



ANNUAL REPORT 2017

IMPROVING ACCESS TO MEDICINES THROUGH

LEGAL, REGULATORY,
AND POLICY REFORM



GAiA IN ACTION 2017

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FROM THE CO- DIRECTORS' DESK



Quentin Palfrey
Co-Director



William Fisher
Co-Director

We created **Global Access in Action (GAiA)** to advance our vision of resilient and sustainable health systems for all, where everyone in need has sufficient access to high quality medicines.

Our mission since 2014 has been to solve the access problem faced by the global poor. We seek solutions to these problems primarily by analyzing known challenges and innovative best practices. We then suggest reforms from both the public and private sector to address gaps and improve access to medicines.

With respect to the private sector, GAiA in 2017 published "Expanding Access to Medicines and Promoting Innovation: A Practical Approach" in the April edition of *Georgetown Journal on Poverty Law and Policy*. This paper highlighted three strategies initiated by pharmaceutical companies to improve access to medicines: humanitarian licensing, intra-country tiered pricing, and sharing research for diseases that primarily affect the global poor.

In 2017, GAiA began to engage governments and launched a pilot program with Namibia to provide a comprehensive, interdisciplinary review of access barriers in low- and middle-income countries (LMIC).

Our approach combines legal and technical expertise with public policy analysis to provide a comprehensive, interdisciplinary review of access barriers in low- and middle-income countries.

Whereas previous efforts of others have focused primarily on intellectual property reform, GAiA's initiative combines legal and technical expertise with public policy analysis, and works closely with in-country partners to review drug regulatory systems, competition laws, intellectual property laws, supply chain management, and anti-counterfeiting systems to identify and address context-specific barriers to access. (One aspect of this project builds upon a collaboration with Global Good, a nonprofit organization based in Seattle that develops innovative technologies for promoting public health.)

FROM THE CO- DIRECTORS' DESK

Encouraged by the results of the Namibia pilot, we are currently in the process of expanding the projects to other countries in the region, including Malawi and Mozambique.

Throughout 2017, GAIa engaged with various stakeholders and built a network of both local and global collaborations. We presented our work and shared our vision and strategies at several conferences and events with scholars, foundations, policy makers and pharmaceutical firms. As an organization, our team has doubled in size, and we have welcomed Ruth Okediji, a leading expert in intellectual property and development, as our new co-director.

We are pleased to share GAIa's 2017 Annual Report with you and our partners around the world.

Sincerely,

William Fisher

Quentin Palfrey

Even those who
have access are at
risk of consuming
counterfeit
medicines in many
countries that often
lead to lethal
consequences.

Who We Are

GAiA is founded on the belief that improving access to medicines and promoting socially beneficial innovation are key strategies for combating the communicable disease burden that disproportionately harms the world's most underserved populations.

In this effort, GAiA is committed to the following principles:

Multi-institutional | In seeking to find ways to improve the operation of health systems, we are equally interested in collaborations with private firms or NGOs, and governmental and nongovernmental actors.

Pragmatic | We seek to identify changes that will have meaningful impact and can be readily implemented.

Interdisciplinary | We examine the interplay between law, medicines regulation, trade, and public health.

Academic neutrality | We insist upon rigorous scholarship and are vigilant in avoiding conflicts of interest.

We accomplish our mission by conducting action-oriented research, supporting breakthrough initiatives, facilitating stakeholder dialogue, and providing policy advice to both public and private sector stakeholders. GAiA seeks to foster dialogue across traditional boundaries between government, industry, civil society, and academia, and to promote new, innovative solutions amongst these parties to create better outcomes.

What We Do

Our areas of interest lie in subject matters that are important to address the problem of access to medicines faced by the global poor:

- Intellectual Property and Contract Law
- Fighting Substandard and Falsified Medicines
- Industry Engagement: Drug Pricing and Fostering Collaborative Exchange
- Pandemic Preparedness
- Bridging The Digital Divide in Access to Healthcare

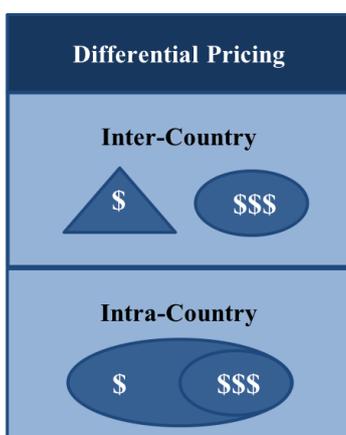


PUBLICATION IN PEER-REVIEWED ACADEMIC JOURNAL ENTITLED “EXPANDING ACCESS TO MEDICINES AND PROMOTING INNOVATION: A PRACTICAL APPROACH”

In 2016, GAIa convened a workshop entitled "Insights into Action" which focused on strategies that could be adopted in the near term by the private sector to increase access to lifesaving medicines, both for medicines already developed and to develop new medicines for disease categories that primarily affect the global poor. The workshop brought together more than sixty leaders from the pharmaceutical industry, foundations, civil society, academia, and government.

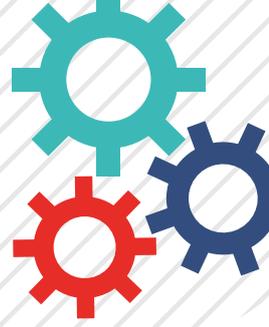
Building on the recommendations from this successful workshop, GAIa Co-Director Quentin Palfrey published a paper in the *Georgetown Journal on Poverty Law and Policy* entitled “**Expanding Access to Medicines and Promoting Innovation: A Practical Approach**.” The paper argues that pharmaceutical companies should consider expanding three approaches to increasing access to lifesaving medicines for the poor and incentivizing R&D into diseases that primarily affect the global poor:

- ① Non-exclusive voluntary licensing partnerships between branded and generic companies
- ② Intra-country price discrimination- charging different prices for similar products targeted at different populations in the same market
- ③ Share research with research collaboratives that seek to develop cures for diseases that primarily affect poor populations



“*Intra-country differential pricing is a strategy worthy of greater attention and replication because a well-crafted program holds great promise for providing win-win outcomes for both the poorest populations and for commercial firms.*”

- “EXPANDING ACCESS TO MEDICINES AND PROMOTING INNOVATION: A PRACTICAL APPROACH,” QUENTIN PALFREY (2017)



PILOT PROJECT FOR REGULATORY CHANGE IN SUB-SAHARAN AFRICA

In 2016, GAiA Co-Directors William Fisher and Ruth Okediji initiated a pilot project in partnership with the **Namibian** government to develop a set of laws, regulations, institutions, and policies that can help deliver a sustainable supply of low-cost medicines to Namibia's residents while continuing to provide pharmaceutical manufacturers with the legal protections necessary to incentivize future innovation. The initiative also incorporates the use of **miniature spectrometers** (provided by our collaborator, Global Good) to reduce the distribution of counterfeit medicines.

The project is well underway in Namibia. We are now beginning to expand it to provide similar services to two other countries in the region: **Malawi** and **Mozambique**. If all goes well, we will create a network of countries- the **Southern Africa Quality Assurance Network**, or **SAQAN**-- that will gather and share throughout the region data concerning falsified medicines.



The goal of the Initiative is to **reduce the communicable disease burden** in Sub-Saharan Africa by **expanding access to affordable health technologies** on a **sustainable, long-term basis**. The projected outcomes of the project are threefold:

- (a) a significant reduction in the quantity of falsified medicines entering, and circulating within, distribution and supply chains in participating countries;
- (b) a significant, associated reduction in treatment failures arising from the use of falsified medicines; and
- (c) a significant reduction in the rates of morbidity and mortality associated with communicable and non-communicable diseases over the long-term, including malaria, multi-drug resistant tuberculosis, and HIV/AIDS.

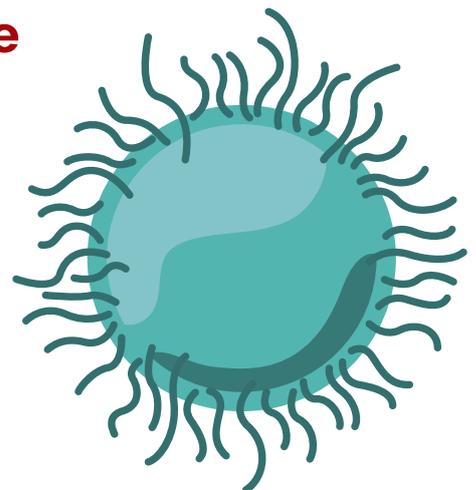


PANDEMIC PREPAREDNESS: “MANAGING LIABILITY CONCERNS ASSOCIATED WITH INTERNATIONAL DEPLOYMENT OF EMERGENCY MEDICAL COUNTERMEASURES”

GAiA Co-Director Quentin Palfrey participated in a one-day workshop at the World Economic Forum in Geneva, Switzerland on September 13, 2017. Organized by the [Coalition for Epidemic Preparedness Innovations \(CEPI\)](#), [Harvard Global Health Institute \(HGHI\)](#) and the [World Economic Forum](#), the focus of this workshop was on [managing liability concerns associated with international development and deployment of emergency vaccines](#).

The absence of an agreed-upon global model to manage liability for stakeholders involved in vaccine development during epidemics, can lead to significant delays in taking timely and necessary actions, which then can lead to significant losses in public benefits. The objectives of the workshop were to reflect on relevant experience during past international responses and to discuss values and criteria shaping consideration of proposed solutions; present WHO proposal to manage liability/compensation associated with use of experimental products during outbreaks and to seek agreement on an approach, engagement plan, and approximate timeline for tangible progress and outcomes during the coming year.

Strengthening health systems is the best way to safeguard against health crises. Outbreaks are inevitable, but epidemics are not. Strong health systems are our best defense to prevent disease outbreaks from becoming epidemics.



- DR. TEDROS ADHANOM GHEBREYESUS, DIRECTOR-GENERAL OF WHO

STAKEHOLDER ENGAGEMENT

LOCAL

GAiA Brown Bag Series: Conversations in Global Health, Innovation, & the Digital World

Over the summer of 2017, GAiA launched a brown-bag lunch series entitled “**Conversations in Global Health, Innovation, and the Digital World**,” featuring the work of our Co-Directors- Quentin Palfrey, Professor William Fisher, and Professor Mark Wu, as well as Berkman Klein Affiliate and GAiA collaborator John Stubbs. The GAiA brown bag series was organized in collaboration with the Harvard Global Health Institute to facilitate discussion among researchers, scholars, practitioners, and policymakers engaged in the development of legal and policy frameworks that govern innovation and global commercialization of medicines.

JUNE 12,
2017

Potential Uses of Miniature Spectrometers to Mitigate the Health Crisis in Developing Countries

GAiA Co-Director and Director of the Berkman Center for Internet and Society, William Fisher presented on the potential for miniature spectrometers to **reduce the use and distribution of counterfeit drugs in Sub-Saharan Africa**. Fisher argues that employing this quality assessment technology would increase the government’s ability to regulate drug distribution and empower individuals to confirm the authenticity of the drugs they purchase, ultimately increasing the use of therapeutically effective medicines. He outlined a pilot project in Namibia being initiated to use this new technology in reducing illegal distribution of counterfeit antimalarial medication. Fisher's talk sparked a rich discussion on the practical considerations and technical limitations of the initiative.

JUNE 26,
2017

Expanding Access to Medicines and Promoting Innovation: A Practical Approach

GAiA Co-Director Quentin Palfrey presented on practical strategies to expand global access to medicines and promote research and development for diseases that primarily affect the world’s most under-resourced populations. He outlined three major obstacles that GAiA seeks to address: **the access to medicines gap, market exclusivity, and the polarization and paralysis of global collaborative research**. Palfrey argues that employing strategies such as **differential pricing, non-exclusive licensing agreements, and patent pooling** can combat these problems and create scenarios which benefit all stakeholders. These win-win-win scenarios increase access to life-saving medicines for low-income individuals, allow humanitarian entities to make a greater impact with limited budgets, and allow pharmaceutical companies to greatly increase access to medicines with the potential to break even or make a modest profit.

Palfrey's talk inspired discussion on intra-country differential pricing strategies, lessons learned from the Ebola epidemic about global collaborative research, and alternative incentive mechanisms for the development of drugs for diseases that primarily affect low-income populations.

JULY 24,
2017

Global Data Flows and the Implications for Health Access in Developing Countries

Governments around the world are increasingly regulating the flow of cross-border data on the basis of privacy, security, and other public interest concerns. These policies take on a variety of forms, such as data localization requirements and obligations for service providers to make data available to law enforcement authorities under certain circumstances. Assistant Professor of Law at Harvard Law School, Director of the Berkman Klein Center, and GAIa Co-Director, Mark Wu had an open discussion on the types of **policies concerning cross-border data flows** that developing countries should be adopting and advocating to safeguard their interests, particularly with respect to health care.

JULY 31,
2017

Trump's America First Trade Agenda: What It Means for Access to Medicines

US foreign policy regulates, incentivizes, and subsidizes access to medicines for patients around the world, from **intellectual property protection** and **market access commitments in trade agreements** to **assistance programs like PEPFAR**. What existing policies is President Trump likely to change, what new policies will his administration introduce, and how will these changes affect global health outcomes? GAIa collaborator and an affiliate at Harvard University's Berkman Klein Center for Internet and Society, John Stubbs addressed these key questions at GAIa hosted 'Conversation on Global Health, Innovation, and the Digital World' brown bag series.



400M people lack health care, including access to medicines, vaccines, diagnostics and medical devices, of whom 300M live in middle-income countries.

- THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES REPORT (2016)

GAiA at Center for Strategic and International Studies (CSIS)

SEP 26,
2017

“Innovation and Access: the Role of IP Licensing” Conference at the Center for Strategic and International Studies (CSIS), Washington DC

GAiA Co-Director Quentin Palfrey was the keynote speaker at the CSIS Scholl Chair in International Business for a conference on **humanitarian licensing**. Palfrey spoke about **access disparity to medicine** and **innovative IP regulations, differential pricing and voluntary licensing**, which have the potential to lower access disparity to life-saving medicines. This exciting new concept in IP regulation seeks to improve access to new innovation in humanitarian contexts while also protecting the rights of IP owners and fostering innovation. The discussion was further enriched by case studies presented by Dr. Robert Bertram, Chief Scientist, Bureau for Food Security, U.S. Agency for International Development; Dr. Carol Mimura, Assistant Vice Chancellor, Office of Intellectual Property & Industry Research Alliances, University of California, Berkeley; and Gregg Alton, Executive Vice President, Corporate and Medical Affairs, Gilead Sciences, Inc.

GAiA Engages Berkman Klein Center Community

OCT 31,
2017

Global Health in 2035: A Discussion on the Use of Technology to Promote Access to Medicines

GAiA Fellow Ashveena Gajeelee presented GAiA’s ongoing projects that seek to expand access to lifesaving medicines in the world’s most vulnerable populations. To the Berkman Klein community of internet security, artificial intelligence and global health experts, Gajeelee posed the question, “**What does access to medicines look like in 2035?**” This sparked a stimulating discussion among the research fellows about the intersection between technology and health in the coming decades. Fellows suggested, in countries that have wide cellular networks, **technology can help to map networks** of health workers and knowledgeable local persons. These reliable and trusted networks of local people could then act as **hubs for information sharing** in the middle of pandemics. **Access to information and education programs** at crucial points in time might be impactful. There were also discussions on the importance of **understanding local contexts**, and the way technologies are used in these limited-resource settings. Cutting-edge technologies, no matter how innovative they are, may fail, if they are not accepted by the local people or are not applicable in the local context.

Other key suggestions that resulted from the hour-long discussion included the need for more WHO diagnostic labs in sub-Saharan Africa, and importance of understanding **social determinants of health** alongside access barriers to medicines. One key issue that was emphasized throughout the discussion is the **deployment of modern technology in an ethical manner** to ensure that the world's most vulnerable populations are not exploited by commercial interest.

NOV 15,
2017

Fighting Substandard and Falsified Drugs: Southern Africa Quality Assurance Network

GAiA Co-Director William Fisher held a workshop with the Berkman Klein community to reflect on the ways to face the problem of **substandard and falsified medicines** in sub-Saharan Africa. He explained that GAiA was working with Global Good to demonstrate a new falsified-drug detection technology that, in conjunction with other complementary drug-quality monitoring systems, can help to reduce the morbidity and mortality associated with treatment failure from the use of falsified medicines. To enhance the social welfare gains of this technology, GAiA is creating a network of countries – the **Southern Africa Quality Assurance Network**, or **SAQAN** – that will utilize the technology to gather and share data on falsified medicines. By enhancing the integrity of regional distribution and supply chains, SAQAN is designed to expand access to affordable, quality-assured medicines on a sustainable, long-term basis. Health experts and technology specialists at the workshop brainstormed over the challenges of implementing SAQAN and how to best address them through regulation, training of healthcare personnel and technology.

1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified.

- WHO GLOBAL SURVEILLANCE AND MONITORING SYSTEM FOR SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS (2017)



OCT
2017**Global Fund to Fight AIDS, Tuberculosis and Malaria,
Geneva**

GAiA Co-Director William Fisher gave a presentation to Global Fund on its “Access to Medicines in sub-Saharan Africa” initiative. Fisher presented the ongoing pilot project in Namibia, the expected impact on the healthcare system including the extensive public-private partnership, and the training workshops held to enable the healthcare professionals to implement GAiA’s recommendations.

The objective of the presentation was to **showcase the capacity of this innovative approach to promote access to medicines through a pragmatic method to narrow the gaps in the healthcare systems, regulatory and institutional framework**. GAiA developed its project for establishing Southern Africa Quality Assurance Network (SAQAN) in collaboration with MEDS, a not-for-profit organization and WHO-certified quality-assurance laboratory. GAiA will support the creation and maintenance of the quality-assurance database.

OCT
2017**Assessing Needs, Providing Technical Legal Advice, and
Establishing Relationship with MEDS, Namibia and Kenya**

GAiA provided **technical legal advice** to the Namibia's Business and Intellectual Property Administration (BIPA), met with the Namibia Medicines Regulatory Council (NMRC) to **discuss their needs**, and met with Kenya-based Mission for Essential Drugs and Supplies (MEDS) for the first time to **establish a long-term relationship for confirmatory medicines testing and technology transfer**, a major milestone for the establishment of the Southern Africa Quality Assurance Network (SAQAN).

NOV 1-3,
2017**“Promoting Policy Coherence on Health Technology
Innovation and Access in the ARIPO Region”, Malawi**

GAiA Research Fellow Katrina Geddes attended a conference in Lilongwe, Malawi, jointly organized by the Malawi Government and the United Nations Development Programme (“UNDP”), titled “Promoting Policy Coherence on Health Technology Innovation and Access in the African Regional Intellectual Property Organisation Region (ARIPO)”.

Katrina met with representatives from the Malawi Ministry of Health, the Ministry of Industry and Trade, the Pharmacy, Medicines and Poisons Board, the Central Medical Stores Trust, the State House, and the Department of the Registrar General to present GAiA’s mission, objectives and framework, and to understand Malawi’s particular concerns regarding access to medicines and falsified drugs.

A local working group was established to guide the provision of technical advice by GAIa to various ministries within Malawi. Issues, priorities and next steps were addressed at the meeting, with significant work to follow, prior to the next in-person meeting, which is expected to take place in early 2018.

NOV 28,
2017

3rd edition of the UNESCO-Merck Africa Research Summit (MARS) 2017, Mauritius

Ashveena Gajeelee, Fellow at GAIa presented our ongoing projects at the third edition of the UNESCO-Merck Africa Research Summit – MARS 2017, which was held in Mauritius. The summit attracted about 200 African researchers representing the whole continent and hosted two ministerial panel discussions with the participation of over 30 African Ministers of Science, Education, Gender and Health, on **better harmonization of life science research between the different stakeholders in the public and private sector.**

Many participants highlighted the difficulty in fighting counterfeit medicines in African countries and had inquiries about the new technology being tested by GAIa and Global Good as part of the SAQAN project. Other questions pertained to the impact of regulation on healthcare and what could countries do better to share their research.

The 3rd edition of the UNESCO-MERCK Africa Research Summit (UNESCO-MARS) consolidates the cooperation between UNESCO and Merck Foundation. Policy makers, ambassadors, academics and NGO representatives comprise the heterogeneous audience; this interaction between different actors catalyzes the aim to support Africa in becoming a hub for scientific excellence and technological innovation and to bridge the gap between investigators and policy makers.

PEOPLE

2017 was a year of expansion for GAiA, both in our achievements as well as our team. We were honored to have one of the foremost authorities on international intellectual property law, **Ruth Okediji**, join us as Co-Director in our endeavor to improve global access to medicines. Additionally, two fellows, **Ashveena Gajeelee** and **Katrina Geddes**, were also recruited to assist with GAiA's upcoming projects.

Over the summer, internship opportunities were provided to two students from Tufts University and John Hopkins Bloomberg School of Public Health, **Jenna Sherman** and **Dexter Waters**. Three Research Assistant positions were also created to support GAiA's ongoing projects in the fall. Our current Research Assistants include PhD candidate at MIT **Myung Sun Kang**, Master student at Harvard Medical School **Lisa Parvin**, and BS Health Science graduate at Northeastern University **KaKei Sum**.

We are extremely grateful for the administrative support we received from **Kira Hessekiel** and **Jon Murley**, project coordinators at the Berkman Klein Center for Internet and Society in the past year. We also appreciate the dedication of our collaborators, **Cherie Ramirez**, faculty member at Simmons College, and **John Stubbs**, Berkman Klein affiliate in supporting the projects in GAiA and advocating for our values.

“

I am delighted to join GAiA. I look forward to working with my Co-Directors and GAiA's staff on the many complex issues at the intersection of law and public health both nationally and globally. ”



Ruth Okediji
Co-Director

CONGRATULATIONS TO OUR CO-DIRECTOR, MARK WU!



Mark Wu
Co-Director

On June 8, 2017 **Mark Wu**, Assistant Professor of Law at Harvard Law School and a Faculty Director of the Berkman Klein Center, was selected by the Class of 2017 for the prestigious **Albert M. Sacks-Paul A. Freund Award for Teaching Excellence** for his dedicated work as a professor. Professor Wu is only the second junior faculty member to receive the award.

ABOUT GLOBAL ACCESS IN ACTION:

Global Access in Action, a project of the Berkman Klein Center for Internet & Society at Harvard University, seeks to expand access to lifesaving medicines and combat the communicable disease burden that disproportionately harms the world's most vulnerable populations. We accomplish this by conducting action-oriented research, supporting breakthrough initiatives, facilitating stakeholder dialogue, and providing policy advice to pharmaceutical firms on best practices to increase impact. **GAiA** uses its pragmatic and neutral viewpoint to enable dialogue across traditional boundaries between government, industry, nonprofits, and academia, and to promote new, innovative solutions amongst these parties to create better outcomes.

STAY CONNECTED

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