

**15 Minutes**

**Victoria Hale**

MacArthur “genius” prize winner creates drugs for the developing world

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# 15 minutes



With a background in academic research, industry, and government, Victoria Hale, founder and CEO of OneWorld Health, is uniquely poised to cross sectors and deliver pharmaceuticals to the world's poorest people.

## Victoria Hale *MacArthur “genius” prize winner creates drugs for the developing world*

**T**he pharmaceutical industry spends billions of dollars developing drugs to cure the ailments of wealthy Westerners, but very little to treat the diseases that kill millions of people a year in the developing world. Victoria Hale, who was recently awarded a MacArthur fellowship for her efforts, is trying to change all that.

Hale's San Francisco-based nonprofit, Institute for OneWorld Health, is partnering with foundations, for-profit drug

companies, NGOs, and governments around the world to bring these neglected drugs to market. She just scored her first success, receiving approval from the Indian government to sell a drug that cures visceral leishmaniasis. This disease, also known as black fever, kills 200,000 people a year and afflicts many times that number. And she has more drugs – to treat malaria, Chagas' disease, and secretory diarrhea – in the pipeline.

In an interview with SSIR managing editor Eric Nee, Hale discusses what role

the Bill & Melinda Gates Foundation plays in her organization, why for-profit drug companies are knocking at her door, and why her optimism about the chances of saving millions of lives every year is growing.

### **Why did you create a nonprofit drug company?**

When there are blockbuster opportunities that generate significant revenues, the pharmaceutical industry runs to them. But when there are opportunities that affect very, very poor people, the industry doesn't respond very well. That was the position that global infectious diseases were in.

So the question was simple: If the barrier to developing drugs for these medicines is the profitability require-

ment, then it should be possible to develop these medicines within a pharmaceutical company that doesn't have that profitability requirement. That's the experiment of OneWorld Health. And the proof of concept is that we just achieved approval from the Indian government for paromomycin IM [intramuscular] injection to treat visceral leishmaniasis.

## **People in other industries have launched for-profit companies with a social mission. Why didn't you take that approach?**

Research and development costs for new medicines are in the tens of millions of dollars. The traditional sources of funding that would lead to a for-profit entity – venture capital – just didn't work. We couldn't even get two minutes in front of a venture capitalist. Therefore, going forward with philanthropy first was the way to do it. Now, is it necessary to remain simply a nonprofit pharmaceutical company? The answer is, we don't know. Because we have proven that we can develop a drug and bring it to market, we now have potential investors stepping forward to ask us to consider other models that are *not* not-for-profit. So would we be willing to open up to other possibilities? Absolutely.

## **How much money did it take to bring paromomycin to market?**

To get it to where it is now with restarting, manufacturing, clinical trials, and regulatory approval, we put in about \$17 million. [The cost of bringing a drug from the research laboratory to the market is usually much more than \$17 million. OneWorld Health was able to do it for less because paromomycin was a preexisting drug that was developed for

another disease and was no longer covered by a patent. OneWorld Health had to conduct only the final clinical trials confirming that the drug would cure black fever.]

## **How much are you going to charge for the drug?**

We priced it at the cost of making it and packaging it. Black fever affects the poorest of the poor. These are people who live on 30 cents a day, so recouping our \$17 million isn't feasible. [A Gates Foundation grant covered those costs.] There are some diseases that just have to be adopted and funded by philanthropic-based approaches. There are other global infectious diseases where I absolutely believe that we can get there by very creative models, whether they are hybrids – something in the middle space between for-profit and not-for-profit – or straight for-profit. Particularly with really big diseases where potential sales are large.

Malaria and diarrhea are our next two programs. The drugs for them are not blockbuster drugs by any means, but these diseases affect enormous numbers of people. They're even important in the West for soldiers and travelers, and [in developing countries] they are also significant for people who live in urban settings and have higher incomes, and for people in the middle class. With tiered pricing we can bring back revenues from sales to some of the wealthier groups and still be able to provide the drugs at cost or maybe even below cost to reach the poorest of the poor.

## **How has the global health industry changed since you started OneWorld Health six years ago?**

We were an oxymoron, something that people would laugh at and say,

"Oh, that'll never work." Now we're winning awards. The world has moved in a relatively quick period, and I think it's because of these public-private partnerships that have come together. To a great degree they have been funded and inspired by the Bill & Melinda Gates Foundation. [Tropical diseases] really was a dead field. Now, they [the Gates Foundation] say, "If you research it and discover it, we will develop it and get it to market." That's a big deal, because that's the risky part that pharmaceutical companies have to do. That's where these drugs have to compete with a diabetes drug or a heart disease drug.

## **Aren't for-profit companies beginning to develop more drugs for tropical diseases?**

Yes. A spark has been lit in the field and people are going back to look at their shelves, to look in their notebooks, to explore projects that were put aside and reviving them. Companies that don't have opportunities in-house are doing a couple of things. Some are working with public-private partnerships to undertake research for new drugs, like the Global Alliance for TB Drug Development or the Malaria R&D Alliance. Others are involved in distribution or development partnerships. We've talked with companies about partnering on distribution or doing pediatric formulations or any number of other elements of their product development. Lots of companies want to get engaged. Global health is no longer seen as an insurmountable problem.

**You're in an industry where people get paid a lot of money – to be a biochemist at a drug company, for example. And you're trying to hire**

**these same people. How do you attract employees?**

It has been hard. There are pharmaceutical scientists who entered the industry because they are healers, and many of them have said: "I can't remember the last time that I felt that my contribution directly benefited humanity. And I can get that by working with you on a daily basis." So some people reach a point in their life, and it may just be for a period of time, where this is what they want to do, and they give up stock options and they give up big bonuses and they even take a cut in their salary. That's who we're looking for, because this is really hard work.

**I assume from this that you can't pay competitive salaries.**

We pay about 75 percent of what they pay at a for-profit drug company.

**Will you ever be able to pay the same as for-profit companies?**

I would like to get to that point. We will never have stock options. And bonuses will be less than in the for-profit industry. But if we generate our own revenues, we can apply those revenues back into the company to retain the best people. Right now we do have some employees who say, "I can only do this for a certain amount of time, but it just means so much to me to be here right now." And if those are people that we really want to keep, we're going to have to step it up in a couple of years.

**What part of the drug development process do you focus on?**

We're in downtown San Francisco, so we don't have a factory and we don't have any laboratories. We partner to do our laboratory work and our manufacturing. We do hold on to the

"D," the development part, where you're doing animal studies and clinical trials. But for the "R," we really do need to partner with the inventors of the technology.

**How difficult has it been to get drug companies and others to give you access to their research and their patents?**

At first it was quite difficult. We had a few donations and offers of a few licenses, but our first product was an off-patent drug. Now we have a very different story. It's not as though every company is stepping forward and saying, "Take whatever you want." But we do have companies saying: "We have millions and millions of compounds. Do you want to use our library, our chemicals, and see if they work for some of your diseases?"

We also have companies who've stepped forward to say: "This drug is on the market for our Western market for disease A, and we know from the literature that for animals it could be effective in this tropical disease B. We'd be willing to consider working with you."

And that's all happened in just a few years. I knew that the industry wanted to do this, and can do this. There just had to be players for them to work with. But it can't just be OneWorld Health. There need to be other players as well whom the industry can work with.

**We've talked about drugs for the developing world. What about drugs for neglected diseases in the Western world?**

Those would be "orphan" diseases, like cancers or neuron-degenerative diseases. There are multiple disease research foundations in the country that have been funded now for a

number of years. The Cystic Fibrosis Foundation is one that has gone on to actually develop products with companies. About 20 of these research-focused foundations have come to us and said: "We think we have something ready for development. Will you do it at OneWorld Health?" And we have said: "No, we won't develop an orphan disease drug at this point. Our focus is on people living in poverty globally. But why don't we help you start a not-for-profit company, or a hybrid company, to get these orphan drug leads moving, and perhaps once they reach a certain stage, maybe you can get a company to take them on?" We may go back and reevaluate whether we want to develop a drug for a Western market, but right now we'd rather help others and share our model and stay focused on global diseases.

**Will we see some of those nonprofits emerge?**

We've helped two nonprofit vaccine companies and two diagnostics nonprofits get started. I do believe that there are some diseases that are best treated without there being a requirement for a return on investment or even a recouping of the R&D costs. The technology's there, the need is there, the passionate expertise is there. It just needs to be housed in something that is a for-profit/not-for-profit hybrid, whatever you want to call it. OneWorld Health's model should have a second generation that has evolved.

Whether OneWorld Health does that – I hope that we do, because I think it could be really fun – or whether we empower others to go out and do that, the more, the better. □