

Balancing the Public's Right to Know With the Government's Obligation to Protect Patients



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Washington Legal Foundation
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First Amendment Protection of Commercial Speech

Four-Part *Central Hudson* Test:

- Inherently false or misleading / promotes an illegal activity
- Substantial government interest
- Directly promotes that interest
- Narrowly drawn



Major Commercial Speech Decisions Regarding Medical Products

- *Washington Legal Foundation v. Friedman*
(manufacturer dissemination of off-label information)
- *Pierson v. Shalala*
(health claims for dietary supplements)
- *Thompson v. Western States*
(pharmacists advertising compounding capabilities)



***Central Hudson* - First Prong (Inherently False or Misleading)**

- FDA has lost this issue

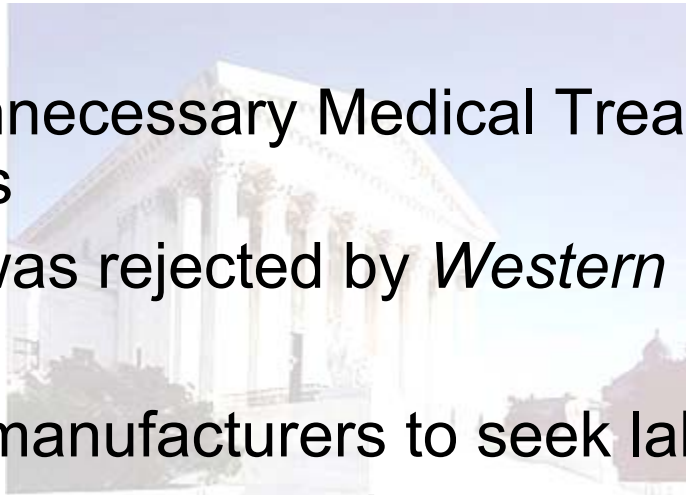
- Information is not "false" simply because FDA has not verified

- FDA "exaggerates the importance of its place in the universe"



***Central Hudson* - Second Prong (Substantial Government Interest)**

- Preventing potentially misleading speech
(this rarely justifies speech bans; at most justifies disclaimers)
- Preventing Unnecessary Medical Treatment, thereby reducing costs
(this interest was rejected by *Western States*)
- Encouraging manufacturers to seek labeling authority
(this interest has generally been recognized as substantial)



***Central Hudson* - Third Prong (Directly Promoting Government Interest)**

- Government May Not Impose Speech Regulations That Don't Directly Advance Its Stated Interest
- If Government Justifies Its Policy by Pointing to Interest in Encouraging Mfrs to Seek Labeling Authority, It Must Show that the Policy Is Likely to Encourage Such Conduct



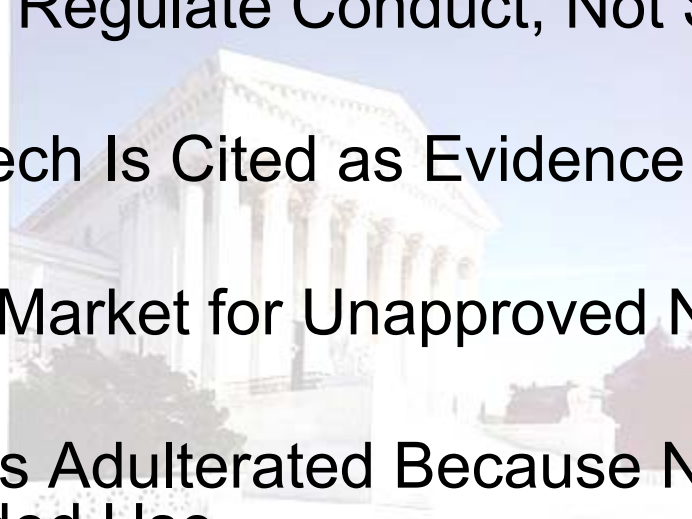
***Central Hudson* - Fourth Prong (Narrowly Drawn)**

- Can Government Achieve Its Policy Goals without Regulating Speech?
- Can It Do So With Regulations Short of a Speech Ban (e.g., Disclaimers)?



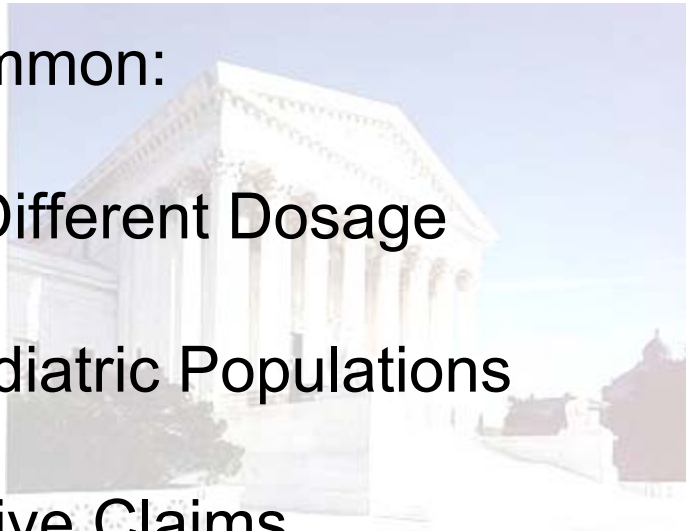
Regulating Speech by Subterfuge

- This is Current Government Policy
- FDA Claims to Regulate Conduct, Not Speech
- Off-Label Speech Is Cited as Evidence of:
 - Intent to Market for Unapproved New Use
 - Product is Adulterated Because Not Labeled for Intended Use



What Is Off-Label Speech?

- Rarely Involves Speech Regarding Treatment of a Different Condition
- Much More Common:
 - Use at a Different Dosage
 - Use in Pediatric Populations
 - Comparative Claims



Recent Enforcement Activity

- False Claims Act
 - Imposes liability on anyone who "knowingly presents or causes to be presented" a "false or fraudulent claim for payment of approval" to U.S.
- Anti-Kickback Statute
 - Prohibits payments to induce another to buy an item for which payment may be made under a federal health care program

Targets of Enforcement

- Continuing Medical Education
- Advertising
- Distribution of Studies
- Consultation Payments to Doctors



What's Going on Here?

- Most investigations are run out of Boston or Philadelphia US Atty offices
- Others want in on the action -- this is a real moneymaker
- FDA has little control
- Coordination is done by Office of Consumer Litigation at DOJ's Civil Div.
 - Little sensitivity to off-label issues
 - WLF correspondence



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Why Off-Label Speech

- Lives Are Lost When Helpful Information Is Suppressed
- FTC Approach -- Substantial Support
- FDA Permits Responses to Unsolicited Requests for Information
- FDA Often Prohibits All Studies Not Deemed "Well-controlled"



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