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# New developments in benefit-risk decision-making for Rx to OTC switch

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Rx to OTC switch has been a viable form of life-cycle management of prescription drugs. However, the push to expand the scope of nonprescription drug use has been stalled by certain barriers pertaining to characterizing benefit and risk in the nonprescription self-care setting. As a result, regulatory agencies have renewed interest in conceptualizing the current approach to benefit-risk for Rx-to-OTC switch to facilitate broader consumer access to medicines.

In March 2012 FDA announced an initiative on Nonprescription Safe Use Regulatory Expansion (NSURE) to hear from stakeholders about potential novel conditions of nonprescription drug use, including for example IT support at the retail pharmacy level. Within a month, FDA held another public meeting in the unusual format of an open Pre-IND meeting to explore nonprescription status of naloxone for prevention of mortality in opioid overdose. As follow-up, FDA contracted with the Brookings Institute to further explore the barriers and opportunities in this area. Concurrently, researchers characterized the scientific/regulatory scope and nature of Rx to nonprescription switch decisions, including specific considerations necessary to facilitate alignment of companies and FDA on the essential data needed for switch decisions. More recently, FDA issued a call for comments on its draft plan to formalize a structured approach to describing its benefit-risk assessment in the human drug and biologic review process.

This session will explore public health implications of these important regulatory developments, in the context of the international movement on Rx-to-nonprescription switch, IT approaches to address unfulfilled requirements of self-selection studies, and novel switch candidates.

## Biography

R. William Soller is Health Science Clinical Professor of Pharmacy at the University of California, San Francisco School of Pharmacy, and Executive Director, Center for Self Care. Soller is a health policy expert and researcher who focuses on gaps and seeks solutions on matters affecting safe and effective use of properly labeled medications, including effective health communications through drug labeling and telehealth, responsible self-care by consumers and patients, physician prescribing practices, and medication therapy management in patients with chronic diseases.

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