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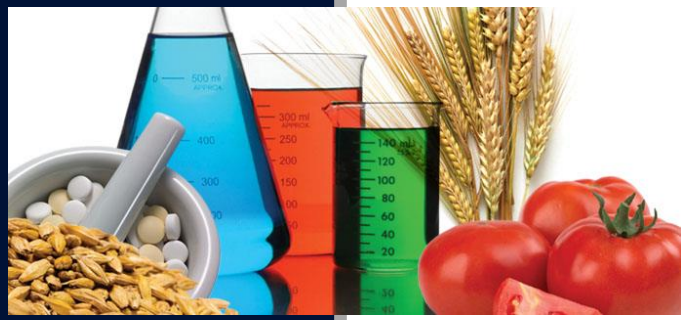

Food, Drug and Cosmetic Law Section Annual Meeting – January 25, 2018

Do Laws Mandate Drug Company Collaboration

Moderated by: Larissa C. Bergin

Michael M. Knight,
Partner, Jones Day

Michael Carrier, Professor,
Rutgers Law School

Today's Topics (1 of 2):

- Current Regulatory Environment
- Potential Methods of Extending Branded Drug Exclusivity
  - "Sham" Citizen Petitions
    - Impact on the FDA review period
  - Distribution Methods, Forestalling Access to Samples:
    - REMS v. Non-REMS Distribution
    - Impact on Pricing
    - Lack of interest in generic entry in some markets

Today's Topics (2 of 2)

- Recent Agency Action
  - FDA- Does the FDA need to address generic entry issues from within?
    - Workshops
    - Investigations
    - Drug Competition Action Plan
  - FTC- What role does antitrust play in regulating these behaviors?
    - Workshops
    - Investigations
- Congressional Action - CREATES Act
  - Private right of action; no antitrust hook

Questions or Comments?