

Status and Implications of Caronia and Other First Amendment Cases Regarding Off-Label Marketing

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Regulatory Framework – FDA Approval

- FDA will approve a drug for a specific use if:
 - 1) There is “substantial evidence” that the drug is safe
 - 2) There is substantial evidence that the drug is effective
 - 3) The labeling is not false or misleading in any particular way
- FDA approval is for the intended use discussed in the labeling; new uses require approval for a new indication

Regulatory Framework – Misbranding

- It is a crime to introduce a misbranded drug into interstate commerce
- A drug is “misbranded” if:
 - 1) The labeling is false or misleading
 - 2) The drug lacks adequate directions for use
- FDA interprets labeling to include any statement, written or oral, about the drug
- A manufacturer can be prosecuted for misbranding if it provides any information, *even if truthful*, about an unapproved use

Conflict with First Amendment

- The First Amendment forbids Congress from enacting laws that “abridg[e] the freedom of speech”
- Commercial speech may be restricted only if:
 - 1) The speech concerns unlawful activity or is inherently false or misleading; or
 - 2) The restriction furthers a substantial government interest and is no more expansive than necessary
- *Cent. Hudson Gas & Elec. Corp. v. Pub. Servs. Comm’n of New York*, 447 U.S. 557 (1980)

Central Hudson's Application

U.S. v. Caronia, 703 F.3d 149 (2d Cir. 2012)

- Second Circuit reversed conviction for conspiracy to introduce a misbranded drug into interstate commerce
- Held that restricting a sales representative's ability to provide truthful and non-misleading information about alternative, unapproved, uses is unconstitutional

Amarin v. FDA

- Court enjoined the Government from prosecuting Amarin when the proposed off-label promotion was neither false nor misleading
- A misbranding claim based on true promotional speech alone – even if it suggested an intent to promote for unapproved uses – was an impermissible restriction of speech

Where Do *Caronia* and *Amarin* Leave FDA Regulation?

- FDA cannot restrain or restrict truthful speech, even if about unapproved uses
- But the *Amarin* Court made clear that the right to promote off-label comes with great responsibility:
 - Manufacturers will often need to provide more information so as to not be misleading
 - Manufacturers will need to explain that such uses have not been approved and why