

A HEALTHY DOSE

Institute for OneWorld Health Newsletter

A Nonprofit Pharmaceutical Company

Issue #2 | Spring 2009

Overcoming Obstacles to Provide Access to Treatment in India

By Karen Schlein, Project Manager, Access, San Francisco & Somesh Kumar Singh, Study Monitor, India



When you think about the process of identifying new sites for our clinical trials, you probably imagine our staff making a few phone calls to known clinics in the area, searching through a database of local physicians or setting up meetings with specialists who clearly advertise their capabilities.

However, when you are tasked with identifying sites in less developed areas of the world, such as Bihar, India, one of the country's poorest states, to participate in a trial for visceral leishmaniasis (VL), the process is slightly more challenging:

At 6 a.m. in mid-July 2008, two iOWH employees, Somesh Singh and Rupabh Srivastava, set out with a driver, Ramu Rai, from Patna, the capital of Bihar, to the district of Sitamarhi, 72 miles away. July falls in the middle of the monsoon season; besides the near 100°F heat and the inclement weather, the team knew they might well run into other obstacles, such as accidents and road closures due to flooding, that would make their task a day-long venture.

After driving for 6 hours, the team was finally nearing the one-room clinic located in Sitamarhi, where VL is endemic. The heavy rains had destroyed the dirt road leading to the clinic, leaving only a muddy trail behind. The team didn't want to return home empty handed so they pushed on but before long, they found themselves stuck. What initially looked like a submerged wheel was actually a back bumper fully entrenched in mud. Unable to find help, Somesh and Rupabh began clearing away a path with their hands and what other crude tools they could find in the vehicle. It took the efforts of all three team members to dig out the bumper, fill the wheel ditch with stones and push the vehicle out of the mud trap. From there, it still took another hour finally to reach the clinic.

In Bihar, road conditions like this are all too common and present a major obstacle to receiving life-saving treatment. Not only can it be costly to travel to a health center, but the extensive travel time forces many to miss work, days for which they are unable to earn much needed income. VL is a disease that disproportionately affects the poor. The disease vector is the sandfly, which thrives in areas of high moisture and livestock—where the poorest Biharis live. In order to reach the people who suffer from VL, iOWH is attempting to expand treatment beyond the urban areas.

[Continued on Page 9]



Letter from the CEO

Dear Friends and Supporters,

As the new CEO of the Institute for OneWorld Health, I am excited to join an organization that is developing medicines for children and families suffering from preventable and treatable diseases of poverty in the developing world. As a child growing up in underdeveloped Korea, I was vaccinated by the World Health Organization. This experience taught me, at an early age, the important role that people in the US and around the globe can play in improving a child's life in the developing world.

As CEO of iOWH, I have the opportunity to lead our organization and help save millions of lives. It is a role that I have been preparing for, from the very beginning of my career as I pursued my medical degree, and later while developing my expertise in drug development with various companies. It is an honor to lead OneWorld Health into its next phase of growth and development and to do so with such a dedicated, passionate and accomplished team.

As you read this newsletter, I hope you get a sense of both the challenges and opportunities that lie before us. Only 10% of worldwide expenditure on health research and development is devoted to the problems that primarily affect the poorest 90% of the world's population. You will find articles in this issue that explain how our current program areas are bridging this gap as we work to develop safe, effective, affordable new medicines for diarrheal diseases, visceral leishmaniasis (VL), malaria, and soil-transmitted helminths as well as address issues related to access to medicines and global health advocacy.

The success of these programs hinges upon the generous contributions of our donors, partners and supporters. My recent trip to iOWH's field office in India underscored my belief that, as we find ourselves amidst a global economic downturn, support from individuals, corporations and foundations is more important now than ever. As governments of developed countries are forced to shrink the amount of foreign aid to the developing world, we as a community must take action.

There are many ways you can help us sustain our life-saving work. I encourage you to visit our website to learn about opportunities to volunteer your time, make a donation, help iOWH expand our network of supporters, or approach your employer about initiating a partnership with iOWH.

iOWH has made great strides in less than a decade. I assure you that we will continue to develop new treatments for those most in need and I acknowledge you for your shared conviction that the promise of modern medicine must be accessible to all.

Sincerely,

Richard Chin, M.D.
Chief Executive Officer



Institute for OneWorld Health

50 California Street, Suite 500
San Francisco, California 94111
tel: (415) 421 4700
fax: (415) 421 4747
email: info@oneworldhealth.org
www.oneworldhealth.org

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For more information on Richard Chin, read *The San Francisco Business Times* article, "Care for the Millions" at http://www.iowh.org/news_coverage

Thank You, Ahvie Herskowitz, iOWH Co-Founder

By Susan Moriconi, Vice President of Human Resources



Ahvie Herskowitz founded the Institute for OneWorld Health with Victoria Hale in 2000, based on their shared vision of bringing the promise of medicine to those most in need. As co-founders, each brought unique gifts to the new organization.

In Ahvie's case, his medical background was an essential underpinning of the organization's success. However, the new venture required that he not only rely on his training and experience, but also broaden his knowledge in areas such as infectious diseases. Equally important, he recognized the need to build and sustain relationships

critical to our work in India. In part due to his efforts, iOWH developed relationships that evolved into true partnerships with people and governmental groups as well as funders who make our crucial work possible.

Because of his contributions in the medical and partnerships areas, Ahvie's work on the business side of iOWH might be overlooked. In fact, the organization has benefited greatly from his ability to bring institutional memory to a business discussion without overlooking today's realities and coupling it with his recognition of the need to make difficult decisions.

Insightful about the "how" of running iOWH, he also had a gift about the "who," particularly when it came to evaluating candidates not only in terms of their skills and

experience, but also their "fit" for our mission and team. I was one of those candidates Ahvie interviewed, later benefiting from his generosity in making time to share his insights and guidance. Together, we interviewed and made recommendations about key hires, sharing our excitement when we knew we had found "the right one" for a critical position.

Ahvie served in a number of roles during his time with iOWH, including CEO and CMO. During my time at iOWH, Ahvie was my manager, my colleague and my source of organizational history. My hope is that I can continue to help move iOWH to its next stage by continuing to identify those "right ones," using the same prism that Ahvie and I used together. In this way, I hope to honor his spirit and wishes for the organization going forward because, as I know Ahvie would say, it is all about the people...those who work here as well as those we serve.

iOWH Advocates for Global Public Health

Neglected diseases are characterized as such, in part, due to the lack of awareness of the unmet medical need faced by the developing world. As part of iOWH's commitment to global advocacy, we attended the UN hosted conference, Special Event on Philanthropy and the Global Public Health Agenda, in New York, on February 23, 2009. The event brought together leaders from foundations, corporations, government and non-profits to discuss raising the profile of neglected tropical diseases as well as ways to strengthen partnerships towards achieving the Millennium Development Goals. In his closing remarks, former US President Bill Clinton noted the extraordinary need, particularly during the current economic crisis, to focus on the effectiveness of public health interventions.

STAY TUNED

iOWH will be enhancing our website in 2009. Please check back periodically for fresh content including videos from India, our 2009 Special Event in San Francisco, donor testimonials and new partnerships.

www.oneworldhealth.org

You Can Help

Collectively we have the knowledge, the resources and the skills to alleviate the burden of disease in the developing world. With every new individual that stands behind our efforts, we illustrate to the world that we now have the final and most important ingredient—the will—to bring an end to diseases of poverty. Please make a contribution, in any way that you can, and help iOWH bring the wonders of modern medicine to those most in need.



Donors Respond – My Commitment to iOWH

“Having worked in a healthcare company for nearly a decade, I have great passion for the work we do and the ability to improve lives every day. My husband and I spent two years working in China and throughout our travels in Asia and volunteer efforts, we saw the need for the work of iOWH first hand. I read about the Institute for OneWorld Health a few years ago and was excited at the prospect of a non-profit pharmaceutical company. Beyond my company’s global portfolio, there are a host of diseases that disproportionately affect those in the developing world. By supporting iOWH, I feel we can work together to make up that gap.”

–Nithya Desikan-Robertelli, iOWH donor

“I come from India, where approximately 27% of the population is below the poverty line, most of which exists in the rural parts of the country. iOWH’s recent success in getting Paromomycin approved as a low-cost therapeutic agent for kala-azar and its research in

TAKE ACTION

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50 California St, Ste. 500
San Francisco CA 94111

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Visit: www.oneworldhealth.org/donate

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apps.facebook.com/causes/1870

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Talk to your legal advisor about
planned giving options

SPREAD THE WORD

Write an article about iOWH in your
company’s internal newsletter

WORKPLACE GIVING

Ask your employer about iOWH and
their corporate giving program

VOLUNTEER

Email volunteer@oneworldhealth.org
for more information.

VISIT OUR WEBSITE TO FIND OUT HOW TO:

- Share Research
- Sign up to receive updates

*For more information about how you
can help, please call (415) 421-4700
or e-mail donate@oneworldhealth.org.*

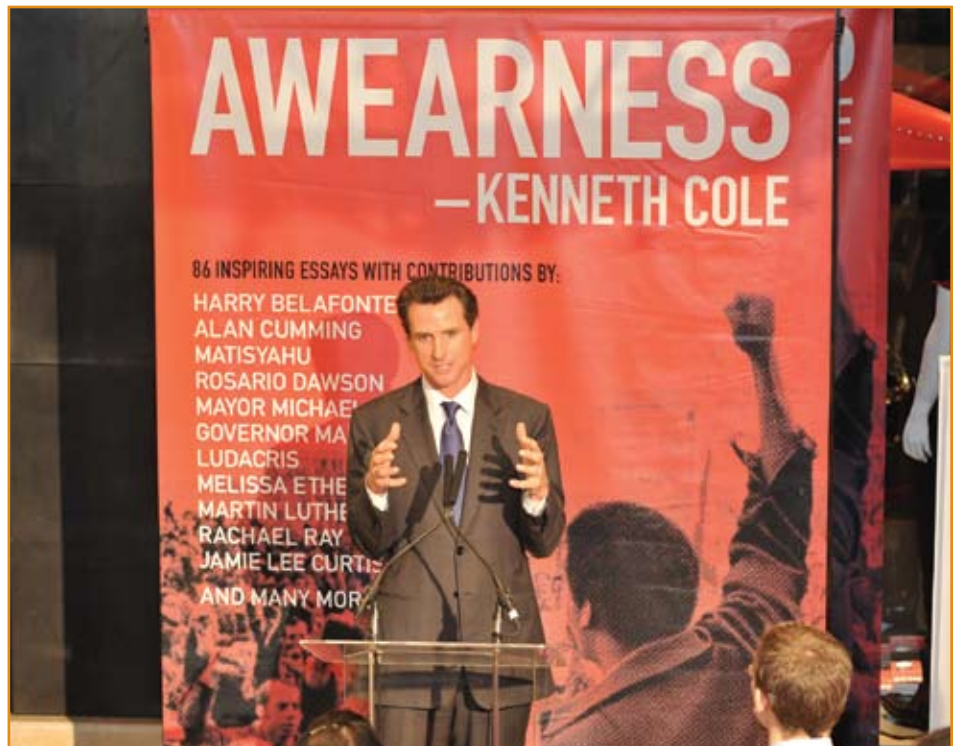
rural areas will hopefully provide new and effective options in resource-constrained rural settings in the Indian subcontinent. Being a member of the pharmaceutical community, I appreciate iOWH’s scientific endeavor and its mission towards global health is important to me.”

–Jaya Pisupati, iOWH donor

*To share why you are committed to iOWH,
please email alesperance@oneworldhealth.org*

Kenneth Cole's AWEARNESS Features iOWH Founder, Victoria Hale

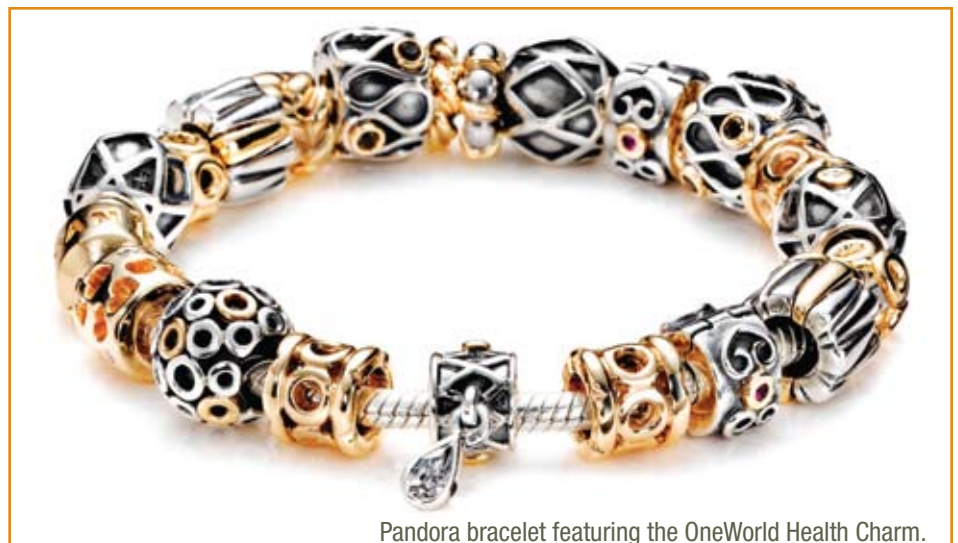
Last fall, iOWH joined Kenneth Cole, San Francisco Mayor Gavin Newsom, and Robert Redford, among other prominent changemakers, to celebrate the launch of *AWEARNESS: Inspiring Stories About How to Make a Difference*. Edited by longtime advocate and designer Kenneth Cole, *AWEARNESS* is an inspiring collection of stories and conversations by eighty-six individuals who have effected meaningful social change. The launch party was held in Kenneth Cole's Union Square store in San Francisco to honor Bay Area *AWEARNESS* contributors, including iOWH founder, Dr. Victoria Hale, whose essay is featured in the book. To stay updated and receive invitations to events like this, go to: www.oneworldhealth.org/stay_informed.



Mayor Gavin Newsom speaking at the AWEARNESS Launch in San Francisco.

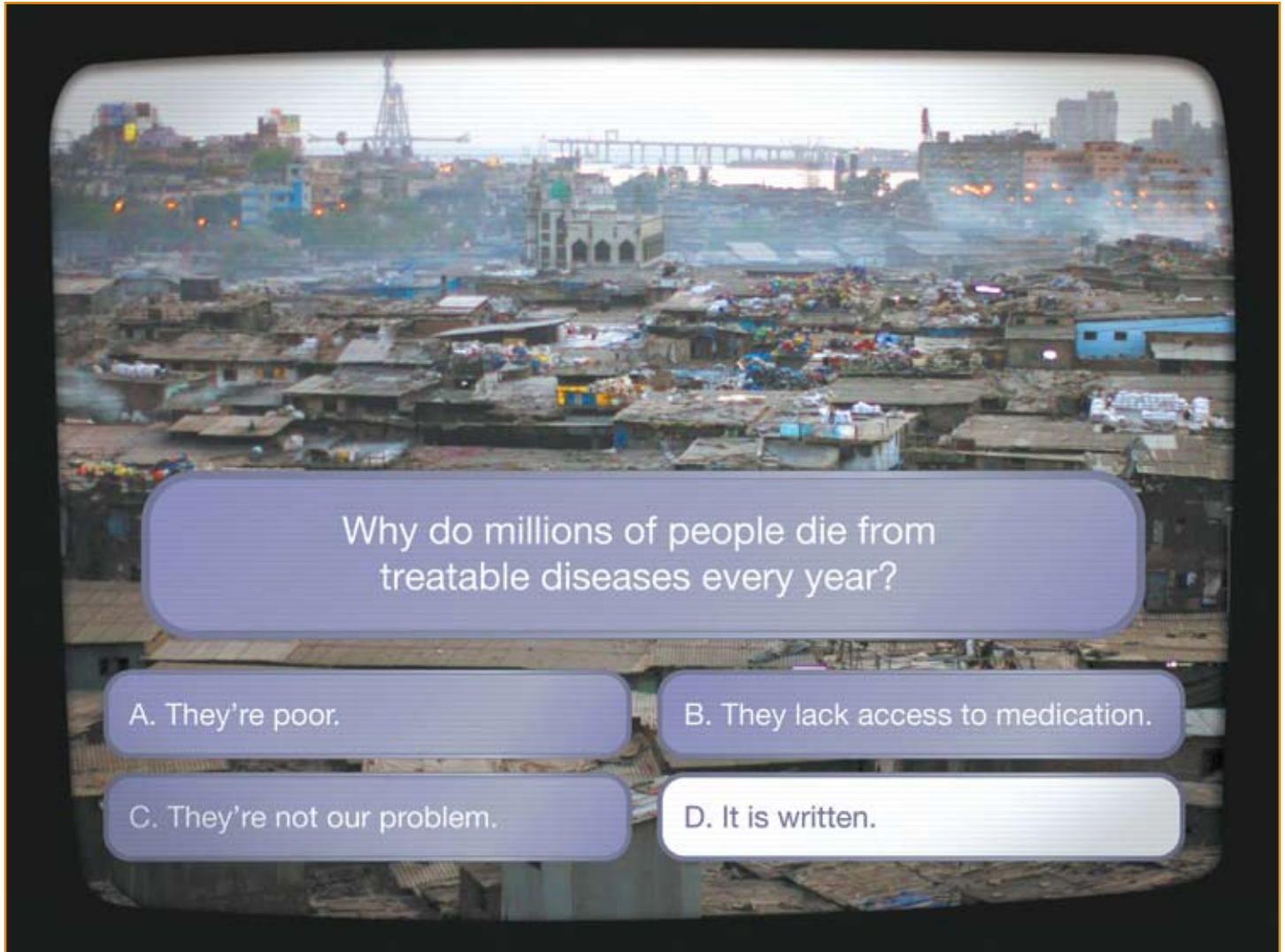
Charm your Mother and Save a Life: iOWH Partners with Pandora Jewelry

OneWorld Health thanks Pandora Jewelry for designing a OneWorld Health-inspired charm and donating \$20 from the sale of each charm to iOWH. The charm's sparkling water drop shape dangling underneath the charm is a symbol of the lifesaving hope OneWorld Health provides with every drop of medicine it develops for those who need it the most but can afford it the least. Pandora is taking their commitment to global health and iOWH one step further this Mother's Day, when participating Pandora retailers will be promoting the OneWorld Health charm as the ideal "do-good-and-look-good" Mother's Day gift. To learn more, visit www.oneworldhealth.org.



Pandora bracelet featuring the OneWorld Health Charm.

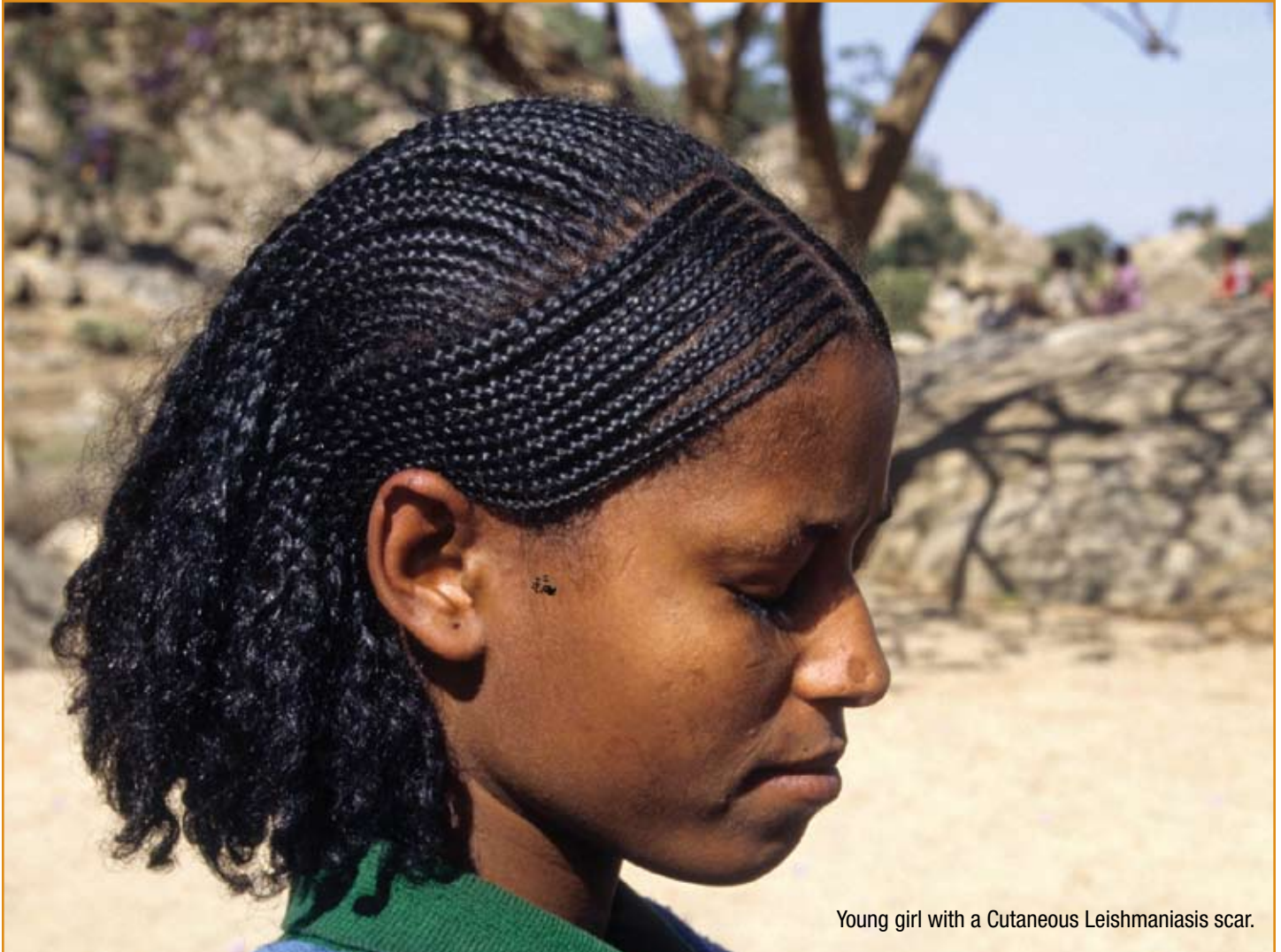
iOHW in *The New York Times*



Can This Year's Feel-Good Movie Do-Good, Too?

On Monday, February 23, OneWorld Health ran a full-page display advertisement in *The New York Times* inspired by the highly acclaimed Oscar-winning film, *Slumdog Millionaire*. Using this unique window of opportunity to leverage America's heightened interest in the developing world, we launched a creative campaign that includes online promotions, social media, and media outreach to raise awareness of neglected diseases. How the Western world channels its enthusiasm for *Slumdog Millionaire* into meaningful action will be the test of whether this feel-good movie can do good, too. To view the full-page as seen in *The New York Times*, visit www.oneworldhealth.org.

Introducing Leishmaniasis Worldwide Eco-Epidemiology DVD



Young girl with a Cutaneous Leishmaniasis scar.

■ OWH is offering complimentary copies of this public health photo DVD collated by Dr. P. Desjeux. The disc is a database of 850 images illustrating the leishmaniasis main eco-epidemiological entities in 26 countries. The images were taken by Dr. Desjeux over 30 years of field work on Leishmaniasis including 20 years with the World Health Organization. To request a free copy of the DVD go to www.oneworldhealth.org/stay_informed and enter 'Please send me a free Leishmaniasis DVD' in the comments section.



Thank You

The Skoll Foundation has been a generous funder and integral partner to The Institute for OneWorld Health for the past four years. Starting in 2005, the Skoll Foundation provided seed funding for iOWH as part of the Skoll Awards for Social Entrepreneurship. Over the years, their support has enhanced our capacity to become a mature organization and enabled us to expand our drug development model within the global health community.

“We wish to extend our sincere appreciation to Jeff Skoll, Sally Osberg, Lance Henderson and the Skoll Foundation staff with whom we have worked over the years, for their unwavering support.”

The value of unrestricted funds from a funder and partner like the Skoll Foundation has been vital to building iOWH's infrastructure. By the end of 2009 total contributions from the Skoll Foundation will amount to over \$1.3 million. In addition to funding, the Skoll Foundation brings together partner organizations at the annual *Skoll World Forum* in the U.K. This forum provides an invaluable opportunity for learning about issues facing the global community and the

value of social entrepreneurship, the bedrock upon which iOWH was founded.

We wish to extend our sincere appreciation to Jeff Skoll, Sally Osberg, Lance Henderson and the Skoll Foundation staff with whom we have worked over the years, for their unwavering support. Our partnership has been deeply gratifying and we are a much stronger organization today because of their commitment to our work.



Paul Nakagaki, Ph.D.

The Institute for OneWorld Health is indebted to Paul Nakagaki, Ph.D. for his kind and generous contribution in strengthening and advancing our corporate strategy to carry out our mission over the next five years. Dr. Nakagaki took a secondment from Roche Pharmaceuticals, Basel, Switzerland to work with iOWH for seven months. As the former head of the Roche Research Strategy Group, as well as the Pharma in 2015 Project Office, Dr. Nakagaki worked closely with the executive and senior program staff at iOWH to lay the groundwork for developing our long range plan and assess and prioritize key areas for corporate strategy development.

The employees of iOWH wish to thank Dr. Nakagaki for his time, dedication, and contribution. We also thank Roche Pharmaceuticals for permitting Dr. Nakagaki his leave of absence.

CONTINUED FROM PAGE 1

iOWH Overcomes Obstacles to Access

iOWH recently conducted a series of field surveys, in conjunction with Rajendra Memorial Research Institute of Medical Sciences, to understand the challenges of those in the rural population who suffer from VL. The research found that, in Bihar, the economic impact of VL on a family can be long term. On average, an individual would spend \$137 (5,600 Rs) on getting treated for VL. Since the average daily wage in Bihar is \$1 a day, this represents an estimated 5 months of an individual's average annual income. Moreover, families who take out a loan to pay for treatment are likely to be repaying their debt far into the future.

Additionally, oftentimes patients with VL are misdiagnosed with another illness like malaria and thus take medicines that do not alleviate their suffering, while adding to the treatment costs. This problem was demonstrated in study results that showed 10-15% of the total cost of treatment for a patient with VL was incurred prior to being correctly diagnosed with VL. The finding implies that the lack of timely VL diagnosis is another key barrier to earlier treatment.

After an extensive site evaluation process, certain clinics were selected to participate in the Phase IV VL study being conducted by iOWH. The clinic staff have since attended training at the iOWH field office in Patna, India for education on topics including diagnosing VL, adhering to Universal Precautions for Infection Prevention, and administration of informed consent to study participants. The iOWH team is pleased that their extra effort to reach these clinics is improving access to VL treatment for those most affected by the disease.



iOWH India office employees, Somesh Kumar Singh, Study Monitor and Rupabh Srivastava, Senior Coordinator, Site Readiness.



Program Updates



Visceral Leishmaniasis

Since our inception, iOWH has taken an off-patent antibiotic, paromomycin, and repurposed it for use as a safe, effective, and affordable treatment for Visceral Leishmaniasis (VL), a parasitic disease with lethal consequences if untreated. IOWH completed a Phase III clinical study in India for Paromomycin IM Injection as a new treatment for visceral leishmaniasis and, in August 2006, Paromomycin IM Injection received regulatory approval by the Drug-Controller General of India. The drug was designated by the World Health Organization in May 2007 for inclusion on its Model List for Essential Medicines. In November 2007, iOWH initiated a 500-patient Phase IV pharmacovigilance study to obtain additional safety information in advance of government adoption. In February 2008, iOWH initiated a 500-patient public health access study to evaluate strategies to improve access to treatment in rural areas. Our goal is to get a safe and effective treatment to those who need it the most. Currently, we are actively engaged with global stakeholders and the Government of India to facilitate the adoption of Paromomycin IM injection uptake into the Government of India's public health program.

Malaria

According to the World Health Organization, malaria is estimated to cost sub-Saharan Africa approximately 1.3% of its Gross Domestic Product (GDP), or about USD 12 billion, in direct losses each year resulting from illness, treatment and premature death. In our Malaria Program, we are working in collaboration with synthetic biology innovators the University of California, Berkeley and Amyris, and our newest partner, pharmaceutical company sanofi-aventis, to develop a semisynthetic form of artemisinin. Artemisinin is a key precursor to one of the active ingredients used in the World Health Organization's recommended treatment for malaria, artemisinin-based combination therapies (ACTs). The goal of this collaboration, known as the Artemisinin Project, is to create a complementary



Jonathan Torgovnik © 2006

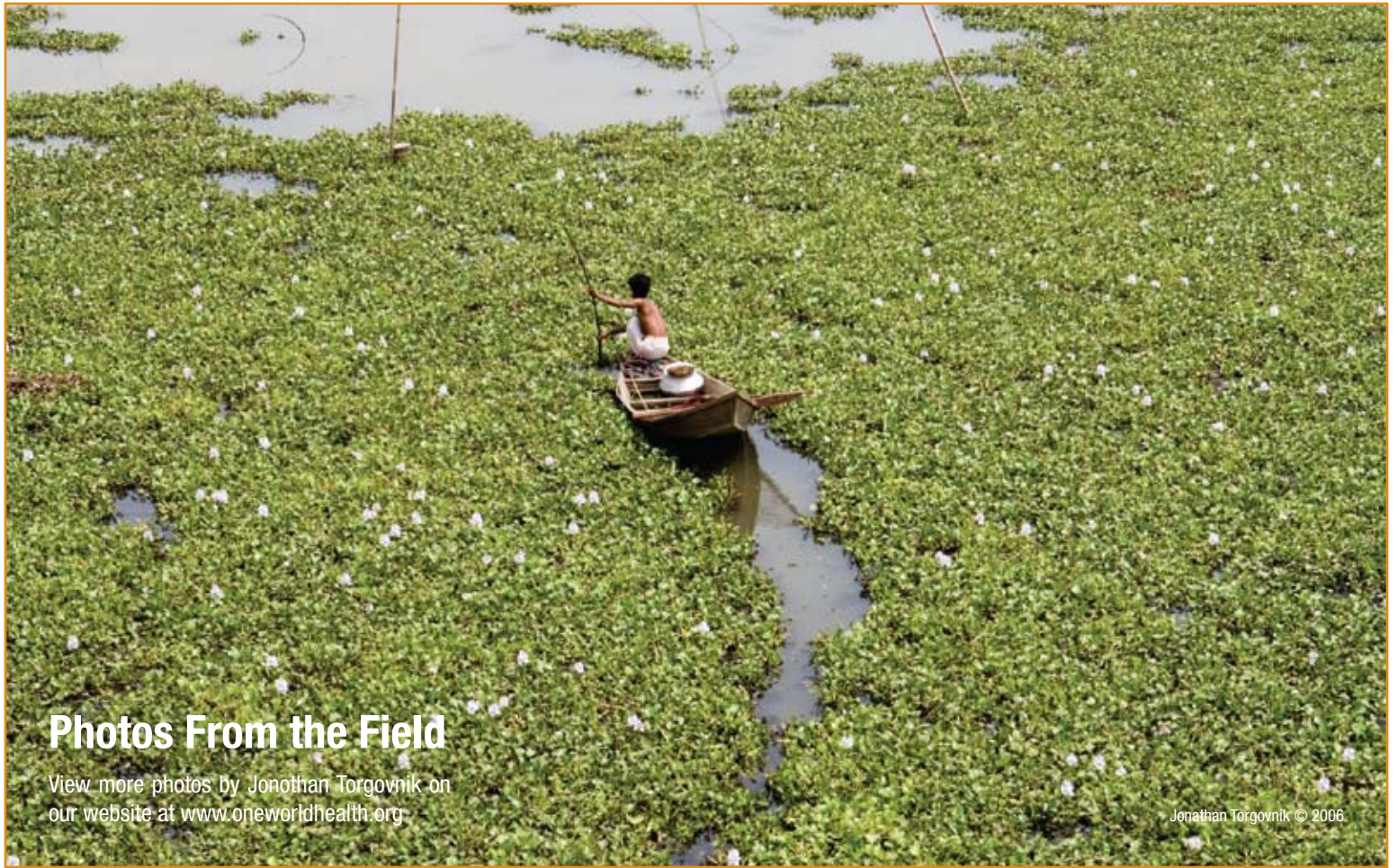
Gastrointestinal Diseases

source of non-seasonal, high-quality, and affordable artemisinin to supplement the current botanical supply and stabilize the supply chain. This will ultimately make treatment more accessible to the hundreds of millions of impoverished people who contract malaria each year. To learn more go to: www.theartemisininproject.org.

Gastrointestinal or “GI” diseases represent iOWH’s most expansive program and includes a portfolio of diseases such as diarrheal diseases and soil-transmitted helminths. Diarrheal diseases remain the second largest killer of infants and children in developing countries, with a mortality rate exceeding that of AIDS, malaria, and TB combined. Our work has initially been focused on developing new drug candidates that reduce intestinal fluid secretion. The intention is to reduce fluid loss and dehydration in acute watery diarrhea, thereby reducing deaths in childhood diarrhea, particularly from cholera and *E. coli* infections. The new drug would be co-administered with Oral Rehydration Salts (ORS), and it is expected that this combination will increase the usage of live-saving ORS.

We have recently broadened the scope of our diarrheal diseases program to include new projects: iOWH has identified a significant unmet medical need in the treatment of drug-resistant *Shigella* (dysentery). The Shigellosis initiative aims to identify and pursue novel drug strategies to create new tools that will counter the problem of increasing bacterial resistance.

Another area of GI diseases we are evaluating is soil-transmitted helminths, commonly known as intestinal worms, that infect over 1 billion people worldwide. The interaction of chronic worm infections and repeated episodes of diarrhea contributes significantly to malnutrition and negatively impacts physical and mental growth and development, particularly in children.



Photos From the Field

View more photos by Jonathan Torgovnik on our website at www.oneworldhealth.org.

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50 California Street :: Suite 500
San Francisco, California 94111