Information Book For the Forum On

ACCESS TO MEDICINES IN GLOBAL HEALTH EMERGENCIES: THE ROLE OF VOLUNTARY LICENSING

June 1-2, 2022
Harvard University

A forum held under the auspices of the project on

Voluntary Licensing and Access to Medicines (VLAM)

led by

Harvard University

in partnership with

Stanford University &
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About The Project on Voluntary Licensing & Access to Medicines (VLAM)

Summary

Background of the Problem.

Covid-19 has caused millions of deaths and much suffering and economic disruption. Governments have relied heavily on vaccines and other medications in efforts to reduce its adverse impacts. Distributions of those medications have, however, been highly disparate. While the U.S. and other relatively wealthy societies have achieved levels of vaccination ranging from 60% to 90% of their populations, many relatively poor and populous countries have much lower levels of vaccinated people, some under 5%.

The proposal initially tabled in early 2021 by India and South Africa to overcome this disparity through the waiver of intellectual property rights is widely considered inadequate, has been rejected by many countries, and is opposed by major pharmaceutical companies. Efforts to secure vaccinations through gifts and purchases failed to ramp up as quickly as hoped and is one of the reasons that as of early 2022, the significant disparity in vaccination rates between wealthier and poorer countries remains. Sales at cost and gifts by manufacturers have ramped up, but only recently, after market-driven commercial sales mainly to the wealthier countries were prioritized. Projects that contemplate the shipping of complete manufacturing lines to developing countries have encountered substantial headwinds.

Perhaps most importantly, few of these efforts, even if successful, would significantly contribute to expanding the ability of low- and middle-income countries to meet their own immediate health-care needs let alone prepare for needs that arise in future pandemics.

The voluntary licensing (VL) approach taken by Gilead Sciences Inc., which began in 2006, has allowed millions of people across low- and middle-income countries to have access to low-cost, high-quality generic medicines for HIV, viral hepatitis and COVID-19. In the context of COVID, Merck and Pfizer have both announced plans to employ VLs to expand access to their COVID anti-viral treatments. A few other companies have engaged in VLs in the past to expand access to their medicines. However, other than Gilead's large-scale, strategic and systematized use of VLs, the use of VLs has been rare and episodic.

This project will examine the potential role of expanded use of VLs a strategic approach that could unite wealthy countries and innovator pharmaceutical companies with their counterparts in low- and middle-income countries (governments and generic manufacturers) to meet the needs of low- and middle-income populations in the current pandemic and to prepare for and respond to future global health emergencies.

Rationale and Specific Needs to be addressed by the project.

As illustrated by the painfully slow access to COVID vaccines in low- and middle-income countries, current approaches do not ensure adequate supplies or capacities needed for current or long-term response in those countries. As such, we believe it is vital to examine the possible expanded role of voluntary licensing to meet these needs, drawing on the lessons of past successes in the use of VLs, such as in response to the HIV/AIDS pandemic. It is also important to understand why, if VLs could be a helpful tool to addressing deficits in LMIC access to medicines, they are not employed more regularly

today, and what factors should be considered and recommended to create an ecosystem to incentivize and expand their use.

To this end, there are a number of potential factors already identified that, if addressed effectively, could contribute to creating such an ecosystem. These needs (and others, as may be determined) also illustrate that the increased utilization of VLs will require collaboration among many players, including innovator pharma companies, generic manufacturers, governments in high-income countries, governments in LMICs, multilateral organizations and NGOs. A brief summary of the initial list of issues to be examined in this project is as follows:

- *Licensing details*: The specific details within the voluntary licenses themselves, including royalty levels, and technology transfer. For example, VLs should provide foreign manufacturers legal authority to make generic versions of vaccines and other medicines and should include transfer of know-how and technical information needed to manufacture, store, and distribute such medications.
- *Regulatory Approval Pathway*: The regulatory approval pathway in the countries where innovators and licensees operate can and should be modified to create a fast-track system that removes impediments to availability of innovator and licensed products, while also ensuring the maintenance of safety and efficacy standards.
- *Pricing*: Low pricing of licensed generic vaccines and medicines is the key to enhanced access. Several factors affecting pricing should be examined, including competition (e.g., number of licensees active in any market), pricing policies of governments (including price controls), taxes and tariffs, and the presence of a branded product in the marketplace.
- *Quality control*: Several factors must be considered. Manufacturers/licensees should be required to obtain Tentative FDA approval or WHO Pre-Qualification for generic substitutes to ensure that high-quality products with demonstrated safety and equivalence are offered for sale in resource-challenged countries. The U.S. imposed this requirement for the PEPFAR (AIDS relief) program. Other steps must be taken downstream, including the ability to track and trace product, thereby ensuring supply-chain security, and local quality control and monitoring, to ensure bona fide product in the destination country.
- *Health Financing and Capacity Building*: Any private sector B2B voluntary licensing program can only go so far in expanding access to vaccines and other medicines since VLs relate only to manufacture and supply. What approaches can be taken by all stakeholders to complement VLs with the demand side of health financing and health systems capacity building in low and middle-income countries (e.g., infrastructure, cold chain/storage, number of trained medical staff, and availability of diagnostic tools)?
- *Advance Purchase Agreements*: During the current effort to vaccinate worldwide, leading innovators are relatively safe in assuming they should source raw materials, acquire space and machinery, and hire the personnel needed to maximize production. In normal times, however, and currently for many if not most manufacturers, there is significant, unmitigated risk. Advance purchase agreements and volume guarantees can provide helpful data for more accurate planning and added security to mitigate production of sizeable quantities of medicines at risk.
- *Patent Protection*: Voluntary licenses that result in the production and availability of low-cost generics depend on adequate patent protection of the underlying IP. Securing key features of a competitive landscape that safeguards the interests of licensees, including practical, balanced patent laws and transparent approval processes, protects both innovators and generic manufacturers.
- *Patent Incentives*: Governments in which innovators (i.e., licensors) are located can supplement patent protection and data exclusivity with other incentives to encourage the development and

widespread distribution of new medicines, including business models such as voluntary licensing. One existing tool that could be adapted to this purpose is the U.S. “Patents for Humanity Program”, which issues priority certificates for FDA review to patent owners who develop innovative medicines that address humanitarian challenges.

Specific Objectives of the Project.

(1) Ascertain whether and how VLs could become a leading mechanism that the international community systematizes for expanding access to medicines in LMICs, and what are the key issues that need to be addressed in doing so.
(2) Develop findings and recommendations (with a goal of publishing a “tool kit”) that would become the basis for governments, multilateral institutions, industry, and NGOs to establish norms and implement policies to expand the use of VLs to accelerate access to medicines in LMICs in response to and preparation for pandemics and health emergencies.
(3) The long-term benefit sought through this project is faster and more universally available access to vaccines and treatments for transmittable diseases in pandemics and other health emergencies in LMICs. This model could also be applied to other technologies, including diagnostics and medical devices.

Logistical Information

Logistical Information

Accommodations: Out of town participants will stay at the Sheraton Commander Hotel, 16 Garden Street, Cambridge, Massachusetts. Please note that check in is at 3pm and check out is by 12 noon. The hotel will do its best to accommodate early check-ins but cannot guarantee it.

Venues

The Forum will take place at the Harvard Faculty Club, 20 Quincy Street, Cambridge, MA, in the Reading Room.

Dinner on June 1 will also be held at the Harvard Faculty Club, in the Reading Room.

COVID-19 Precautions

As you are likely aware, the COVID-19 infection rate is once again rising throughout the United States. To minimize the chances of that occurring, we have adopted the following precautions:

(a) We will supplement the (already robust) air-circulation systems of the rooms in which the forum will be held with two large Alen 75i Air Purifiers. These are the top-rated devices for removing pathogens (and other particles) from the air. Each is capable of handling a 1300-square-foot room, which should be more than sufficient.
(b) To verify the functioning of the filtration systems, we will be continuously monitoring the CO2 level in the conference rooms, using an Amprobe CO2-100 Carbon Dioxide Meter.
(c) When you arrive at the hotel, you will find a packet containing (among other things) two COVID antigen tests. We strongly encourage all participants to take one of the tests prior to coming to the forum on Wednesday morning.
(d) We will make available to you high-quality US-made N95 masks. (Wearing them is optional.)
(e) If the infection rate on June 1 is troubling, we will shift the conference dinner from the Harvard Faculty Club to an appropriate outdoor venue.

Transportation: The hotel is located in the heart of Harvard Square, approximately 9 miles (14.5 km) or 20 minutes from Boston's Logan International Airport.

- The conference organizers have arranged transportation to and from the airport for those participants who have requested it and provided their travel information. Those participants will have been provided with information such as a phone number to call in case of issues, pick up time, pick up area, and reservation number**.**

- The limo company (Boston Coach) monitors the status of flights and dispatches a car accordingly.

- For return to the airport upon the end of the forum, the chauffeur will meet those participants for whom transportation has been arranged either at the Loeb House or at the hotel, depending on the date and time of the return flight.

- If you have trouble locating your driver upon arrival, please contact Boston Coach Events Division at 888-735-5038. For any other concerns, please feel free to contact Judith Duvivier-Qashat (contact info below).

Dress Code: The dress code is business casual for all sessions and the dinner.

Internet: There will be Wi-Fi access at the conference venue (Harvard Faculty Club) and the hotel.

Questions regarding logistics: Judith Duvivier-Qashat, +1-781-526-4163, jduvivier@law.harvard.edu

Contact Information for organizers:

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Format and Speaker Guidelines

Format

The roundtable style format of the forum is designed to create a conversation between peers. While session discussion leaders are expected to help lead the conversation, they only provide brief scene-setting remarks guided by the session facilitator, preserving the majority of the session for an open back and forth among all of the participants in the room.

The Voluntary Licensing & Access to Medicines Forum is held under the Chatham House Rule, which states that:

- When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.

The intellectual content generated by the forum will help in advancing the VLAM project's ultimate goal, which is the drafting and publication of recommendations and a tool kit for use and implementation by global stakeholders shaping the ecosystem for access to medicines in pandemics and health emergencies. Additional content may include spin-off papers and online content over the course of the VLAM project.

Speaker Guidelines

The Voluntary Licensing & Access to Medicines (VLAM) Forum is being held to advance our understanding of issues that are timely in the current context of the COVID pandemic, to inform the VLAM project's goal of producing recommendations that, if implemented, could enhance and expand access to medicines in low- and middle-income countries.

This forum is also an opportunity to strengthen networks and understanding among the participants and the broad spectrum of stakeholder communities they represent.

Skillfully facilitated sessions among experts on the specified topics will maximize the forum's impact. Here are some rules of thumb to help the Forum accomplish its goal of providing a compelling participatory format.

- The purpose of each discussion session is to inform the overarching project goal of developing analysis, context and recommendations addressing voluntary licensing as a tool in advancing the cause of access to medicines. All participants are asked to think within this framework in approaching each topic.

- The forum is designed to stimulate engaged participation and foster open dialogue that involves all participants in the room.

- Each session will be moderated by a facilitator who will offer brief framing comments and lead the conversation. Facilitators should also briefly introduce the session leads – name and

affiliation are sufficient. All session speakers (including the facilitator) should keep their opening remarks to five minutes or less.

- There will be no prepared speeches during the discussion sessions and participants are requested to refrain from lengthy remarks. The facilitator will not hesitate to intervene if remarks run long.

- Designated facilitators will be the guides for the open discussion sessions and will be looking for your participation.

- All participants, as they engage in the discussion, are asked to give succinct observations and questions to allow time for others to contribute.

- Please keep in mind throughout the forum, that Chatham House Rule applies. Chatham House Rule is an honor-bound agreement that states, “participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.”

Agenda

WEDNESDAY, JUNE 1

Day 1: Reading Room, Harvard Faculty Club, 20 Quincy Street, Cambridge, MA 02138

1.	7:45 a.m. – 8:30 a.m.	**Buffet continental breakfast/coffee will be provided**
2.	8:30 a.m. – 8:40 a.m.	**Hosts' Welcome** (Terry Fisher and Ruth Okediji, Harvard Law School)
3.	8:40 a.m. - 9:00 a.m.	**Introduction to the Project** (Claudio Lilienfeld, Harvard Law School)
4.	9:00 a.m. - 9:15 a.m.	**Introductory comments by Project Partners**: Ken Shotts, Stanford Graduate School of Business Ashley Tellis, Carnegie Endowment for International Peace
5.	9:15 a.m. - 10:15 a.m.	**Session One.** <u>The Current Context of Pandemic Response</u> *Vaccine and treatment access and consequences - assessment of: charitable transfers, the India/S Africa proposal on IP waivers, and other tools being considered and implemented.* Discussion Leaders: Aaron Kesselheim (Harvard Medical School), Jayashree Watal (MPP board and former WTO), Ruth Okediji (Harvard Law School)*
6.	10:15 a.m. - 10:30 a.m.	**Break**
7.	10:30 a.m. - 12:00 p.m.	**Session Two**. <u>The Successes, Hurdles and Potential of Voluntary Licensing</u> *Description and analysis of use of VLs, including PEPFAR, TB, Malaria, Polio vs. shoe-string responses such as HCV* Discussion Leaders: Eric Goosby (ex-PEPFAR head), Clifford Samuel (Harvard Law School and former SVP Gilead)*, Subhanu Saxena (Cipla ex-CEO), Ellen 't Hoen (former MPP head)
8.	12:00 p.m. – 1:30 p.m.	**Lunch**: Reading Room, Harvard Faculty Club **Speaker:** Michel Sidibé (African Union Special Envoy). State of Play in Africa: Healthcare, Pharma industry, and Access

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9. 1:30 p.m. – 3:00 p.m. **Session Three**. Doing Business in LMICs - Theory and Opportunity
A range of perspectives on the market at the base of the economic pyramid, including conceptual and practical approaches.

Discussion Leaders: Kash Rangan (Harvard Business School), Ken Shotts (Stanford Graduate School of Business)*, Krishna Udayakumar (Duke University), Peter Mamacos (USAID), Jessica Martinez (Gates Foundation)

10. 3:00 p.m. – 3:15 p.m. **Break**

11. 3:15 p.m. – 4:30 p.m. **Session Four.** On the Ground - The Operators' Perspectives
Discussion on challenges for innovators, generics, and implementation partners in considering Voluntary Licensing.

Discussion Leaders: David Ripin (CHAI - Clinton Health Access Initiative), Denis Broun (ex-Cipla), Swraup Sarkar (ex-Indian Council on Medical Research), Claudio Lilienfeld (Harvard Law School and ex-Gilead)*

12. 4:30 p.m. – 5:00 p.m. **Summary/Highlights of the Day's Sessions, Wrap up and Logistics**
(Terry Fisher)

13. 7:00 p.m. – 9:00 p.m. **Reception and Dinner**: Reading Room, Harvard Faculty Club

* Session Facilitator

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Agenda (Continued)

THURSDAY, JUNE 2

Day 2: Loeb House, 1st Floor, Harvard Faculty Club, 17 Quincy Street, Cambridge, MA 02138

1. 8:00 a.m. – 8:30 a.m. **Buffet continental breakfast**

2. 8:30 a.m. – 8:40 a.m. **Recap and Review of the day's agenda** (Clifford Samuel)

3. 8:40 a.m. – 8:45 a.m. **Video Message** from Macky Sall, the President of Senegal

4. 8:45 a.m. – 10:00 a.m. **Session Five:** Health Financing and Capacity Building

   Discussion Leaders: Onno Schellekens (Joep Lange Institute and CarePay), Rachel Silverman (Center for Global Development (CGD)*, Rajiv Kumar (ex-Vice Chairman National Institute for Transforming India - Govt of India apex public policy agency), Rifat Atun (Harvard School of Public Health)

5. 10:00 a.m. – 11:00 a.m. **Session Six:** Pharma Perspectives

   Discussion Leaders: Abe Sofaer (Stanford University/Hoover Institution)*, Jeff Kindler (ex-Pfizer CEO), Josh Boger (ex-Vertex CEO), Greg Perry (IFPMA), Stavros Nicolaou (Aspen Pharmacare)

6. 11:00 a.m. – 11:15 a.m. **Break**

7. 11:15 a.m. – 12:15 p.m. **Session Seven:** Considerations of Civil Society and the Public Interest

   Discussion Leaders: Jamie Love (Knowledge Ecology International), Brook Baker (Northeastern University), Terry Fisher (Harvard Law School)*

8. 12:15 p.m. – 1:15 p.m. **Session Eight:** Brainstorming on Next Steps

   Discussion leaders: Clifford Samuel, Terry Fisher, Ruth Okediji, Abraham Sofaer, Claudio Lilienfeld, Ken Shotts

9. 1:15 p.m. – 2:15 p.m. **Closing Lunch**: Loeb House, 1st Floor (side room), Harvard Faculty Club

* Session Facilitator

Participants List

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Participant Bios

Dr. Rifat Atun Dr. Rifat Atun is Professor of Global Health Systems at Harvard University and the Faculty Chair for the Harvard Ministerial Leadership Program. In 2006-13, Dr. Atun was Professor of International Health Management and Head of the Health Management Group at Imperial College London. In 2008-12 he served as a member of the Executive Management Team of The Global Fund to Fight AIDS, Tuberculosis and Malaria as the Director of Strategy, Performance and Evaluation Cluster, where he chaired the panel that oversaw investments of around $4 billion each year in more than 100 countries. Professor Atun's research has two major strands. The first examines health systems performance and how design and implementation of health systems reforms impact on outcomes. The second strand of research explores adoption and diffusion of innovations in health systems (e.g., health technologies, disease control programmes, and primary healthcare reforms), and innovative financing in global health. Professor Atun has published more than 400 papers in leading journals including the Lancet, NEJM, Academy of Management Journal, Lancet Global Health, Lancet Infectious Diseases, Lancet Oncology, and Lancet Psychiatry and PLoS Medicine. He has led or has been a commissioner in 12 Lancet Commissions and was a co-author and member of the Advisory Committee for the Editors for Disease Control Priorities (DCP) 3. In 2020, he was recognized by the Web of Science as one of the World's Highly Cited Researchers. Prof. Atun has worked with more than 30 governments globally and with the World Bank, World Health Organization, and the UK Department for International Development (DfID) to design, implement and evaluate health system reform initiatives.

Brook Baker is Professor of Law at Northeastern University School of Law. Professor Baker teaches disability discrimination law, negotiations and a new course on human rights, intellectual property, and access to medicines. He taught and consulted in South African law schools and law school clinics between 1997-2012. Professor Baker is an honorary research fellow at the University of KwaZulu Natal in Durban, South Africa. Professor Baker is also a senior policy analyst for Health GAP (Global Access Project) and is actively engaged in campaigns for universal access to treatment, prevention, and care for people living with HIV/AIDS, especially expanded and improved medical treatment. More recently he has been working on accelerating research on and equitable global access to vaccines, medicines, and diagnostics to respond to the COVID-19 pandemic. He has written and consulted extensively on intellectual property rights, trade, investor-state dispute settlement, access to medicines, and medicines regulatory policy, including with the African Union, NEPAD, South Africa, Uganda, ASEAN, Thailand, Indonesia, Brazil, Venezuela, CARICOM, UK DfID, the World Health Organization, the Millennium Development Goals Project, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Open Society Institute, UNAIDS, UNDP, Unitaid, the Medicines Patent Pool, the Global Commission on HIV and the Law and others. He has served as a key, alternative board member and board member of the NGO delegation to Unitaid, which acts to improve market dynamics and early market entry of medicines and diagnostics needed to address HIV/AIDS, TB, Hepatitis C and malaria. He presently is a civil society representative to the Therapeutics Pillar of the Access to COVID-19 Tools Accelerator.

Dr. Joshua Boger is the Founder & Former Chief Executive Officer, Vertex Pharmaceuticals Incorporated. Dr. Boger founded Vertex in 1989 and was the company's Chief Executive Officer from 1992 until May 2009. He served in the additional role of Chairman of the Board from 1997 until 2006. After retiring as CEO in May 2009, he continued on the Vertex Board of Directors until June 2017 and was Chair of its Science and Technology Committee. Dr. Boger began his industry career at Merck in 1978. Immediately before he founded Vertex, he was Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories and headed both the Departments of Chemistry of Immunology & Inflammation and of Biophysical Chemistry. Dr. Boger holds a B.A. in chemistry and philosophy from Wesleyan University and A.M. and Ph.D. degrees in chemistry from Harvard University.

Dr. Denis Broun is a Doctor of Medicine from Paris University with a specialization in infectious diseases, parasitology, and epidemiology. He also graduated from the Paris Institute of Political Sciences and holds a masters in biomathematics. Denis Broun has worked in the field of international health for the past thirty years, first as a health economist with a French company, then as senior health specialist in the World Bank, where he oversaw the pharmaceutical sector from 1992 to 1996. He was head of health section in UNICEF until 1998 and joined Geneva as programme manager for the control of tropical diseases and director of resource mobilization in the World Health Organization. Denis Broun then became European director of the American consulting firm "Management Sciences for Health" from 2000 to 2005. In 2005, he joined UNAIDS, first as country director in India (2005-2008), then director of partnerships and finally regional director for Europe and Central Asia (2009-2011), based in Moscow. In 2011, he was selected to become executive director of UNITAID, a specialized agency providing financing to leverage innovation in global health. Since 2014, he has been an advisor to Indian generic manufacturers, notably on issues of access and licensing in HIV and malaria, in addition to teaching and diplomatic activities. Denis is a French citizen, born in Paris. He is married and has four children. In addition to his native French, he speaks English, Russian and Spanish.

Judith Duvivier-Qashat serves as the Project Manager for VLAM. Originally from France, Ms. Duvivier-Qashat moved to the US in 2012. After graduating from Université Paris Nanterre with a Bachelor of Science in French Law. She joined Harvard Law School in 2019 and has been helping Professors Fisher and Okediji with CopyrightX ever since.

Professor William "Terry" Fisher received his undergraduate degree (in American Studies) from Amherst College and his graduate degrees (J.D. and Ph.D. in the History of American Civilization) from Harvard University. Between 1982 and 1984, he served as a law clerk to Judge Harry T. Edwards of the United States Court of Appeals for the D.C. Circuit and then to Justice Thurgood Marshall of the United States Supreme Court. Since 1984, he has taught at Harvard Law School, where he is currently the Wilmer Hale Professor of Intellectual Property Law and the Director of the Berkman Klein Center for Internet and Society. His academic honors include a Danforth Postbaccalaureate Fellowship (1978-1982) and a Postdoctoral Fellowship at the Center for Advanced Study in the Behavioral Sciences in Stanford, California (1992- 1993).

Eric Goosby, M.D., School of Medicine, UCSF. Dr. Eric Goosby is an internationally recognized expert on infectious diseases, with a specialty in HIV/AIDS clinical care, research, and policy. During the Clinton Administration, Dr. Goosby was the founding director of the Ryan White CARE Act, the largest federally funded HIV/AIDS program in the U.S. He went on to become the interim director of the White House's Office of National AIDS Policy. In the Obama Administration, Dr. Goosby was appointed Ambassador-at-Large and implemented the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), which significantly expanded under his tenure life- saving HIV treatment to millions in Sub Saharan Africa, SE Asia, and Eastern Europe. After serving as the U.S. Global AIDS Coordinator, he was appointed by the UN Secretary-General as the Special Envoy on Tuberculosis in 2015 where he focused on the first-ever UN High-Level Meeting on TB in 2019. Most recently, he served as a member of the Biden-Harris Transition COVID-19 Advisory Board. He is currently a Professor of Medicine at the UCSF School of Medicine and leading the Center for Global Health Delivery, Diplomacy and Economics, Institute for Global Health Sciences. He is a member of the Western States Scientific Safety Review Workgroup, and serves on the San Francisco Dept. of Public Health, Policy Group for the COVID-19 Response.

Dr. Shivon Boodhoo Goullet possesses a unique program management and business strategy-building skill set amassed over the course of almost two decades spent at the highest levels of academia, pharmaceuticals and in a range of healthcare settings. She began her career in the pharmaceutical industry by leading the design and implementation of the global metrics program for Catalent Pharma Solutions (formerly Cardinal Health PTS). Her subsequent doctoral work created a novel performance framework called the HOSx: Hospital Operations Excellence Model used to measure and evaluate the operations productivity of hospitals across the United States. At NJIT she has advised over 1,700 students and taught courses ranging from undergraduate and graduate-level healthcare systems engineering and engineering cost management to Executive MBA-level global project management. Dr. Goullet holds both B.S. and Ph.D. degrees in Industrial Engineering and an M.S. in Engineering Management with a specialization in Pharmaceutical Management. McKinsey & Company trained in business strategy, she is an inducted member of Tau Beta Pi - the National Engineering Honor Society and an Honorary Member of the National Academy of Inventors. In her current role as NJIT's Founding Director of the Faculty Awards office, she has university-wide responsibility for all nationally competitive faculty recognitions. Concurrently, she is also the Principal Advisor to PCMS1 Consulting LLC, a global business consulting firm.

Kathryn Hockman is the South Asia program coordinator at Carnegie Endowment for International Peace. Previously she was a Gary Eichten News Fellow at Minnesota Public Radio News. Hockman has a B.A. in International Relations from the College of St. Benedict and St. John's University in Collegeville, MN.

Aaron S. Kesselheim MD JD MPH is a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Aaron created and leads the Program On Regulation, Therapeutics, And Law (PORTAL, www.PORTALresearch.org), an interdisciplinary research center focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. PORTAL is now among the largest, independent (non- industry-funded) academic centers focusing on these issues in the country (Twitter: @PORTAL_research, @akesselheim). Aaron also serves as a Visiting Professor of Law at Yale Law School, where he teaches a yearly course on Food and Drug Administration Law and Policy (and at the Yale School of Public Health). He recently developed a massive open online course called Prescription Drug Regulation, Cost, and Access: Current Controversies in Context disseminated via the HarvardX platform to over 100,000 participants world-wide (and still available for viewing here: https://www.edx.org/course/the-fda-and-prescription-drugs-current-controversies-in-context). He is the editor-in-chief of the Journal of Law, Medicine, and Ethics. In 2020, he was elected to the National Academy of Medicine.

Jeff Kindler joined Centrexion Therapeutics as the chief executive officer in 2013. He brings more than three decades of business experience and has held leadership positions at some of the world's most recognized companies. Jeff is also executive chair of vTv Therapeutics, venture partner at Lux Capital, managing director at Starboard Capital and the global chair for the GLG Institute. Prior to joining Centrexion, Jeff was the chairman and CEO of Pfizer, the world's largest research-based biopharmaceutical company. As CEO, he led Pfizer's $68 billion merger and acquisition of Wyeth, diversified its product portfolio, improved its research and development pipeline, and reshaped the company's commercial, innovation and leadership models to drive growth and cultural change. Earlier in his career, Jeff served as the executive vice president and general counsel for McDonald's Corporation and was the vice president of litigation and legal policy for the General Electric Company. Prior to GE, Jeff practiced civil and criminal litigation as a Partner of William & Connolly. Jeff holds a B.A. from Tufts University and a J.D. from Harvard University.

Dr Rajiv Kumar was the Vice-Chairman of the National Institution for Transforming India (NITI Aayog) with the rank and status of a Cabinet Minister from September 2017 to April 2022. In earlier stints with the Government of India, he has served with the Ministry of Finance as Economic Advisor to the Department of Economic Affairs and as Senior Consultant to the Bureau of Industrial Costs and Prices, Ministry of Industries. While at NITI Aayog, Dr Kumar was instrumental in launching several strategic policy initiatives, including: driving a system-scale whole-of-government collaboration on mainstreaming regenerative agriculture in India; Electric mobility mission; Initiative on Integrated Medicine; Chairing Government of India committees on Hydro-Carbon and Mining Sector Reforms and Chairing the Mission High Level Committee on Atal Innovation Mission. Dr Rajiv Kumar is the Chancellor of Gokhale Institute of Politics and Economics, Pune and Chairman of the Giri Institute of Development Studies, Lucknow India. He is a renowned economist and a widely published author with over 4 decades of varied experience in government, academia, industry, and multilateral institutions. His past strategic engagements with academia and industry

include: CEO of the Indian Council for Research on International Economic Relations (ICRIER); Chief Economist at the Confederation of Indian Industry (CII); Secretary-General of the Federation of Indian Chamber of Commerce & Industry (FICCI); Senior Fellow at the Centre for Policy Research, New Delhi; Professor at the Indian Institute of Foreign Trade (IIFT); and Board positions in several institutions of significance, both in India and abroad. Dr Kumar served with the Asian Development Bank, Manila, Philippines from January 1995 to July 2005. While in ADB he served as Country Economist for China and Mongolia and the Principal Economist for Central Asian Republics (viz Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan). He also worked in the Research Department of the ADB for three years. He holds a Ph.D. in Economics from Lucknow University, India, and a D. Phil. In Economics from Oxford University.

Neel Lakhani, Senior Director, Clinton Health Access Initiative (CHAI). Neel joined CHAI in 2011 focused on identifying market issues and developing innovative interventions to sustainably increase access to critical health commodities and services in low- and middle-income countries. Neel's work has primarily focused on market shaping initiatives, and he's worked on numerous deals using a wide array of market shaping tools, including volume guarantees, public-private partnerships, loans, and licenses. Neel has contributed to numerous global initiatives, including advising on the design of a large global malaria subsidy mechanism and exploring stockpiling key commodities to mitigate supply chain issues. Prior to joining CHAI Neel was a management consultant providing strategic advice to clients in Africa, the Middle East, and Europe. Neel has an undergraduate degree in economics from the London School of Economics and two master's degrees from Cornell University - a Master's in Business Administration and Master of Industrial and Labor Relations.

Claudio Lilienfeld Fellow, Harvard Law School. Mr. Lilienfeld currently is a Fellow at the Berkman Klein Center at Harvard University where his work focuses on voluntary licensing and access to medicines in pandemics and health emergencies. For 5 years ending in 2020, Mr. Lilienfeld served as Gilead Sciences' Senior Director, Government Affairs leading external engagement in support of Gilead's Global Patient Solutions business unit, with a focus on Asia. Mr. Lilienfeld previously served as Principal in the International practice at the Podesta Group, was a senior international policy advisor at Google, and headed the India practice at McLarty Associates, advising a cross-section of Fortune 200 firms. Prior to that, Mr. Lilienfeld spent over 20 years in the U.S. Government, ending in 2010. He was Deputy Assistant and Acting Assistant U.S. Trade Representative for South/Central Asia (2006-2010), leading trade negotiations with the region. From 1999 to 2006, during a critical era, he led South Asia policy in the Office of the U.S. Secretary of Defense. From 1993 to 1999, he oversaw Defense Department policy planning for humanitarian operations, including in the Balkans, Central Africa, and Iraq. Mr. Lilienfeld received a BA in Geophysics in 1984 and an MA in International Relations in 1987, both from the University of Chicago. In 2003-2004, Mr. Lilienfeld was an Office of the Secretary of Defense Fellow and Visiting Scholar at Johns Hopkins' School for Advanced International Studies.

Lillian Lou has worked at The John C. Martin Foundation since its inception and formation in 2014. Prior to joining the Foundation, Lillian had over 20 years of work experience in the pharmaceutical industry. She directed discovery biology research and clinical studies in several pharma and biotech companies focusing on disease areas including hepatitis B and hepatitis C. As a medical director in medical affairs and the Gilead Access Programs immediately prior to joining the Foundation, she was responsible for managing programs of investigator-sponsored studies, medical communications and advisory boards leading the medical science activities in HIV/AIDS and viral hepatitis for developing countries. Lillian serves on the board of directors at The Scripps Research Institute and the Center for Disease Analysis Foundation. She is an executive board member of the Coalition of Global Hepatitis Elimination. Lillian was trained as a research scientist and holds a BS degree in Chemistry from California State University at Fullerton, and a PhD degree in Biochemistry from University of California, Los Angeles. She was a National Institute of Health post-doctoral research fellow at Stanford University in California. She was further trained in certification programs offered by University of California Santa Cruz and received certificates in clinical research and management, and regulatory affairs.

James Love is Director of Knowledge Ecology International. His training is in economics and finance, and work focuses on the production, management, and access to knowledge resources, as well as aspects of competition policy. The current focus is on the financing of research and development, intellectual property rights, prices for and access to new drugs, vaccines, and other medical technologies, as well as related topics for other knowledge goods, including data, software, other information protected by copyright or related rights, and proposals to expand the production of knowledge as a public good. James Love holds a Master's of Public Administration from Harvard University's Kennedy School of Government and a Master's in Public Affairs from Princeton's Woodrow Wilson School of Public and International Affairs.

Peter Mamacos is a Senior Advisor in USAID's Center for Impact and Innovation in the Global Health Bureau. He is a career civil servant and previously served in the White House as Director for Global Health and Development on the National Security Council. Prior to that, he was Director of Multilateral Relations in the Office of Global Affairs at the Department of Health and Human Services. He also previously worked at USAID on the President's Malaria Initiative; in the Office of the Global AIDS Coordinator; and as a consultant for Project HOPE in Malawi. He has a Master's Degree in International Relations from Yale University and is a graduate of Hampshire College.

Muz Mansuri joined F-Prime Capital in January 2020 as a Venture Partner and is based in the Boston office. Muz will be working with various F-Prime team members to evaluate therapeutic and digital investment and company creation opportunities. Muz has more than 35 years of experience in various R&D roles as a senior executive within the global biopharmaceutical industry. Prior to joining F-Prime, Muz was a member of the Executive Committee at Sanofi, as Executive Vice President, Strategy, Business Development, and Licensing. Among other responsibilities, Muz headed the Strategy, Business Development, Alliance Management, and the Venture Group for Sanofi. Before this, he was at Gilead Sciences as Senior Vice President, Research and Development Strategy and Business Development. In that capacity he led the R&D Strategy, Business Development, and M&A activities for the company. Muz has served as Chief Executive Officer of several biotech companies and as a General Partner at Flagship Ventures (now Flagship Pioneering). He began his career in the pharmaceutical industry as a bench medicinal chemist with Bristol Myers. Muz received his B.Sc. and Ph.D. in Chemistry from the University College London. He conducted postdoctoral research at UCLA and Columbia University.

Stavros Nicolaou is a member of Aspen Pharmacare Holdings Limited Group Executive Committee and is the Group Senior Executive responsible for Strategic Trade Development. Previously he was CEO of Aspen's Export Business. Aspen is Africa's largest pharmaceutical manufacturer and a now world leader in anaesthetics and injectable anti-coagulants. Aspen is one of South Africa's most globalized multinational companies with a presence in over 50 geographies globally, with 26 manufacturing facilities across 6 continents. He was instrumental in introducing the first generic ARV's on the African Continent developed by Aspen, which has gone on to save hundreds of thousands of lives in South Africa and on the African Continent. Nicolaou is a graduate of Wits University and has over 31 years experience in the South African and International Pharmaceutical Industry, 27 years of which have been with the Aspen Group or its subsidiaries and is a previous winner of the SA Institute of Marketing Management (IMM) Health Care Marketer of the year Award. He is a previous recipient Monty Rubenstein Award for proficiency in Pharmaceutics from the Wits University Pharmacy Health Sciences Faculty. He was awarded, the Order of the Lion of St Mark by the Greek Orthodox Pope Theodoros II and recently received the title of "High Commander of the Order of the Apostle & Evangelist Mark" of the Patriarchate of Alexandria. He has been inducted as a Fellow of the Pharmaceutical Society of South Africa (PSSA), one of the highest honours bestowed by the PSSA, and was recently awarded an Honorary Doctorate in Medicine from Wits University. Nicolaou is particularly passionate about diversity, transformation, championing localization and building bridges between the private and public sector in order to improve access to treatment for patients in emerging markets and improving healthcare outcomes in these markets. He has been involved in a number of social responsibility and charitable causes aimed at reducing poverty, inequality and assisting economic growth and development in South Africa. He has been a speaker at a number of conferences, including the Economist Roundtable, the World Economic Forum (WEF) and has delivered a lecture on ARV developments at the Raigon Institute, a JV between Harvard Medical School and the Massachusetts General Hospital.

Professor Ruth L. Okediji is the Jeremiah Smith. Jr, Professor of Law at Harvard Law School and Co-Director of the Berkman Klein Center. A renowned scholar in international intellectual property (IP) law and a foremost authority on the role of intellectual property in social and economic development, Professor Okediji has advised inter-governmental organizations, regional economic communities, and national governments on a range of matters related to technology, innovation policy, and development. Her widely cited scholarship on IP and development has influenced government policies in sub-Saharan Africa, the Caribbean, Latin America, and South America. Her ideas have helped shape national strategies for the implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). She works closely with several United Nations agencies, research centers, and international organizations on the human development effects of international IP policy, including access to knowledge, access to essential medicines and issues related to indigenous innovation systems. Professor Okediji was a member of the United States National Academies' Board on Science, Technology and Policy Committee on the Impact of Copyright Policy on Innovation in the Digital Era. She served as the Chief Technical Expert and Lead Negotiator for the Delegation of Nigeria to the 2013 WIPO Diplomatic Conference to Conclude a Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities (Marrakesh VIP Treaty). Okediji was appointed by United Nations Secretary-General Ban Ki-moon to the 2015 – 2016 High Level Panel on Access to Medicines. Professor Okediji is a recipient of numerous awards for excellence in teaching, research and mentoring. She is an editor of the *Journal of World Intellectual Property Law* and an elected member of the American Law Institute. Her most recent book, *Copyright Law in an Age of Limitations and Exceptions,* was published by Cambridge University Press in 2017. Professor Okediji is a graduate of the University of Jos and Harvard Law School.

Greg Perry joined IFPMA 2018 as Assistant Director General and has been responsible for extending organization's external outreach and stakeholder engagement in global health focusing on innovation, access, regulatory scientific affairs , youth and Africa. Greg is also the Vice Chair of the Fight the Fakes Alliance and a Fellow and member of the Advisory Council of TOPRA - the organization for professional regulatory scientists. Immediately prior to joining IFPMA, Greg was the Executive Director of the UN backed Medicines Patent Pool. During Greg's 5 years leadership MPP succeeded in negotiating a range of ground-breaking IP licenses for increasing access to innovative HIV treatments and pediatric formulations and extend the organization's mandate to include HCV and TB treatments. The then WHO DG Margaret Chan stated that "The MPP, with its public health- driven business model, has pioneered ways to improve access by partnering with generic and originator companies alike. This is a new system of IP management that engages industry and shows great promise for the future." From 1999 - 2012 Greg was Director General of the European Generic Medicines Association (Now Medicines For Europe) During this period the EGA succeeded in transforming EU pharmaceutical law to create a better regulatory and legal environment for generic medicines, established the regulatory pathway for biosimilars, enhanced the uptake of generic medicines in European healthcare systems. Previously Greg worked as Managing Director and partner in a Brussels office of a leading UK public affairs company , ran his own company in European Union policy for corporate and non- governmental organizations, and worked as a Parliamentary Advisor to Members of the European Parliament in Brussels. Greg holds the Golden Cross of Merit of the Republic of Poland for contribution to industry and European integration - one of a few non-Polish nationals to hold the honor.

Kash Rangan is the Malcolm P. McNair Professor of Marketing at the Harvard Business School. Formerly the chairman of the Marketing Department (1998- 2002), he is now the co-chairman of the school's Social Enterprise Initiative. He has taught in a wide variety of MBA courses, including the core First-Year Marketing course (was its head across multiple sections from 1993-1996), and the second-year electives, Business Marketing and Channels-to-Market. He has also taught marketing in the Advanced Management Program for senior managers. Currently Rangan teaches the elective course, Business at the Base of the Pyramid. In addition, he teaches in a number of focused executive education programs: Business-to-Business Marketing Strategy, Strategic Perspectives on Nonprofit Management, and Corporate Social Responsibility.

Dr. David Ripin is the Executive Vice President of Infectious Diseases, and the Chief Science Officer at the Clinton Health Access Initiative (CHAI). In these roles, he oversees CHAI's work on increasing access to medicines and diagnostics for HIV, malaria, tuberculosis, and other disease areas through the use of sustainable market interventions. CHAI's Access program has successfully implemented agreements with pharmaceutical companies to lower the price of key drugs and diagnostics by up to 80 percent, among other achievements. He also oversees the strategy and work of CHAI's Malaria program. Dr. Ripin joined CHAI in 2007. Prior to assuming his current role, he led CHAI's Pharmaceutical Sciences Team, which conducts research and development work. These efforts focus on reducing the cost of key drugs through recommending formulation, manufacturing process, and sourcing improvements, as well as conducting the transfer of these processes to manufacturing partners. Dr. Ripin is actively involved in setting international priorities for HIV drug optimization work, including organizing the Conference on Antiretroviral Drug Optimization in 2009. Before joining CHAI, he worked at Pfizer, Inc. for 10 years as part of the research and development group, focusing on the commercialization and manufacturing of drug candidates. Dr. Ripin received a Bachelor of Science in Chemistry and Asian Studies from Washington University in St. Louis and obtained his Ph.D. in Chemistry from Harvard University.

Clifford Samuel, Principal at PCMS1 Consulting, advises large caps, start-ups, and NGOs on issues surrounding the access and distribution of life-saving medicines in emerging markets and low- and middle-income countries. He offers 30+ years of commercial leadership experience in the biopharmaceutical industry, with more than two decades at Gilead Sciences in leadership roles across sales, managed markets, and global commercial operations. Clifford consults on biopharma investment opportunities, early-stage clinical studies, and go-to-market strategies in emerging markets and low/middle-income countries. Having built multiple global strategic partnerships, including collaborations with governments, non-governmental organizations, and generic drug manufacturers, he is able to facilitate the delivery of critical medicines internationally in very complex/opaque markets. His expertise extends to matters such as the implications of holding market authorization rights and the role of voluntary licensing in ensuring that life-saving medical innovations are available to resource-challenged areas globally. From 2007 to 2020, Clifford served at Gilead Sciences, culminating with SVP, Global Patient Solutions, with responsibility for more than 140 countries. His successful initiatives in emerging markets drove both access to medicines and ROI in geographies spanning Latin America and the Caribbean, Africa, South/Southeast Asia Pacific, and Eastern Europe. Leveraging a deep knowledge of the regulatory landscape and distribution network across the globe, Clifford spearheaded Gilead's entry into generic licensing agreements with companies in Pakistan, India, and South Africa that created a competitive market for generic HIV and hepatitis B & C medicines, and most recently, Remdesivir to treat COVID-19. His efforts resulted in the provision of medicines to more than 19 million people living

with HIV/AIDS in these resource-limited countries. In 2022, Clifford was granted a fellowship at the Berkman Klein Center for Internet & Society at Harvard University to explore voluntary licensing and access to medicines in the context of pandemics and health emergencies. He is a Fellow of the American Institute for Medical and Biological Engineering (AIMBE). He sits on the Board of Antiva Biosciences and the MTV Staying Alive Foundation, and serves as a business advisor to Siolta Therapeutics, Pardes Biosciences, and Karkinos Healthcare (India). A graduate of the New Jersey Institute of Technology (NJIT) with a BS in Mechanical Engineering, he received an Honorary PhD from his alma mater and sits as a member of the Industrial Advisory Board for NJIT's Albert Dorman Honors College. He is also the recipient of an Edward F. Weston Medal for Professional Achievement and was inducted as a member of the National Academy of Engineering in 2019.

Swarup Sarkar is an Indian epidemiologist, public health professional and diplomat known for his work in the field of Infectious Diseases and HIV/AIDS in particular. He retired as the Director of Communicable diseases at the World Health Organization, South-East Asia regional Office (WHO SEARO) in November 2018. Sarkar has been awarded for his contribution in Public Health by World Health Organization (WHO) in 2018. Prior to his role in the WHO, he has served as the Head of South Asia and Regional Advisor of the Asia Pacific region of the UNAIDS and Director of Asia Pacific Country Programs of The Global Fund. Sarkar joined the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1998, and served UNAIDS at various roles for a decade, from being an Epidemiologist stationed in Geneva, to being the UNAIDS Team Leader, South Asia and Regional Adviser to the Asia Pacific region. Sarkar's UNAIDS group pushed South Asian countries to focus prevention services for the marginalized groups in ways which were not traditional in the field. He proposed and formed self-run services by the high-risk communities and created an enabling environment by breaking the barriers that obstruct people from accessing essential services. He has advocated for political commitment, acceptance of the HIV problem by the Governments, allocation of resources, mitigation of stigma associated with HIV/AIDS and an all-inclusive approach for target group identification, prevention, and care. Before returning to UNAIDS again in 2011, Sarkar worked with the ADB and The Global Fund to Fight AIDS, TB, and Malaria. In 2015, Sarkar joined the WHO as the Director of Communicable diseases for its South-East Asian Regional Office. Sarkar's main activities were centered around the reduction in stigma as a part of prevention interventions within activities meant to reduce transmission among sex workers, injection drug users, MSM and their partners.

Dr. Ameet Sarpatwari is an Assistant Professor of Medicine at Harvard Medical School, an Associate Epidemiologist at Brigham and Women's Hospital, and Assistant Director of the Program On Regulation, Therapeutics, And Law (PORTAL) within the Division of Pharmacoepidemiology and Pharmacoeconomics. His research draws upon his interdisciplinary training as an epidemiologist and lawyer and focuses on the effects of laws and regulations on therapeutic development, approval, use, and related public health outcomes.

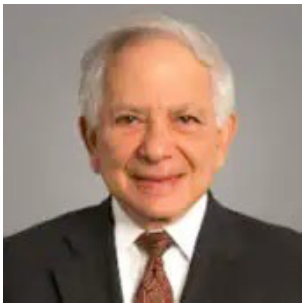
Subhanu Saxena is the Director, Innovation Introduction for Bill & Melinda Gates Foundation. Subhanu spearheads key cross-functional initiatives for the foundation and is building capabilities to enhance the foundation's ability to support introduction of new innovations at scale. He is a highly accomplished global executive whose experience has spanned markets in Europe, North America, Africa, and Asia. He has worked in various industries including in pharmaceuticals, fast-moving consumer goods (FMCG), consulting and banking. Prior to his current role, Subhanu was with Cipla, a pharmaceutical manufacturing company with a presence in over 170 countries as MD and global CEO. He has also served as a member of Novartis' Pharmaceutical Executive Committee where he was head of Global Product Strategy and Commercialization responsible for marketing, sales, global medical affairs, and health economics. He assumed this role after a four-year stint as Novartis' UK Pharma CEO and country president. Subhanu has also worked with Citigroup, Boston Consulting Group, and Pepsi Co Inc. His early industry experience includes developing entry and growth strategies for Pepsi. Subhanu graduated with an MBA from INSEAD France, Fontainebleau, and a M.A. (Hons) in Engineering Science from Oxford University, both with distinction. A citizen of the United Kingdom, and an India OCI cardholder, he is fluent in English, Hindi, and Sanskrit, and has a good working knowledge of French, German, and Russian. On the non-professional side, Subhanu loves loud music and Sanskrit and Vedanta teaching. He is a lecture /teacher of Sanskrit and ancient Indian literature and has a love for Urdu poetry. He also plays classical guitar and is an executive committee member of the Bharatiya Vidya Bhavan, UK.

Onno Schellekens is the Chairman of the Joep Lange Institute. In his daily life Onno is CEO of CarePay International, a mobile payment platform for healthcare, number 7 on the Fortune "Change the World 2020 list". CarePay provides millions of people in Africa with a health wallet on their cell phones. CarePay won the 2017 Financial Times/IFC Transformational Business Award, was named 2018 Technology Pioneer by the World Economic Forum and won the 2019 Swiss Re Entrepreneurs for Resilience Award. Prior to CarePay International Onno was the CEO of PharmAccess Group, a pioneer of HIV Aids treatment programs and health insurance in Africa. The specific approach to development attracts international attention, including a G20 prize for innovative financing presented by President Obama. Onno holds a master's degree in Business Economics from the University of Groningen and has taken several courses at Harvard Business School and INSEAD. He has over 25 years of experience in technology, healthcare financing, and private equity. He was also one of the editors of two World Bank publication on health insurance in developing countries and was one of the winners of the 2008 *IFC/Financial Times Essay* competition with an essay titled 'A new paradigm for increased access to healthcare in Africa'.

Ken Shotts is The David S. and Ann M. Barlow Professor of Political Economy at Stanford Graduate School of Business. In his research, he uses game theory to analyze how elections and political institutions influence government policy choices. He has published papers on electoral accountability, leadership and pandering, racial redistricting, term limits, political risk, policy entrepreneurship, and media and propaganda in fragile democracies. Ken teaches core MBA classes on Leading with Values and is the author (with Neil Malhotra) of the recently-published book *Leading with Values: Strategies for Making Ethical Decisions in Business and Life.*

Michel Hamala Sidibé African Union Special Envoy for the African Medicines Agency (AMA). Sidibé is a renowned tireless champion of African-owned solutions and has been an outspoken advocate for local pharmaceutical production of medicines and other essential health commodities. He contributed to the efforts towards access to quality and safe medicines and vaccines and in fighting global inequities. In April 2021, he was appointed African Union Special Envoy for AMA. Thanks to his high-level advocacy efforts, the treaty entered into force on 5 November, much more quickly than expected. A former Minister of Health and Social Affairs for Mali (2019-2020), Sidibé has championed a people centered approach to health and development for over 40 years. He served as Executive Director of UNAIDS, holding the rank of Under-Secretary-General of the United Nations (2009-2019). Prior to joining UNAIDS, Sidibé worked at UNICEF and for Terre des Hommes, where his passion for advancing global health and social justice began. Under his leadership at UNAIDS, more than 25 million people started life saving HIV treatment. In 2021 he was appointed a board member of The Global Commission on Drug Policy. An economist by training, Sidibé is the recipient of various African and global awards, including honorary doctorates from world's leading universities.

Rachel Silverman-Bonnifield is a Policy Fellow at the Center for Global Development, a non-profit, non-partisan, and independent think tank that focuses on issues affecting low- and middle-income countries and the global commons. In her role, she leads policy-oriented research and convenings on global health financing and policy, including efficient global health procurement; financing for pandemic preparedness and response; innovation and access models for global health products; and neglected global health crises such as the spread of antimicrobial resistance and widespread lead poisoning of children. In addition to her role with CGD, she has also consulted extensively with the World Bank, including authorship of the most recent Flagship Report on the future of primary health care. Before joining CGD in 2011 she worked with the National Democratic Institute to support democracy and governance strengthening programs in Kosovo. She holds a Master of Philosophy with distinction in public health from the University of Cambridge, which she attended as a Gates Cambridge Scholar. She also holds a BA with distinction in international relations and economics from Stanford University.



Abraham D. Sofaer was born in India and moved permanently to the U.S. when he was 14 years old. After a tour of duty in the U.S. Air Force he attended Yeshiva College and then NYU Law School, where he was editor in chief of the law review. He clerked for Judge Skelly Wright of the DC Circuit Court of Appeals and for Justice William J. Brennan, Jr. He served as an Assistant U.S. Attorney from 1967 to 1969, and then taught for 10 years at the Columbia University School of Law. He was a U.S. District Judge from 1979 to 1985, after which he served as Legal Adviser of the U.S. Department of State for 5 years. He spent 4 years in the private practice of law. In 1994 he joined the Hoover Institution, Stanford University, as the George P. Shultz Senior Fellow, where he is now Emeritus. He has considerable experience in Intellectual Property and product licensing as a judge, arbitrator, and board member at Genprobe, Inc., and Rambus, Inc.

Ashley J. Tellis holds the Tata Chair for Strategic Affairs and is a senior fellow at the Carnegie Endowment for International Peace, specializing in international security. Additionally, he is the research director of the National Bureau of Asian Research's Strategic Asia program and serves as an advisor to the Chief of Naval Operations. While in the U.S. government during the George W. Bush administration, he served both in the White House and in the State Department, where he was intimately involved in negotiating the civil nuclear agreement with India. He also served on the National Security Council staff as special assistant to President George W. Bush and senior director for strategic planning and Southwest Asia. He is the author of India's Emerging Nuclear Posture (2001) and co-author of Interpreting China's Grand Strategy: Past, Present, and Future (2000). In addition to numerous Carnegie and RAND reports, his academic publications have appeared in many edited volumes and journals.

Dr. Ellen 't Hoen is the Director of Medicines Law & Policy, a group of legal and policy experts offering advice to international organizations and governments. From 1999 until 2009 she was the director of policy for Médecins sans Frontières. In 2009 she joined UNITAID in Geneva to set up the Medicines Patent Pool (MPP). She was the MPP's first executive director until 2012. She has published widely and is the author of several books. In 2017 she received the Prix Prescrire for her book "Private Patents and Public Health: Changing intellectual property rules for public health." In 2005, 2006, 2010, 2011 and in 2020 she was listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property. In 2020, the King of the Netherlands appointed her Officer of the Order of Oranje-Nassau, in recognition of her work on access to medicines. She has a master's degree in law from the University of Amsterdam and a PhD from the University of Groningen where she remains a Global Health Law Fellow at the law faculty.

Dr. Krishna Udayakumar is the founding Director of the Duke Global Health Innovation Center, focused on generating deeper evidence and support for the study, scaling, and adaptation of health innovations and policy reforms globally. He is also Executive Director of Innovations in Healthcare, a non-profit co-founded by Duke, McKinsey & Company, and the World Economic Forum to curate and scale the impact of transformative health solutions globally. At Duke University, Dr. Udayakumar holds the rank of Associate Professor of Global Health and Medicine, and is a core faculty member of the Duke-Margolis Center for Health Policy. He also serves as Associate Director for Innovation of the Duke Global Health Institute. His work has been published in leading academic journals such as the New England Journal of Medicine, Health Affairs, and Academic Medicine, and he has been interviewed or quoted in media outlets around the world, including CNN, BBC, NPR, Al Jazeera, New York Times, Washington Post, and Politico. Born in Bangalore, India, Dr. Udayakumar spent his childhood in Virginia, and is a Phi Beta Kappa graduate of the University of Virginia, with a bachelor's degree in interdisciplinary studies with distinction. He received both an MD and an MBA (with a concentration in Health Sector Management) from Duke University, where he was a Fuqua Scholar. Dr. Udayakumar completed his residency training in internal medicine at Duke and served as Assistant Chief Resident at the Durham VA Medical Center before joining the faculty of Duke University.

Jayashree Watal retired from the Intellectual Property, Government Procurement and Competition Division of the World Trade Organization in mid-2019, where she had contributed inter alia to work on TRIPS and public health, Patents, Undisclosed information, Economics of TRIPS, IP and Transfer of Technology, and IP and Competition Policy. She assisted the then Director of the Intellectual Property Division on the negotiations that led up to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in November 2001; the interim waiver solution in August 2003; and the Protocol on the amendment that resulted in a new article 31bis in December 2005. She currently holds the position of Honorary Professor at the National Law University, Delhi since August 2019 and has been a part-time Adjunct Professor position at the Georgetown University Law Centre since 2009, teaching a course on International Trade, Intellectual Property and Public Health every year. She was a member of the Governance Board of the Medicines Patent Pool, a non-profit organization based in Geneva for six years until mid- 2021 and continues to be consulted on MPP strategy. She holds several part-time consulting positions to assist WTO members and observers on TRIPS-related issues. Ms. Watal holds post-graduate degrees in both law and economics and, prior to joining the WTO, has had more than twenty-two years of experience in government in India. She represented India at a crucial stage in the Uruguay Round TRIPS negotiations from 1989-90, contributing substantially to the development of the text. She is the co-editor of three WTO books: A Handbook on the TRIPS Agreement, (Cambridge University Press, 2012/2021); The Making of the TRIPS Agreement, (WTO, 2015); and Trade in Knowledge (Cambridge University Press, 2021). She has authored a book Intellectual Property Rights in the WTO and Developing Countries (Oxford University Press, India and Kluwer Law International, 2001) and several peer-reviewed journal articles on issues related to the law/economics of intellectual property rights.

Thomas Winkler studied biology in Hamburg (Germany) and Wageningen (Netherlands) to obtain his PhD in Molecular Biology/Genetics in 1997. He started his path in Intellectual Property with the IP law firm Boehmert & Boehmert (Germany) in 2001 to become a German Patent Attorney. In 2004 he began working with F. Hoffmann-La Roche AG (Switzerland) and qualified during this time as European and Swiss Patent Attorney and gained an Executive Master's Degree in international negotiation and policy-making from the Graduate Institute (Geneva) in 2021. Since November 2020 Thomas works as Head IP Policy in the global IP function of Roche.

About the John C. Martin Foundation

The John C. Martin Foundation is a privately-funded non-profit organization in the United States. It was established in 2014 with the goal to facilitate the establishment of sustainable improvement of health care for populations in socially and economically-disadvantaged settings. Our focus is the advancement of control and prevention of endemic illnesses among underserved populations of the world.

The Foundation's charitable activity takes the form of grantmaking. Funding priority is for local projects that can deliver marked, self-sustaining, self-advancing and long-lasting impact to target communities.

Our supported grants include knowledge-building among healthcare providers, disease epidemiologic investigations to better define public health burdens and inform health policy decisions, prevention of transmission of viral infections, and healthcare infrastructure improvement for impoverished populations.

About John C. Martin

"There are two types of unmet needs: One, there are medical conditions that there is no good treatment for; the other, there are good drugs, but patients do not have access." - Dr. John C. Martin, former C.E.O. & Chairman Gilead Sciences, Founder of the J.C.M. Foundation

Dr. John Charles Martin was a chemist, longtime C.E.O., philanthropist, and global health advocate dedicated to addressing health disparities in communities around the world. A quiet, unassuming force, John's overwhelming generosity and brilliance forever changed what it meant to receive a diagnosis of H.I.V. or viral hepatitis - from a death sentence to manageable disease for HIV and a cure for Hep C. His commitment to helping people around the world never faltered, and millions are alive today because of his dedication to access to medicine regardless of geography or socioeconomic status.

John received his B.S. in Chemical Engineering from Purdue University and Ph.D. in Organic Chemistry from the University of Chicago. At Syntex in Palo Alto, California, John synthesized ganciclovir, thus co-inventing the first acyclic nucleoside antiviral drug to treat and prevent infections caused by cytomegalovirus. These remain cornerstones of treatment today. Later, at Bristol Myers, he directed the development and eventual licensure of two dideoxynucleoside antivirals to treat HIV/AIDS—didanosine and stavudine.

In 1990, John joined the then early-stage biotechnology company Gilead Sciences in California and led the evolution of its research. Appointed Gilead's C.E.O. in 1996, John presided over 20 innovative medicines and made Gilead drugs accessible to millions of patients in developing countries while increasing the company's value 140-fold. He was appointed Chairman of the Board of Directors in 2008 and would remain in that role until 2019. Under his legendary leadership, the company developed multiple breakthrough medicines, perhaps most notably for people with H.I.V., hepatitis B, and hepatitis C.

An early trailblazer, John directed Gilead in forming an unprecedented partnership that led to the creation of the first single-tablet regimen for HIV. Approved in 2006, this transformed the care of people living with H.I.V. by avoiding regimens of multiple drugs that made compliance challenging and led to the potential for drug-resisting treatment failures.

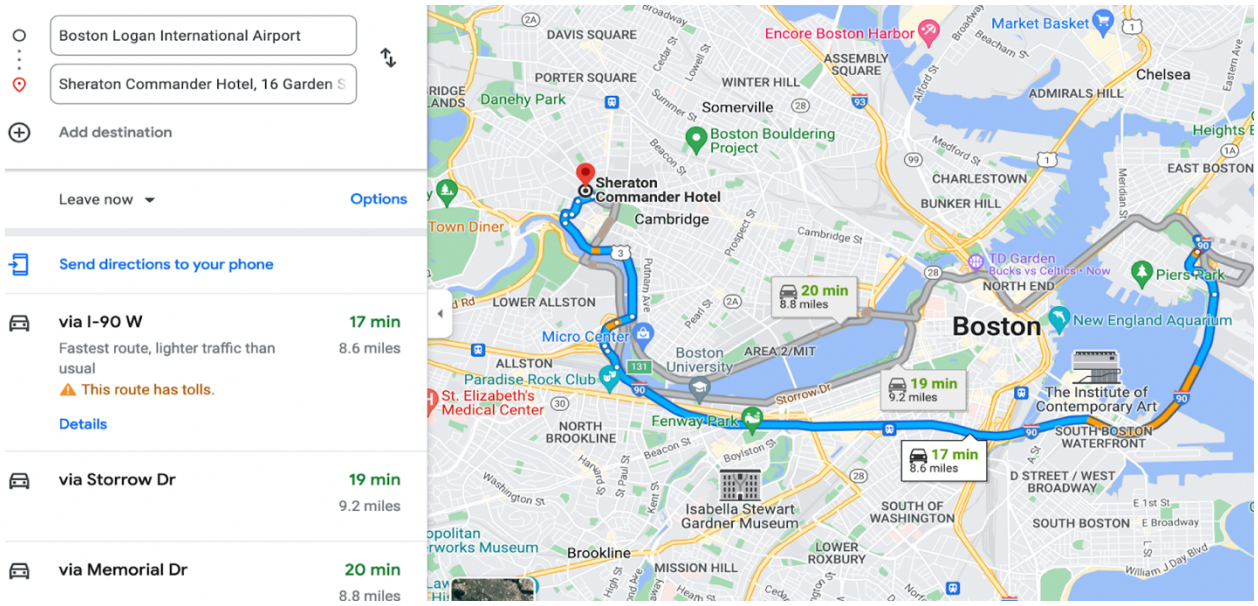
John's pursuit of innovative science expanded into pioneering solutions for global health. In 2003, when John traveled to Africa with Tommy Thompson (then the U.S. Secretary of Health and Human Services), he was struck by the immense devastation HIV/AIDS was having across the continent. He recognized that this devastation extended beyond human lives, impacting economies and societies. In a world-first, John directed the design of a revolutionary 'Access to Medicines' program that would deliver the company's H.I.V. treatments to more than 130 resource-limited countries. This access program provides licenses, technology transfers and know-how to generic manufacturers in India and other countries, thus enabling the licensees to rapidly-produce low-margin, high-quality products. The program later extended beyond H.I.V. to include Gilead's medicines for viral hepatitis B and C. Today, more than 19 million people in low-and-middle-income countries around the world receive these life-saving HIV medicines at an affordable cost each day.

John was widely recognized for his scientific and global health contributions to humanity. He received many awards, including the Stanford Medicine Lifetime Achievement Award for contributions to science benefiting humanity (2019) and the National Academy of Sciences Award for Chemistry in Service to Society (2019). He was elected to the National Academy of Engineering in 2008. In addition, John was recognized at the highest levels of civilian honor, receiving Belgium's Order of the Crown (2017), Senegal's Order of the Lion (2017), and the Republic of Georgia's Golden Fleece (2017). He received Honorary Doctoral Degrees from Katholieke University Leuven (2017) and The Scripps Research Institute (2019).

Directions

AIRPORT TO CONFERENCE HOTEL:

Boston Logan Airport to Sheraton Commander Hotel [16 Garden St, Cambridge, MA 02138]



HOTEL TO CONFERENCE VENUE :
Sheraton Commander Hotel [16 Garden St, Cambridge, MA 02138] to
Harvard Faculty Club [20 Quincy St, Cambridge, MA 02138]