

*The Hong Kong Polytechnic University*  
*Department of Logistics and Maritime Studies*  
*Research Seminar*

**Inducing Compliance with Post-Market Studies for Drugs under FDA's Accelerated Approval Pathway**

by

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**Date: 27 March 2019 (Wednesday)**  
**Time: 10:30am -11:30pm**  
**Venue: R508, Shirley Chan Building**  
**The Hong Kong Polytechnic University**

**(Conducted in English)**

**Abstract:**

In 1992, FDA instituted the accelerated approval pathway (AP) to allow promising drugs to enter the market based on limited evidence, but requiring manufacturers to verify the drugs' true clinical benefits through post-market studies. However, most post-market studies are not completed due to many incentive issues, and FDA must endure an onerous process to withdraw an unproven drug from the market when a post-market study is uncompleted. The prevalence of this non-compliance problem poses considerable public health risk, compromising the original purpose of a well-intentioned AP initiative. We address this problem by providing an internally consistent and implementable solution through a comprehensive analysis of the myriad complicating factors and tradeoffs facing FDA, including information asymmetry and moral hazard. Specifically, we adopt a Stackelberg framework in which regulator, which cannot observe manufacturer's private cost information or level of effort, leads by imposing a post-market study deadline. The profit-maximizing manufacturer then follows by establishing its level of effort to invest in its post-market study. We develop a deadline-dependent user fee mechanism that establishes an incentive for manufacturer compliance. We show that effectiveness of the mechanism in inducing compliance depends fundamentally on what we distill as the enforceability of sanction ( $s$ ), a drug-specific measure that indicates how difficult it is to withdraw a drug from the market, and the drug's success probability ( $\alpha$ ): The higher is either, the higher is the probability that the mechanism induces compliance. Using data for a real drug, we calibrate our model and quantify the value of such a mechanism and its impact. We also discuss alternatives when such a mechanism is less effective. From public policy perspective, we provide guidance for FDA to increase the viability and effectiveness of AP.

**Bio:**

Dr. Hui Zhao is an Associate Professor of Supply Chain Management and Charles and Lilian Binder Faculty Fellow at the Smeal College of Business of the Penn State University. Her research focuses on healthcare systems with particular interests in pharmaceutical supply chain, healthcare public policy, and innovative design of healthcare systems (such as telehealth and online platforms). Most of her work looks at the incentive misalignment in the healthcare system, seeking solutions to resolve such problems. Aside from healthcare, she is generally interested in incentives and contracts, collaboration in decentralized supply chains, and information asymmetry. She is also interested in the behavioral aspects of decision making. Her work has appeared in leading journals such as Management science, Operations research, M&SOM, and POM, and has received multiple awards including finalist for Pierskalla award by INFORMS and the runner-up for the 2018 Ralph Gomory Best Industry Studies Paper Award by the interdisciplinary Industry Studies Association (ISA). She has written invited book chapters on pharmaceutical/healthcare supply chains. She serves as an associated editor for the Decision Sciences Journal and is an officer for INFORMS Health Applications Society (HAS). In addition to academia, she is actively involved with government agencies (e.g., serving on FDA expert panel) and industry forums (e.g., Artificial Intelligence in Healthcare Initiative). Prior to joining Smeal, she had been on faculty at Krannert School of Management at Purdue University. She has taught extensively on topics such as business analytics, quantitative decision making, and healthcare supply chains at the undergraduate, MBA, and PhD levels. She is the phd coordinator of the Supply Chain and Information Systems Department at Smeal.

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**All are welcome!**