D.C. Circuit Invalidates HHS Rule Requiring Drug-Price Disclosures in Direct-to-Consumer Television Advertisements

On June 16, 2020, in *Merck & Co., Inc., et al.* v. *United States Department of Health and Human Services, et al.*, Case. No. 19-5222, 2020 WL 3244013 (D.C. Cir. June 16, 2020), the Court of Appeals for the District of Columbia Circuit affirmed a district court's ruling that the Department of Health and Human Services ("HHS") had exceeded its authority under the Social Security Act by promulgating a rule requiring drug manufacturers to disclose in television advertisements the "list price" of prescription drugs. Although the rule was meant to increase price transparency, HHS required drug manufacturers to disclose prices that, in practice, are substantially higher than the prices generally paid by most consumers. The drug manufacturers argued that the rule was invalid for a variety of reasons, including because it constituted compelled speech in violation of the First Amendment. The Court avoided the constitutional question and instead held that HHS lacked statutory authority to impose the rule. The decision demonstrates that courts will scrutinize government efforts to regulate prescription-drug advertising.

I. Background

In the face of intense public scrutiny of healthcare costs and controversy over the price of prescription drugs, on May 10, 2019, HHS promulgated a rule requiring drug manufacturers to disclose in direct-to-consumer television advertisements the "list price" of prescription drugs for which payment is available under Medicare or Medicaid.[1] HHS promulgated the rule pursuant to the Social Security Act, which empowers the Secretary of HHS to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be necessary to the efficient administration of the functions with which [the Secretary] is charged" under the Medicare and Medicaid statutes.[2] The Social Security Act also provides that the "Secretary shall prescribe such regulations as may be necessary to carry out the administration of the [Medicare] insurance programs."[3]

The rule required direct-to-consumer television advertisements to include the following disclaimer: "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."[4] HHS claimed that it enacted the rule to "improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs."[5]

The rule defined a drug's "list price" as the "wholesale acquisition cost" for a typical 30-day regimen of the drug or for a typical course of treatment.[6] In turn, the "wholesale acquisition cost" was defined as "the manufacturer's list price for the prescription drug . . . to wholesalers or direct purchasers."[7] On June 14, 2019, a group of pharmaceutical manufacturers and a trade association filed a lawsuit in the United States District Court for the District of Columbia seeking to set aside the rule. Plaintiffs also moved to stay the rule pending judicial review on the grounds that the rule violated the First Amendment and exceeded HHS's statutory authority.[8]

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1 Regulation To Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (the "Disclosure Rule").

2 42 U.S.C. § 1302(a).

3 42 U.S.C. § 1395hh(a)(1).

4 Disclosure Rule, 84 Fed. Reg. at 20,732 (internal quotation marks omitted).

5 *Id.*

6 *Id.*

7 *Id.* at 20,758.

8 *Merck & Co., Inc., et al.* v. *United States Department of Health and Human Services, et al.*, Case. No. 19-5222, 2020 WL

First, plaintiffs argued that the rule violated the First Amendment because the compelled price disclosures were content-based regulations that could not survive intermediate scrutiny.[9] Although plaintiffs noted that *any* content-based regulation of speech — including commercial speech — is subject to strict scrutiny,[10] plaintiffs argued that the regulation could not survive even the less-exacting intermediate-scrutiny standard typically applied to regulations of commercial speech.[11] Under the intermediate-scrutiny standard, government regulation of speech is presumptively unconstitutional unless the government can show that (1) its asserted interest is substantial, (2) the restriction directly and materially advances that interest, and (3) the restriction is narrowly tailored.[12]

Plaintiffs argued that HHS could not show that the price-disclosure rule advanced a substantial government interest because the rule would undermine — rather than further — the government's stated interest of bringing transparency to drug prices.[13] Plaintiffs noted that a drug's "list price" is almost always higher than the price most consumers actually pay[14] and that requiring the disclosure of "list prices" in advertisements would more likely cause confusion than bring clarity.[15] Plaintiffs also argued that HHS could not show that the price-disclosure rule would reduce costs to consumers because HHS provided no evidence that disclosing "list prices" would result in lower prices.[16] Finally, plaintiffs argued that the rule was not narrowly tailored to the government's stated interest because less-restrictive means — *e.g.*, requiring drug manufacturers to post price information on their websites — were available.[17]

Second, plaintiffs argued that the price-disclosure rule exceeded HHS's authority because no statute permits HHS to require pricing disclosures in pharmaceutical advertisements.[18] Under the Social Security Act — pursuant to which HHS adopted the rule — the Secretary of HHS may "disapprove[] the distribution of" marketing materials only if they are "materially inaccurate or misleading or otherwise ma[de] a material misrepresentation."[19]

The day before the rule was to take effect, the district court granted plaintiffs' motion to stay. In its decision, the district court avoided the First Amendment question and instead ruled that the Social Security Act did not authorize HHS to impose the disclosure requirement.[20] The Court held that the Social Security Act authorized HHS

3244013, at *2 (D.C. Cir. June 16, 2020).

9 *See* Memorandum of Law in Support of Plaintiffs' Motion for a Stay Pending Judicial Review ("Plaintiffs' Brief") at 28, Case No. 19 Civ. 1738 (Dkt. No. 12) (D.D.C.).

10 S*ee, e.g., National Institute of Family and Life Advocates* v. *Becerra*, 138 S. Ct. 2361 (2018) (content-based restrictions on speech are presumptively invalid and subject to strict scrutiny); *Reed* v. *Town of Gilbert, Arizona*, 135 S. Ct. 2218 (2015) (same).

11 *See* Plaintiffs' Brief at 28-29.

12 *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

13 Plaintiffs' Brief at 29-38.

14 *See* Principal Brief for Plaintiffs-Appellees at 7-8, Case. No. 19-5222 (Dkt. No. 1815371) (D.C. Cir.) (noting that the wholesale acquisition cost is "almost always *higher* — and often a great deal higher — than what patients would actually pay, including virtually all Medicare and Medicaid beneficiaries" (emphasis in original)).

15 *Id.*

16 *Id.*

17 *Id.*

18 *Id.*

19 Plaintiffs' Brief at 29-38; *see also* 42 U.S.C. § 1395w-21(h).

20 *Merck & Co., Inc.* v. *United States Department of Health and Human Services*, 385 F. Supp. 3d 81, 90-98 (D.D.C.) (2019)

only to undertake the "administration of the Medicare and Medicaid statutes" and that those grants were limited to "establish[ing] rules and regulations for 'running' or 'managing' the federal public health insurance programs."[21] The Court further held that because the pharmaceutical manufacturers were "not direct participants in the Medicare or Medicaid programs," HHS exceeded its authority by enacting the rule.[22] HHS appealed this decision to the D.C. Circuit.

II. The D.C. Circuit's Decision in *Merck*

On appeal, the D.C. Circuit upheld the district court's decision. Like the district court, the D.C. Circuit avoided the First Amendment question and instead held that HHS had exceeded its statutory authority to administer the Medicare and Medicaid programs.[23] The Court noted that under the Social Security Act, the Secretary of HHS has the authority to "'make and publish such rules and regulations not inconsistent with [the Act], as may be *necessary to the efficient administration of the functions* with which [the Secretary] is charged under' the Medicare and Medicaid programs."[24] In addition, the Social Security Act "directs the Secretary to 'prescribe such regulations as may be *necessary to carry out the administration of the insurance programs* under' the Medicare Act."[25] Applying these standards, the Court found that the "Disclosure Rule's blunderbuss operation falls beyond any reasonable exercise of the Secretary's statutorily assigned power."[26]

First, the Court noted that a drug's "list price" typically "bears little meaningful relationship to the price that . . . Medicare and Medicaid beneficiaries pay for the drug[]."[27] Accordingly, "it is difficult to see how requiring the disclosure of wholesale acquisition cost to consumers generally promotes price transparency in any material way, or how it is otherwise related to the 'administration' of either Medicare o[r] Medicaid."[28]

Second, the Court noted that the rule "regulates advertising directed at the general public and not communications targeted specifically, or even predominantly, to Medicare or Medicaid recipients."[29] The Court concluded that this fact "further increases the distance between the Disclosure Rule and any actual administration of those programs."[30]

("[W]hen viewed as a whole, the [Social Security Act] unambiguously does not delegate to [HHS] the power to promulgate the [Disclosure Rule].").

21 *Id.* at 90.

22 *Id.* at 94 (noting that the rule "regulates primary conduct several steps removed from the heartland of [HHS's] authority under the Social Security Act").

23 *Merck II*, 2020 WL 3244013, at *1.

24 *Id.*, at *4 (emphasis in original).

25 *Id.* (emphasis in original).

26 *Id.*

27 *Id.*, at *5.

28 *Id.*, at *6.

29 *Id.*, at *7.

30 *Id.*

Finally, the Court found that "the sweeping nature and scope of the authority being claimed by [HHS] underscores the unreasonableness of [HHS's] claim that it is just engaged in general 'administration.'"[31] The Court reasoned that HHS's "construction of the statute would seem to give it unbridled power to promulgate any regulation with respect to drug manufacturers that would have the arguable effect of driving down drug prices — or even healthcare costs generally — based on nothing more than their potential salutary financial benefits for the Medicare or Medicaid program."[32]

III. Conclusion

The D.C. Circuit's decision in *Merck* demonstrates that although courts typically grant substantial deference to executive agencies when reviewing administrative actions regulating drug companies, efforts to regulate advertising by those companies may be subject to greater scrutiny. While the D.C. Circuit ruled on the narrow ground that "no reasonable reading of [HHS's] general administrative authority" permitted HHS to enact the disclosure rule, by ruling in this way, the D.C. Circuit avoided difficult and important constitutional issues, including whether the Secretary of HHS "is categorically foreclosed from regulating pharmaceutical advertisements" and whether the government has the "authority to regulate the public speech of companies just because some percentage of the audience is involved in a governmental program from which the businesses indirectly derive financial benefit" — issues that are left for another day.

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If you have any questions about the issues addressed in this memorandum, or if you would like a copy of any of the materials mentioned in it, please do not hesitate to call or email authors Joel Kurtzberg at 212.701.3120 or jkurtzberg@cahill.com; Adam Mintz at 212.701.3981 or amintz@cahill.com; or John MacGregor at 212.701.3445 or jmacgregor@cahill.com; or email publications@cahill.com.

[31] *Id.*

[32] *Id.*