

# A HEALTHY DOSE

Institute for OneWorld Health Newsletter

A Nonprofit Pharmaceutical Company

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## iOWH Makes Strides in Development of Key Treatments

This year, iOWH developed key partnerships that will enable significant advancements in providing treatments to those afflicted by neglected diseases, including malaria, diarrheal diseases and visceral leishmaniasis (VL).

OneWorld Health's Malaria Team is working to diversify the source of artemisinin – a key ingredient in Artemisinin-based Combination Therapies (ACTs). The World Health Organization recommends ACTs as a first-line treatment for uncomplicated malaria, yet the world's supply of artemisinin is currently subject to quality and supply fluctuations due to the fact that it is extracted from a botanical source (a wormwood plant). This inconsistent supply leads to price swings, which can make treatment unaffordable for many impoverished people. To address this problem iOWH entered into a collaboration with the University of California at Berkeley and Amyris Biotechnologies to develop high-quality semisynthetic artemisinin to ensure that there is a second supply of artemisinin to meet the ever-increasing global need. This collaboration is known as "The Artemisinin Project."

The Artemisinin Project has recently expanded its partnership with the addition of a new critical collaborator in this endeavor. Sanofi-aventis, a leading international pharmaceutical company, will provide technical expertise in the area of scale-up and commercial production. If technical milestones are met and the manufacturing process reaches commercial scale, this alternative source of artemisinin would supplement the current plant supply. At peak production, semisynthetic artemisinin could then be used to manufacture a significant portion of global ACT demand.

Furthering our commitment to collaboration, iOWH announced a research partnership with Roche in support of our Diarrheal Diseases Program. Through this agreement, OneWorld Health will have access to compounds in Roche's library, with the goal of finding a potential medicine to treat childhood diarrhea in developing countries. Diarrheal diseases kill almost two million children under the age of five in developing countries each year. The pediatric death toll due to diarrheal illnesses exceeds that of AIDS, tuberculosis and malaria combined.

iOWH has also launched a Phase IV clinical trial for Paromomycin IM Injection. This phase will further investigate the safety and efficacy of paromomycin to treat visceral leishmaniasis (VL), as well as testing an access model for delivery and administration of the drug in rural areas in India's Bihar State. For more information about Phase IV of the VL program, please read the article entitled "Saving Lives: Paromomycin at Work" on page 3.



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# LETTER FROM OUR LEADERS

Dear Friends and Supporters,

I hope you enjoy reading our very first edition of *A Healthy Dose*. All of us at the Institute for OneWorld Health are excited to present this new publication where we will share with you, our valued donors and friends, recent organizational accomplishments and information about our programs.

In this first issue we want to update you on our very important work combating the disease visceral leishmaniasis (VL) in India. As you will read in the article “Saving Lives: Paromomycin at Work” on page 3, iOWH has hired a team of staff dedicated to creating, sustaining and increasing access to the life-changing treatment we developed for VL, even for those in the most remote villages in India. Of course, getting a drug to everyone who needs it is not a simple task, and we have a long way to go before universal access is achieved. However, with a team of experts in place and an on-the-ground study being carried out right now, we are hopeful that this program will ultimately save many lives.

You will also learn about our newest program which addresses the frighteningly common problem of intestinal worms, or helminths. Many people don't know a lot about these harmful parasites or what an impact they have worldwide, which is why we've created a “Did You Know?” section (on page 6) to help create awareness and understanding of helminth infections.

Most importantly, we want *A Healthy Dose* to keep you abreast of the topics that interest you the most. If you are interested in learning more about a particular disease or program, are curious about our business model, or have any other suggestions for content – please let us know!

As you flip through the next few pages and read about the remarkable progress that is being made in our different programs, please keep in mind that none of this work would be possible without the generous support of individuals like you. If you have already made a donation to iOWH this year, we send our sincerest thanks. And if you haven't yet given, I encourage you to do so today. With your support, iOWH will have the necessary resources to accomplish our critically important mission of developing medicines for people with infectious diseases in the developing world.

On behalf of our Board of Directors, staff, and those benefiting from our work, thank you for your support.

Sincerely,



James H. Hickman  
Vice President  
(415) 421-4700



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# SAVING LIVES: PAROMOMYCIN AT WORK

## “I am so happy to see the smile back on my daughter’s face after such a long time”

These are the words of a man whose eight year-old daughter was, until just a few weeks ago, suffering from the deadly disease visceral leishmaniasis (VL) or, as it is known in India, kala-azar. The little girl was severely malnourished and had been sick with VL for several months. It seemed as if the end was near. Fortunately, she was able to get free treatment with a drug called Paromomycin IM Injection, developed by iOWH.

This father had lost his son one year earlier to VL. The son began treatment with another medicine but the treatment was never completed because the family couldn’t afford it, and the boy died. Fortunately for this family, his sister was able to enroll in iOWH’s Phase IV study, through which she received a full course of treatment.

After the 21-day course of medicine, the girl had gained 3 kg (more than 6 and a half pounds) and appeared healthy and active. Dr. Atul Mittal, one of the managers of the study, says that when the girl and her father left for their home village, “the shine was back on her face – she was very cheerful.” Needless to say, her father was thrilled that his daughter was again healthy and happy.

OneWorld Health achieved its first success in taking an already approved antibiotic called paromomycin and developing it into a treatment for VL, an infection that affects hundreds of thousands of people every year in South Asia and Africa. As a result of OneWorld Health’s efforts, Paromomycin IM Injection was approved by the government of India in 2006 to treat VL, and the drug was recently added to the World Health Organization’s essential medicines list.

iOWH has recently embarked on a project to expand access to this new treatment. A team of public health experts, both at iOWH headquarters in San Francisco and the India office in Patna, the capital of Bihar State, is developing a model for delivery and administration of Paromomycin IM Injection in resource-constrained areas of India.

OneWorld Health has treated more than 500 patients for VL thus far through seven main health centers in urban areas. Now, several more satellite centers in mid-sized towns are also participating in the study and are treating patients. iOWH equipped these centers with the skills and medical materials, such as drug supplies and safe syringes, needed to administer the treatment. iOWH trained the clinic staff in correct administration of the drug and proper maintenance of medical records for the patients. Since many of the patients live far from the urban health centers and because the treatment is a 21-day course, iOWH secured guest houses near the clinics where a patient and a family member may stay during treatment.

Says Dr. Mittal, “The clinics feel proud to be associated with OneWorld Health and grateful for assistance in building their overall clinical capacity.” The study goal is to initiate several satellite centers as well as additional outreach centers located closer to the village level so that patients do not have to travel far to get care.



## VL Facts

- Visceral Leishmaniasis (VL) is an infection caused by parasites and transmitted by sandflies.
- Symptoms of VL include chronic intermittent fever, weight loss, anemia and enlargement of the spleen and liver.
- When left untreated, VL is almost always fatal.
- VL currently occurs in 62 countries, primarily in the developing world.
- With approximately 500,000 new cases occurring annually, VL is the world’s second most deadly parasitic disease, after malaria.
- Bihar State, the location of iOWH’s India office, is the epicenter of the disease in India, with an estimated 250,000 people infected there each year.

# YOU CAN HELP



The Institute for OneWorld Health depends on contributions from generous individuals like you to carry out our life-changing work. Our priority needs for this year are described here. Please make a gift today!

#### **Advocacy and Communications:**

Diarrhea, VL, worms and malaria are called “neglected” diseases for a reason. The global community is largely unaware of the enormous burden of these ailments, as well as many other tropical infectious diseases. OneWorld Health’s advocacy and communications team is working to raise awareness and convince governments around the world to invest in the elimination of neglected diseases. Your gift will help us bring attention and resources to the impoverished people who needlessly suffer from these illnesses.

#### **Diarrheal Diseases Program:**

Help iOWH’s Diarrheal Diseases Team study resistance of *Shigella* to current antibiotic treatments. These studies will inform our efforts to develop new drug combinations to combat dysentery, one of the deadliest of the diarrheal diseases.

#### **Intestinal Worms (Helminth) Program:**

OneWorld Health’s newest initiative seeks to provide a new de-worming treatment for children and adults in the developing world. Helminths, or intestinal worms, affect one third of the world’s population, creating a huge health and economic burden for many communities across the globe. Please read more about helminth infections in the “Did You Know?” article on page 6, and make a donation to help OneWorld Health develop a new drug to treat these worms.

#### **New Program Development:**

OneWorld Health’s commitment to saving lives goes beyond our current four disease programs. We are constantly evaluating the burden of other neglected diseases and the treatment gaps that exist, while working with pharmaceutical companies and research centers to identify promising compounds that could be made into new treatments. You can help iOWH add a new drug candidate to our pipeline by contributing today.

To make a donation, simply mail a check to  
The Institute for OneWorld Health,  
50 California St, Ste. 500,  
San Francisco CA 94111,  
or visit [www.oneworldhealth.org](http://www.oneworldhealth.org)  
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**“Philanthropy is almost the only virtue which is sufficiently appreciated by humankind.”**

—Henry David Thoreau

Creating an estate plan is like building a structure. You spend your lifetime gathering materials – tangible possessions such as your home, plus intangible assets such as stocks. You find tools – a will, trusts, and a life insurance policy – with which to work. You develop blueprints – strategies that provide for the needs of your beneficiaries and save taxes – to guide you. Building a sound estate plan may also require the skills of an attorney, an accountant, a financial advisor and a gift planning officer. While this article cannot lay out a blueprint for you, it will provide some information about one tool that is available to help you build an effective estate plan – a valid, up-to-date will.

A will is probably the single most important document for ensuring that your wishes are carried out after your lifetime. If you die without a will, a situation known as dying intestate, the distribution of your estate is determined by the laws of your state. Dying without a will means you give up your right to determine who receives what, how and when. Assuming that the law will do a satisfactory job for you is very unlikely for a simple reason: the law has general rules that apply to every situation, regardless of special circumstances.

Potential problems can be illustrated by some examples. In the case of a man survived by a wife and minor children, state law may give a substantial portion of his estate to the children – instead of all to the wife, who is responsible for caring for the children. Or, upon the death of one spouse with no children, a portion of the estate may go to the decedent’s parents instead of all to the surviving spouse.

Unless you have a valid, up-to-date will, the state can’t know and won’t try to figure out your wishes.

An up-to-date will is a valuable tool for estate planning, but there are also many other strategies available. Whatever strategy you choose, charitable gifts result in considerable tax savings. There is an unlimited estate tax deduction for gifts to qualified organizations. The benefits also include income tax deductions, avoidance of capital gains tax, improved rates of return on assets, tax-favored income, and reduction or elimination of estate taxes otherwise payable.

We would be pleased to discuss your plans and provide you with additional information—at no obligation, of course. If you would like more information, please contact our fund development office via email at [donate@oneworldhealth.org](mailto:donate@oneworldhealth.org) or by phone at (415) 421-4700.

The information in this publication is not intended as legal advice. For legal advice, please consult an attorney.

## DID YOU KNOW?

# The Intestinal Infection Affecting One Third of the World's Population



**D**id you know that one third of the world's population suffers from intestinal worms? Scientists call these worms soil-transmitted helminths – and there are many different species. Basically, helminths are intestinal parasites that infect human hosts and feed off the body's nutrients. While helminths infect both adults and children in the poorest regions of developing countries, the health impact is the greatest among young children and pregnant women.

Typically, people who get infected with worms are those with minimal access to health care and who lack a safe water supply for drinking and sanitation. The infection is often transmitted through soil, hence the term "soil-transmitted helminths," and can also spread through contaminated water or food that contains worm larvae or eggs. Young children who play on the ground often put their unwashed hands in their mouths, ingesting the larvae or eggs and becoming infected. The parasites enter the body and live inside the digestive tract, leading to ailments such as abdominal pain, diarrhea, intestinal obstruction, anemia, ulcers, and various other health problems. The worms mature and lay eggs, all the while consuming the body's essential nutrients.

Because helminths disrupt nutrient absorption, they can cause malnutrition, especially in populations already prone to undernourishment due to their economic status. Patients also show weakened immune systems and children suffer from slowed development. Children

with worms may also be too weak to go to school, which has a negative impact on their intellectual development. Worse yet, helminth infections may weaken immunity to other infectious diseases such as malaria, thus exacerbating the occurrence of those diseases. If not treated, helminth infections can indirectly contribute to a significant number of deaths.

Four drugs are currently recommended by the World Health Organization to treat helminths, though only two are routinely used. These de-worming treatments were adopted from veterinary medicines more than 30 years ago. Unfortunately, recent studies indicate that these drugs may be losing their effectiveness, raising concern that parasite resistance to these medicines may be emerging. Thus, safe and affordable new drugs are urgently needed to ensure the long-term success of control efforts.

The Institute for One World Health aims to develop new treatments for intestinal infections caused by soil-transmitted helminths. Once developed, the drug or drugs will become part of the global control efforts through mass distribution in schools. De-worming treatment not only improves the health of the individual, it benefits the entire community. Communities with healthier children, strengthened immunity to fight malaria and other infectious, and an improved ability to learn and work can thrive economically and socially.

# THANK YOU

## BBC World Viewers Vote Film Featuring OneWorld Health Year's Best Documentary

The BBC World documentary *Kill or Cure? Kala-Azar 2* featuring OneWorld Health, was voted Best Documentary by BBC World viewers in early 2008. Focusing on the disease visceral leishmaniasis (VL), which in India is known as kala-azar, the film chronicles the story of Dilip, a 13 year old boy from India who received treatment with Paromomycin IM Injection, iOWH's treatment for VL, and made a full recovery.

BBC World first filmed Dilip in 2004 when his family agreed to participate in

a Phase III clinical trial of Paromomycin IM Injection. The film revisits Dilip in 2007 as a healthy and active young man, thriving on his cricket team. *Kill or Cure* is a series covering the hunt for effective and affordable treatments for people earning less than a few dollars a day.

Watch both parts of *Kill or Cure? Kala-Azar* on iOWH's website, or on YouTube – just search for OneWorld Health.



## Thank You to Our Most Recent Funders

**“iOWH aims to develop new antimicrobial drug combinations to address increasing antibiotic resistance to *Shigella*, a group of bacteria that causes dysentery, or bloody diarrhea.”**

**The Annenberg Foundation** recently awarded iOWH a \$175,000 grant for our Diarrheal Diseases Program (DDP). iOWH aims to develop new antimicrobial drug combinations to address increasing antibiotic resistance to *Shigella*, a group of bacteria that causes dysentery, or bloody diarrhea. Support from the Annenberg Foundation will allow iOWH to obtain clinical samples of *Shigella* from endemic regions and test these samples to better understand resistance in geographic regions with high need. This funding will also allow iOWH to evaluate the activity of promising new drug combinations for testing in future clinical trials.

**The Lehman Brothers Foundation** awarded a second grant of \$100,000 to iOWH, in support of our Diarrheal Diseases Program. A portion of this grant underwrote an iOWH-sponsored symposium at the 45th National Conference of the Indian Academy of Pediatrics held in Orissa, India this past January. At this conference, also known as PEDICON, iOWH brought together a panel of experts who highlighted clinical and programmatic evidence of the success of zinc as an effective therapy for diarrheal diseases, a critical health issue that disproportionately affects impoverished populations. This symposium enabled iOWH to further educate pediatricians in India about the important role of zinc in treating diarrheal diseases.



## Photos From the Field

View more photos by Jonothan Torgovnik on our website at [www.oneworldhealth.org](http://www.oneworldhealth.org)



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