

Michele Forzley, JD, MPH



Nationality: USA

Executive Profile: Global Public Health Legal and Policy Expert

Ms. Michele Forzley is an international lawyer and policy with expertise in international trade and business development, finance, health and medicines sectors administrative reform, global health security, and legislative drafting. Ms. Forzley has experience on projects at the global level and in regions of AFRO, SEARO, WPRO, EMRO, EURO and PAHO and in numerous countries, including those in emerging economies, fragile, conflict and post-conflict states, and small and island states 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 has been a law professor teaching global public health law and policy, international business transactions and mergers and acquisitions.

Subject matter expertise includes: Global health security / International health relations; 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, Medicines; access, regulation and harmonization; Private health sector regulation/PPPs; Disease, development program and global strategy knowledge; Procurement and contracting; International business strategic planning and execution; Business management and finance.

Summary of Experience:

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| 1999 – Present | Global Public Health Lawyer Consultancy , Forzley & Associates, New York, Boston, Washington DC, DE USA (including various assignments worldwide) |
| 2017 – 2021 | Editor in Chief and Publisher , UN Health Update, Conversations on Global Health |
| 1979 – 1999 | General Counsel (independent) and International Business Development Consultant , Law Offices of Michele Forzley and Forzley & Associates, New York, USA |
| 1976 – 1979 | Account Executive , Merrill Lynch Pierce Fenner & Smith, New York |

Details of Experience:

Forzley & Associates

1999 – Present

New York, Boston, Washington, DC, USA

Various Independent Advisory Consultancies grouped by technical area including:

Global Health Law and Policy: 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 to the Access to Medicines Index and on Cardno/Unitaid projects. Policy Advisor in the Office of Global Health. U.S. Dept. of Health and Human Services on revisions to International Health Regulations, the Maryland General Assembly and Depts. on Aging and Human and Health Services, and for the Montgomery County Maryland Department of Adult Mental Health and Substance Abuse Services.

- Hera/WHO, Legal Advisor on Mpox Medical Countermeasures 2023-2024
- UN Health Update LLC Editor in Chief Dec 2017–2021

- Access to Medicines Index Technical Expert Jun 2013–2018
- US Dept. Health and Human Services 2002–2003
- State of Maryland, USA 2001–2003

International Medical Products Procurement and Supply Chain: Procurement and intellectual property 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 one hundred countries.

- World Bank 2007–2015
- Supply Chain Management System (PEPFAR) 2005–2014
- MAP International Director of Commercial Relations 2005–2006

Health Sector Reform and Health Insurance: 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 Health in Afghanistan 2013–2016
- Director Commercial Alliances PSP One/USAID project 2004–2005, global.

Global health security: Analysis, update and reform of laws relating to the WHO International Health Regulations, communicable diseases and public health for Lao, Zambia, Uganda, Libya, and other countries; 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 targets for US Centers for Disease Control and created assessment tool and analysis of twenty-five country legal systems.

- WHO Lao Senior Technical Advisor 2021- 2023 on public health law reforms.
- International Development Law Organization 2021-2022. Revisions to public health legislation on public health emergencies in Rwanda, Uganda, and Zambia.
- International Federation of Red Cross and Red Crescent Societies 2020 – 2021.
- 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

Health Sector Administrative and Regulatory Design and Reform: 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 fifteen countries. The 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 regional 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 the pharmaceutical sector.

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.

- Pacific Islands Region Jun 2018–Mar 2019
- Caribbean Region Sep 2018–Feb 2019
- World Bank 2007–2016
- World Health Organization March 2003–Present
- 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

**Law Offices of Michele Forzley and Forzley & Associates
New York, USA**

1979 – 1999

General Counsel 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.

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.
- 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.
- Winning in Foreign Markets, Your Global Guide®
- Bylined author – over sixty articles 1993-2000 The Exporter Magazine: Markets and Marketing
- Combating Counterfeit Drugs: A Concept Paper for an International Framework Convention and Related Strategies
- Counterfeit Goods and the Public's Health and Safety
- Use of Criminal Laws to Protect Public Health
- 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
- "Provider Networks: The Role of Viability in Expanding the Supply of Reproductive Health and Family Planning Services," PSP-One, USAID
- "Home Based Care Kits- How to Sustain this Solution to Increasing Access to Treatment," Supply Chain Management System, (PEPFAR) Working Paper
- "The World Trading Organization and Public Health – What does trade have to do with health?" Global Health Link, Issue #124, November-December 2003
- A Tool for Mental Health Legislation – integrate principles of public health and human rights
- International Comparative Analysis of Complementary and Alternative Medicine Regulatory Schemes
- Internet Jurisdiction Project; International legal materials on telemedicine
- Winning in Foreign Markets, Your Global Guide®
- Bylined author – over sixty articles 1993-2000 The Exporter Magazine: Markets and Marketing
- Model International Legal Agreements Series (MILAS), an on-line model international

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- business legal agreement database with distance educational materials
 - Handbook on Customs & International Trade Law, 2nd edition

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
- 1976 Juris Doctor, New England School of Law, Massachusetts, USA
- 1973 Bachelor of Arts, Simmons University (formerly College), 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, Arabic: Basic