

## MICHELE D. FORZLEY, JD, MPH

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### EXECUTIVE PROFILE

A global public health development and legal practitioner; through the application of governance and rule of law principles, best public health practices and the reform, implementation and enforcement of laws, Michele builds health institutions and staff capacity and designs and builds effective systems and mechanisms to regulate the health and pharmaceutical sectors to achieve national goals and obligations. A senior legal scholar, author, presenter and law professor.

### AREAS OF EXPERTISE AND PRACTICE

- Governance and rule of law; SDG16/3
- Ministry level capacity building/institutional development
- Policy development and regulatory effectiveness
- Legislation drafting, review, implementation and enforcement
- Medicines access, regulation & harmonization
- Public health, IHR, and global health security
- Health care services
- Falsified and substandard medical products
- Management and Administration
- Private Health Sector and PPP Regulation
- Health Insurance
- Procurement and Contracting
- Disaster and humanitarian relief
- Trade, health and intellectual property
- Anti-corruption
- Entrepreneurship and economic development
- Experience in AFRO, SEARO, WPRO, EMRO, EURO countries and emerging economies, fragile, conflict and post-conflict states, small and island states.

### CORE ACCOMPLISHMENTS and ONGOING PROJECTS

- *Institutional reform* of ministry of health and medicines regulatory agency for decision making on all matters including UHC, the regulatory system and enforcement mechanisms, draft health laws and amendments to public health and medicines laws, coordinate campaign to achieve stakeholder consensus: Example: Swaziland.
- *Thought leadership*; rule of law and governance in health and medicines sector, advised WHO EMRO states on implementing principles and practices.
- *Medicines regulation*; drafted medicines and pharmacy laws and design new medicines regulatory agency: Papua New Guinea. Drafted Model Law on Medicines Regulation and Harmonization for continent wide use. African Union Regional Medicines Harmonization Initiative.

- *Falsified and substandard medicine*; Drafted national strategy to amend legal and regulatory system to combat the problem. Example Uganda.
- *Global health security agenda*; developed legal framework of optimum combination of laws to enable achievement of global health security agenda targets, created assessment tool and analysis of 25 country legal systems. JEE legal assessment of Pakistan: US Centers for Disease Control and World Health Organization.

**CORE ACCOMPLISHMENTS and ONGOING PROJECTS (CONT.)**

- *Legislative Implementation*; International Health Regulations Technical Expert, WHO/EMRO and SEARO regions and country work in Pakistan, Turkey and others.
- *Policy Advisor*: Supported Office of Global Health, U.S. Dept. of Health and Human Services on revisions to International Health Regulations. Chaired WHO consultation to revise IHR legislative implementation guidance materials, define best practices for international legal consultants. Maryland General Assembly and Depts. on Aging and Human and Health Services, and Montgomery County Adult Mental Health and Substance Abuse Services.
- *Legal Governance Adviser*; USAID Health Policy Project; Designed and implemented ministry system to regulate private health sector within framework of rule of law, and provided capacity building across ministry in Afghanistan.
- *Legislative and Anti-Corruption Adviser*; Advised drafting team on new health and drug law, aligned with EU standards, presented to parliament for enactment and assessed pharmaceutical sector for vulnerability to corruption and developed national strategy to reduce corruption in the sector. Albania Ministry of Health.
- *Legislative and Policy Adviser*; Developed recommendations for solutions from legal, public health and health services delivery perspectives in relation to the Ordinance on Prevention and Control of HIV/AIDS for the National Assembly of the Socialist Republic of Vietnam.
- *Health Insurance General Counsel*; George Washington University Health Insurance Plan. Advised on integration of primary /reproductive health care coverage into national health insurance law in Nigeria.
- *Hospital General Counsel*; Johns Hopkins Hospital System and North Shore Community Hospitals, drafted and negotiated numerous contracts and managed implementation.
- *Procurement and Intellectual Property Rights Expert*; Advised World Bank on problem identification and solutions in medical products procurement in Bank clients; legal advisor to PEPFAR/SCMS/Global Fund AMTB on procurement and IP issues in more than 100 countries.
- *Director Commercial Alliances*; PSP-One and MAP International
- *Economic Development Adviser* to States of Massachusetts, New York and Rhode Island.
- *General Counsel*, 1979-1999, to private sector commercial entities.

**PROFESSIONAL EXPERIENCE BY ORGANIZATION**

**FORZLEY & ASSOCIATES, GLOBAL PUBLIC HEALTH LEGAL ADVISERS; NEW YORK, BOSTON, DC**

*Protecting Public Health with Rule of Law and Governance*

1999-Present

**WORLD BANK; WASHINGTON, DC**  
LEGAL VP AND HEALTH, NUTRITION AND POPULATION DEPARTMENTS 2007- Present

**PALLADIUM, FORMERLY FUTURES GROUP; HEALTH POLICY PROJECT/ NOW HSR/ AFGHANISTAN** 2012- Present

**WORLD HEALTH ORGANIZATION; GENEVA, SWITZERLAND**  
DEPT. ESSENTIAL DRUGS AND IHR SECRETARIAT/GLOBAL CAPACITIES 2003-Present

**PRESIDENT'S EMERGENCY PROGRAM FOR AIDS RELIEF (PEPFAR); ROSSLYN, VA**  
LEGAL COUNSEL SUPPLY CHAIN MANAGEMENT SYSTEM AND **GLOBAL FUND** VOLUNTARY PROCUREMENT 2005-2014

**GLOBAL HEALTH COUNCIL; WASHINGTON, DC**  
POLICY AND RESEARCH DEPARTMENT 2007-2012

**U.S. PATENT AND TRADEMARK OFFICE; WASHINGTON, DC** 2002-2013

**LAWYER/GENERAL COUNSEL GLOBAL** 1979 -1999

### **ACADEMIA EXPERIENCE**

**GEORGETOWN LAW CENTER 2012- CURRENT** WASHINGTON, DC  
Senior Scholar, O'Neill Institute for National & Global Health Law.

**WIDENER SCHOOL OF LAW 2007- 2012** WILMINGTON, DE  
Visiting Distinguished Professor, Health Law Institute. Taught comparative and international health law, supervised graduate law students, and developed and managed global health externship program.

**HOWARD UNIVERSITY 2004-2006** WASHINGTON, DC  
MPH Advisory Board

**PTO ACADEMY 2002-2013** WASHINGTON, DC  
Trainer and curriculum developer; IP and health and safety; delivered multiple trainings to ministry of health and law enforcement officials, members of judiciary, intellectual property office staff and others on protecting health and safety.

**NEW ENGLAND SCHOOL OF LAW 1998-1999** BOSTON, MA  
Adjunct Professor of International Business Transactions.

**PACE UNIVERSITY LUBIN GRADUATE SCHOOL OF BUSINESS 1982- 1983** NEW YORK, NY  
Adjunct Professor of Mergers and Acquisitions,

### **PROFESSIONAL AFFILIATIONS**

- Federal Bar Association International Law Section Chair Int'l Development and Investment Committee
- Public health expert: Rule of Law Index World Justice Project
- ITAC 15 Member; Formerly public health representative on U.S. Commerce Advisory Committee 15 on intellectual property.

- Chair, Global Forum for Law, Justice and Development; Community of Practice on Health and Conference on Counterfeit Medicines.
- Technical Expert: Access to Medicines Index
- Reviewer American Journal of Public Health, Yale Journal of Health Policy and Law, IDLO Manual on Drafting Public Health Legislation others World Medicines Situation Report, Good Governance Assessment Tool.
- OECD: Health as Tracer Sector Team
- Global Health Council
- World Federation of Public Health Associations
- American Bar Association, Past Chair of International Life Sciences and Health Committee
- Society for International Development

### **PUBLICATIONS & MULTIMEDIA (SELECTED)**

*Unless otherwise noted, Forzley is the sole author. A full list available at [www.micheleforzley.com](http://www.micheleforzley.com)*

- *Internal Review Boards; An innovation in health sector governance.* World Bank Law Journal Vol. 7. Spring 2016.
- Forzley M, Sears K, Sayedi O. *Law as a Guide to Regulatory System Design for Health: An Essential Tool for Regulating the Private Health Sector in Afghanistan and Other Developing Countries.* World Bank Law Journal Vol. 7. Spring 2016.
- Forzley M, Robertson J, Smith A. *Legislation an essential tool for ensuring access to medicines policy goals.* WHO South-East Asia J Public Health 2013; 2:69-71.
- *Consultant and author of Pain and Palliative Care Medicines Application to Model Essential Medicines List. Resulting in change to EML and WHA resolution.*
- *Essential Laws for Medicines Access; WHO Study on Rule of Law and Access*
- *World Bank and PSM Toolbox webinar “Business Skills, Practices & the Law: Essential Tools in Medical Products Procurement.”*
- *Problems in Medical Products Procurement across World Bank Clients (on request only)*
- *The Nomenclature of Counterfeit Medicines in National Legislation*
- *Combating Counterfeit Drugs: A Concept Paper for an International Framework Convention and Related Strategies*
- *Impact of Tariffs and Non-Tariff Barriers on Access to Essential Drugs for the Poorest People, a Global Health Council Policy Brief, September 2007*
- *Improving Transparency in the Pharmaceutical Sector: Report On the Study to Identify and Strengthen Decision Points against Corruption in Albania*
- *Private Provider Networks: The Role of Viability in Expanding the Supply of Reproductive Health and Family Planning Services, PSP-One, USAID*
- *International Comparative Analysis of Complementary and Alternative Medicine Regulatory Schemes*
- Winning in Foreign Markets, Your Global Guide®
- Bylined author – over 60 articles 1993-2000 *The Exporter Magazine: Markets and Marketing*

## **SPEAKING ENGAGEMENTS & TRAININGS (SELECTED)**

A full list is available at [www.michele.forzley.com](http://www.michele.forzley.com) or on request.

- Legal Reform: Focus Health Sector, 4<sup>th</sup> International Legislation and Law Reform Conference
- Georgetown Law, Medicines Law Harmonization, Summer Institute on Medicines Law
- Afghanistan Ministry of Public Health: Options for regulating the private health sector and Understanding the market economy.
- Afghanistan Ministry of Public Health: Law as Path from Service Provider to Regulator with a focus on Private Health Sector Regulation
- World Federation of Public Health Association (Ethiopia) “ Law as a Tool for Public Health”
- WHO WPRO and SEARO National Medicines Conference,” Legislation and National Medicines Policy,” “Legal Aspects of Opioids”, “Legal Aspects of Drug Promotion and Marketing”
- SIAPS/MSH/USAID: “Legislation and national pharmaceutical policy”
- ASEAN: “Combating Counterfeit Medicines”
- World Health Organization Lawyers Working Group, “ The role of lawyers in health
- Southwestern University of Political Science and Law, China, “Rule of Law as a Benchmark for Health Sector Reform”
- US Library of Congress Global Legal Information Network “Health Legal Information”
- World Health Organization Secretariat “Governance and Global Public Health”
- Global Health Council and Women in International Trade “The Nexus of Trade and Health”
- DC Fellows- Research Triangle Institute “Legal and Regulatory Dimensions of Health Governance”
- World Bank HDHNE Learning Week “Demystifying Pharmaceutical Procurement”

## **EDUCATION**

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH	Baltimore, Maryland
Master of Public Health, 2003	
INTERNATIONAL COURT OF JUSTICE	Den Hag, Netherlands
Private& Public International Law, 1984 and 2000	
NEW ENGLAND SCHOOL OF LAW	Boston, Massachusetts
Juris Doctor, 1976	
SIMMONS COLLEGE	Boston, Massachusetts
Bachelor of Arts, 1973	

## **PROFESSIONAL LICENSURE**

New York State Bar, 1978, Massachusetts State Bar, 1977  
US District Court of New York Eastern and Southern Districts, 1979, US Court of Appeals 2<sup>nd</sup> Cir.

## **LANGUAGES**

Native English speaker; working knowledge of French, basic Spanish and Arabic.