



Scientific Exchange and the First Amendment

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Overview

- **Key Court Cases**

- *Sorrell v. IMS Health Inc.* (Supreme Court 2011)
 - Speech in aid of pharmaceutical marketing is protected by the First Amendment
 - Content- and speaker-based restrictions subject to “heightened scrutiny”
- *US v. Caronia* (2nd Cir 2012)
 - “The government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.”
- *Amarin v. FDA* (SDNY 2015)
 - First Amendment protects all truthful and non-misleading off-label speech, including proactive, promotional statements made by a manufacturer

Overview

- **Recent FDA Actions**

- Public Hearing (November 2016)
- First Amendment Memo (January 2017)
- *FDA Draft Guidance: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers* (January 2017)
- *FDA Draft Guidance: Medical Product Communications that are Consistent with the Labeling—Questions and Answers* (January 2017)
- Intended Use Rule (Effective Date Delayed Until March 2018)

Overview

- **Legislative Activity**

- Pharmaceutical Information Exchange Act (H.R. 2026) (Guthrie)
- Medical Product Communications Act (H.R. 1703) (Griffith)