USP Quality Institute and Georgetown University Name Two Fellows in Quality Medical Products

Fellows Will Examine the Link Between Substandard and Falsified Medicines and Antimicrobial Resistance

FOR IMMEDIATE RELEASE

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Rockville, MD – December 6, 2017 – The USP Quality Institute and Georgetown University Medical Center announce the inaugural fellows selected for the institutions’ Fellowship in Quality Medical Products. The fellows will examine the role that substandard and falsified antimicrobials play in fostering antimicrobial resistance (AMR).

As the inaugural fellows, Matthew Hassett, Ph.D., and Marissa Malchione, M.S., will conduct research to address evidence gaps relating to the impact of poor-quality medicines on AMR. Poor-quality medicines can accelerate AMR by exposing patients to sub-therapeutic doses of medicine, thereby enabling the development of resistant pathogens. One in ten medicines in low- and middle-income countries is substandard or falsified, with antimicrobial medicines accounting for the largest number of reports, according to new research from the World Health Organization announced last week.

“We are thrilled to welcome the new fellows. Their expertise, skillset and passion for research will be valuable in exploring an often overlooked aspect of public health,” said Michael Levy, vice president and leader of the Quality Institute. “Poor-quality medicines present a significant challenge to public health and more data is needed to help governments and health policy makers around the world make evidence-based policy decisions. Quality medicines are important to public health in general, but they are especially critical to ensuring the success of strategies aimed at addressing AMR.”

The fellows, who will be based at Georgetown University Medical Center, will have the unique opportunity to engage in real-world training experiences, as well as interactions with USP and other stakeholders.

“While we know that quality medicines are important for treating diseases effectively and slowing or preventing the emergence of antimicrobial resistance, we do not yet have quantified measures that support this understanding,” said Erin Wilhelm, executive director of the Program for Regulatory Science & Medicine at Georgetown University. “Through these projects, Dr. Hassett and Ms. Malchione, together with their mentors, will begin to address this evidence gap and provide scientific support for regulatory or policy decision-making to enhance quality medicines.”

Dr. Hassett’s doctoral research focused on mechanisms by which the malarial parasite develops resistance to therapies. His thesis work was highly interdisciplinary, and aided the understanding of drug resistance and identified novel potential drug targets for the next generation of antimalarial medicines. It was through this research that his interest in substandard and falsified antimalarial...
medicines and their impact on the spread of antimalarial drug resistance developed. Dr. Hassett has a Ph.D. in chemistry from Georgetown University.

Ms. Malchione most recently was a research specialist at the Georgetown University Center on Medical Product Access, Safety and Stewardship (COMPASS) studying the prevalence and distribution of a drug-resistant strain of E. coli in Asia. Ms. Malchione will enhance the knowledge and awareness of the epidemiology and impacts of substandard and falsified antimicrobials in high-risk areas. She has a Master of Science in Public Health Microbiology and Emerging Infectious Diseases from The George Washington University.

The fellows will begin their research this fall, under the guidance of Fouad Atouf, Ph.D., USP vice president Science-Global Biologics; Jesse Goodman, M.D., M.P.H, professor of medicine and director, of COMPASS; and Paul Roepe, Ph.D., M.A., professor of chemistry, and biochemistry and cellular & molecular biology at Georgetown University, and co-director of its Center for Infectious Diseases.

The Quality Institute, introduced at a reception held on the sidelines of the recent U.N. General Assembly meetings in New York, is a new research center within USP dedicated to providing research and data to enable evidence-based policy decisions to help ensure the availability of quality medicines around the world.

**About the Quality Institute**
The Quality Institute is a research center within USP, generating and disseminating objective research and data on the benefits of quality medicine, enabling evidence-based policy decisions that can help increase the availability of quality medicines everywhere. Guided by an advisory group of global health thought leaders and informed by USP’s extensive expertise, the Quality Institute sponsors fellowships at leading universities to conduct research critical to understanding the benefits of quality medicines to individuals, populations and global public health.

**About USP**
USP is an independent non-profit organization that collaborates with the world’s top health and science experts to develop high-quality standards that set the bar for manufacturing and distributing safe and effective medicines, supplements and food around the globe. Two billion people world-wide have access to quality medicines, dietary supplements and food as a result of USP’s standards, advocacy and education.

**About Georgetown University Medical Center**
Georgetown University Medical Center (GUMC) is an internationally recognized academic medical center with a three-part mission of research, teaching and patient care (through MedStar Health). GUMC’s mission is carried out with a strong emphasis on public service and a dedication to the Catholic, Jesuit principle of cura personalis -- or “care of the whole person.” The Medical Center includes the School of Medicine and the School of Nursing & Health Studies, both nationally ranked; Georgetown Lombardi Comprehensive Cancer Center, designated as a comprehensive cancer center by the National Cancer Institute; and the Biomedical Graduate Research Organization, which accounts for the majority of externally funded research at GUMC including a Clinical and Translational Science Award from the National Institutes of Health.

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