

# GRIPS-Mansfield Foundation Joint Seminar

Date: 9, April 2014 Time: 12:00-13:30

Venue: The National Graduate Institute for Policy Studies (GRIPS) 1st Floor, Room 1AB

## ***“Pediatric Drug Development – U.S. and Japan”***

Speaker : **Catherine Soo Lee, DrPH** (Mansfield Fellow)

Scientific Data Analyst  
Office of Pediatric Therapeutics  
U.S. Food and Drug Administration

Moderator **Mari Suzuki**

: Professor (Health Services Center)  
National Graduate Institute for Policy Studies (GRIPS)

Description: Increased pediatric clinical trials are being performed globally because of stronger incentive to obtain pediatric information among national regulatory agencies. The lack of access to pediatric clinical trial information and the lack of consensus with regard to globally-recognized standard pediatric definitions for primary endpoints has been a challenge. It is incumbent upon regulatory authorities to ensure enrollment of children in clinical trials that are ethical and answer a valid scientific question, given the limited pediatric patient population with a given disease/condition. To achieve this objective, increasing communication and transparency among international regulators has been a priority for the U.S. Food and Drug Administration (FDA).

To this end, FDA has established a collaborative exchange of scientific information related to pediatric product development with international regulators. It is through these exchanges that trials are designed to provide the data necessary to label products for their safe and effective use in the pediatric population and make sure unnecessary or duplicative trials in children are avoided. Given the emergence of the Asia-Pacific region as a contributor to clinical pediatric trial sites, it is imperative that FDA collaborate with regulatory colleagues in Asia, specifically Japan.

Recently the Japanese government has taken various measures to promote clinical development activities of new drugs. They have taken an active role in developing harmonization of the principles of clinical research (ICH E-11) guidelines and incentive programs, which have slowly increased the number of pediatric trials. Japanese regulatory agencies have also been more involved in contributing to international dialogue on pediatrics product development and continue to work on bringing pediatric product development studies into the Japanese regulatory “routine” processes.

Dr. Catherine Lee is currently a Mansfield Fellow and Scientific Data Analyst for the U.S. Food and Drug Administration. She will provide a description of the history and organization of the FDA and provide a brief introduction of pediatric legislation and pediatric drug development in the U.S. Her presentation will also include a basic comparative view of the pediatric drug approval process in Japan and in the U.S. and discuss the dialogue among international regulatory agencies on the globalization of pediatric trials.

Mari Suzuki, professor of National Graduate Institute for Policy Studies will serve as a moderator for the event. She is an internist, received a doctorate degree from Tokyo Women’s Medical University and worked for many years at the TWMU as researcher and assistant professor. She joined GRIPS in 2002 as professor. Her current research interests include endocrinology, adolescent medicine, and eating disorders.

**\*Language: English**

**\*Admission Free**

**\*Please bring your own lunch.**

**For registration and inquiries please**

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## The National Graduate Institute for Policy Studies

GRIPS was established in October 1997, superseding the Graduate School of Policy Science (GSPS) at Saitama University, which was the first graduate school for Policy Studies in Japan. GRIPS is a government-sponsored graduate school and research institute which has been restructured into an entirely new and unique entity. GRIPS aims to be an international center of excellence for the education of future leaders in the policy arena, for the advancement of policy research, and for the systematic collection and dissemination of policy-related information. In order to accomplish these aims, a Graduate School, a Policy Research Center and a Policy Information Center have been established. GRIPS is the first graduate school without facilities for undergraduates in Japan in the wider disciplines of social science. GRIPS is located in Roppongi, Tokyo, with easy access to the political and business headquarters of Japan.

The degree programs are designed to attract outstanding students and thoroughly prepare them for distinguished careers in policy setting. After a period of thorough preparation since its foundation in 1997, GRIPS welcomed its first domestic students in April 2000, followed six months later by the first international students. More than half of the student-intake of GRIPS consist of international students coming from nearly forty countries in Asia, Africa and Eastern Europe. Our students normally have three to five years experience working for governments, central banks, custom offices or other relevant organizations. The International Programs at GRIPS are conducted solely in English, while Domestic Programs are taught in Japanese.

GRIPS aims to be the center of a consortium, consisting of industry, government and academia, for the exchange of information, ideas and personnel among graduate schools, government-related institutes and private research institutes in Japan. In addition, through its international faculty, student body and alumni, and by promoting international exchange of policy research and information, GRIPS aims to establish an international network among academics and government officials in the field of policy studies, contributing to the promotion of a better understanding among peoples around the world in an age of globalization.

## The Maureen and Mike Mansfield Foundation

The Maureen and Mike Mansfield Foundation was created in 1983 to advance Maureen and Mike Mansfield's life-long efforts to promote understanding and cooperation among the nations and peoples of Asia and the United States. The Foundation sponsors exchanges, dialogues and publications that create networks among U.S. and Asian leaders, explore the underlying issues influencing public policies, and increase awareness about the nations and peoples of Asia. The Mansfield Foundation's geographic focus is Northeast Asia and India as it relates to that region. The Foundation receives support from individuals, corporations and philanthropic organizations. It also provides support to [The Maureen and Mike Mansfield Center at the University of Montana](#).

The Mansfield Fellowship Program - named after Mike Mansfield, former U.S. ambassador to Japan, U.S. Senate majority leader, and U.S. congressman from Montana - is a first-of-its-kind program for the United States and Japan. The U.S. Congress created the Mansfield Fellowships in 1994 to build a corps of U.S. federal government employees with proficiency in the Japanese language and practical, firsthand knowledge about Japan and its government. During the one-year program in Japan, Fellows develop an in-depth understanding of Japan's government and policymaking process and establish relationships with their counterparts in the government of Japan and the business, professional and academic communities. The Mansfield Fellowships are administered by the Maureen and Mike Mansfield Foundation, with the United States Department of State, Bureau of Educational and Cultural Affairs, as grantor.

The Foundation has offices in Washington, D.C., Tokyo, Japan, and Missoula, Montana.