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Drug Prices in Television Advertisements

Impact of Final Rule on Drug Price Transparency

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Agenda

- Review the content of the Final Rule
- Discuss what comes next
- Address possible impact on promotional practices

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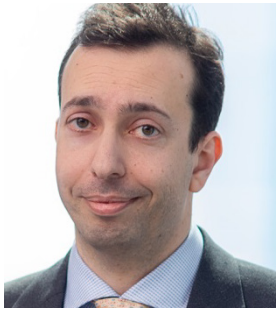

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How Did We Get Here?

- Context of concern for high drug prices.
- American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018).
  - "HHS may: Call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising."
  - A surprise hit.
- Focus moved from FDA to CMS.

HHS Acts

- October 18, 2018 Proposed Rule.
  - Positive media attention.
  - Generally positive public and stakeholder reaction.
- May 8, 2018 Final Rule.

Content of the Final Rule

Key Requirement of Final Rule

- Televised drug advertisements must contain a textual statement indicating the current list price for a 30-day regime or typical course of treatment, whichever is most appropriate.
  - "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different."
  - Text must be presented at the end of the advertisement in a "legible manner," meaning that "it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily."
- Narrow exceptions:
  - Drugs with a list price of less than $35.
  - Drugs not provided to Medicare or Medicaid beneficiaries.
- Effective **July 9, 2019**.

Definition of List Price

- List price = Wholesale Acquisition Cost (WAC)
- WAC is price manufacturers report to wholesale price guides as the amount at which they sell drugs to wholesalers.
- List price must be current, i.e., reflects WAC in effect at the first day of the quarter during which the advertisement is aired.
- Is including list price in ads useful to consumers?
  - Very few actually pay WAC.
  - Concern that consumers may be confused and avoid obtaining prescriptions.
  - However, WAC can be helpful in calculating coinsurance.
  - CMS points to studies showing consumers were more able to accurately predict their drug costs when they knew WAC.

Additional Information Permitted

- Manufacturers may include list price of competing products.
  - Some commentators expressed concern that advertisements may include prices of products that are not true competitors.
  - CMS declined to clarify what qualifies as a competing product.
- Manufacturers may notify consumers that costs may be higher in the case of drugs typically used in combination with other drugs.
  - CMS rejected comments suggesting that such a notification be required.

What's a Television Advertisement?

- Television advertisements included "broadcast, cable, streaming or satellite."
- Unclear when an internet advertisement is subject to the rule.
  - Television streaming services such as Hulu.
  - YouTube.
  - Media company websites (CNN vs. New York Times vs. Vice).
- Lack of guidance creates significant uncertainty.

Enforcement

- No federal agency has the power to enforce the rule.
- Consumers will not have standing to enforce the rule.
- CMS will monitor ads and publicize a list of violations.
- CMS anticipates manufacturers may sue each other under the Lanham Act.

Lanham Act suits

- Lanham Act prohibits unfair competition in the form of false or misleading advertisements.
  - Must be a "false or misleading description of fact, or false or misleading representation of fact" that either:
    - "is likely to cause confusion, or to cause mistake… as to the origin, sponsorship, or approval of [the product]" OR
    - "misrepresents the nature, characteristics, qualities, or geographic origin of [the product]"
  - Plaintiff must also show that damages.
- May be disincentive for manufacturers to sue one another.
  - Question as to whether would succeed on the merits (is failure to disclose list price actually misleading?)
  - Lack of proof of damages.
  - Litigation costs.
  - Filing suit could increase likelihood that would be sued.

Preemption

- Final Rule preempts all state and local laws that impose “any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to” the requirements under the Final Rule.
- CMS says it does not want meritless lawsuits filed under state laws that could increase drug costs.
- Potential for state role?
  - Adopting statute that mirrors federal law.
  - Regulating print, radio, and internet advertisements that fall outside the scope of the rule.

What Comes Next

So, What Happens Now?

- Not expecting any further immediate HHS actions as requirements are self-implementing.
- "Naughty List"
  - Public list of "products identified by the Secretary to be advertised in violation."
  - No timetable for creation.
  - "We expect that this information will be posted publicly on a CMS internet website no less than annually."
- July 9 – "Must watch TV"?

Litigation Outlook

- Response to public comments more of a legal defense than a policy discussion.
- Main Possible Legal Objections.
  - Beyond statutory authority of CMS.
  - Violates First Amendment of U.S. Constitution.
- Timing of Litigation
  - Could come before July 9 implementation.
  - But, not necessarily.

Statutory Challenge

- Courts usually prefer to review on statutory grounds before getting to Constitutional issues.
- HHS relied on very general statutory language that it has "authority to promulgate regulations as necessary for the efficient administration of Medicare and Medicaid."
- HHS cites need for beneficiaries to have information on the price of their drugs.
- *Chevron* Test:
  - If statute speaks directly to the question, defer to agency.
  - If not, is it a permissible interpretation (or a reasonable interpretation).
- Congress could resolve this.

Constitutional Challenge

- First Amendment protects speech, even commercial speech.
- It also protects people from being forced to speak.
- Unsettled area of the law that appears to be moving toward increased protection of speech.

Zauderer Test

- Supreme Court upheld statute that forced lawyer to disclose that he took cases on a contingency fee basis (*Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)).
- "purely factual and uncontroversial information about the terms under which his services will be available."
  - Is WAC purely factual?
  - Is it noncontroversial?
- "warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception."
  - Is not including WAC deceptive?
  - Will including WAC reduce or add to confusion.

Central Hudson Test

- If rule doesn't get protected by Zauderer, it faces an arguably tougher standard.
- Central Hudson test of permissible government burdens on commercial speech (*Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980)).
- Government may regulate speech where:
  - Substantial government interest.
    - Certainly arguable that government has interest in drug pricing.
  - Regulation directly advances government interest.
    - CMS argues that disclosure will have impact on Medicare and Medicaid.
  - Regulation no more extensive than needed to advance that interest.
    - CMS argues that disclosure requirement is brief and narrowly tailored to achieve result.

Possible Litigants

- Challengers must have standing.
- Possible litigants.
  - Drug trade association.
  - A manufacturer.
  - Someone who sells television advertising.

Outlook

- Court challenges represent a real threat to implementation.
- Politics of drug pricing may determine fate of regulation.
- Drug company compliance likely in the absence of court action.

Possible Impact on Promotional Practices

How will Promotional Review Committees Implement Final Rule?

- Final rule leaves much room for interpretation on how to comply.
- Text must be presented at the end of the advertisement in a "*legible manner*," and must be "*placed appropriately and presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily*."
- Unclear if manufacturers can include information to provide context for pricing rather than simply listing pricing at the end of the ad.
- Vagueness of the rule similar to determination of what constitutes "fair balance" – e.g., for print ads how much of the page needs to be safety/risk information v. efficacy?
  - This leads to much debate for promotional review committees!
  - Typically Marketing Team wants to maximize time in TV ads and space in print!
  - Regulatory/Legal will likely be responsible for enforcement.
- Companies may need to figure out ways to document attempts to comply.
  - Veeva notes retain information on promotional review committee discussions.

Specifics Still TBD in How to Comply

OPEN QUESTIONS:

WHAT TEXT SIZE FONT/COLORS/DURATION REQUIRED:

- How large must the text be to meet the requirement that it is "in a size and style of font" so it can be "read easily"
- What is an appropriate color scheme for a "contrasting background"
- What is "sufficient duration' to display the price?

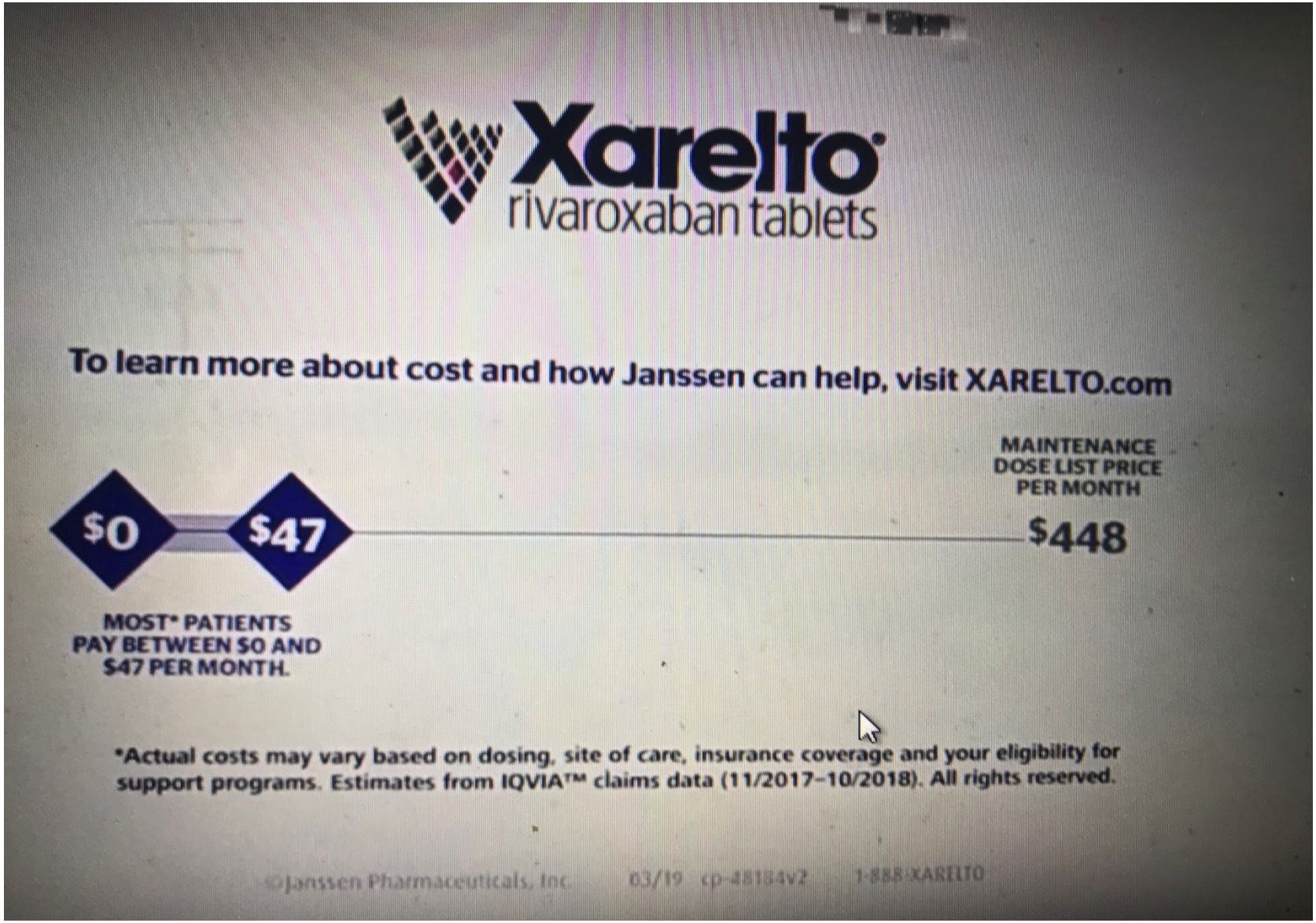
COMPETITOR PRICING

- What about listing competitor pricing?
- Do same rules re: text size, prominence, contrasting color scheme, duration apply to listing competitor pricing?
- Potential for differing approaching between listing own price and competitor price!

Will Manufacturers Comply? What about PhRMA?

- TBD if and how manufacturers will comply with this requirement.
- Does appearance on "bad list" provide enough consequence for manufacturers to immediately comply?
- As noted, CMS believes that enforcement of this requirement will come from competitors who sue for false advertising under the Lanham Act.
- At the time of proposed rule (Oct. 2018) PhRMA encourage companies to voluntarily disclose pricing information with addition context in DTC ads as an alternative to the CMS rule.
  - Companies generally have not followed PhRMA's request.
  - J&J/Janssen have disclosed price in their DTC ads for Xarelto®.
  - J&J is including both the list prices and potential out-of-pocket costs to help patients better understand how pricing will directly affect them.

Xarelto 2019 Ad



PhRMA Response to Final Rule and Impact on Patients

- PhRMA CEO and President Steven J. Ubl's statement about Final Rule expressed multiple concerns.
- He said that the inclusion of pricing in DTC television advertising "could be confusing for patients and the inclusion of list prices could discourage them from seeking needed medical care."
- "While we are still reviewing the administration's rule, we believe there are operational challenges, particularly the 60-day implementation timeframe and think the final rule raises First Amendment and statutory concerns."

CMS Indicates Ability to Provide Disclaimer About WAC Price

- HHS Secretary Alex M. Azar II said that the disclaimer on insurance covering costs will limit patient confusion over the WAC price v. what they will pay.
  - "if you have insurance that covers drugs, your cost may be different."
- The disclaimer aims to address manufacturer concerns that the list price alone does not convey to patients meaningful information about how much they will actually pay for a medicine.
- Unclear if manufacturers can provide additional context on expected patient costs other than the required disclaimer.

What About Print Ads and Other Ads Not Covered by the Rule?

- Unlikely that manufacturers would voluntarily include pricing in print ads or other ads not covered by the Rule.
- Only reason to include prices in print ads is to highlight that a company's pricing compares favorably to competitors.
- Again open to interpretation and possible misuse.
- Potential Lanham Act suits by competitors may limit inclusion of pricing or competitor information outside of television ads.

Potential Impact on Detailing by Field-Based Representatives

- Final Rule will require substantial training of sales representatives, medical science liaisons (MSLs), marketing and other healthcare practitioners with patient-facing roles.
- Sales reps and other company representatives will be more likely to be asked questions about pricing and be put in a position to defend the company's pricing and/or discuss competitor pricing!
- Additional questions around pricing lead to a greater risk that sales reps will go outside of the bounds of approved materials and discussions.
- Companies should provide very clear scripts on what representatives can/can't say about their product pricing and about competitor pricing.

Enhanced Risk That Reps Will Engage in "Marketing the Spread"

- Prior to this rule, most companies advised sales reps to stay away from discussions around pricing other than very factual statements.
- There is a historical concern around "marketing the spread" which has led to warning letters and substantial fines.
- Marketing the spread violates the False Claims Act because the physician or hospital seeks reimbursement from Medicaid or Medicare at a falsely inflated price that the pharmaceutical company provided to the government rather than the lower discounted price paid.
- New rule will require training and monitoring by Legal/Compliance to limit discussions around pricing to factual statements and not open flood gates to "marketing the spread."

Discussion Questions