



# Universities Allied for Essential Medicines National Conference

with Keynote Speaker

## Dan Ravicher

Executive Director, Public Patent Foundation (PUBPAT)  
Lecturer in Law, Benjamin N. Cardozo School of Law

### October 9-10, 2010

## Duke University & UNC Chapel Hill

Registration is available online at:  
[www.essentialmedicine.org/conference/2010](http://www.essentialmedicine.org/conference/2010)

# Our labs, our drugs, our responsibility.



# **Universities Allied for Essential Medicines 2010 Annual Conference, North Carolina**

***“Our labs, our drugs, our responsibility”***

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# Welcome Letter

Dear Friends,

Welcome to North Carolina! And welcome to the expanding, international grassroots movement that has become Universities Allied for Essential Medicines (UAEM). Almost 10 years has passed since that initial student-led protest on Yale's campus, which pushed the university to take action to ensure that one of its discoveries would travel from New Haven all the way to clinics in South Africa. There are now over 40 UAEM chapters across the US and Canada, UK, and Germany, with growing chapters and seeds in Uganda, Brazil, Australia and around the world. We have eight countries and 43 different institutions plugging into and contributing to the exchange of ideas at our gathering.

We hope you have a memorable conference weekend! Student activists and HealthGAP will share updates and experiences from campus and policy campaigns. Leaders from Doctors Without Borders and the UNITAID Patent Pool will give their perspectives on the global access to medicines movement, the consequences of inaction and creative potential solutions being pursued. UNC has recently adopted Global Access Principles to guide its licensing practices, and those who pioneered this will share their vision. We'll reflect further on the historical and future role of the university in developing medicines. And Dan Ravicher will talk about the commercialization of genes implicated in causing breast cancer and his fight against it.

UAEM students are trying, against the odds, to change a culture at universities and emphasize that advancing the global public interest should always be the highest priority. The past year had some significant advances in this important movement. Harvard and Yale unrelentingly publicized that their universities were not doing as much as they could be doing to promote access to their technologies for developing countries. The result was the drafting and adoption of the "Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies," now signed by over 25 institutions, including the US National Institutes of Health. It's far from perfect, but it's a sign that we are changing university priorities.

All of us with UAEM would also like to say thank you to Ethan Guillen, Executive Director of UAEM for the last three years, who has led UAEM through recent campaigns and expansion efforts. Ethan will be stepping down this year in January and will be dearly missed. Many thanks to members of the UNC and Duke UAEM, and to UAEM members far and wide who have helped to make this conference happen, as well to as our financial sponsors at both universities. We are proud to be hosting you on both of our campuses, although it makes transportation complicated. Please see the information in this packet for further details on maneuvering around Durham and Chapel Hill—don't hesitate to call one of us.

As always, thank you for campaigning for medicines to reach both Durban and Durham. As a UAEMer once said, you are not tweaking the world, you are not adjusting the world. You are changing the world. And patients are thankful for it.

In solidarity,

Manisha Bhattacharya and Duke-UAEM, Derek Lundberg and UNC-UAEM

## Sponsors

**We're grateful for the support from the following groups:**

- Program on Global Health and Technology Access, Duke University
- Duke Global Health Institute
- UNC Office of Global Health
- UNC Center for AIDS Research
- The Doris Duke Charitable Foundation
- The Perls Foundation

## Contact Information

Lost? Questions? For any reason, please call one of the numbers below:

### **Duke**

609-933-7450 Manisha Bhattacharya  
252-725-9551 Richard Waters

### **UNC**

919-265-3167 Derek Lundberg  
919-741-8703 Naman Shah

## Travel and Lodging Resources

**Conference Housing Map:** Find your host and proximity to campus:

<http://tinyurl.com/UAEM2010MAP>

**TaxiShare:** Coordinate travel to-and-from RDU with fellow UAEMers online:

<http://tinyurl.com/taxishare2010>

# Conference Agenda

To register for the 2010 International Conference of Universities Allied for Essential Medicines, visit:  
[www.essentialmedicine.org/conference/2010](http://www.essentialmedicine.org/conference/2010)

## **FRIDAY, OCTOBER 8 – Michael Hooker Research Center BCBS Auditorium, UNC**

6:30pm-onwards      Welcome reception for conference participants, donors and sponsors

## **SATURDAY, OCTOBER 9 – Duke University**

### **Schiciano Auditorium & Lobby**

- 7:00-8:00      Buses from UNC campus to Duke campus will be provided.  
Registered participants will receive more information.
- 7:30-8:20      Breakfast and Registration  
*Chapter Resource Fair: please send at least one chapter representative  
Taylor Gilliland and Gloria Tavera, UAEM Chapter Outreach Coordinators*
- 8:30-8:45      Welcome to 2010 UAEM International Conference  
*Dr. Michael Merson— Director, Duke Global Health Institute*  
Overview of weekend logistics  
*UNC & Duke UAEM chapters*
- 8:45-9:15      UAEM: History and Mission  
*Rachel Kiddell-Monroe, Chair of UAEM Board of Directors*
- 9:15-10:15      An Access to Medicines Crisis: From the clinic to international policy  
*Dr. Matthew Spitzer – President, US Board of Directors, Doctors Without  
Borders/MSF*  
*Emi MacLean – US Director of the Access to Essential Medicines Campaign,  
Doctors Without Borders/MSF*  
*Suerie Moon – Advisor, Medicines Patent Pool*
- 10:15-10:30      Audience Q&A

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**Introductory Track**  
**Teer Building 115**

**Advanced Track**  
**Teer Building 203**

10:40-11:30	<b>Problems:</b> -Intellectual Property Barriers to Access to Medicines -The Research & Development Gap -Status-quo metrics: How we Measure Research and Access <i>Aria Ilyad Ahmad</i>	<b>Session 1:</b> -Implementing the “Statement of Principles and Strategies”: One Year Later <i>Karolina Maciag</i> <i>Jillian Irwin</i>
11:30-12:30	<b>Solutions:</b> -Advancing University Policy -UAEM Framework for Changing Practices -Closing the Research Gap <i>Gloria Tavera, UAEM student-leader</i> <i>Michael Lin, UAEM student-leader</i>	<b>Session 2:</b> -National and International Mechanisms for Promoting Medical Innovation <i>Sara Crager</i>

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**Schiciano Auditorium & Lobby**

12:30-1:20	Lunch, catered by Nourish International <i>Seating by participant interest in International UAEM Working Groups</i>
1:30-2:10	State of UAEM Address <i>Ethan Guillen, Executive Director, UAEM</i>
2:15-3:45	UAEM Around the World: Campus Campaign and Working Group Presentations <i>Campus representatives and videos from chapters</i>
3:45-4:00	Break
4:00-4:45	Plenary on Technology Transfer <i>Cathy Innes – Director, UNC Office of Technology Development</i> <i>Bob Johnston – Director, Global Vaccines, Inc; Professor of Virology, UNC</i> <i>Maryann Feldman— S.K. Heninger Distinguished Professor of Public Policy, UNC</i>
4:45-5:00	Audience Q&A
5:15-6:30	<i>Transparency and the Research Gap: Breakout Sessions</i> <i>(See your conference packet on which you attend first).</i>

Seminar A: Social-impact metrics: Measuring the success of technology transfer  
*Bucky Fazen, UAEM-Yale*  
**Teer Building 115**

Seminar B: Strategies for advancing the neglected diseases campaign  
*Alex Lankowski, UAEM-Boston University*  
*Sara Crager, UAEM-Yale*  
**Teer Building 203**

6:30 onwards Dinner in Durham or Chapel Hill

9:00 onwards **Activities in Chapel Hill near UNC**  
UAEM and GH Funding Crisis Strategy Brainstorming Session  
*UNC Campus, Campus Y Building*  
Concert @ Cat's Cradle: Deerhunter, Ducktails, Casino vs Japan  
*300-G Main St, Arts Center Plaza, Carrboro*  
Networking at the Wine Bar  
*450 W. Franklin St, Chapel Hill*

## **SUNDAY, OCTOBER 10 – Michael Hooker Research Center, UNC**

### **School of Public Health Atrium**

7:45-8:20 Southern Breakfast Bites

### **133 Rosenau Hall Auditorium**

Welcome to UNC  
*Peggy Bentley, Associate Dean for Global Health*

8:30-9:15 UAEM/AMSA Biologics Campaign: A review and a look forward  
*Chris Manz, Chair, AMSA PharmFree Campaign*

9:15-9:30 Audience Q&A

9:30-10:30 **Plenary**  
Universities and Drug Development, International Expansion of Bayh-Dole  
*Bhaven Sampat – Dept of Health Policy and Management, Columbia University*  
*Arti Rai – Duke University Law School*  
*Krista Cox – UAEM staff attorney*  
Audience Q&A

### **Keynote Speech**

10:30-11:30 Gene Patenting & Access to Medicines  
*Dan Ravicher, Executive Director, Public Patent Foundation*

11:30-11:45 UAEM involvement in challenging gene patenting  
*Krista Cox, UAEM staff attorney*

11:45-12:00 Q&A

### School of Public Health Atrium

12:00-12:45 Speaker Reception/ Lunch

### 133 Rosenau Hall Auditorium

1:00-1:30 **Activism by Example**  
An introduction to the Global Health Funding Crisis  
*Matt Kavanagh, Director of US Advocacy, Health GAP*

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1:30-2:30 **Breakout Sessions (see conference packet on which session to attend first)**

<i>Session A</i>	<i>Session B</i>
<b>133 Rosenau Hall Auditorium</b>	<b>Blue Cross Auditorium, Hooker Research Center</b>
Introduction to advocacy - Launching an advocacy campaign <i>Matt Kavanagh, Health GAP</i>	Writing workshop - Letters to Congress, Editorials, Petitions <i>Jane Andrews, UAEM-Hopkins</i>

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### 133 Rosenau Hall Auditorium

2:30-3:00pm Closing Remarks  
*Ethan Guillen, Executive Director, UAEM  
UNC & Duke UAEM*

## Speaker Bios

**Taylor Gilliland**  
*UAEM Coordinating  
Committee and  
Chapter Outreach  
Coordinator*

Taylor is a fourth year graduate student in the Biomedical Sciences Ph.D. program at the University of California San Diego and was a National Science Foundation Graduate Research Fellow. He is now in his third year as a member of the UAEM Coordinating Committee as part of the Chapter Outreach and Empowerment teams as well as head of the UAEM chapter at UCSD. He formerly served as the Grassroots Outreach Coordinator for the Steering Committee of the Student Global AIDS Campaign while at the University of Florida.

**Gloria Tavera**  
*UAEM Coordinating  
Committee and  
Chapter Outreach  
Coordinator*

Gloria is currently conducting malaria research as an intramural training fellow at the National Institute of Allergy and Infectious Diseases. In 2009, she graduated from the University of Florida with degrees in neurobiology, political science and public health. She co-founded a chapter of UAEM at the University of Florida and has been a member of the Coordinating Committee since 2006. She spent last year in Mexico as a Fulbright scholar researching the pathology of dengue hemorrhagic fever. This year, she looks forward to empowering UAEM chapters to accomplish their goals!

**Krista Cox**  
*UAEM staff attorney*

Krista is an attorney living in the San Francisco Bay Area. She earned her J.D. with honors from the University of Notre Dame and where she served on the Executive Board of the Journal of Legislation and was a member of the Jessup International Moot Court team. At Notre Dame, she focused her studies on international law and human rights. She has always had a passion for access to healthcare and medicines issues and is super excited to be doing work for UAEM. Prior to her work at UAEM, she worked extensively on immigrant rights and human rights issues through a fellowship with the International Institute of the Bay Area and pro bono work with other local non-profit organizations.

**Jane Andrews**

Jane has been working with the policy working group as part of the UAEM-CC for the last year. She recently obtained her Master of Public Health and is now in her last year at the school of medicine and quite ready to finish so she can get a job- which will hopefully be a residency in internal medicine. Specifically she plans to focus on adolescent medicine or women's health and to work with patients to apply principles of nutrition and integrative therapies to combat disease. Within public health she plans to do health advocacy and research in the areas of: access to medicines, obesity and malnutrition, environmental sustainability and population, immigrant health within the US. Prior to medical school Jane received a Fulbright grant to research barriers to rural antiretroviral access in Tanzania. Favorite things include blueberries, backyard composting, long walks on the beach and better national pharmaceutical and licensing policies.

**Rachel Kiddell-  
Monroe**  
*Chair of UAEM  
Board of Directors*

Rachel has worked in the humanitarian field for over 20 years, served as the Special Assistant for the East Timor campaign at the United Nations and has extensive field experience in Africa and Latin America working for Doctors Without Borders (MSF). She served as head of mission in Djibouti and lead emergency humanitarian missions in Rwanda (1994-1995) and the Democratic Republic of Congo (1993-1994, 1996-1997). She started up an MSF advocacy office in Canada and spearheaded MSF's Regional humanitarian and advocacy coordination office in Latin America. Upon returning to Montreal, she headed up MSF's Access to Medicines Campaign in Canada where she gained notoriety and respect for her groundbreaking work on the Canadian initiative to allow the export of generics to developing

countries under the 2003 World Trade Organization patent waiver. In 2007, she was appointed to chair the UAEM Executive Board and has a particular interest in the international expansion of UAEM. She has also consulted for the Drugs for Neglected Diseases initiative (DNDi), is a member of the United Kingdom Law Society and is currently co-teaching an international development course at McGill University.

**Sandeep Kishore**  
*UAEM Board of  
Directors*

Sandeep (Sunny) is enrolled in the Weill Cornell Medical College/Rockefeller/Sloan-Kettering Institute Tri-Institutional MD-PhD program. His scientific research concerns characterizing gene activation in the parasite responsible for malaria. He has been involved in student-led global health efforts through assembling a Forum on Neglected Diseases, integrating global health and neglected disease issue into current medical school curricula, and successfully advocating for the inclusion of a cholesterol-lowering statin on the World Health Organization's Model List of Essential Medicines. He currently serves as a Global Health Specialist for the Earth Institute at Columbia's Master's in Development Practice program and consults for the New York Academy of Sciences Scientists Without Borders program. He completed his B.S. in Biology at Duke University in 2004 and his M.Sc in Immunology at Oxford University in 2006.

**Karolina Maciag**  
*UAEM Coordinating  
Committee*

Karolina is a fifth-year MD/PhD Candidate at Harvard Medical School/MIT-HST. She graduated from Harvard College with a degree in Biochemical Sciences in 2004 with a focus on research in computational biology. She currently studies innate immunity to intracellular bacteria, including tuberculosis, as a graduate student in Immunology. As a Radcliffe Volunteer Fellow, she worked with local health promoters and visiting medical teams in indigenous Guatemalan villages for six months. Karolina is a leader in the Harvard and MIT chapters of UAEM and was closely involved with initial outreach to the Harvard TTO and faculty and the ensuing negotiation. She is a new member of UAEM's CC.

**Jillian Irwin**

Jillian is a senior at Harvard College, majoring in Social and Cognitive Neuroscience and minoring in Medical Anthropology. Jillian's research has focused on visuomotor learning in primates as well as examination of the differences in the electroencephalogram signal of women with a history of childhood sexual abuse. This past spring, Jillian spent the semester in Santiago, Chile, where she attended the Universidad de Chile Medical School and researched the country's unique health system and mental health outcomes. As an active member of Harvard UAEM for the past three years, Jillian has been integrally involved in the orchestration of the Say Yes To Drugs campaign, and hopes for many future successes for UAEM in the realm of neglected disease advocacy.

**Dr. Matthew Spitzer**  
*President, US  
Board of Directors,  
Doctors Without  
Borders/MSF*

Dr. Spitzer joined MSF in 1999, establishing primary care services and training medical providers in Khampa Tibet, southwestern China. He has worked as field coordinator with MSF in Sierra Leone, with MSF-USA to explore the medical needs of asylum seekers in detention in the New York area, and most recently in Cambodia, where he coordinated MSF's response to epidemic dengue. Dr. Spitzer was elected President of the Board of Directors for Doctors Without Borders in 2008 and had served on the Board since 2006. Dr. Spitzer worked for ten years at the St. Anthony Free Clinic in San Francisco and its affiliated rehabilitation program. This past year, he has been working in San Quentin State Prison's primary care services and trauma/treatment area, and he teaches in the case-based curriculum of UC-Berkeley's Joint Medical Program. He graduated from Yale with Distinction in Philosophy, and obtained his medical degree from Cornell University Medical

College. Additionally, he received the Diploma in Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine.

**Emi MacLean**  
*US Director of the  
Access to Essential  
Medicines  
Campaign, Doctors  
Without  
Borders/MSF*

Emi is the US Director of the Access to Essential Medicines Campaign of Doctors without Borders (Medecins Sans Frontieres, MSF). MSF established the Campaign for Access to Essential Medicines in 1999 to improve access to existing medical tools (medicines, diagnostics and vaccines) and to stimulate the development of urgently needed tools for people in low- and middle-income countries. Emi previously worked as the Deputy Head of Mission at MSF's HIV/AIDS project in South Africa. She has also worked at the Center for Constitutional Rights on issues related to Guantánamo and other forms of executive detention. She graduated magna cum laude from Harvard College and Georgetown University Law Center.

**Suerie Moon**  
*Advisor, Medicines  
Patent Pool*

Suerie is a Research Fellow at Harvard's Center for International Development, a doctoral candidate in the Public Policy Program at Harvard's Kennedy School of Government, and a member of the Harvard branch of Universities Allied for Essential Medicines. Her research interests include the role of international civil society in global governance; access to medicines and intellectual property rights policies; and equity in public health in the developing world. Prior to coming to Harvard, she was a campaigner, researcher, and writer for the Médecins Sans Frontières/Doctors Without Borders (MSF) international Campaign for Access to Essential Medicines, where she focused on intellectual property rights, equity prices for medicines, and research and development into 'neglected diseases.' She holds a Masters in Public Affairs, with a focus on international relations, from the Woodrow Wilson School of Public and International Affairs at Princeton University, and a BA from Yale University.

**Aria Ilyad Ahmad**  
*UAEM Coordinating  
Committee*

Aria is wrapping up his Masters in International Pharmaceutical Policy at the University of Toronto. As a member of the Laboratory for Collaborative Diagnostics as well as the Initiative for Drug Equity and Access, his research interests include drug quality evaluation in poorly regulated pharmaceutical supply chains and counterfeit medicines.

**Michael Lin**  
*UAEM Coordinating  
Committee*

Michael is a second-year medical student at UCSF. As an undergraduate at Stanford, he became interested in global health while working in a free pediatric clinic in Honduras. He currently does research with the Malaria Elimination Group at UCSF while trying to pass his classes, and is passionate about rallying peers around issues of health access.

**Cathy Innes**  
*Director, UNC  
Office of  
Technology  
Development*

Cathy has several years of experience in manufacturing management, industrial engineering, contract management, marketing and technology transfer. She serves as the Director of the Office of Technology Development at UNC-Chapel Hill. She previously worked as a Software Licensing Associate with the Office of Technology Licensing at the University of California, was Campus Liaison Officer with the University of California system and spent time with the University of Washington Technology Transfer unit heading up Directorships in Technology Licensing, Policy and Strategic Initiatives. She is an active member of the Association of University Technology Managers (Board of Trustees, 2003-2005), the Licensing Executives Society, Council for Governmental Relations and the National Council of University Research Administrators. She is a frequent speaker at technology transfer conferences and seminars world wide. Cathy received her BS in Industrial Engineering and Operations Research from the University of California, Berkeley.

**Bob Johnston**  
*Director, Global  
Vaccines Inc  
Professor of  
Virology, UNC*

Dr. Johnston is an internationally recognized expert in viral genetics and vaccine development, having worked notably on the modification of alphaviruses for use as vaccine vectors. In 1997, he was a co-founder of AlphaVax, a biotechnology company devoted to developing vaccines based on vectors, which he and others derived from Venezuelan Equine Encephalitis virus. He served as CEO, Chairman of the Board and as a consultant to the company, resigning in 2001 to establish Global Vaccines. Dr. Johnston is on the editorial board of Virology, and he shared the 2001 World Technology Award. He received his BA from Rice University, PhD from the University of Texas and completed his Postdoctoral research at Queens University.

**Maryann Feldman**  
*S.K. Heninger  
Distinguished  
Professor of Public  
Policy, UNC*

Dr. Feldman is the S.K. Heninger Distinguished Chair in Public Policy at the University of North Carolina, Chapel Hill. Her research and teaching interests focus on the areas of innovation, the commercialization of academic research and the factors that promote technological change and economic growth. A large part of Dr. Feldman's work concerns the geography of innovation – investigating the reasons why innovation clusters spatially and the mechanisms that support and sustain industrial clusters. Dr. Feldman held the Miller Distinguished Chair in Higher Education at the University of Georgia (2006-2008) and the Jeffery S. Skoll Chair in Technical Innovation and Entrepreneurship and Professor of Business Economics at the Rotman School of Management, University of Toronto (2002-2006). She started her career at Johns Hopkins University. She has served on the Advisory Panel for the U.S. National Science Foundation's Program on Societal Dimensions of Engineering, Science and Technology.

**Ethan Guillen**  
*UAEM Executive  
Director*

Ethan has been with UAEM as its executive director since September 2007. Prior to joining UAEM, Ethan worked on policy for the Speaker of the Nevada Assembly, various campaigns and as a researcher and manager at a political consulting firm. After receiving his bachelor's degree in political science from Yale University in 2002, Ethan taught primary school in rural India.

**Bucky Fazen**  
*UAEM- Yale*

Louis (Bucky) is currently in his fourth year in the MD/PhD program at Yale University where he is pursuing a PhD at the School of Public Health in the Epidemiology of Microbial Diseases. Bucky has been active with UAEM since 2006, and has been on the CC for the past two years. During this time, he has primarily been focused on the composition of a new set of metrics for the evaluation of success in technology transfer and the development of UAEM's Access Metrics Initiative.

**Chris Manz**  
*AMSA PharmFree  
Campaign Chair*

Chris is a 3rd year medical student at Duke University. Prior to becoming Chair of the PharmFree campaign, he worked with students, faculty and administrators to improve Duke's Industry Relations policy and was last year's Director of Education, where he led the development of AMSA's Model PharmFree Curriculum. Previously, he worked as a research associate at the at Duke's Sanford School of Public Policy.

**Bhaven Sampat**  
*Department of  
Health Policy  
Management,  
Columbia University*

Dr. Sampat teaches in both the Department of Health Policy and Management and the Sustainable Development PhD program at Columbia University. He is recipient of a Robert Wood Johnson Foundation "Investigator Award" to study how the NIH allocates its funds across disease areas, serves as principal investigator on a Ford Foundation initiative examining patent policy in developing countries and is director of the Columbia-Stanford Consortium on biomedical innovation. Dr. Sampat has also written extensively on the effects of university patenting and "entrepreneurship" on academic medicine, and is actively involved in policy debates related to these issues. He co-created the first free, searchable database of post-TRIPs patent applications in India.

From 2003 to 2005 he was a Robert Wood Johnson Foundation Scholar in Health Policy Research at the University of Michigan.

**Arti Rai**  
*Duke University  
Law School*

Arti is an authority in patent law, administrative law, law and the biopharmaceutical industry, and health care regulation. Her current research on innovation policy in areas such as green technology, drug development, and software is funded by NIH, the Kauffman Foundation, and Chatham House. She has published widely in both peer-reviewed journals and law reviews and is currently editing a book on intellectual property rights in biotechnology. She has also testified before the U.S. Senate on innovation policy issues. Rai is currently the chair of the Intellectual Property Committee of the Administrative Law Section of the American Bar Association. She has clerked for the Honorable Marilyn Hall Patel of the U.S. District Court for the Northern District of California; was a litigation associate at Jenner & Block (doing patent litigation as well as other litigation); and was a litigator at the Federal Programs Branch of the U.S. Department of Justice's Civil Division. Rai graduated from Harvard College, *magna cum laude*, with a B.A. in biochemistry and history and received her J.D., *cum laude*, from Harvard Law.

**Dan Ravicher**  
*Executive Director,  
Public Patent  
Foundation*

Daniel B. Ravicher is Executive Director of the Public Patent Foundation ("PUBPAT") and a Lecturer in Law at Benjamin N. Cardozo School of Law. He was associated with the patent law practice groups of Skadden, Arps, Slate, Meagher & Flom LLP, Brobeck, Phleger & Harrison, LLP, and Patterson, Belknap, Webb & Tyler, LLP, all in New York, and served the Honorable Randall R. Rader, Circuit Judge for the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. As a registered patent attorney, he writes and speaks frequently on patent law, including twice testifying as an invited witness before Congress on the topic of patent reform. In 2008, he was named to both Managing Intellectual Property magazine's '50 Most Influential People in IP' list and IP Law & Business magazine's 'Top 50 Under 45' list. Professor Ravicher received his law degree from the University of Virginia School of Law, where he was the Franklin O'Blechnan Scholar of his class, a Mortimer Caplin Public Service Award recipient and an Editor of the Virginia Journal of Law and Technology, and his bachelors degree in materials science magna cum laude with University Honors from the University of South Florida. Professor Ravicher writes about patent policy issues for The Huffington Post and patent related corporate valuation issues for Seeking Alpha.

**Matt Kavanagh**  
*Director of US  
Advocacy, Health  
GAP*

Matthew is an AIDS and human rights activist and Director of US Advocacy at Health GAP (Global Access Project). He was previously the director of Global Justice, a national human rights organization working on AIDS, trade, and child health, and is an active member of the AIDS activist group DC Fights Back. He has worked with a wide variety of NGOs and social-movement organizations in the US, Latin America, and Southern Africa—recently on water rights and Apartheid reparations campaigns in Johannesburg. He has written articles and curricula on issues ranging from US family law to the economic roots of the global HIV/AIDS pandemic. He holds a BA in political science from Vassar College and a Masters in community organizing and education from Harvard.

**Aria Ilyad Ahmad**

Aria is wrapping up his Masters in International Pharmaceutical Policy at the University of Toronto. As a member of the Laboratory for Collaborative Diagnostics as well as the Initiative for Drug Equity and Access, his research interests include drug quality evaluation in poorly regulated pharmaceutical supply chains and counterfeit medicines.

**Sara Crager**

Sara Crager did her undergraduate work in Neuroscience at McGill University, and is currently in her final year of medical school at Yale University. She is completing a MS in microbiology, and is engaged in basic science research on malaria vaccine development. She is a former leader of the Yale UAEM chapter, and has worked with UAEM since 2005 on various projects including promoting R&D for neglected diseases, the development of the Global Access Licensing Framework, and the Generic Biologics campaign. She has authored several papers on access to vaccines and other biologics. Sara is also the former director of a Yale student-run free primary care clinic providing healthcare to the uninsured, and is a current Issue Analyst on HIV, TB, and Malaria for Americans for Informed Democracy. She recently returned from doing family planning education in Guatemala.

**Alexander Lankowski**

Alex is currently a 3rd-year medical student at Boston University, originally from coastal Maine. Although a medical student, he sometimes secretly wishes he was studying public health instead. Having worked in biomedical research labs in both academic and industry settings, Alex has a strong interest in making sure that the benefits of research and technological development are distributed in an equitable manner to all citizens of the world. Research interests include immunopathogenesis of bacterial and parasite pathogens, therapeutic uses of bacteria, and correlates of immunologic protection in vaccines. Alex has spent time living in Germany, Denmark, Italy, and Peru, and hopes to see much more of the world in the near future. In his free time, he enjoys anything involving snow, mountains, waves, grass, caffeine, and/or hops.

**Dr. Michael Merson**  
*Director, Duke Global Health Institute*

Michael H. Merson, M.D. is the founding director of the Duke Global Health Institute and Vice Chancellor for Duke-National University of Singapore Affairs at Duke University. Merson is a graduate of Amherst College and the State University of New York, Downstate Medical Center. He has held leadership positions at the Centers for Disease Control, Cholera Research Laboratory in Bangladesh, Diarrheal Diseases Control Program and Global Program on AIDS at World Health Organization. In 1995, Merson became the first Dean of Public Health at Yale University. In 2001, he was named Professor of Public Health in the Yale School of Medicine, and director of the Center for Interdisciplinary Research on AIDS. He is senior editor of *Global Health: Disease, Programs, Systems, and Policies*, a leading global health textbook. He has advised UNAIDS, WHO, Global Fund, World Bank, Doris Duke Foundation, World Economic Forum, and the Gates Foundation. He is a member of the Commission for Smart Global Health Policy - CSIS and Institute of Medicine, National Academy of Sciences.

**Dr. Peggy Bentley**  
*Associate Dean for Global Health, UNC*

Dr. Bentley's is a medical anthropologist whose research focuses on women and infant's nutrition, infant and young child feeding, behavioral research on sexually transmitted diseases, HIV, and community-based interventions for nutrition and health. She is a member of the Advisory Board of the Indo-US Joint Working Group on Maternal and Child Health and is a member of the ASPH Global Health Committee. She also holds membership in the American Institute of Nutrition, the American Anthropological Association, the Society for Medical Anthropology, and the American Public Health Association. She is a Fellow of the Society for Applied Anthropology. In 2005 she was named Paul G. Rogers Ambassador for Global Health.

# Global Access Licensing Framework

Every university-developed technology with potential for further development into a drug, vaccine, or medical diagnostic should be licensed with a concrete and transparent strategy to make affordable versions available in resource-limited countries for medical care. Licenses are complex and each will be unique. Universities should therefore implement Global Access Policies that adhere to the following six principles:

## Goals

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).
2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

## Strategies

3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements should be used as a supplement to generic provisioning terms but should never replace those terms.
4. Proactive licensing provisions are essential to ensure that follow-on patents and data exclusivity cannot be used to block generic production. Other barriers may need to be addressed for the licensing of biologics.
5. University technology transfer programs should facilitate future innovation by patenting only when truly necessary to promote commercialization, utilizing non-exclusive licensing, creating streamlined processes for materials transfer, and reserving broad rights to use licensed technology in future research.
6. A global access licensing policy should be systematic in its approach, sufficiently transparent to verify its effectiveness, and based on explicit metrics that measure the success of technology transfer by its impact on access and continued innovation.

## EXPLANATORY NOTES

### **Licenses for *all* drugs with actual or potential global health applications should contain global access provisions.**

Access concerns are not limited to diseases such as HIV/AIDS, tuberculosis, malaria, and other communicable diseases. The World Health Organization reports that chronic diseases such as cardiovascular disease, chronic respiratory diseases, cancer, and diabetes made up 60% of the 58 million annual worldwide deaths, 80% of which occur in low and middle income countries.<sup>1</sup> Over three times as many people die annually from cardiovascular diseases as from HIV/AIDS, tuberculosis, and malaria combined.<sup>2</sup> To ensure access for all essential medicines, it is important that every drug, vaccine, and

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<sup>1</sup> *Preventing Chronic Disease: A Vital Investment*, World Health Organization (2005), [http://www.who.int/chp/chronic\\_disease\\_report/en/](http://www.who.int/chp/chronic_disease_report/en/).

<sup>2</sup> *The World Health Report 2003—Shaping the Future*, Geneva: WHO, 2003

medical diagnostic license contains access provisions.

Universities Allied for Essential Medicines (UAEM) is sensitive to the opinion that generic production is not essential for medicines indicated for “lifestyle” conditions such as hair loss, acne, or erectile dysfunction. However, because it is difficult to know at licensing time whether a product will have an essential medical use, even products that are originally licensed for lifestyle indications should have global access provisions in their license. These provisions should automatically allow for generic production in the event that any new, non-lifestyle use is demonstrated to be effective, for example via a meta-analysis published in a peer-reviewed journal. Lifestyle uses should be defined narrowly.

### **The Global Access Licensing Framework should apply to all low and middle income countries.**

The decision to include or exclude particular countries in a license has grave human consequences. One key concern remains the treatment of lower-middle income countries like China, Brazil and India. More than a billion poor people live in those three countries. Although a small portion of these countries’ population may be technically able to afford to pay monopoly prices for medicines and vaccines, the vast majority cannot. Coverage is doubly important because these countries, particularly India, serve as the pharmacies for the rest of the world’s developing countries. China, India, and other countries in similar situations must be covered by universities’ global access licensing policies. Resource-limited countries should be defined to include those countries not ranked as high income on the World Bank’s List of Economies (<http://go.worldbank.org/K2CKM78CC0>).

### **Generic provision is the best way to facilitate access.**

Market competition generated by generic provision of drugs is recognized as the most effective means of driving down prices and increasing access.<sup>3</sup> There are several reasons that generic provisions should be required in all licenses:

1. Generic provision enlists competitive market forces to develop the most affordable, most efficient ways to get drugs to patients and providers. Generic companies sustainably supply large volumes of drugs as cheaply as possible. In contrast, pharmaceutical companies’ drug donation programs do not provide an effective long-term solution—charitable providers have fewer incentives to drive down costs and are not sustainable options for meeting continuous demand.<sup>4</sup>
2. Generic provision eliminates the measurement and enforcement problems inherent in “at-cost” approaches.<sup>5</sup>
3. Approaches that foster generic access, such as open licensing, can also foster important innovations specific to the developing-world. For example, such approaches could allow generic companies to create pediatric and heat-stable formulations of new drugs.<sup>6</sup>

### **Generic provisions for resource-limited countries will have a negligible financial impact on the pharmaceutical industry.**

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<sup>3</sup> *Report to Congress by the U.S. Global AIDS Coordinator on the Use of Generic Drugs in the President’s Emergency Plan for AIDS Relief*, PEPFAR (May 2008), <http://www.pepfar.gov/documents/organization/105842.pdf>.

<sup>4</sup> E-mail from Daniel Berman et al., MSF, to Robert Lefebvre, Bristol-Myers Squibb (Feb. 8, 2002), <http://www.essentialdrugs.org/edrug/archive/200202/msg00055.php>.

<sup>5</sup> Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, Berkeley Tech. L.J., 20, 1031 (2005).

<sup>6</sup> *UNITAID and CHAI Announce Lower Prices for AIDS Drugs and Affordable Formulations for Children*, UNITAID (Apr. 28, 2008), <http://www.unitaid.eu/index.php/en/NEWS/UNITAID-and-CHAI-announce-Lower-Prices-for-AIDS-Drugs-and-Affordable-Formulations-for-Children.html>.

The financial impact to pharmaceutical companies of allowing generic competition in resource-limited countries is negligible, especially when the global access license offers licensees revenues from reasonable royalties on the generics. Drugs with a global market generate only a tiny fraction of their revenue in resource-limited countries. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that between 2002 and 2007, Africa accounted for only 0.4% of the global pharmaceutical market for PhRMA members, China accounted for only 0.4%, and India only 0.2%.<sup>7</sup> Sales in the United States, European Union, and Japan accounted for 93.2% of all pharmaceutical revenues for PhRMA members during that same period.<sup>8</sup>

To ensure a fully competitive market, production of generics should be allowed in any country, so long as the products are sold only in resource-limited countries, as defined above. This approach is consistent with the framework adopted in the World Trade Organization's Doha Declaration.<sup>9</sup> Differential appearance and packaging requirements can be used to ensure that products destined for developing world market are not illegally sold elsewhere.<sup>10</sup>

A subset of the pharmaceutical industry is increasingly hospitable to controlled licensing of their drugs for generic use in developing world settings. For example, Gilead recently provided an open voluntary license of its important AIDS medication tenofovir to generic producers in India,<sup>11</sup> and both Gilead and Johnson & Johnson announced at the 2008 World AIDS conference that they would be willing to put intellectual property into a new patent pool being created by UNITAID to allow further generic production of AIDS medications.<sup>12</sup> Even where pharmaceutical companies are initially resistant to a generic production arrangement, universities can and should insist on such terms as critical to the overall licensing goal of getting innovations to patients, just as they now insist on due diligence terms and measurable development milestones to ensure licensed innovations reach wealthier patients in primary markets.

**Additional legal barriers that prevent access to the end product needed by patients must be removed.**

Some universities have argued that simply not patenting their own discoveries in resource-limited countries constitutes a sufficient access policy. However, if a university does **not** include specific access provisions in its license, there are still several ways licensees could block a generic company from producing the drug for use in resource-limited countries:

**Follow-On Patents:** Licensees can patent many of the incremental developments inherent in turning the basic licensed compound into a finished marketable drug, creating barriers to access.

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<sup>7</sup> *Industry Profile 2008*, PhRMA, <http://www.phrma.org/files/2008%20Profile.pdf>.

<sup>8</sup> *The Pharmaceutical Industry in Figures*, European Federation of Pharmaceutical Industries and Associations (2008), p. 5, <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4883>.

<sup>9</sup> *Ministerial Declaration*, World Trade Organization (Nov. 14, 2001), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm).

<sup>10</sup> Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Pol'y L. & Ethics 193, 261-265 (2005).

<sup>11</sup> *Gilead Announces Licensing Agreements*, Gilead (Sep. 22, 2006), [http://www.gilead.com/pr\\_908393](http://www.gilead.com/pr_908393).

<sup>12</sup> James Love, *The Health Impact Fund and product monopolies*, Knowledge Ecology International (Nov. 17, 2008), <http://www.keionline.org/blogs/2008/11/17/health-impact-fund-monopolies/>.

Several kinds of “follow-on” patents exist:

- *Product patents* cover modifications to, or new formulations of the original compound, such as those permitting increased solubility.
- *Process patents* cover the techniques, paths, and intermediates that producers use to synthesize the chemical compound at scale.
- *Use patents* cover the use of the drug for a particular indication.

**Data Exclusivity:** It currently takes years for a generic company to gain the right to refer to the clinical trial data of drugs that are “bioequivalent” to its own, delaying its ability to provide these drugs in developing countries. In order to sell its drugs to the public, an originator pharmaceutical company must show that the drug is safe and effective by performing clinical trials. A generic company, in contrast, can sell a drug without performing such trials by proving that its drug is bioequivalent to a previously approved drug. In order to do so, it must make reference to the originator pharmaceutical company’s clinical trial data. This “right of reference” is limited by law; in the United States, for example, generic companies must wait five years before referring to clinical trials already registered with the FDA. This delay is particularly problematic for drugs that treat diseases like HIV, where resistance to first- and second-line therapies develops rapidly.

There are a number of strategies to address the issues of follow-on patents and data exclusivity, including non-assert clauses, sublicensing agreements, patent pools, data waivers, and grantback provisions.<sup>13</sup>

**At-cost or other access provisions are sometimes necessary, but they should never replace generic provisions.**

At-cost provisions, which require the licensee to sell the licensed technology in resource-limited countries for no profit, may be necessary:

1. When the drug, process, technology, diagnostic, or other component of the licensed product is too complex to be feasible for replication and generic production. For example, many biologics may require at-cost provisions.
2. When the demand for the product in resource-limited countries is too small to induce a generic company to enter into production. Causes of a small demand could include a very small affected patient population as in rare genetic diseases, or an isolated or constrained geographic distribution.

**Additional barriers to access must be overcome for biologics.**

While there is a clear paradigm for the production of small molecule generics, there are a number of important issues related to the production of biosimilar vaccines and other biologics that this framework does not address; there are multiple additional barriers—many of which are non-proprietary—that need to be addressed in order to ensure efficient, cost-effective generic development.

Still, universities that license biologics should follow the same basic principle: generic provision is the best method for ensuring access, and biologic licenses should do as much to facilitate generic provision as possible. In particular, universities should seek commitments from licensees to transfer materials and know-how to follow-on producers when necessary.<sup>14</sup> Where such agreements are impractical or impossible; when they may be insufficient to ensure follow-on provision; and while there remains no established legal pathway for follow-on biologics, at-cost provisioning commitments should be required.

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<sup>13</sup> April E. Effort and Ashley J. Stevens, *The Critical Role of Academic Licensing in Promoting Global Social Responsibility* (2008); Kapczynski et al., *supra*; UNITAID Mission (2005), <http://www.unitaid.eu/index.php/en/UNITAID-Mission.html>.

<sup>14</sup> Sara E. Crager, Ethan Guillen, and Matt Price, *University contributions to HPV vaccines and implications for access in developing countries: Potential models for improving access to university discovered vaccines*, *American Journal of Law & Medicine* 110-132 (forthcoming, 2009).

## **Intellectual property barriers to innovation should be minimized**

While patents and other forms of intellectual property are commonly justified on the grounds that they promote innovation, such property rights can also have the unintended consequence of discouraging future innovation.<sup>15</sup> Costly licensing fees, as well as “reach through” provisions that call for royalties on products developed from upstream technologies, place taxes on downstream research that discourages commercialization and use of future technologies. Patenting also raises concerns about patent thickets, blockages that result when numerous patents on a product lead to bargaining breakdowns that can prevent downstream research and development from taking place. Exclusively held patents may also block useful follow-on innovation that can result in combination products that magnify the impact of a technology, or in products that are tailored to serve the needs of people in developing countries. Finally, the practices of patenting and licensing can have a negative impact on longstanding academic norms regarding the open, swift, and disinterested scientific exchange of knowledge.

To avoid these unnecessary barriers to innovation, universities should craft policies that allow for patenting only those inventions that would fail to be commercialized in absence of the patent incentive. For example, universities need not seek patents on research platforms, diagnostic tests, and other technologies that can be adapted for commercial use in a short period with little additional investment. Such patents hinder innovation while providing no social benefits beyond enrichment to the patent-holding institution. Where patents are acquired, such technologies should be licensed non-exclusively to encourage the broadest possible dissemination of university research. Universities should reserve rights to grant future researchers the right to work with products in order to make improvements and modify them for uses particular to developing countries. Finally, universities should work to foster the scientific exchange of knowledge by adopting streamlined processes for materials transfer and providing internal incentives for the exchange of knowledge among researchers.

## **Implementation requires effective governance: policies must be systematic, transparent, and utilize explicit access metrics**

The dynamic nature of the technology transfer process means that no single set of mechanisms, policies, or commitments is likely to be sufficient to ensure the greatest possible access to university technologies in the long term. For this reason, universities must strive to continuously improve on existing licensing practices, evolving policies and practices in order to improve access to medicines for all people, regardless of income. Effective governance is essential to ensure the implementation of global access licensing policies and to help guide this evolution. Transparency and accountability are essential features to ensuring effective governance.

One way to ensure transparency and accountability is to make redacted licenses available through publication. Where such publication is not practicable, governance may be accomplished by committees that, like institutional review boards, have public stewardship and review responsibilities. Governance mechanisms should be accountable to the broader university community, for example by including faculty with expertise in medical research and global health, as well as students and administrators.

Each university should develop and implement metrics to account for their own access-oriented licensing strategies. These metrics should include operational or process measures of university licensing activities in order to support and further develop technology transfer strategies that prioritize access. Metrics should measure not only university implementation of access licensing strategies through concrete licensing terms and provisions, but also the frequency of implementation of such terms for all health-related invention disclosures. The indicators should be clear and publicly-available.

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<sup>15</sup> See generally, Anthony D. So, et. al, *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, PLoS Biol 6(10): e262.

# Statement of Principles and Strategies:

## For the Equitable Dissemination of Medical Technologies

### Background

Universities have a fundamental role in fostering public health. Their greatest contributions may occur through discovery of new knowledge, education of students, and dissemination of knowledge for others to build upon through publications, library collections, and most recently, open courseware.

In addition, universities in the developed world work to facilitate the commercialization of the health-related inventions of academic researchers by developing and disseminating these technologies for the public good. We have created new methods to deploy cutting-edge knowledge toward potential public benefit by enticing risk takers to invest in our early stage technology in the hope of possible downstream commercial applications. In recent years, the licensing practices involved in such commercialization have expanded to promote explicitly global access to university-developed technologies, ensuring that advances in health reach those who need them most.

This sensitivity to global health was reflected in *Nine Points to Consider in Licensing University Technology*, a statement endorsed by nearly seventy universities and other organizations since the spring of 2007. In acknowledgement that conventions in this field are ever evolving, and building on recent experience, the institutions named below believe a more concrete statement of goals as well as licensing practices would help to promote further progress in advancing health in developing countries. The principles reflect the current state of the art that can vary considerably from case to case and from institution to institution. The principles represent the collective voice of the following institutions:

**Association of University Technology Managers (AUTM)**  
**Boston University**  
**Brown University**  
**Harvard University**  
**Oregon Health & Science University**  
**University of Pennsylvania**  
**Yale University**

### Statement of Principles and Strategies

We are committed to implementing effective technology transfer strategies that promote the availability of health-related technologies<sup>1</sup> in developing countries for essential medical care. This Statement primarily addresses one area of engagement through which universities contribute to the broader effort to address the challenges of global health: the management and licensing of medical innovations. Other approaches include the development and dissemination of new knowledge and technologies, the training of physicians and medical researchers, and the delivery of treatment and care.

<sup>1</sup> The decision about precisely which health-related technologies merit global access licensing is complicated and will be the subject of ongoing evaluation by our organizations. While the principles articulated in this statement currently are directed primarily at therapeutics and vaccines, their application to medical diagnostics and devices will be assessed case-by-case on an ongoing basis.

Because each license is unique, as it reflects the complexities of its subject technology, our approaches will vary from case to case. Our aspirations are constrained by the limits of the role our early stage technologies can play, as well as the modest leverage our technology transfer professionals can exert, in the complex interplay of a delicate ecosystem in which essential medical innovations are made, developed and distributed. We will, nonetheless, be innovative and persistent in order to achieve our goals through patenting and licensing. Toward these goals, the technology transfer offices of the institutions named above commit to follow these guiding principles:

1. In our negotiations with potential licensees we will make vigorous efforts to develop creative and effective licensing strategies that help to promote global access to health-related technologies:

- We will apprise potential commercial partners of our institutions' commitment to contribute to the health and well-being of populations throughout the developing world and to cultivate productive relationships with companies that share our values and are able and willing to advance our global health mission; and
- We will recognize, and fairly balance, both the early-stage nature of our institutions' biomedical innovations and the importance of originator pharmaceutical and biopharmaceutical companies in making the substantial investment needed to demonstrate the safety and efficacy of new medicines which, in turn, will allow them to be brought to market in developing countries.

2. Our intellectual property should not become a barrier to essential health-related technologies needed by patients in developing countries. In cases where universities can fully preclude intellectual property barriers to generic provision by not patenting in developing countries, or by filing and abandoning patents, we will pursue these strategies. Early publication and wide dissemination of results will be encouraged to reduce opportunities for interfering patents. While there are many additional barriers to access, such as insufficient healthcare infrastructure, preventing intellectual property barriers is critical to achieving access.

- We will seek patent protection for such technologies in developing countries only in a manner that is consistent with our objective of facilitating global access. For example, it may be necessary to account for special circumstances (e.g., in India, China or Brazil) that may warrant patenting in such countries on a case-by-case basis, including but not limited to:
  - The existence in a developing country of pharmaceutical manufacturing capacity suitable to support product distribution both within and outside the developing world; or
  - The opportunity to gain greater leverage in seeking concessions, such as access to others' intellectual property, that would help to ensure that the health-related technology can be made available affordably; or
  - To enable our licensee(s) to implement tiered pricing in those developing countries where a significant private market exists.

3. In those cases where we pursue patent rights, we will negotiate license agreements that draw upon a variety of strategies that seek to align incentives among all stakeholders to promote broad access to health-related technologies in developing countries. Those strategies include, but are not limited to:

- Financial incentives to licensees (e.g., elimination or adjustments to royalty rates);
- Reserved or ‘march-in’ rights, mandatory sublicenses or non-assert provisions;
- Affirmative obligations of diligence, with license reduction, conversion (i.e., to non-exclusivity) or termination as the penalty for default; and
- Tiered- or other appropriate pricing on a humanitarian basis (e.g., subsidized, at-cost or no-cost).

4. It is not always possible at the time of license negotiation to anticipate all of the ways a health-related technology may be used in developing countries. Accordingly, we will strive to preserve our institutions’ future rights to negotiate effective global access terms through implementation of such measures as notice requirements coupled with “agreements to agree.”

5. Without regard to the economic value to our respective institutions, we will further support the development of new health-related technologies aimed at diseases that disproportionately burden individuals in the developing world, such as tuberculosis, AIDS, water-borne disease, tropical- and other region-specific ailments and parasitic infections endemic to the developing world, through such means as:

- Continued partnerships with not-for-profit and charitable organizations to provide much needed collaboration and funding for research in neglected disease areas;
- Active efforts to attract and secure appropriate commercial partnerships in further support of such research; and
- Engagement with public-private partnerships that can advance the resulting health-related technologies toward regulatory approval.

6. We will work together to develop and apply meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation with particular relevance to global health.

7. We acknowledge that best practices with respect to ensuring that the fruits of university research benefit those in greatest need are emerging and evolving rapidly. To avoid unintended negative consequences with respect to product development in general, and availability in developing countries in particular, flexibility and creativity must be maintained. We understand that this Statement must be a “living document” which, by its nature, needs to evolve and mature in a manner consistent with - and guided by - our accumulated knowledge. Therefore, consistent with all applicable laws and regulations, we will:

- Share with one another our collective experiences from working with our licensees in implementing these principles to continually advance our goals. To that end, we will cooperate in the creation of:
  - A compendium of best practices, tools and techniques; and
  - A consistent means of reporting on our global access initiatives and activities.
- Educate others and encourage their consideration, endorsement and application of the principles articulated in this statement; and
- Revisit these principles on a biennial basis, to ensure that they reflect currently-understood best practices.

# UAEM Response to the SPS

February 16, 2010

UAEM welcomes the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS) published on November 9, 2009, and signed by 20 institutions as of March, 2010, including the Centers for Disease Control, the National Institute of Health, and the Association of University Technology Managers.

UAEM has worked intensively with universities on global access licensing since 2001, and we commend all of the signatories for their commitment to the principles and strategies laid out in the document. UAEM supports the publication of the SPS, and looks forward to working with its signatories to implement and improve the document over the coming years.

In early 2009, UAEM released the Global Access Licensing Framework (endnote 1) which lays out in detail the type of technology transfer practices that we believe are essential to enhancing global access to university-developed medical technologies. For the reasons explained below, that Framework remains a rigorous standard for achieving global access, and UAEM will continue to advocate for adoption of robust university policies in line with the Framework.

This brief memorandum is intended to help students, scholars, activists, university administrators, and other interested parties understand the strengths and the shortcomings of the SPS. This memorandum begins by describing the important advancements represented by the SPS. It then identifies the document's shortcomings. Finally, it makes substantive and procedural recommendations for improving the document.

## **An Important Step Forward**

The SPS is an important step forward and those who worked on the principles deserve praise for advancing the global dialogue about the role of universities in enhancing access to medical technologies. We commend the signatories for building upon the earlier "Nine Points" statement and announcing both concrete principles and specific strategies. In particular, we applaud them for:

- recognizing that university "intellectual property should not become a barrier to essential health-related technologies needed by patients in developing countries" and the corollary commitment either not to patent (or to file and abandon patents) in developing countries in order to "preclude intellectual property barriers to generic provision." The SPS also mentions other innovative licensing strategies, most importantly the use of "reserved or 'march-in' rights, mandatory sublicenses or non-assert provisions."
- adopting language broad enough to cover all therapeutics and vaccines, as opposed to addressing only those for neglected disease
- committing to "develop and apply meaningful metrics"
- committing to revisit the SPS "on a biennial basis, to ensure that [it] reflect[s] currently-understood best practices," in recognition of the need to continue evolving the statement.
- committing to neglected disease research

We are encouraged that the statement affirmed these principles and strategies and that the signatories are committed to educating others about them and to obtaining additional endorsements.

We particularly emphasize the importance of Point 2 of the SPS, which recognized generic provision as an approach to ensuring access to medicines. Extensive empirical evidence shows that generic competition is unquestionably the most effective means for driving down the price of medicine and thus expanding global access (endnote 2).

Generic provision enlists competitive market forces to develop the cheapest, most efficient ways to get drugs to patients and providers. Generic companies are in the business of supplying a large volume of

drugs as cheaply as possible. In contrast, pharmaceutical companies' drug donation programs do not provide an effective long-term solution—charitable providers have fewer incentives to drive down their costs and do not have the expertise or distribution networks that are necessary to get drugs to patients in resource-limited countries (endnote 3).

In addition, generic provision eliminates the measurement and enforcement problems inherent in “at-cost” approaches (endnote 4). Finally, generic licensing approaches foster important innovations specific to the developing-world. For example, such approaches allow generic companies to create pediatric and heat-stable formulations of new drugs (endnote 5).

### **Room for Significant Improvement and Shortcomings that Must Be Addressed**

Although the SPS represents an important step towards improving global access, it has a number of significant shortcomings. UAEM looks forward to working with current and future signatories to improve and implement the document to account for the issues raised here.

(1) It remains unclear how the signatories propose to treat China, India, and Brazil and countries similarly situated. More than a billion poor people live in those three countries. Although a small portion of these countries' population may be able to afford to pay monopoly prices for medicines and vaccines, the vast majority cannot. As research institutions dedicated to the public interest, universities cannot prioritize marginal increases in pharmaceutical company profit above the health of hundreds of millions of people. Generic provision is the most effective means to ensure access in these countries. China, India, and Brazil and other countries in similar situations must be covered by universities' global access licensing policies. Coverage in these three countries is doubly important because they serve as the pharmacies for the rest of the world's developing countries. If patents and licensing agreements preclude pharmaceutical companies in these countries from producing generic drugs for export to the rest of the developing world, then generic versions drugs will not be produced anywhere. Asserting patent protection in these countries would cut off generic production at the source, rendering meaningless any university efforts to avoid creating intellectual property barriers to generic provision in the developing world.

(2) Although Point 2 of the SPS identifies generic provision as one important approach to ensuring access to medicine, the document fails to recognize the preeminent importance of generics as the most effective means for driving down price and expanding access. More broadly, while the SPS lays out an array of useful strategies for improving access in poor countries, it fails to prioritize one strategy over another. All strategies are not equally effective. For example, mandatory sub-licenses, which allow generic sub-licensees to disseminate drugs and vaccines widely, will be far more effective at ensuring access than will reduced royalty rates or due diligence clauses. Open licensing, one approach that the SPS fails to mention, should be recognized as a valuable strategy for expanding access. In addition, the SPS does not commit its signatories to using global access strategies every time a technology with actual or potential global health applications<sup>16</sup> is patented or licensed. Pharmaceutical companies that are resistant to the use of global access strategies will only accept such provisions if they become an indispensable component of all university technology transfer agreements.

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<sup>16</sup> Global health concerns are not limited to communicable diseases. The World Health Organization reports that 80% of the deaths from chronic diseases such as cardiovascular disease, chronic respiratory diseases, cancer, and diabetes occur in low and middle income countries. Universities Allied for Essential Medicines (UAEM) is sensitive to the opinion that generic production is not essential for medicines indicated for “lifestyle” conditions such as hair loss, acne, or erectile dysfunction. However, even products that are originally licensed for lifestyle indications may later be discovered to have new indications that can have an impact on global health. For this reason, all health technologies should have access provisions in their licenses that automatically allow for generic production for newly discovered global health indications.

(3) Although the signatories to the SPS have made the highly commendable commitment that university intellectual property should not become a barrier to patient access to essential health-related technologies, the commitment will be meaningless unless it allows patients to have access to the final end product. To ensure access, universities must also ensure that their licensees' intellectual property does not become such a barrier. If universities do not adopt such pro-active measures, then a licensee may preclude access by filing follow-on product, process, or use patents, utilizing trade secret protection, or exercising data exclusivity.

(4) While the statement is to be commended for incorporating a commitment to metrics and a biennial process for review, it fails to call for greater transparency and accountability in university patenting and licensing. Such features are essential to ensure effective governance at the university level. In cases where redacted licenses cannot be made available, such governance may be accomplished by committees that, like institutional review boards, have public stewardship and review responsibilities. Such committees should be representative of the broader university community, including faculty with expertise in medical research and global health, as well as students and administrators.

(5) It is also essential to recognize that the SPS itself was not developed in a transparent process befitting the world's great universities. While students and faculty were contacted for input, no attempt was made to solicit comments or feedback from the access to medicines community or the broader university stakeholder community during the drafting process of the document. This is true despite the extensive expertise that exists among faculty at the signatory universities and at non-profit organizations with missions closely related to the missions of universities.

(6) Finally, carrying out the SPS's goal of promoting access to health technologies in developing countries will require looking beyond technology transfer to consider the impact universities have in a broader social and political context. In recent years, universities have lobbied actively for legislation that obstructs access to health technologies by strengthening and lengthening monopoly protection on biologics. Also recently, AUTM, one of the SPS signatories, publicly opposed a set of federal recommendations seeking to expand access to research and diagnostic testing performed with gene patents (while protecting product development based on gene patents). Too often, these positions are indistinguishable from those taken by industry, failing to recognize the distinct needs and objectives of universities as not-for-profit research institutions. These actions undercut the commitments made by signatories in the SPS. Universities must work to promote access to knowledge in all areas of university policy in order to fully implement the spirit of this document.

### **Recommendations for Next Steps**

In order for the SPS to represent a truly transformative set of principles and strategies, UAEM recommends that the following modifications be adopted:

(1) The biennial review of the SPS should be undertaken through a transparent and open process that allows for meaningful contribution by the access to medicines advocacy community, academic faculty (especially those scientists responsible for medical discoveries and experts on global health and development and technological innovation), and the broader public. This input should include some mechanism for feedback on revisions to the document during the drafting process.

(2) The next iteration of the SPS should prioritize among strategies by recognizing mechanisms that work best to assure the broadest possible access. The best current evidence makes clear that generic provision, through such approaches such as open licensing and mandatory sub-licensing, is more effective at ensuring access. These more effective approaches should be privileged over royalty reductions or commitments to tiered-pricing.

(3) The next iteration of the SPS should clearly announce the signatories' commitment to ensuring affordable medicines for patients in China, India, and Brazil and similarly situated countries, and to the rights of companies in those countries to produce generic therapies and vaccines for export into other developing countries.

(4) The signatories should provide for effective governance mechanisms. This should include fulfilling the statement's commitment to developing "meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation." These metrics should include operational or process measures of university licensing activities in order to support and further develop technology transfer strategies that prioritize access. Such metrics should measure not only university implementation of SPS principles through concrete licensing terms and provisions, but also the frequency of implementation of such terms for all health-related invention disclosures. The indicators should be clear, publicly-available, and all signatories should be expected to participate. Revisions to the SPS should be responsive to these metrics. UAEM has worked extensively in this area with signatories and looks forward to further collaboration in developing these metrics. Universities should also promote greater transparency and accountability by making the redacted terms of licenses publicly available, or where such measures are impracticable, establishing review committees that include representation from the broader university community, including medical and global health faculty, students, and administrators.

(5) The SPS should recommend inclusion of medical devices and diagnostics in Global Access Licensing programs.

(6) Individual signatories and university consortia of which signatories are members should stand by the spirit of the statement by promoting access to knowledge in all areas of university policy. This includes maintaining a separate identity from for-profit industry and taking positions on local, national, and international legislation that encourage access to knowledge, in particular knowledge relating to global health.

### **Guidance for UAEM Chapters**

While UAEM sincerely welcomes the SPS, we do not believe that it represents a fully adequate response to the access to medicines crisis on the part of our universities. We therefore believe that after signing the statement universities maintain a responsibility to strengthen their own policies, in line with the UAEM-developed Framework. When working for a global access licensing policy on campus, universities should be asked to adopt a binding policy in line with the Framework. Chapters should urge universities wishing to sign the SPS to address the shortcomings of the document, which are noted above, by implementing stronger policies on their home campuses. Universities should be urged to utilize transparent policies in adopting the document, including seeking feedback from students, faculty, and other university stakeholder. The SPS represents a step on the path to achieving equitable access to medicine, but there remains a long way to go. In response, we, the students of our institutions, must continue to be a voice working alongside those unjustly denied access to life-saving medicines in demanding true accountability of these non-profit institutions.

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Endnote 1: The Global Access Licensing Framework may be found at <http://essentialmedicine.org/projects/university-technology-transfer>

Endnote 2: Report to Congress by the U.S. Global AIDS Coordinator on the Use of Generic Drugs in the President's Emergency Plan for AIDS Relief, PEPFAR (May 2008), <http://www.pepfar.gov/documents/organization/105842.pdf>.

Endnote 3: E-mail from Daniel Berman et al., MSF, to Robert Lefebvre, Bristol-Myers Squibb (Feb. 8, 2002), <http://www.essentialdrugs.org/edrug/archive/200202/msg00055.php>.

Endnote 4: Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, Berkeley Tech. L.J., 20, 1031 (2005).

Endnote 5: UNITAID and CHAI Announce Lower Prices for AIDS Drugs and Affordable Formulations for Children, UNITAID (Apr. 28, 2008), <http://www.unitaid.eu/index.php/en/NEWS/UNITAID-and-CHAI-announce-Lower-Prices-for-AIDS-Drugsand-Affordable-Formulations-for-Children.html>.

# UAEM International Working Groups, 2010-2011

## **Empowerment**

UAEM's Empowerment Working Group creates and maintains tools that enable students to successfully begin and lead effective chapters. We manage chapter outreach and chapter outreach tools within the US and around the world. We also manage the national website, the UAEM newsletter and help organize the national conference. Current resources available to chapters are available online at: [essentialmedicine.org/chapters/resources](http://essentialmedicine.org/chapters/resources). You can learn more by joining the Chapter Leaders Google group. We are also working on revising the chapter handbook online and designing a chapter welcome kit. If you are passionate about student leadership and activism, join us! We are always interested in finding new ways to offer more resources to our members and maintain effective communication with all our chapters.

## **Policy**

The focus of the Policy Working Group is to increase access to essential medicines through policy-based initiatives. Our activities include campaigns at the university, national, as well as international level. At the university level, we seek to decrease the global access gap to healthcare by informing administration and faculty on the shortcomings of current biomedical intellectual property policies, such as the Bayh-Dole act. We also encourage universities to license their discoveries to generic companies to allow for production of affordable drugs and embrace other policies designed to ensure that publicly funded research is used for public benefit. Recently, the Policy Working Group launched a national campaign aimed at reducing unfair patent rights given to pharmaceutical companies for biologic drugs. With the goal of influencing congress, this campaign is known as the Biobetter campaign. Internationally, we work with the National Institutes of Health on their drug access policy, partner with Unitaid on their projects to deliver essential medicines, and have lobbied the Obama Administration to fund AIDS medicines. The NIH and the Obama administration have recently announced policy initiatives that are in-line with the goals of UAEM.

## **Science/Innovation/ND**

The Science, Innovation, and Neglected Diseases (ND) Working Group is excited for another year of advocacy and education! We are looking forward to forging ahead on several ongoing projects, and are eager to hear any ideas for new directions. This past year saw the ND Working Group embark on a collaboration with the Global Health Education Consortium (GHEC) to develop and distribute educational modules on neglected tropical diseases and other topics relating to global public health. Additionally, several UAEMers presented the UAEM-developed module on Hookworm, Chagas Diseases, and African Trypanosomiasis during seminars at their respective universities. Continuing on the theme of educational initiatives, UAEMers have created a mini-course for physicians on Chagas Disease, aimed at raising awareness of this emerging infection amongst North American medical practitioners. The ND Working Group has also been involved in the planning of 2 upcoming events this fall: 1) a UAEM-sponsored symposium session at the annual meeting of the American Society of Tropical Medicine and Hygiene in Atlanta on November 4th, and 2) the UAEM conference on Open Innovation and the Role of Universities, taking place in Washington DC on November 20th.

## **Campus Campaigns**

Being co-shepherded by two Canadians this year, the Campus Campaigns (CC) working group is sometimes dubbed the Canadian Club - after the spirit, not an ominously prejudicial whitecap society. We should level with you, though: the CC does almost nothing the name suggests. No,

wait, keep reading because we do do (tee hee) undertake an exciting melange of ambitious projects that are sure to put the ABBA back in flabbargasting. The UAEM prescribed mandate of the CC working group is to support national and campus campaign efforts by aggregating and sharing resources to avoid "reinventing of the wheel." Realizing that the empowerment working group has done a phenomenal job putting that wheel in motion, the CC troupe has shouldered at least three equally rousing projects. First, in launching the Academics for Access website in November 2009, we have laid the groundworks for what will hopefully become a collaborative network of luminaries that share UAEM's vision. This database would be open to all members for tracking who has pledged eternal allegiance to UAEM and who still needs wooing. The CC working group has also been given the reigns of a mission code-named within the UAEM corridors as the "drug bios project." As the cryptic moniker suggests, the aim of this venture is to build an accessible compound library for UAEM members that succinctly details development of what could potentially become significant essential medicines. What we're looking for here, ladies and gentlemen, is another d4T titan that we can rally around, campus campaigns style. Lastly, the CC working group is hoping to continue working with the brilliant folks at empowerment in making the many statements and frameworks of UAEM more accessible to our members, in addition to creating a centralized database of powerpoints and presentation notes. The campus campaigns team would be delighted to hear from any and all who wish to pursue these projects or have CC-infused ideas of their own!"

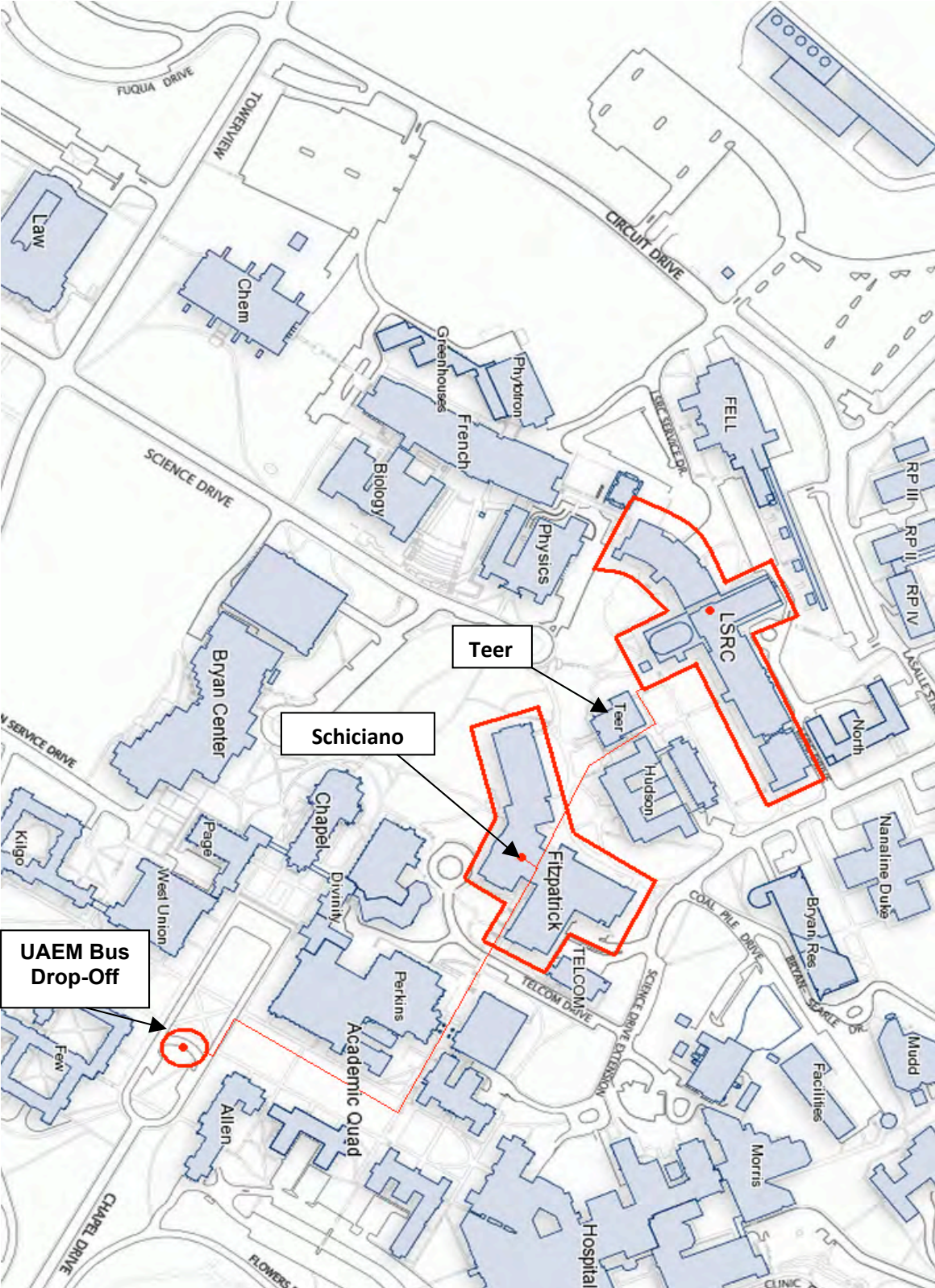
### **Metrics**

Most university technology transfer offices (TTOs) acknowledge their mission of advancing academic research to benefit society and ensuring public access to university innovations. More than 60 top research institutions have endorsed the Stanford Nine Points, which explicitly recognizes universities' role in ensuring access to life-saving treatments in the developing world. In addition, the NIH, AUTM and 18 major research institutions have adopted the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies, which recognizes the need for metrics, or monitoring and evaluation of progress, in this field.

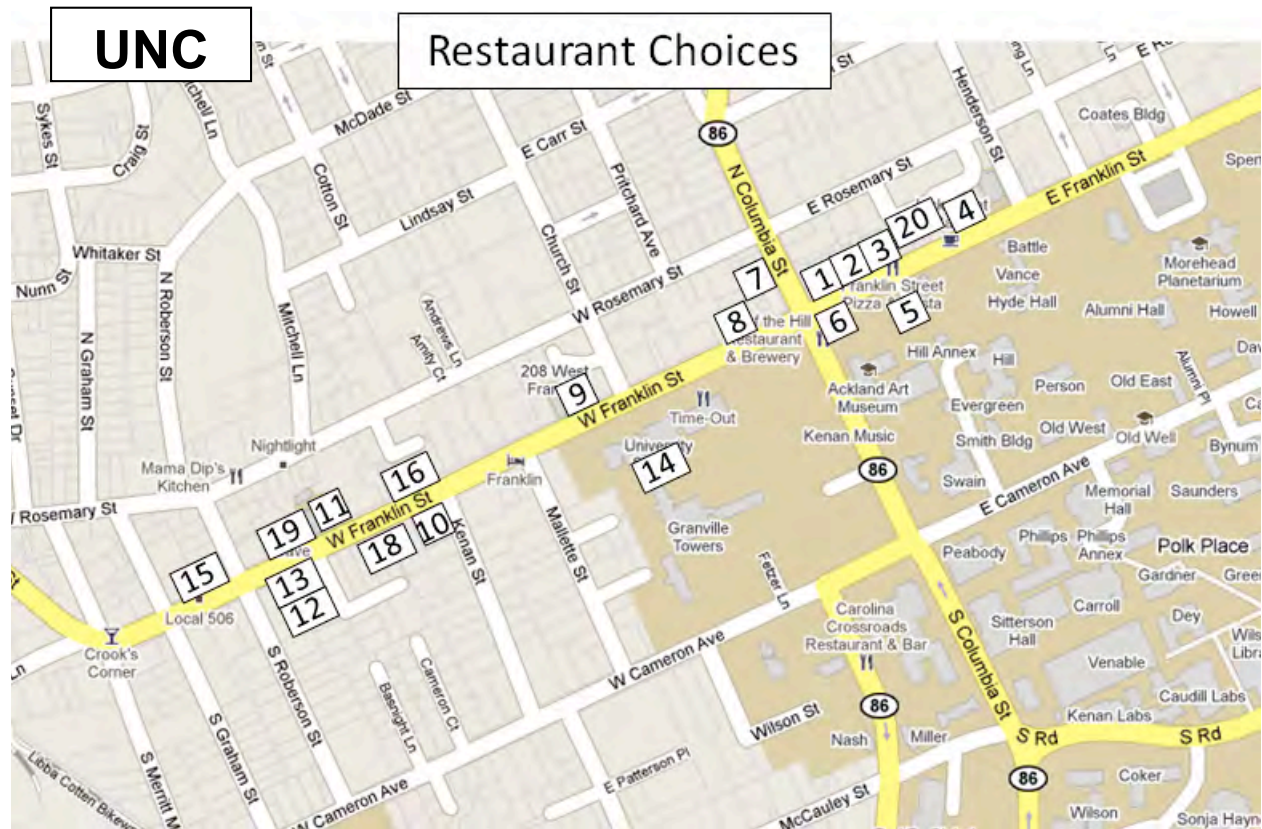
Nevertheless, despite the widespread and growing interest in access-oriented licensing, there is no effective measure of licensing success that accords with the university mission and technology transfer strategy. The current use of financial indicators not only fails to capture the value of university innovation to the public but provides incentives to maximize short-term returns at the expense of long-term growth. Without the accountability and focus generated by appropriate metrics, these strategic visions remain inspirational but ultimately ineffective.

The Access Metrics Initiative seeks to rectify the incongruity between the universities strategic goal of achieving public benefit and the current measures of success in technology transfer. Specifically, the AMI defines success as the dissemination of university innovation and provides research institutions with a means to monitor and evaluate their progress towards this strategic goal. The metrics project has recently compiled the results of its first pilot survey, and is putting these together in a user-friendly web page to increase communication between TTOs on best practices in licensing medical technologies. Please look for coming announcements about this new UAEM website!

# Map of Duke University Campus







**Franklin St. (UNC) and surroundings are packed with restaurants. We've included a variety of places of consistent quality we have experience with. We made some arbitrary selections for this list and we may be missing some gems, so don't feel bound to this list! Cost of an average meal per person:**

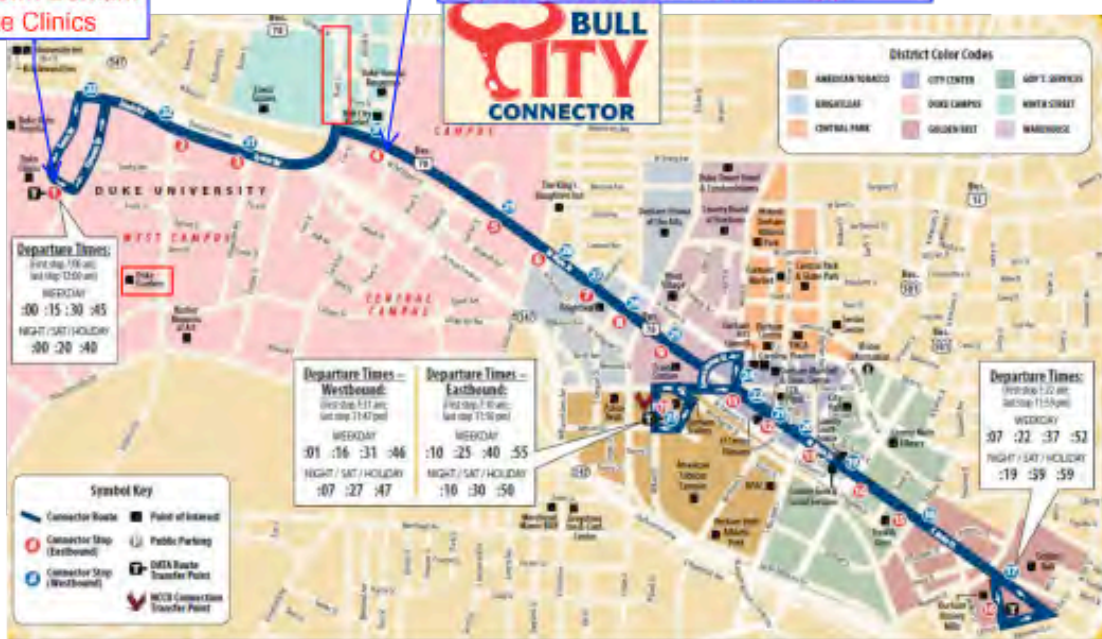
\$ = 7 or less dollars    \$\$ = 7-12 dollars    \$\$\$ = 12-17 dollars

1. Spanky's \$\$\$ - Good sandwiches and atmosphere
2. Starbucks Coffee \$ - Coffee
3. Pepper's Pizza \$\$ - made fresh, higher quality than Franklin St. Pizza and Pasta
4. Franklin St. Pizza and Pasta \$ - good deal
5. Cosmic Cantina \$ - Extremely veggie friendly and cheap, open late
6. Top of the Hill \$\$\$ - Variety of entrees & they brew their own beer, very popular
7. Buns \$ - good burgers
8. The Yogurt Pump \$ - frozen yogurt
9. Lime and Basil \$\$ - Vietnamese, excellent pho.
10. Sandwich \$\$ - Sandwiches
11. Carolina Brewery \$\$\$ - Good sports bar that brews its own beer
12. Vimala's Curryblossom Café \$\$ - probably the best Indian food in the area
13. Penang \$\$\$ -Thai
14. Butternut Squash \$\$ - All vegan
15. Mint \$\$ - Indian buffet
16. Mediterranean Deli \$\$ - Great veggie friendly Mediterranean food.
18. 411 West \$\$\$ - classy Italian
19. West End Wine Bar \$\$ - drinks
20. Artichoke and Basil \$ - pizza, burgers

# Ninth St and downtown Durham

Pickup to go to Downtown Durham @ Duke Clinics

Stop to walk to Ninth Street (dining)



Bull City Connector Bus Stops			
		🔴 = Eastbound Stop	🔵 = Westbound Stop
<b>Duke Medical Center (South)</b>	1	26	
- Flowers Dr at Trent Dr (Eastbound only)			
<b>Duke Medical Center (North)</b>	13	8	
- Erwin Rd at Trent Dr			
<b>Duke West Campus</b>	2	12	
- Erwin Rd at Anderson St (Eastbound)			
- Erwin Rd at Fifteenth St (Westbound)			
<b>Duke Central Campus</b>	3	31	
- Erwin Rd at Alexander Ave			
<b>Ninth Street District</b>	4	10	
- Main St at Sixth Ave (Eastbound)			
- Main St at Tenth St (Westbound)			
<b>Duke East Campus</b>	5	26	
- Main St at Campus Dr			
<b>Buchanan Blvd/Watts St</b>	6	28	
- Main St at Buchanan Blvd (Eastbound)			
- Main St at Watts St (Westbound)			
<b>Brightleaf Square (West)</b>	7	27	
- Main St at Albemarle St			
<b>Brightleaf Square (Main)</b>	4	25	
- Main St at Grogan St			
<b>Amtrak/West Village</b>	8	25	
- Main St at Durham Train Station (Eastbound)			
- Main St at Fuller St (Westbound)			
<b>Durham Arts Council</b>	24		24
- Morris St at Morgan St (Westbound only)			
<b>Durham Station &amp; American Tobacco</b>	20	23	
- 515 W. Pettigrew St			
<b>Five Points</b>	11	27	
- E Chapel Hill St at Main St (Eastbound)			
- Main St at E Chapel Hill St (Westbound)			
<b>City Center/CCB Plaza</b>	15	21	
- Main St at Concan St			
<b>Mangum St</b>	18	20	
- Main St at Mangum St			
<b>Durham County Government</b>	18	26	
- Main St at Robblee St			
<b>Health Department</b>	15	18	
- Main St at Dilard St			
<b>Durham Hosiery Mills</b>	16	26	
- Angier Ave at Elm St (Eastbound only)			
<b>Golden Belt</b>	17		
- Main St at Angier Ave (Westbound only)			

For more information, call 485-RIDE or visit [bullcityconnector.org](http://bullcityconnector.org)

**DURHAM** Where great things happen

The **Bull City Connector** is a fare-free, hybrid-electric bus service that connects Duke University campus and medical facilities with downtown Durham.

The route provides direct access to Duke and includes stops along Main Street for East Campus, including one at Buchanan Boulevard. There are other stops on Erwin Road at Anderson Street and Alexander Avenue and Duke Clinic at Trent Drive. The service also includes a stop at Durham Station, the city's transportation hub with public bus service and within walking distance of the American Tobacco Campus.

**Bull City Connector Hours of Operation:**

**Mon-Fri:**  
 7am - 6pm, every 15 min.  
 6 pm - Midnight, every 20 min.

**Sat & Holidays:**  
 7am - Midnight, every 20 min.

# Getting around from Duke ↔ UNC

## UAEM Bus, Saturday Oct 9th

From Morehead Planetarium, Franklin St, UNC to Duke Chapel, West Campus  
7:00am, 7:30am, 8:00am, 8:30am

From Duke Chapel, West Campus to Morehead Planetarium, Franklin St, UNC  
7:00pm, 8:00pm

## Robertson Scholars Bus

A Robertson Fund has made available a continuously running free bus designed to promote collaboration between the two universities. Buses depart from and arrive at Duke (Chapel Circle Stop) and UNC-Chapel Hill (Morehead Planetarium Stop). This express bus makes no stops between Duke and UNC-Chapel Hill. One way, the trip is scheduled for 30 minutes: 28 minutes travel time with a 2-minute turnaround

**Friday:** Departs from both campuses on the half hour until 7:30pm, then from UNC on the hour and Duke on the half hour. Last bus is from UNC at 11pm.

**Saturday:** Starting at 11:30am, departs from Duke on the half hour and UNC on the hour. Last bus is from UNC at 12am

**Sunday:** Starting at 11:30am, departs from Duke on the half hour and UNC on the hour. Last bus is from UNC at 10pm

## Triangle Transit Authority (TTA)

TTA busses cost \$2 cash per trip. They do not run on Sunday. Relevant schedules for the conference are below. Full schedules can be viewed online at <http://www.triangletransit.org/>

### **Duke → UNC (Friday)**

-Catch the #400 from the "Erwin Rd at VA Hospital" stop, departing: 6:22am, 6:52am, 7:22am, 7:55am, 8:25am, 8:55am, 9:22am, 10:07am, 11:07am, 12:07pm, 1:07pm, 2:07pm, 3:07pm, 3:38pm, 4:08pm, 4:38pm, 5:08pm, 5:37pm, 6:07pm, 6:37pm, 7:07pm, 8:07pm, 9:07pm, 10:07pm

### **UNC → Duke (Friday)**

-Catch the #400 from the "Manning Dr at UNC Hospitals" stop, departing: 6:45am, 7:15am, 7:45am, 8:15am, 8:45am, 9:15am, 10:00am, 11:00am, 12:00pm, 1:00pm, 2:00pm, 3:10pm, 3:40pm, 4:10pm, 4:40pm, 5:10pm, 5:40pm, 6:10pm, 7:00pm, 8:00pm, 9:00pm, 10:00pm

-Catch the #400 from the "E Franklin St at Coffee Shop" stop, departing: 6:51am, 7:21am, 7:51am, 8:21am, 8:51am, 9:21am, 10:06am, 11:06am, 12:06pm, 1:06pm, 2:06pm, 3:18pm, 3:48pm, 4:18pm, 4:48pm, 5:18pm, 5:48pm, 6:18pm, 7:06pm, 8:06pm, 9:06pm, 10:06pm

### **Duke → UNC (Saturday)**

-Catch the #400 from the "Erwin Rd at VA Hospital" stop, departing: 7:07am, 8:07am, 9:07am, 10:07am, 11:07am, 12:07pm, 1:07pm, 2:07pm, 3:07pm, 4:07pm, 5:07pm, 6:07pm.

### **UNC → Duke (Saturday)**

-Catch the #400 from the "Manning Dr at UNC Hospitals" stop, departing: 7:05am, 8:05am, 9:05am, 10:05am, 11:05am, 12:05pm, 1:05pm, 2:05pm, 3:05pm, 4:05pm, 5:05pm, 6:05pm.

-Catch the #400 from the "E Franklin St at Coffee Shop" stop, departing: 7:10am, 8:10am, 9:10am, 10:10am, 11:10am, 12:10pm, 1:10pm, 2:10pm, 3:10pm, 4:10pm, 5:10pm, 6:10pm

## Taxi

Here are some of many available taxi services. The ones that advertise flat rates tend to be the cheapest. Expect to pay around \$25-\$35 for a cab between campuses or to the airport. Best to split the fare with someone else!

<a href="http://chapelhilltaxicab.com">http://chapelhilltaxicab.com</a>	\$22-25 UNC to Duke, \$25-\$32 UNC to RDU	(919) 357-1085
<a href="http://www.rdu22.com/">http://www.rdu22.com/</a>	\$22 Duke to RDU	(919) 357-1085
<a href="http://www.taxiontime.com/">http://www.taxiontime.com/</a>	—	(919) 493-5050
<a href="http://www.charlenesaferide.com/">http://www.charlenesaferide.com/</a>	\$30 either campus to airport	(919) 309-7233
<a href="http://www.aclasstaxi.com/unc.php">http://www.aclasstaxi.com/unc.php</a>	—	(919) 539-4583
<a href="http://www.afalconride.com/">http://www.afalconride.com/</a>	\$28 Duke to UNC, \$32 RDU - Duke	(919) 309-2700
<a href="http://www.supershuttle.com">http://www.supershuttle.com</a>	—	—
<a href="http://www.durhamtaxi.com/rates.html">http://www.durhamtaxi.com/rates.html</a>	\$24-\$30 Duke to UNC	1-866-680-3330
<a href="http://www.rdctaxi.com/index.html">http://www.rdctaxi.com/index.html</a>	—	(919) 452-7176
<a href="http://www.taxi-rdu.com/">http://www.taxi-rdu.com/</a>	—	(919) 848-8488
<a href="http://www.rdutaxiservice.com/index.html">http://www.rdutaxiservice.com/index.html</a>	—	(919) 282-6688

## Duke/UNC ↔ RDU airport

### Taxi

Taxi is the easiest. See the list of taxis services above. Expect to pay \$25 to \$35 per cab from either campus to the airport.

### Triangle Transit Authority (TTA)

TTA busses cost \$2 cash per trip. They do not run on Sunday. For the conference, they are only really practical for getting from the airport to UNC on Friday or Saturday. These relevant schedules are below. Full schedules can be viewed online at <http://www.triangletransit.org/>

**RDU to Regional Transfer Center (Friday):** Take the “Route 100: Raleigh-Airport-RTC” to the Regional Transfer Center for a transfer. Departures from RDU terminal 1 (2 minutes later from terminal 2): 6:33am, 7:03am, 7:33am, 8:03am, 8:35am, 9:05am, 9:35am, 10:09am, 11:09am, 12:09pm, 1:09pm, 2:09pm, 3:09pm, 4:09pm, 4:39pm, 5:09pm, 5:39pm, 6:09pm, 6:39pm, 7:09pm, 8:09pm, 9:09pm, 10:09pm

**Regional Transfer Center to UNC (Friday):** Transfer at the RTC to either Route 800 or Route 805, whichever you see first. The 800 and 805 leave the RTC continuously on the half hour, and sometimes on the hour also, until the last Route 800 leaves at 10:30pm. Get off at UNC at South Road or at Manning drive.

**Regional Transfer Center to Duke (Friday):** No available routes

**RDU to Regional Transfer Center (Saturday):** Take the “Route 100: Raleigh-Airport-RTC” to the Regional Transfer Center for a transfer. Departures from RDU terminal 1 (2 minutes later from terminal 2): 7:09am, 8:09am, 9:09am, 10:09am, 11:09am, 12:09pm, 1:09pm, 2:09pm, 3:09pm, 4:09pm, 5:09pm, 6:09pm

**Regional Transfer Center to UNC (Saturday):** Transfer at the Regional Transit Center (RTC) to Route 800. It leaves on the half hour until the last bus heads to Chapel Hill at 6:30pm.

**Regional Transfer Center to Duke (Saturday):** No available routes

## A. UAEM Member-Authored Publications Related to UAEM Activities

### Articles and comments in peer-reviewed publications:

Chaifetz S., Chokshi D., Rajkumar R., Scales D. and Benkler Y. Closing the Access Gap for Health Innovations: An Open Licensing Proposal for Universities. *Globalization and Health*, 2007,; 3:1. February 1, 2007.

<http://www.globalizationandhealth.com/content/3/1/1>

- Describes the ideal Equitable Access License (EAL) and how it may have been applied to a recent licensing negotiation among Emory University, Gilead Sciences, and Royalty Pharma.

Chen C., Gilliland T., Purcell J., and Kishore S. The Silent Epidemic of Exclusive University Licensing Policies on Compounds for Neglected Diseases and Beyond. *PLoS NTD*, March 2010

<http://www.plosntds.org/article/info:doi/10.1371/journal.pntd.0000570>

- Analyzes the potential negative effects of the expansion of Bayh-Dole-style laws to developing countries and the countering role of academia in expanding access to medicines. Case study: challenges faced by the UC system in working towards a commitment to global access licensing (GAL)

Chokshi, D. "Universities should foster neglected-disease work." (Letter) *Nature* 435, 12 May 2005.

<http://www.ncbi.nlm.nih.gov/pubmed/15889064>

- Academic technology transfer offices (TTOs) should forge partnerships with nonprofit/nontraditional pharmaceutical ventures, promote 'dual-market' licenses, forego royalties from sales in developing countries, and implement metrics based on social good. Universities should consider preclinical testing and participation in open-access research collaborations in promotion or tenure decisions.

Chokshi D. Improving Access to Medicines in Poor Countries: The Role of Universities. *PLoS* June 2006, Volume 3, Issue 6 e136.

<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030136>

- Argues that universities are well-positioned to address the access gap by innovation and technology transfer; advocates for EAL implementation to achieve these goals and addresses counterarguments.

Chokshi D. and Rajkumar. Leveraging University Research to Advance Global Health. *JAMA* October 24/31 2007;298(16):1934.

<http://jama.ama-assn.org/cgi/content/full/298/16/1934>

- Revisits the role of universities in closing the access gap and emphasizes EAL implementation, support for ND research, and metrics.

Chokshi D. and Kesselheim A. Rethinking global access to vaccines. *British Medical Journal* 2008 Apr 5;336(7647):750-3 2008

<http://www.bmj.com/content/336/7647/750.full.pdf+html>

- Lifesaving vaccines must be made globally available; mechanisms towards this include building local/regional capacity for clinical trials and production facilities. Availability of vaccines may spur the development of local infrastructure, rather than being held up by its lack.

Effort A. and Stevens A. The Critical Role of Academic Licensing in Promoting Global Social Responsibility. 2008.

[http://www.autm.net/AM/Template.cfm?Section=Public\\_Policy&Template=/CM/ContentDisplay.cfm&ContentID=3748](http://www.autm.net/AM/Template.cfm?Section=Public_Policy&Template=/CM/ContentDisplay.cfm&ContentID=3748)

- Summary of options available to universities for GAL. Comprehensive analysis of UAEM's EAL, both supportive and critical. Thorough discussion of previously implemented social responsibility clauses in academic licensing agreements

Hickey B. Recent Developments in Health Law: The Public Research in the Public Interest Act.. *The Journal of Law, Medicine & Ethics* 35 (2), 329–339. doi:10.1111/j.1748-720X.2007.00144.x. Summer 2007.

<http://www.allbusiness.com/government/government-bodies-offices-us-federal-government/8911237-1.html>

- Describes the benefits and potential implementation challenges of the Public Research in the Public Interest Act, introduced by Senator Patrick Leahy (D-VT) in 2006, which would allow generic competition in low- and low-middle income countries for all medical technologies developed at federally-funded institutions.



Kapczynski, Amy. "Access to essential medicines and university research: Building best practices." Yale University Center for Interdisciplinary Research on AIDS, 2003.

[http://cira.med.yale.edu/law\\_policy\\_ethics/access\\_ess.pdf](http://cira.med.yale.edu/law_policy_ethics/access_ess.pdf)

- Reports on a workshop session addressing universities' role in improving global access to health through patenting and licensing, specific terms and mechanisms to do so, metrics, and conditions that would catalyze effective implementation of GAL.

Kapczynski A., Chaifetz S., Katz Z., and Benkler Y. Addressing Global Health Inequities: An Open Licensing Approach for University Innovations. *Berkeley Technology Law Journal* 2005;20(2):1031-1114.

[http://www.btlj.org/data/articles/20\\_02\\_02.pdf](http://www.btlj.org/data/articles/20_02_02.pdf)

- A very complete treatment of the access and innovation gap and previous approaches to narrow the gap, such as compulsory licensing and the Doha Declaration, as well as academia's role in reducing these gaps. Proposes global access licensing as a powerful way for universities to help; predicts and addresses potential obstacles to its implementation. Extremely extensive footnotes and references make this a terrific, though slightly dated, resource for writers.

Kapczynski A., Crone E.T., Merson M. Global Health and University Patents. *Science* 2003;301(5640):1629.

<http://www.sciencemag.org/cgi/content/summary/301/5640/1629>

- Concise call for non-patenting in developing countries and for the institution of global access licensing.

Kishore, S. Comment: Accessibility Of Statins Can Help Curb Cardiovascular Disease In The Developing World. *Health Affairs*, January 13, 2007.

<http://content.healthaffairs.org/cgi/eletters/26/1/13>

- Support for increasing the availability of statin drugs in developing countries to help reduce the incidence of cardiovascular disease. The recent increase in generic statins has made this idea cost-effective. WHO should add statins onto the WHO essential medicine list to let them qualify for price breaks, for UN and WHO drug donation programs, and inclusion in national pharmacopeias.

Kishore S. and Dhadialla P. A Student-Led Campaign to Help Tackle Neglected Tropical Diseases., *PLoS Medicine*, July, 2007.

<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040241>

- Illustrates how students can impact diseases of the developing world through advocacy, research, clinical training, and education, through the perspective of a group of students at Weill Cornell Medical College/Rockefeller University/Memorial Sloan-Kettering Cancer Center.

Kishore, S. Seeding a Global Movement on Neglected Diseases. Global Forum Update on Research for Health, 2008

[http://se1.isn.ch/serviceengine/Files/ISN/93570/ichaptersection\\_singledocument/307CD778-20EA-4EEF-BFF9-78C33B89C52C/en/15\\_Update5\\_SeedingGlobalMovment\\_Kishore.pdf](http://se1.isn.ch/serviceengine/Files/ISN/93570/ichaptersection_singledocument/307CD778-20EA-4EEF-BFF9-78C33B89C52C/en/15_Update5_SeedingGlobalMovment_Kishore.pdf)

- Proposes a neglected disease curriculum at universities and medical schools, including community-based service and education, to empower students to respond to the access crisis.

Kishore S., Tavera G., Hotez P. The Global Health Crisis and Our Nation's Research Universities. *PLoS NTD*, February 2010

<http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0000635>

- Convincingly argues that universities can do far more for global health by 1) seeding funds for NTD research, 2) implementing global access licensing, and 3) valuing NTD research in faculty recruitment, retention, and promotion decisions. Updated, timely examples of related initiatives are given.

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- Provides a brief history of UAEM and the Statement of Principles and Strategies for Equitable Dissemination of Medical Technologies (SPS). Argues for a focus on generic provision over other mechanisms proposed in the SPS.

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## UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

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## **Working Documents**

### **Philadelphia Consensus Statement (PCS). October 2006**

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- A statement urging universities to promote a widespread availability of their technologies in the developing world. Promote equal access to university research, license terms in transfer agreements, develop strategies to ensure provision access. Promote research and development for neglected diseases, adopt policies to promote in-house research. The PCS has been endorsed by nine Nobel Laureates and countless luminaries in science, medicine, public health/policy, and many more!

### **Global Access Licensing Framework (GALF). May 6, 2010**

<http://essentialmedicine.org/archive/global-access-licensing-framework-galf-v20>

- UAEM's recommendations for the strategies university technology transfer offices should adopt to promote global access to their technologies.

### **Stanford White Paper. In the Public Interest: Nine Points to Consider in Licensing University Technology. March 6, 2007**

<http://www-leland.stanford.edu/group/OTL/documents/whitepaper-10.pdf>

- Guidelines for licensing in a way that prioritizes public interest through access to technologies and freedom for further research; the ninth point is specifically applicable to global health.



## Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS). November 9, 2009

<http://www.autm.net/Content/NavigationMenu/TechTransfer/GlobalHealth/statementofprinciples.pdf>

- Guidelines for best practices in global access licensing, compiled by a consortium of technology transfer offices. UAEM had limited input at the roundtable discussions leading up to the publication of the document.

### UAEM's response to the SPS. March 30, 2010

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