

Michele Forzley, JD, MPH



Nationality: USA

Position: Global Public Health Legal Expert

Key Qualifications:

Ms. Michele Forzley is a global public health legal and policy expert with experience in multiple countries and regions in international trade and business, policy development and implementation, and health sector and medicines regulatory strengthening and reform, and legislative drafting. She is a thought leader who shares her expertise through consulting, research, analysis, publishing, training, and technical assistance. Ms. Forzley has experience in AFRO, SEARO, WPRO, EMRO, EURO and PAHO regions and countries, and in emerging economies, fragile, conflict and post-conflict states, small and island states on projects on behalf of the WHO, World Bank, EU, national governments, advocacy organizations, and trade associations. She is a member of the WHO IHR Roster of Experts on Health Law, Ethics and Human Rights, author, and is a law professor teaching global public health law and policy.

Subject matter expertise includes: Trade and intellectual property; Access to medicines/market access; Regulatory design and strengthening; Health care services delivery and systems strengthening, hospital autonomy; Health legislation, regulation, governance; Health insurance, finance, UHC; Medicines, access, regulation and harmonization; Private health sector regulation/PPPs; Disease, development program and global strategy knowledge; Global health security / International health relations; Procurement and contracting; International business strategic planning and execution; Business management / finance; ESG and investing / Social entrepreneurship.

Education:

- 2003 Master of Public Health, Johns Hopkins Bloomberg School of Public Health, Maryland, USA
- 2000 International Court of Justice, The Hague, Netherlands
- 1984 International Court of Justice, The Hague, Netherlands
- 1977 Juris Doctor, New England School of Law, Massachusetts, USA

Professional Licensure:

- 1979 New York Eastern and Southern Districts, US Court of Appeals 2nd Circuit
- 1978 New York State Bar
- 1977 Massachusetts State Bar

Languages:

English: Native, French: Good

Experience Record:

- 1999 – Present **Consultancy**, Forzley & Associates, New York, Boston, Washington, DC, USA (including various assignments worldwide)
- 1979 – 1999 **General Counsel (independent) and International Business Development Consultant**, Law Offices of Michele Forzley and Forzley & Associates, New York, USA

Relevant Experience:

Forzley & Associates
New York, Boston, Washington, DC, USA

1999 – Present

Various Independent Advisory Consultancies grouped by technical area including:

Market Access and Policy Development: Editor in Chief, UN Health Update, newsletter on multilateral organization activities related to health matters including medicines, food, and social goods. Advisor on Access to Medicines: Access to Medicines Index and Cardio/Unitaid projects. Policy Advisor; Supported Office of Global Health. U.S. Dept. of Health and Human Services on revisions to International Health Regulations. Maryland General Assembly and Depts. on Aging and Human and Health Services, and Montgomery County Adult Mental Health and Substance Abuse Services.

- UN Health Update LLC Editor in Chief Dec 2017–Present
- Access to Medicines Index Technical Expert Jun 2013–Present
- Consulting: global health policy and law (various assignments) 1999–Present
- US Dept. Health and Human Services 2002–2003
- State of Maryland, USA 2001–2003

Policy Research and Development: Medicines Regulatory Strengthening and Harmonization; African Medicines Regulatory Harmonization Initiative MRH, drafter of model law to determine options and way forward for a sustainable harmonized medicines regulatory system for African on behalf of the World Bank. Pacific Islands Regional Platform feasibility study for Pacific region of 15 countries. Study included regulatory functions, financial sustainability, medicines covered, location of and staff profiles, political and legal implications, value proposition and other aspects. Guided national implementation plans for participation in harmonized systems in PNG and Swaziland and implemented national pharmaceutical policies and drafted new legislation. Member of WHO Medicines Department Consultation to draft guide on good regulatory practices and technical advisor on good governance, access to medicines and on falsified and substandard medicines. Advised WHO EMRO states on implementing rule of law principles and practices in pharmaceutical sector.

- Pacific Islands Region Jun 2018–Mar 2019
- Caribbean Region Sep 2018–Feb 2019
- Swaziland Apr 2015–March 2018
- Papua New Guinea Aug 2015–Jun 2017
- World Bank 2007–2016
- World Health Organization March 2003–Present

Trade and Intellectual Property: Represented Global Health Council on ITAC 15 (intellectual property) as public health representative, appointed by Sec. of Commerce. US Patent and Trademark Office Grantee (multiple awards); as principal investigator 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 from counterfeit medicines and other products. Drafted national strategy for Uganda to amend legal and regulatory system to combat the problem. Advised WHO Director General on counterfeit medicines terminology. Advised on intellectual property and trade matters to private sector clients.

- Global Health Council World Health Assembly Delegation 2013–2019
- Uganda 2014–2016
- WHO research and analysis (see various reports on website) 2004–2010
- Global Health Council ITAC 2007–2013
- US PTO Counterfeit Goods and the Public's Health and Safety 2002–2013
- Private sector client representation 1979–1999

International Medical Products Procurement and Supply Chain: Procurement and intellectual property rights expert; Advised World Bank on problem identification and solutions in medical products procurement in Bank clients. Advisor to the Legal Vice-Presidency and Health, Nutrition and Population Global Practice. Legal and Procurement Advisor to PEPFAR/ Supply Chain Mgt. System and Global Fund Voluntary Procurement on procurement and intellectual property/TRIPS flexibilities issues in more than 100 countries.

- World Bank 2007–2015
- SCMS 2005–2014

Private Health Sector Regulation: USAID Health Policy Project/Futures Group; Implemented new law on private sector regulation and designed ministry system to regulate private health sector and provided capacity building including PPPs.

- Ministry of Afghanistan 2013–2016
- MAP International Director of Commercial Relations 2005–2006
- Director Commercial Alliances PSP One/USAID project 2004–2005

Policy Analysis and Development: ESG/Corporate Social Accountability; Every Woman Every Child (EWEC) Senior technical advisor to develop private health sector/corporate social responsibility and accountability framework in relation to the SDGs focusing on the pharmaceutical and the financial sectors. Multilateral organizations and rule of law; Special Advisor to the President of the Federal Bar Association on admission to and management of UN Economic and Social Council NGO accreditation.

- Federal Bar Association Special Advisor to the President on ECOSOC 2020
- EWEC Sept 2017–Sept 2018

Regulatory Design: Advised reform process of ministry of health and medicines regulatory agency on all matters including UHC, the regulatory system and enforcement mechanisms, drafted new health law and amendments to establish regulatory functions and ministry of health units based on assessment of national laws, health policies and international obligations and best practices. 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 in Albania. 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.

- Swaziland Apr 2015–March 2018, follow on in 2021
- Papua New Guinea Aug 2015–Jun 2017
- Albania Ministry of Health Jan 2007–Dec 2008
- Vietnam July 2003–Aug 2003

Infectious Disease Control: Global health security agenda and WHO International Health Regulations; International Federation of Red Cross and Red Crescent Societies project on public health emergencies and disaster management. International Health Regulations Technical Expert, WHO/EMRO and SEARO regions and country work. Developed legal framework of optimum combination of laws to enable achievement of global health security agenda targets for US Centers for Disease Control and created assessment tool and analysis of 25 country legal systems.

- International Federation of Red Cross and Red Crescent Societies 2020 - present
- Pacific Islands and Caribbean Region: Advisor on sub-regional regulatory platforms for medicines regulation.
- CARPHA: for Benin, Guyana and Jamaica, review and revise public health laws to comply with the International Health Regulations.
- Legal expert on WHO Joint External Evaluation of Pakistan Jun–Jul 2016
- US Centers for Disease Control Jun 2015–Jun 2016
- IHR Evaluation of Turkey November 2015

General Counsel (independent) and International Business Development Consultant

Developed and implemented global business strategies, guided international business transactions, advised on international trade and economic development for small and medium sized businesses, and 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.

Additionally, while pursuing a MPH (2001–2003) served as temporary Health Insurance General Counsel; George Washington University Health Insurance Plan and as Hospital General Counsel; Johns Hopkins Hospital System and North Shore Community Hospitals. 1996–2001. Other roles: Board Member, Vice President; Lower East Side Services Center, a substance abuse rehabilitation center, New York City. 1990–1993 and Economic Development Adviser to States of Massachusetts, New York and Rhode Island. 1996–2000.

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 Development and Investment Committee, Logistics and Program Committees Conference Program (2017-present)
- 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
- 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
- American Bar Association, Past Chair of International Life Sciences and Health Committee
- Society for International Development

Publications:

- Forzley M, et al. Public Health Legislation in The Time of a Pandemic. The Loophole October 2020.
- 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 M. et al 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.