

Court Invalidates Final Rule Requiring Advertisements to List Drug Prices Finding that CMS Exceeded Its Statutory Authority

July 9, 2019 – *Dorsey Health Law*

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In a much anticipated decision, a federal judge ruled this week that the Trump Administration’s rule requiring drug manufacturers to list drug prices in television advertisements exceeds the agency’s authority.

Back in May 2018, the Trump administration spoke on drug pricing and published its [“Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs”](#). One of the specific strategies outlined in the President’s speech at the time included requiring drug manufacturers to state the drug list price in television advertisements (read our previous article on this topic [here](#)).



Since the President’s speech in 2018, the U.S. Department of Health and Human Services (“HHS”) published a final rule that required drug manufacturers to disclose, in any television advertisement, the list price of a thirty day supply (or a typical course of treatment) of prescription drugs and biological products (excluding prescription drugs or biological products that have a list price of less than \$35 per month for a thirty day supply or typical course of treatment). See [84 Fed. Reg. 20,732](#) (May 10, 2019) (“Final Rule”).

Commenters to the Final Rule raised concern that the proposal was “beyond the authority of CMS to promulgate these regulations under a reasonable interpretation of sections 1102 and 1871 of the Social Security Act.” 84 Fed. Reg. 20,735-36 (May 10, 2019). HHS stated that it disagreed with the commenters because these two provisions “confer broad discretion upon the Secretary to determine the regulations that are necessary to the efficient administration of the functions with which he or she is charged

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under the Social Security Act (in the case of section 1102), and the administration of Medicare (in the case of section 1871”.

Shortly thereafter, a lawsuit was brought by three pharmaceutical companies and a marketing association. In the lawsuit, the industry not only opposed CMS’ authority to promulgate the Final Rule, but also argued that it violated the First Amendment, as the disclosure of the list price was compelled speech that did not pass the intermediate scrutiny standard outlined in various U.S. Supreme Court Cases. See *Merck & Co, Inc v. United States Department of Health and Human Services*, Case No. 19-cv-01738 (AMP) (U.S. Dist. Columbia, July 8, 2019) (available [here](#)).

In its decision published on July 8, 2019, U.S. District Judge Amit Mehta ruled that the Final Rule exceeds the rulemaking authority Congress granted HHS under the Social Security Act. *Id.* at 12. The Court found that “the basic power that Congress gave to the Secretary was to establish the rules and regulations for ‘running’ or ‘managing’ the federal public health insurance programs through CMS [, but that] HHS seeks to do more than that here. It has adopted a rule that regulates the conduct of market actors that are not direct participants in the Medicare or Medicaid program.” *Id.* at 13. Given that the Court found HHS’ rulemaking authority was exceeded, it did not decide the Plaintiff’s First Amendment challenge. *Id.* at 2.

The New York Times reported that Caitlin Oakley, a spokeswoman for HHS said that “the administration was disappointed and consulting with the Justice Department on what to do next.” Katie Thomas and Katie Rogers, *Judge Blocks Trump Rule Requiring Drug Companies to List Prices in TV Ads*, N.Y. Times, July 8, 2019, available at <https://www.nytimes.com/2019/07/08/health/drug-prices-tv-ads-trump.html>.

Given the Trump Administration’s continued focus and action on drug pricing, including news last week that the Administration was preparing an executive order that would declare a “favored nations clause” for drug prices, it is safe to expect many more legal challenges and appeals with respect to these issues in the near future, although the long-term impact to the industry is still questionable. Stephanie Armour, *Trump Plans Order to Tie Drug Prices to Other Nations’ Cost*, Wall St. J., July 5, 2019, available at <https://www.wsj.com/articles/trump-plans-order-to-tie-drug-prices-to-other-nations-costs-11562348629>.