

Faculty, Students and Staff across CWRU Campus

Please join the School of Medicine for an exclusive discussion with

Allan M. Green, MD, PhD, JD (MED'72)
and
Lee S. Simon, MD

THURSDAY, NOVEMBER 21, 2019

4 p.m. Lecture ■ 6:30 p.m. Reception

**Biomedical Research Building
Frohring Auditorium, BRB 105
2109 Adelbert Road**

Why Is There an FDA?

***The Challenge of Regulation to Public Policy,
Private Enterprise and Patient Care***

This presentation will explore the operating realities of the FDA and will provide background on the legislative authority which underlies FDA activities, the processes and procedures by which the Agency carries out its mandate and the public policy debates which deal with the tension between accelerating approval of new treatments for incurable diseases and the demand to improve the safety of marketed drugs. It will include a summary of the Hatch-Waxman Act and a Case Study based on a recent controversial approval.

Dr. Green is Adjunct Professor of Law at Boston College Law School where he teaches Food and Drug Law. Dr. Simon served as the FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products.

**RSVP by November 20, 2019 to Nanette
Hodermarsky at 216.368.5203 or nmh46@case.edu
or register online: <http://cglink.me/r624199>**



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