Managing IP for Access in Global Health and Development

WIPO eTISC

Richard Wilder
Associate General Counsel – Global Health

June, 2013

BILL & MELINDA
GATES *foundation*

Overview

- Introduction to the Bill & Melinda Gates Foundation

- Overview of Global Health Program

- Legal Form of Investments by Foundation

- Management of IP and Global Access

- Questions

Every person deserves the chance to live a healthy, productive life.

Our History

1998	2000	2006	2008

Bill and Melinda read an article about rotavirus.

They officially create the foundation.

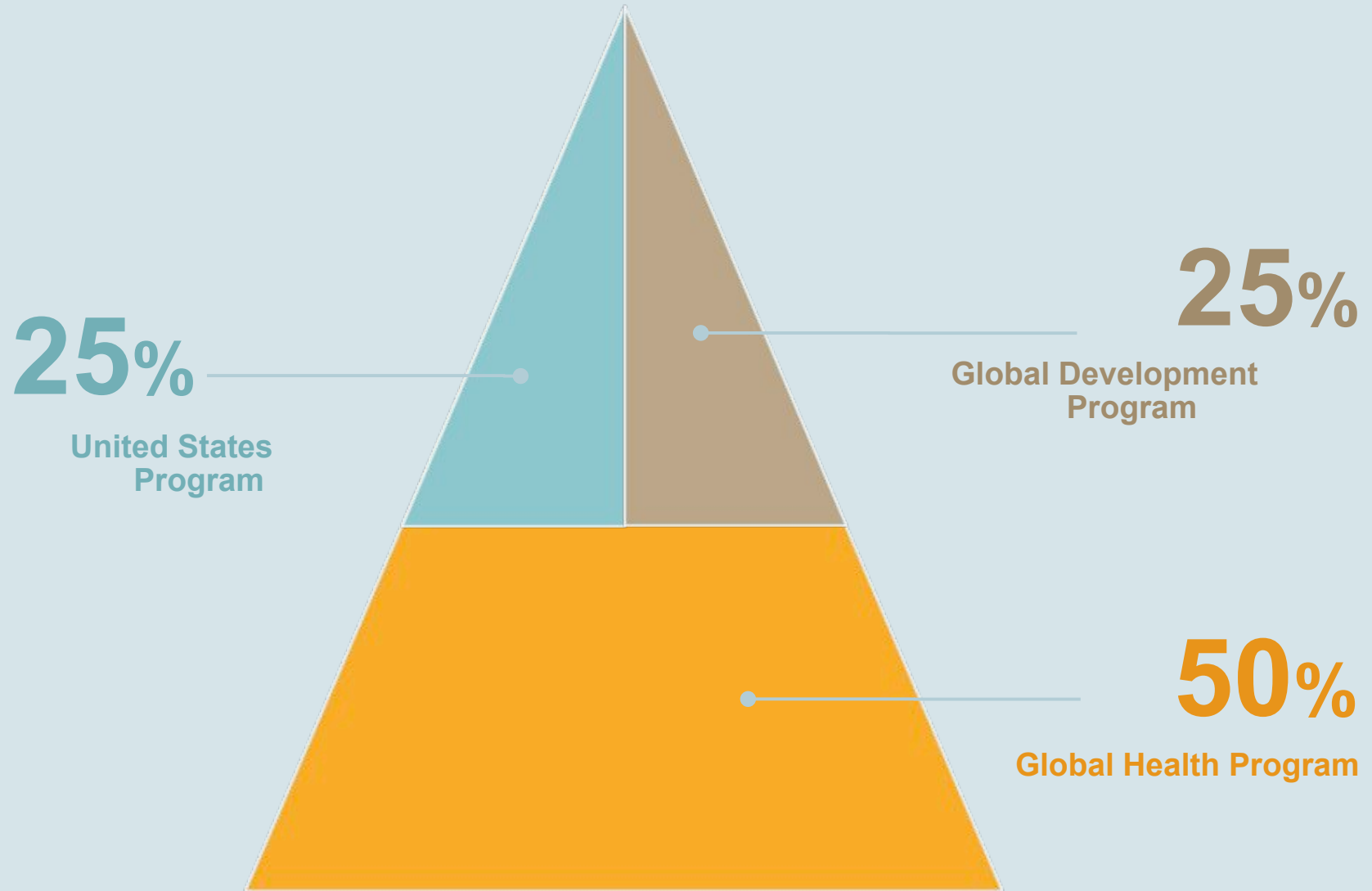Warren Buffett decides to give Berkshire Hathaway stock.

Bill joins Melinda full-time at the foundation.

What We Focus On

What affects the most people with the most urgent needs?

Where can we make the greatest impact?

Our Areas of Focus

25%

United States Program

25%

Global Development Program

50%

Global Health Program

Our Approach to Giving

Four Steps:

Develop Strategy

Make Grants

Measure Progress

Adjust Strategy

1 Develop Strategy

2 Make Grants

3 Measure Progress

4 Adjust Strategy

GLOBAL DEVELOPMENT PROGRAM

TOGETHER WE WILL COMBAT POVERTY WITH BETTER AGRICULTURE.

By 2025, working with partners, we aim to help **150 million** of the world's poorest families **lift themselves** out of extreme poverty.

Areas of Focus

Increasing opportunities for the world's poorest people to lift themselves out of hunger and poverty.

Agricultural Development	**Helping small farmers boost their productivity, increase their incomes, and build better lives.**
Financial Services for the Poor	**Expanding access to safe, affordable financial services—especially savings—in developing countries.**
Water, Sanitation, and Hygiene	**Providing hundreds of millions safe and sustainable access to sanitation and improving the quality of their water and hygiene.**
Global Libraries	**Providing free access to computers and the Internet in thousands of public libraries in emerging economies.**
Special Initiatives	**Pursuing other ways of making focused, innovative, and results-driven investments in partnerships we believe can have an impact on people's lives.**

GLOBAL HEALTH PROGRAM

TOGETHER WE WILL SAVE THE LIVES OF MILLIONS OF CHILDREN.

By 2025, we will immunize **90 percent** of children against diseases like measles, pneumococcal pneumonia, and rotavirus.

Areas of Focus

**Harnessing advances in science and technology
to save lives in developing countries.**

Enteric and Diarrheal Diseases — **Working to develop and deliver low-cost interventions that prevent and treat diarrhea-related illness.**

Family Planning — **Improving health and saving lives by increasing access to high-quality, voluntary family planning services.**

HIV — **Reducing the burden of HIV by accelerating the development of prevention technologies and demonstrating effective and efficient models for delivering HIV prevention and treatment.**

Malaria — **With proven control programs and promising new research, making headway against the eventual goal of malaria eradication.**

Areas of Focus (cont.)

Maternal, Neonatal, and Child Health	**Advancing the use of practical tools and strategies to reduce the number of mothers and newborns who die during and immediately after childbirth.**
Neglected and Other Infectious Diseases	**Working with our partners to reduce the burden of neglected diseases, such as guinea worm and river blindness.**
Nutrition	**Focusing on preventing malnutrition in young children to ensure proper physical and cognitive growth and improve disease resistance.**
Pneumonia	**Through improved access to affordable vaccines, significantly reducing the number of children in developing countries who contract pneumonia.**

Areas of Focus (cont.)

Polio	**With our partners in the Global Polio Eradication Initiative, exploring every avenue to help eradicate this crippling disease.**
Tobacco	**By accelerating the adoption of strategies to prevent and reduce tobacco use, reducing the occurrence of tobacco-related disease in developing countries.**
Tuberculosis	**Developing and introducing with our partners new ways to prevent, diagnose, and treat tuberculosis.**
Vaccines	**Focusing on the discovery, development, and delivery of vaccines, which offer the greatest and most cost-effective way to prevent disease.**

Our Strategy: Build Partnerships

Photo: World Economic Forum / Peter Klaunzer

- Partnerships with Public, Private, Academic and NGO Sectors

- Global Collaborations

- Coordination with Other Funders

Foundation Funding Options

<u>Grants:</u> Grantees manage project and resulting IP to ensure that "Global Access" is achieved:

- Secure necessary third party access rights

- Manage IP that arises in performance of grant

- Agreements depend on nature and stage of the technology - from agreeing not to create impediments to commitments of specific quantity/pricing/delivery

<u>Contracts:</u> Foundation generally takes ownership in IP that arises under contract (in particular for studies, reports, videos, software, etc.), and takes a license to any incorporated IP.

- Complex contracts often require close negotiation of IP rights

<u>Program Related Investments (PRIs):</u> Varies depending on nature of investment (loans, equity, guarantee) and nature of project (supporting R&D v. manufacturing capacity).

- Can include commitments regarding licensing, manufacturing, quantity or pricing

Key Point: For All Investments, IP Managed to Achieve Global Access

Global Access

Primary Goal Is . . .

- to conduct and manage foundation funded projects and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, "Funded Developments") in a manner that ensures "Global Access."

Global Access Requires That . . .

- the knowledge and information (including data) gained from the projects be promptly and broadly disseminated, and

- the Funded Developments be made available and accessible at an affordable price (i) to people most in need within developing countries or (ii) in support of the U.S. educational system and public libraries, as applicable to the funded projects.

IP Management Essential to Global Access – But Not Only Factor

Global Access Encompasses:

Market Analysis	IP Management	Local Infrastructure	Regulatory Approvals
Manufacturing and Distribution	Information Dissemination	Collaboration Agreements	Pricing

ETC.

IP Management

- Exercise leverage to achieve foundation goals:
    - Within foundation fields of interest or use
    - Within markets of interest
- Identify and manage third-party rights
- Role of IP management to achieving "access" to products, information and data
- Remedies to ensure "access"

IP Management Tools

Research	Pre-clinical	Clinical	Reg.	WHO PQ	Accessible to Developing Country Patients

- Research license agreements
- Technology access agreements
- Research collaboration agreements
- Material transfer agreements
- Research plan

- Commercialization license agreement
- Clinical supply agreements
- Clinical trial agreements
- Vaccine or drug development plans
- Technology transfer agreements

- Product access strategy
- Commercial supply agreements
- Procurement and financing strategy
- Advocacy and communication plan
- Forecast and demand analysis

Key Point: Nature of Agreements, IP and Global Access Commitments Varies Depending on Stage of Development and Entities Involved

Concluding Remarks

- We have a number of tools to invest in research; overarching goal is Global Access:

  - ✓ knowledge and information (including data) gained from the projects be promptly and broadly disseminated, and

  - ✓ Funded Developments available and accessible at an affordable price to target markets

- Work directly with industry, universities, government and intergovernmental organizations, and other not-for-profit organizations to conclude appropriate global access agreements, data access plans and licenses

- Requires clarity of purpose, motivations and objectives to manage projects and ensure technical success and achieve global access

Thank You

BILL&MELINDA
GATES *foundation*