



# MICHELE D. FORZLEY, JD, MPH

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## EXECUTIVE PROFILE

Global public health development and legal practitioner. Member of the WHO IHR Roster of Experts on Health Law, Ethics and Human Rights, author, and law professor. A thought leader who shares her expertise through technical assistance, consulting, research, analysis, publishing, and training. Through the application of governance and rule of law principles, best public health practices and the reform, drafting, implementation and enforcement of laws, Michele builds health institutions and staff capacity and designs and implements effective systems and mechanisms such as strategic purchasing contracts to regulate the health and pharmaceutical sectors to achieve national and international goals. Michele has experience in AFRO, SEARO, WPRO, EMRO, EURO countries and emerging economies, fragile, conflict and post-conflict states, small and island states.

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## AREAS OF EXPERTISE

### Public health

- Health care services delivery
- Private health sector regulation/PPPs
- Hospital autonomy and board development
- Health insurance, finance, UHC
- Medicines, access, regulation and harmonization
- Falsified and substandard medical products
- International Health Regulations (IHR)
- Global health Security/humanitarian relief

### Policy Development and Rule of Law

- Regulatory effectiveness
- Legislation drafting, assessment, implementation and enforcement
- Procurement and strategic purchasing
- Sustainable development goals (SDG 16/3)
- Advocacy and knowledge management
- Editor-in-Chief UN Health Update

### Governance

- Ministry level capacity building and institutional development
- Regulatory enforcement; licensing, inspection and sanctions boards
- Private Health Sector Accountability
- Health systems strengthening
- Anti-corruption in health and medicines sectors

### Trade, intellectual property and health

- TRIPS flexibilities
- Cross border health services

### Entrepreneurship, business and economic development

- Financial markets UHC, Health Insurance
- Procurement and Contracting
- ESG and Impact Investing



## PROFESSIONAL EXPERIENCE

- Institutional reform of ministry of health and medicines regulatory agency for decision making on all matters including UHC, the regulatory system and enforcement mechanisms, legislative drafting of health law to establish regulatory functions and ministry of health units for each and amendments to public health and medicines laws, coordinate campaign to achieve stakeholder consensus: Example: Swaziland.
- Thought leadership; Every Woman Every Child Senior technical advisor to develop private health sector accountability framework; impact investing and blended finance, member of WHO Medicines Department Consultation to draft guide on good regulatory practices; developed training on rule of law and good governance in health and medicines sector, frequent presenter, advised WHO EMRO states on implementing principles and practices; and global medicines sector analysis for Chemonics. Program and logistics coordinator for annual International Legislation and Law Reform Conference, Editor in Chief, UN Health Update, newsletter on multilateral organization activities related to health matters including medicines, food, and social goods. Procurement and intellectual property rights expert; Advised World Bank on problem identification and solutions in medical products procurement in Bank clients.
- Medicines regulation; drafted medicines and pharmacy and professional council laws to institutionalize medicines regulatory functions within the ministry of health and create new medicines regulatory agency: Example Papua New Guinea. Served as a drafter on the Model Law on Medicines Regulation and Harmonization for continent wide use for African Union Regional Medicines Harmonization Initiative.
- Supply Chain Legal Advisor to PEPFAR/SCMS/Global Fund AMTB on procurement and intellectual property/TRIPS flexibilities issues in more than 100 countries.
- Falsified and substandard medicine; Drafted national strategy to amend legal and regulatory system to combat the problem. Example Uganda. Author of numerous studies, trainings and analysis of the legal and regulatory aspects of the problem. See numerous publications.
- Private Health Sector Regulation; 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, including PPPs.
- Global health security agenda and WHO International Health Regulations; 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. Example JEE legal assessment of Pakistan: US Centers for Disease Control and World Health Organization.
- Legislative Implementation; International Health Regulations Technical Expert, WHO/EMRO and SEARO regions and country work in Pakistan, Turkey.
- 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. Maryland General Assembly and Depts. on Aging and Human and Health Services, and Montgomery County Adult Mental Health and Substance Abuse Services.
- Legislative and Anti-Corruption Adviser; Medicines Sector; Advised drafting team on new health and drug law, aligned with EU standards, presented to parliament for enactment and assessed

## PROFESSIONAL EXPERIENCE (CONT.)

pharmaceutical sector for vulnerability to corruption and developed national strategy to reduce corruption in the sector. Example: 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.
  - Board Member, Vice President; Lower East Side Services Center, a substance abuse rehabilitation center, New York City.
  - Private Health Sector: 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. International business transactions, international trade, economic development for small and medium sized businesses, represented UN Missions on matters of public international law, represented not for profit associations as counsel and served on numerous boards including schools, chambers of commerce, international trade clubs and substance abuse treatment center in New York City.
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## PROFESSIONAL EXPERIENCE BY ORGANIZATION

- FORZLEY & ASSOCIATES, Global Public Health Legal Advisors; New York, Boston, DC. 1999-Present
- WORLD BANK; Legal VP and Health and Nutrition and Population Departments. 2007- Present
- PALLADIUM; Health Policy Project / now/ HSR/ Afghanistan
- 2012- 2016 WORLD HEALTH ORGANIZATION; Geneva, Switzerland, Departments of Essential Medicines and IHR Secretariat/Global Capacities, 2003- present.
- PRESIDENT'S EMERGENCY PROGRAM FOR AIDS RELIEF (PEPFAR); Rosslyn, VA Legal Counsel, Supply Chain Mgt. System and Global Fund Voluntary Procurement, 2005-2014.
- GLOBAL HEALTH COUNCIL; Washington, DC, Policy and Research Dept. Represented Council on ITAC 15 (intellectual property) as public health representative, appointed by Secretary of Commerce, 2007 – 2012
- PATENT AND TRADEMARK OFFICE; Principal Investigator, Washington, DC, 2002-2013 Conducted three studies on IP and health and safety; delivered multiple trainings to health and law enforcement officials, judiciary, intellectual property office staff and others on protecting health and safety.
- MERRILL, LYNCH, PIERCE, FENNER & SMITH; New York City, Registered Representative, 1976-79



## PROFESSIONAL AFFILIATIONS

- Commonwealth Association of Legislative Counsel
  - WHO IHR Roster of Experts in Health Law, Ethics and Human Rights 2017-2021.
  - WHO Consultation Expert on Guide to Good Regulatory Practices 2017.
  - Federal Bar Association International Law Section, Board Member and Chair Int'l Development and Investment Committee
  - Access to Medicines Index; Legal and Technical Advisor
  - 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.
  - Reviewer American Journal of Public Health, WHO Bulletin, Yale Journal of Health Policy and Law, IDLO Manual on Drafting Public Health Legislation, 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
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## PUBLICATIONS & MULTIMEDIA

(SELECTED - A FULL LIST IS AVAILABLE AT [WWW.MICHELE.FORZLEY.COM](http://WWW.MICHELE.FORZLEY.COM) OR ON REQUEST.)

Unless otherwise noted, Forzley is the sole author.

- Forzley M, Wemhoff D. Strategic Purchasing in the Health Sector and Trade Law Implications. The Federal Lawyer March 2018; 64-69.
- Global Health Security Agenda: Joint External Evaluation and Legislation—A 1-Year Review. Health Security Volume 15, Number 3, 2017.
- 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.
- Global Health Security Agenda - Comparative Cross-Country Analysis, Co-author with FHI360 et al, September 2016.
- GHSA Legal Domain Assessment Tool and Guidance, Forzley, Meier and FHI360, September 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.

## PUBLICATIONS & MULTIMEDIA (CONT.)

- 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, for WHO DG.
  - 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
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## SPEAKING ENGAGEMENTS & TRAININGS (SELECTED)

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

- Cross Border Purchase of Health Services, Focus Strategic Purchasing, World Health Care Congress 15
- Complexity Theory and Legal Reform in the Health Sector; Loyola ProLaw Conference, Rome
- Rule of Law: Next Frontier in Medicines Regulatory Strengthening; 3<sup>rd</sup> Scientific Conference African Medicines Regulation, Accra
- Legal Reform: Focus Health Sector, 4<sup>th</sup> International Legislation and Law Reform Conference, DC
- 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 and Law as Path from Service Provider to Regulator
- 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”



## ACADEMIA

GEORGETOWN LAW CENTER 2012- 2016, 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

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.

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## 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

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## 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.

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## LANGUAGES

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