

PROFESSOR GOSTIN CHAIRS AND CO-AUTHORS NATIONAL ACADEMY
REPORT ON DANGERS OF FAKE DRUGS

For Immediate Release
February 13, 2013

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A committee formed by the Institute of Medicine (IOM), National Academy of Science, and chaired by O'Neill Institute for National and Global Health Law Faculty Director and Georgetown University Law Center Professor Lawrence Gostin has issued a new report, "Countering the Problem of Falsified and Substandard Drugs," which offers recommendations to the United States and globally on protecting citizens against the health risks posed by illegitimate medications.

"Given the international nature of modern manufacturing and trade, every nation has a stake and a role to play in ensuring the production and sale of high-quality medications," said Gostin. "Falsified and substandard medicines are a grave public health problem because they are ineffective, promote drug resistance and even cause severe illness and death, particularly in developing countries where they regularly flood the market."

The Food and Drug Administration (FDA) commissioned the IOM study in 2012 to investigate the global problem of poor quality medicine and to identify solutions for countering the production and sale of counterfeit, substandard, falsified and unregistered products.

Gostin was selected to chair the IOM Committee on Understanding the Global Public Health Implications of Substandard, Falsified and Counterfeit Medical Products, which prepared the report over the course of the last year. The group of 12 volunteers included academics, global public health experts, researchers and pharmaceutical leaders.

The report examines the health, economic and social consequences of substandard and falsified medicines and shows that a lack of clarity about the scope and magnitude of the problem has prevented coordinated international action. According to the report, the illegal trade and manufacture of medicines affected at least 124 countries in 2011, and the burden is disproportionately felt in the developing world.

The report identifies several contributing factors to this global problem, including failure to adhere to good manufacturing practices, high demand and erratic supply of drugs, weak regulatory

systems and government oversight and low levels of public awareness, particularly in the poorest countries.

The report states that reducing the problem requires international cooperation. It calls for global agreement on an international code of practice on drug quality. It also recommends establishing a mandatory drug tracking system and tightening the licensing requirements on medication wholesalers in the United States.

“We’re calling on the World Health Organization (WHO), in collaboration with regulators, companies and civil society worldwide, to adopt a global code of practice, build national regulatory capabilities and promote international cooperation,” said Gostin.

Gostin is University Professor at Georgetown Law, where he directs the O’Neill Institute for National and Global Health Law. He is also the director of the WHO Collaborating Center on Public Health Law and Human Rights. From 2004 to 2008, he served as associate dean for research at Georgetown Law.

Gostin holds a number of international academic appointments. He is professor of global health law at the University of Sydney, visiting professor and research fellow at the University of Oxford and a distinguished scholar and visiting professor at the University of Witwatersrand (Johannesburg, South Africa).

Gostin serves on the director-general’s Advisory Committee on Reforming the World Health Organization. In 2007, the WHO director-general appointed him to the International Health Regulations Roster of Experts and the Expert Advisory Panel on Mental Health.

An elected lifetime member of the Institute of Medicine/National Academy of Sciences, Gostin currently chairs the IOM Committee on National Preparation for Mass Disasters and has also chaired committees on privacy, genomics and prisoner research. He has received numerous honors and awards for his contributions to public health law.

Gostin has led major law reform initiatives in the U.S., including the drafting of the Model Emergency Health Powers Act to combat bioterrorism and the “Turning Point” Model State Public Health Act. He is also leading a team on developing a Model Public Health Law for WHO and is currently involved in three major international initiatives on global health governance: a framework convention on human services for the World Bank, a framework convention on global health and a global plan for justice.

In the United Kingdom, Gostin was the legal director of the National Association for Mental Health, director of the National Council of Civil Liberties and a fellow at Oxford University. He helped draft the Mental Health Act (England and Wales) and brought several landmark cases before the European Commission and Court of Human Rights.

Gostin is the author of several books and holds numerous editorial appointments in academic journals around the world.

About The O'Neill Institute for National and Global Health Law

The O'Neill Institute for National and Global Health Law at Georgetown University was established in 2007 to respond to the need for innovative solutions to the most pressing national and international health concerns. Housed at Georgetown University Law Center in Washington D.C., the O'Neill Institute reflects the importance of public and private law in health policy analysis. The O'Neill Institute draws upon the University's considerable intellectual resources, including the School of Medicine, the School of Nursing & Health Studies, the Public Policy Institute, and the Kennedy Institute of Ethics.

About Georgetown University Law Center

Georgetown University Law Center, one of the world's premier law schools, is pre-eminent in several areas, including constitutional, international, tax and clinical law. The full-time faculty is among the largest in the nation. Drawing on its Jesuit heritage, it has a strong tradition of public service and is dedicated to the principle that law is but a means, justice is the end. With this principle in mind, Georgetown Law has built an environment that cultivates an exchange of ideas and the pursuit of academic excellence. It brings together an extraordinarily varied group of teachers, scholars and practitioners, as well as an outstanding student body representing more than 60 countries.

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