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# HHS Can't Force Disclosure of Drug Prices in Ads with "Blunderbuss" Rule

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Among its various attempts to regulate drug prices, the Trump administration recently sought to force pharmaceutical advertisements to disclose the wholesale acquisition cost (WAC) of certain drugs. This effort was dealt a setback in June, when the D.C. Circuit found that the Department of Health and Human Services (HHS) overstepped its regulatory authority by compelling disclosure of these costs. Merck & Co., Inc. v. U.S. Dep't Health & Human Servs. ("*Merck*"). Although limited to a particular rule, the *Merck* decision foreshadows the likely future success of similar forced-disclosure rules.

## Efforts to Force Disclosure of Drug Prices

The push to force disclosure of drugs' WAC prices in ads began in earnest when HHS proposed a rule to require direct-to-consumer television advertisements of prescription drugs and biological products paid for via Medicare or Medicaid to include these drugs' WAC prices (sometimes called the "list price"). 83 Fed. Reg. 52,789 (Oct. 18, 2018). In support, HHS identified various sources of authority for its proposed rulemaking including the Social Security Act and the First Amendment.

### *Social Security Act (SSA)*

HHS conceded that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public . . . ." It claimed, however, that its authority to enact the proposed rule stemmed from the SSA, citing two key provisions: 42 U.S.C. § 1302(a) (SSA § 1102(a)) and 42 U.S.C. § 1395hh(a)(1), which relate to the "administration" of SSA programs.

HHS asserted that its proposed rule was necessary to the efficient administration of the Medicare/Medicaid programs. It noted that "the cost to the federal government, Medicare beneficiaries, and State Medicaid programs of prescription drugs and biological products has been increasing at an alarming rate due both to increasing prices and increasing utilization," which it characterized as "wasteful and abusive increases in drug and biological list prices."

The solution, according to HHS, is that consumers needed "some idea of the magnitude of the cost

of the advertised drug" in order to make "critical decisions" about the drug. For example, according to HHS, "[a]rming a beneficiary with basic price information will provide him or her with an anchor price . . . to be used when making decisions about therapeutic options." This information could lead to consideration of the cost of various alternatives and the possible ultimate choice of a cheaper drug. HHS also found a "clear nexus" between the SSA and the proposed rule because it "uses means that Congress has generally endorsed—disclosures about drug prices—to advance an end that Congress endorsed—minimizing unreasonable expenditures."

***First Amendment***

HHS also claimed that rules requiring factual commercial disclosures pass muster under the First Amendment "where the disclosure advances a government interest and does not unduly burden speech." It asserted that the "required disclosure here advances the government's substantial interest in the efficient administration of both Medicare and Medicaid programs by minimizing unreasonable expenditures." HHS also justified the proposed rule on the ground that its compelled speech "consists of purely factual and uncontroversial information about a firm's own product, namely the list price of the drug or biological product."

Following a review and comment period, HHS announced a final rule titled "Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency" (the Rule). The Rule's key provisions required that television advertisements for prescription drugs and biological products disclose a drug's WAC for a typical 30-day regimen or typical course of treatment, if covered by Medicare/Medicaid and if such cost would be $35 or more. *See* 84 Fed. Reg. 20,732 (May 10, 2019).

## Challenges to the WAC Disclosure Rule

***Merck District Court Decision***

Several pharmaceutical companies promptly challenged the Rule, arguing that it violated the Administrative Procedure Act. Plaintiffs' two key arguments were (1) the Rule exceeded HHS's statutory authority granted under the SSA, and (2) it compelled speech in violation of the First Amendment. See Merck & Co., Inc. v. U.S. Dep't Health & Human Servs. They argued that disclosure of the drugs' WAC risked misleading and confusing consumers, as it "rarely captures the actual out-of-pocket costs that most Americans pay for drug products due to, among other things, insurance coverage and patient assistance programs, and that the forced disclosure did not pass constitutional muster under either intermediate scrutiny (*Central Hudson Gas*) or a more relaxed standard (*Zauderer*).

HHS countered, relying on the bases asserted in support of its proposed rule. It claimed that the WAC was a "recognized benchmark of cost within the industry and correlated with out-of-pocket expenses," and that its disclosure (with caveats) would spur physician-patient decisions about drug choice.

The district court did not engage with the First Amendment issue, limiting its holding to its conclusion that the Rule exceeded the rulemaking authority that Congress granted HHS under the SSA. Consequently, it vacated and stayed the Rule. Under *Chevron* Step One, the court determined that the SSA does not unambiguously delegate to HHS the power to promulgate the Rule. Rather, HHS was merely permitted to "run[]" or "manag[e]" federal public health insurance programs. The Rule also exceeded HHS's delegated powers because it "regulates the conduct of market actors that are not direct participants in the Medicare or Medicaid programs"—i.e., the pharmaceutical industry.

The court also observed that earlier laws expressly empowered a different agency—the FDA—to regulate direct-to-consumer advertising of pharmaceutical products. Thus, HHS's claims "to discover in a long-extant statute an unheralded power" to regulate "a significant portion" of the American economy should be "greet[ed] . . . with a measure of skepticism." The court also expressed concern that to accept HHS's position "would swing the doors wide open" to "any" rule or policy that "might reasonably result in cost savings" to Medicare/Medicaid, without any "limiting principle" to rein in its application.

On appeal, various amici supported the pharmaceutical companies, arguing that the Rule threatened "anti-democratic" consequences by forcing a company to recite information—including misleading information—designed to facilitate public policy goals, and that HHS had not done enough research to support its intrusion onto First Amendment rights. Other amici backed HHS, arguing that increasing drug price transparency would empower consumers.

***Merck Appeals Court Decision***

The D.C. Circuit affirmed, finding that the Rule imposed "a sweeping disclosure requirement that is largely untethered to the actual administration" of Medicare/Medicaid. It decided only one issue: whether HHS properly relied on the SSA to enact the Rule. In doing so, it sidestepped the lower court's analysis of *Chevron* Step One, observing that "we need not decide whether Sections 1302(a) and 1395hh(a)(1) unambiguously foreclose *any* regulation of pharmaceutical advertisements or price disclosure requirements." It relied instead on *Chevron* Step Two, finding that even if the SSA "confer[s] some relevant regulatory authority . . . the . . . Rule's blunderbuss operation falls beyond any reasonable exercise of [HHS's] statutorily assigned power."

The *Merck* court identified four reasons that the Rule did not effect "administration" of Medicare/Medicaid:

- It found that the WAC has little correlation to the price that the federal government and program beneficiaries actually pay for drugs. It also observed that consumers might not understand the relationship between the WAC and the price they pay.
- It expressed skepticism that WAC disclosure better informs consumer healthcare decisions. The court noted HHS's concession that the Rule could cause "harmful confusion" and deter consumers from asking physicians about medical conditions or beneficial medications, and that that these consequences could increase the total cost of care under Medicare/Medicaid.
- It found that the Rule regulated advertisements for the general public and did not "specifically, or even predominantly" target Medicare or Medicaid recipients, further distancing the Rule from "administration" of those programs.
- It found that the Rule's asserted authority is far too broad to be considered "administration" of the programs and instead opened the door for broad regulation of drug manufacturers (assuming potential financial benefits to Medicare/Medicaid) despite "a substantial constitutional question" regarding government regulation of commercial speech.

The *Merck* court emphasized, however, that "nothing in this opinion holds that the Secretary is categorically foreclosed from regulating pharmaceutical advertisements." It expressly did not decide whether §§ 1302(a) and 1395hh(a)(1) unambiguously foreclose any regulation of drug price disclosure. Rather, the court found that "no reasonable reading" of the HHS's general administrative authority permitted the Rule's compelled disclosure to the public at large "of pricing information that bears at best a tenuous, confusing, and potentially harmful relationship" to Medicare/Medicaid.

## Future Challenges

By declining to decide whether such rules were categorically permissible under the SSA, the *Merck* opinion leaves the door open for the administration to continue to promulgate drug pricing disclosure regulations. As the Trump administration continues to engage in rule-making directed at curbing drug prices, it may well resume these efforts.

The *Merck* decision raises more questions than it answers, however. It remains to be seen whether the administration has the authority to force *any* kind of price disclosures in pharmaceutical advertisements. Neither *Merck* decision rules on the question of what level of compelled commercial speech is permissible under the First Amendment in this context, or whether such rules should be considered arbitrary and capricious. If similar rules are enacted in the future, however, the issues raised in the *Merck* dispute provide a useful roadmap to mount responsive challenges.



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