



Roundtable on Clinical Trials and Access to Essential Medicines in African Countries

University of Maryland Carey School of Law
October 29-30, 2015

Jointly sponsored by UM Carey Law's Law & Health Care and International and Comparative Law Programs and the University of Maryland Baltimore Center for Global Education Initiatives

Thursday, October 29, 2015

3:15-3:30 Registration

3:30-3:45 Welcome and Introductions

3:45-4:30 Access to Essential Medicines as a Human Right

Opening Remarks and facilitator: Peter Danchin, Professor of Law and Director, International and Comparative Law Program, University of Maryland Carey School of Law

Topics:

- What are the barriers (historical/political/legal/socioeconomic) to access to medicines in the African context?
- What can a human rights framework offer to this conversation as a matter of both national and international law and policy?

Speakers:

- 1) Danwood Chirwa, LLB, LLM, PhD, Professor, University of Cape Town Law Faculty
- 2) Hilda Kaluwa Soko, Law Lecturer, University of Malawi Chancellor College of Law
- 3) Lucie E. White, Louis A. Horvitz Professor of Law, Harvard Law School

4:30-4:45 Break

4:45-6:00 Discussion: Access to Essential Medicines as a Human Right

6:00 Dinner for invited guests

Friday, October 30, 2015

9:00-9:45 Continental Breakfast

9:45-11:15 The Law and Ethics of Clinical Trials: What Rules Should Govern Clinical Research in Africa?

Opening Remarks and Facilitator: Diane Hoffmann, Professor of Law and Director, Law & Health Care Program, University of Maryland Carey School of Law

Topics:

- Consent (ethical standards v. procedures; universal v. culturally relativism; individual v. community-based; issues of domination and subordination)
- Privacy and Stigmatization
- Host country laws that make certain identities/conduct illegal and may jeopardize clinical trial and/or participants safety (e.g., laws against homosexuality or sex work may threaten HIV research)
- Standard of care in multinational research

Speakers:

- 1) Victor Mwapasa, MBBS MPH PhD, Associate Professor, University of Malawi College of Medicine
- 2) Miriam Laufer, MD, MPH, Associate Professor, University of Maryland School of Medicine
- 3) Mark Barnes, JD, LLM, Partner, Ropes & Gray, LLP

11:15-11:30 Coffee Break

11:30-1:00 What do Clinical Researchers and Sponsors Owe to Host Communities?

Opening Remarks and Facilitator: Leslie Meltzer Henry, Professor of Law, University of Maryland Carey School of Law

Topics:

- Interpretations of the requirement to provide “reasonable availability” of any product developed during the trial to the host country/research population (e.g., CIOMS/Declaration of Helsinki/NBAC)
- Ancillary care obligations
- Provision of fair benefits

Speakers:

- 1) Joseph Mfutso-Bengo, PhD, Professor of Bioethics and Director of Centre for Bioethics, University of Malawi College of Medicine
- 2) David S. Wendler, MA, PhD, Head, Section on Research Ethics, Department of Bioethics, National Institutes of Health
- 3) Seema Shah, JD, Faculty Member, Clinical Center Department of Bioethics, National Institutes of Health

1:00-2:00 Lunch

2:00-3:30 Legal Regimes and Obstacles: Free Trade, Intellectual Property, and Access to Medicine

Opening Remarks and Facilitator: Robert Suggs, JD, Professor of Law, University of Maryland Carey School of Law (moderator)

Topics:

- Effects of TRIPS and GATT on access to essential medicines
- Impact of patents and other IP rules on drug development and access to medicine in Africa
- Role of human rights arguments in IP-related cases to increase access to medicines
- Legal and policy developments in the SADC and COMESA regions

Speakers:

- 1) Chikosa Banda, LLM, LLB Faculty of Law, University of Malawi Chancellor College of Law (and co-organizer)
- 2) Lisa Forman, LLB, MA, SJD, Assistant Professor, Dalla Lana School of Public Health, University of Toronto
- 3) Heinz Klug, JD, SJD, Professor and Director, Global Legal Studies Center, University of Wisconsin
- 4) Sean Flynn, JD, Associate Director, Program on Information Justice and Intellectual Property, American University Washington College of Law

3:30-4:00

Conclusion, Final Remarks



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2. Leslie Meltzer Henry, Professor, University of Maryland Carey School of Law
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3. Danwood Chirwa, LL.B, LL.M, PhD, Professor, University of Cape Town Law Faculty
4. Lisa Forman, LL.B, MA, SJD, Assistant Professor, Dalla Lana School of Public Health, University of Toronto
5. Burcu Kilic, Legal Counsel, Public Citizen Global Access to Medicine Program
6. Heinz Klug, JD, SJD, Professor and Director, Global Legal Studies Center, University of Wisconsin
7. Miriam Laufer, MD, MPH, Associate Professor, University of Maryland School of Medicine
8. Joseph Mfutso-Bengo, PhD, Professor of Bioethics and Director of Centre for Bioethics, University of Malawi College of Medicine
9. Victor Mwapasa, MBBS MPH PhD, Associate Professor, University of Malawi College of Medicine
10. Oswald Nyirenda, Clinical Coordinator, Blantyre Malaria Project, Malawi
11. Seema Shah, JD, Faculty Member, Clinical Center Department of Bioethics, National Institutes of Health
12. Hilda Kaluwa Soko, Law Lecturer, University of Malawi Chancellor College of Law
13. Robert Suggs, JD, Professor of Law, University of Maryland Carey School of Law (moderator)
14. David S. Wendler, MA, PhD, Head, Section on Research Ethics, Department of Bioethics, National Institutes of Health

15. Lucie E. White, JD, Louis A. Horvitz Professor of Law, Harvard Law School

Invited Guests

1. William A. Blattner, MD, Professor and Associate Director, Institute of Human Virology, University of Maryland School of Medicine
2. Doug Colbert, JD, Professor, University of Maryland Carey School of Law
3. The Honorable Necton D. Mhura, Malawian Ambassador to the United States
4. Myaing M. Nyunt, MD, MPH, PhD, Assistant Professor, University of Maryland School of Medicine
5. Karen Rothenberg, MPA, JD, Marjorie Cook Professor of Law University of Maryland Carey School of Law
6. Henry J. Silverman, MD, MA, Professor of Medicine, University of Maryland School of Medicine
7. Michael R. Ulrich, JD, MPH, Research Scholar, Senior Fellow in Health Law, and Lecturer in Law, Yale School of Law