



DTC Advertising in the Washington Labyrinth

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Zauderer Sets the Standard

- The Supreme Court said that government can impose mandatory disclosures in advertising **BUT** ...
 - These disclosure must overcome deception
 - They must be strictly factual
 - They must be noncontroversial
 - The disclosure must directly and materially advance a state interest.



The Mandatory Disclosure Challenge Continues to Grow

- *National Institute of Family and Life Advocates v. Becerra* (NIFLA)
 - SCOTUS decided the case June 26, 2018
 - **They upheld the previous standard set forth in *Zauderer (1985)***
 - This precedent will affect other cases currently going through the court system
- *American Beverage Association (ABA) v. San Francisco*
 - Mandating disclosure warnings on sugar-sweetened beverages
 - Was reargued in the 9th Circuit Court of Appeals
 - three-judge panel reversed the lower court decision, finding the ordinance violated the First Amendment

Mandatory Disclosure Challenge Cont'd

- *CTIA v. Berkeley*
 - revolves around a Berkeley, California ordinance that requires wireless producers and sellers to provide a point of sale public notice regarding radio frequency safety.
 - Is currently under rereview due to the Supreme Court's decision in *NIFLA*.
- *Cigar Association of America v. U.S. Food and Drug Administration*
 - includes requiring health warnings on packages (30% of a package, or 20% of an ad).
 - The DC Circuit Court agreed to enjoin the rule on the grounds that the Supreme Court's opinion in *NIFLA* casts a new light on the cigar maker's First Amendment challenge.
 - Also, a DC Circuit Court Judge ordered FDA to complete a rule on graphic warnings in tobacco ads by 2020.
- *American Meat Institute v. USDA* and a couple of other cases have raised questions as to whether deception has to be proved in mandatory disclosure cases.

The Price is Wrong

- Lowering prescription drug costs is one of the few areas of bipartisan agreement in Washington.
- Last year, Sen. Grassley and Sen. Durbin introduced an amendment requiring prescription drug list price disclosures



The Price is Wrong Cont'd

- Sen. Shaheen has introduced the **End Taxpayer Subsidies for Drug Ads Act** cosponsored by 14 other Senate Democrats
 - this bill would prohibit the ability to claim ad deductions for costs associated with direct to consumer pharmaceutical advertising

HHS Approves DTC Price Disclosure

- On May 8 HHS promulgated a new rule that requires “direct-to-consumer television advertisements for prescription pharmaceuticals covered by Medicare or Medicaid to include the list price ... if that price is equal to or greater than \$35.”
 - ANA, as part of TAC, previously filed comments in opposition to the rulemaking during the comment period



HHS DTC Rule is Unconstitutional

- The rule threatens a radical expansion of government mandatory disclosure law.
- It would blow several major holes in the First Amendment protections for advertising.
- It would create broad precedents that sweep far beyond prescription drug advertising.

Reasons the Rule is Misguided and Unconstitutional

- Implementing the rule would fail to provide accurate information to consumers. Due to rebates and insurance coverage and the overall complexity of drug pricing, the majority of consumers who purchase prescription drugs do not pay the list price.
- The rule will not substantially advance its purported substantial government interest to increase marketplace efficiency and lower Medicare and Medicaid and drug costs.
- The rule does not meet the constitutional test promulgated by the Supreme Court for governmentally mandated disclosures, and therefore would violate the First Amendment (the Zauderer test).



Unconstitutional Reasoning

- Government has stated that this rule would stop consumers from buying more expensive medicines because it would allow consumers to see that cheaper medicines were available.
 - However, in *44 Liquormart, Inc. v. Rhode Island*, the Court stated that it violates the First Amendment to restrict speech for “what the government perceives to be [the people's] own good.”

The HHS Rule is Unprecedented

- No other mandatory disclosure law would provide inaccurate information to substantial portions of consumers.
- No other mandatory disclosure law requires further “discussion” and research to determine key data.
- A so called “savings-clause”
 - “prices may vary” – is useless

Deception



- The HHS rule claims that the rule does not overcome deception, nor is that necessary.
- The rulemaking claims that if mandated disclosures are factual they will meet the non-controversial prong of the *Zauderer* test

Major Dangers Ahead



- There are 31 000 cities and counties in the U.S. If they can impose mandatory disclosures in ads by merely determining that additional factual information would be useful in a particular category of advertising then the potential for sweeping ad restrictions increases dramatically.

Explosion of Requirements



- Without a requirement to overcome deception, government entities at all levels would have broad leeway to impose mandatory disclosures that would create enormous costs for advertisers

Lanham Act Problems

- The rule envisions primary enforcement through private Lanham Act cases.
- The rule states that the required disclosures do not need to overcome deception.
- However, not having the disclosure would be treated as a deceptive act or practice.

Thompson v. Western States Medical Center

- The Supreme Court held in *Thompson v. Western States Medical Center* that “if the First Amendment means anything, it means regulating speech must be a last - not first-resort.”



What We Need From You

1. Any information that demonstrates that list prices are rarely what consumer will pay.
2. Anything that shows how complicated it can be to calculate actual costs for consumers.
3. Consider financial support for a possible lawsuit challenge to the rule.

WE NEED YOU!



Now is the Time for Action

- Rule takes effect 60 days from finalization:

July 7, 2019