the center. <br/>
<time begin="01:04:21.20"/>I think I forgot a word in <br/>
the center. <br/>
<time begin="01:04:23.93"/>Global, yeah, oh my <br/>
goodness. <br/>
Yes. Okay.

I'll get next; invite me back next time I'll get it right.

Okay. No, this is it, this is my life philosophy.

Never believe that a small number of people can't change the world, it truly is the only thing that ever has.

Thank you.