



Forzley & Associates is a global public health development legal advisory firm, is 100% women owned and a certified small business. F&A has over 20 years of experience in international development in more than 30 countries, having worked in USAID, World Bank, WHO, UNDP, EU and direct country funded projects. We have acted in this capacity for public and private sector clients who are international, national and regional governmental and non-governmental organizations in AFRO, SEARO, WPRO, EMRO and EURO countries including emerging economies, fragile, and conflict and post-conflict states. F&A operates virtually with a home office in the Washington DC metro area and has footprints in Europe and Africa.

We are unique as one of the very few legal advisory firms in the health development space and are globally recognized as health legal experts that design and build solutions drawn from the law at the practice and operational level. Our core competencies are in the domain of law; our work is informed by the critical thinking and problem-solving skills of practitioner scholars. F&A team members are licensed lawyers with postgraduate degrees in law, public health and development economics. We maintain a global network of seasoned legal advisors we can call upon for projects as needed.

We have extensive experience and capability in these subjects among others:

Public health

- Health care services delivery
- Private health sector regulation/PPPs
- Hospital autonomy and board development
- Health insurance, finance, UHC
- Access to medicines
- Medicines 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
- SDGs 16/3
- Advocacy and knowledge management
- Publishing: UN Health Update

Governance

- Ministry capacity building and institutional development, public administration
- 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
- Access to Medicines
- Cross border health services

Entrepreneurship, business and economic development

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

Our experience spans diverse industries and regions within the global health law space. Some examples of our work are listed here:

- **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 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, advised WHO EMRO states on implementing principles and practices; developed global medicines sector analysis. 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 Publications on website.
- **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, defined best practices for international legal consultants. Served in Maryland General Assembly and Depts. on Aging and Human and Health Services, and Montgomery County Adult Mental Health and Substance Abuse Services Department.
- **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 pharmaceutical sector for vulnerability to corruption and developed national strategy to reduce corruption in the sector. Example: Albania Ministry of Health.

Key Team Members

Michele Forzley, JD, MPH is the director and founder of the firm. She serves as a senior legal, technical or governance advisor to international, national and regional governmental and non-governmental organizations, national government ministries. Her expertise is on the legal aspects of all health matters ranging from reforming and implementing health and pharmaceutical legislation and regulation, private sector regulation and governance, trade, intellectual property, corruption, PPPs and public procurement. From 1979-1999: Michele was an independent general counsel to private sector clients from her office in New York City, and since 1999, based in the Washington, DC area her focus has been on the public sector in developing countries. Michele holds an MPH from Johns Hopkins and a Juris Doctor from New England Law. She is regarded as an expert in Health Law by the WHO and was appointed to its Roster of Experts as an expert on Health Law, Ethics and Human Rights.

Mar Martínez, LLM, MA provides advisory services on governance and global health. She has over a decade of field experience that spans Asia, Europe, Africa, and the Americas. As a World Bank consultant, she worked in West Africa, coordinating the medicines regulatory harmonization initiative. Previously she worked in various projects in the United States, Brazil, India, UK, Italy, Spain, and the European Commission in Belgium. She earned a M.A. in development economics from the Edmund A. Walsh School of Foreign Service at Georgetown University in Washington, D.C. in 2014, a post-graduate diploma in foreign trade sponsored by the Madrid Chamber of Commerce and Industry in 2010, and LL.M. in intellectual property law from Charles III University of Madrid in 2006. Her current assignment is for the German Corporation for International Cooperation (GIZ) in Bolivia. Her working languages are English, Spanish, French, and Portuguese.

Organizational Data:

Founded in 1979 by Michele Forzley and continuously in operation since.

DUNS/Cage: 78-696-0823/4XRS1

Employees: one full time, one admin and 4 associate team members

Geographic reach: global

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