Real High Prices, Unreal Authority: HHS Lacks Rulemaking Power to Force Drug Price
Disclosures

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I. Introduction

The cost of medicine in the United States has become prohibitively expensive. Take insulin for example; one in ten people in the U.S. are diabetic and about 5% of them depend on insulin to survive. The average price for a vial of insulin in 2016 was $666, which doubled in price just since 2012. The amount of insulin needed varies by patient, but some need six vials per month. This amounts to a nearly $4,000 a month bill for life-saving medications, and insurance will likely cover only a portion of the cost. The cost of insulin, let alone additional medications and medical expenses patients incur, is unsustainable. Increasingly patients must make a hard choice – ration or forgo their expensive prescriptions entirely and quite literally risk their lives or sacrifice their

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financial stability in order to survive. The media have reported stories of patients who have died because they cannot afford insulin.1

State and federal governments have responded to this public health crisis with a variety of policy measures, although all have proven either ineffective or have been struck down in court. In 2017, Maryland passed a law that would limit excessive price gouging on essential medicines,2 which would have helped stop insulin’s spike in price between 2012 and 2016. Unfortunately, this law was challenged in court and eventually struck down for violating the dormant commerce clause, as the court interpreted Maryland’s law as trying to regulate the price of goods manufactured and sold outside of its borders.3 Minnesota passed a law in response to the insulin rationing deaths that set a guaranteed price of insulin for qualifying individuals.4 This law was challenged by the pharmaceutical lobby in the summer of 2020 and it remains to be seen if it will survive.5 The California state government and some U.S. senators have recently floated proposals for state and/or federal governments to start a “public label” offering of certain medicines, with the hope being the government subsidized competition would

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3 Association for Accessible Medicines v. Frosh, 778 F.3d 664 (4th Cir. 2018).


5 Complaint, Pharmaceutical Research and Manufacturers of America v. Williams et al., 0:20-cv-01497 (D. Minn. 2020). PhARMA does not contest the legality of Minnesota setting the cost of insulin as sold by the pharmacy, but rather a provision of the law that requires insulin manufacturers to send pharmacies replacement insulin at no cost when pharmacies dispense insulin to individuals who qualify for the set low price.
help bring down the cost of medicines (similar to a public option in the health insurance market).

One of the most recent attempts to address exorbitant drug costs at the federal level began in May 2018, when the Trump Administration and the U.S. Department of Health and Human Services (HHS) developed a “blueprint” addressing this issue. The blueprint offers four strategies for reducing drug costs: increase competition, promote better negotiation, increase incentives for lower list prices, and reduce out-of-pocket costs. The blueprint hints at requiring drug price listing on television advertisements. As a part of this blueprint, HHS embarked on notice and comment rulemaking to promulgate new regulations for pharmaceutical advertisements. HHS sought to require that pharmaceutical advertisements disclose the price of pharmaceutical products.

A year after the first blueprint release, HHS’s Centers for Medicare and Medicaid Services announced the final rule to require direct-to-consumer price disclosures in television advertisements for prescription pharmaceuticals covered by Medicare or Medicaid (the Disclosure Rule). HHS believed that patients have a right to know about drug prices. Major pharmaceutical companies disagreed. HHS received 147 comments regarding the final rule, but it added only one modification and some minor technical changes to its initial proposal. The final rule drew several comments disputing HHS’s authority under sections 1102 and 1871 of the Social Security Act. Additional comments

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disputed HHS’s authority to issue this rule and asserted that the FDA would have proper authority.

Furthermore, several commenters mentioned that the Disclosure rule would not show the consumer the out-of-pocket cost and deter them from purchasing overpriced brands of medicine. HHS did not find the comments or any research persuasive. While HHS garnered some comments in favor of the rule, most comments disapproved of the final rule. Consequently, the major pharmaceutical companies challenged the regulation in court and argued that the HHS lacked legal authority to regulate advertising in this manner.

II. Facts

Three drug manufacturers, Merck & Co., Inc.; Eli Lilly and Company; and Amgen Inc. and the National Association of Advertisers, Inc. objected to the final rules regulating the marketing of prescription drugs.\(^a\) The final rule required the disclosure of drug prices through direct-to-consumer television advertisements, for any drugs covered through Medicaid and Medicare programs.\(^b\) Drug manufacturers mainly communicate to consumers through direct-to-consumer advertisement.\(^c\) The list price or wholesale acquisition cost (WAC) for a 30 day supply would have to be listed if the drug cost more than $35 per month.\(^d\) The rule required a statement on the television advertisement that would note “The list price for a [30-day supply of] [typical course of

\(^a\) Merck & Co. v. United States HHS, 962 F.3d 531, 534 (D.C. Cir. 2020)
\(^b\) Id.
\(^c\) Merck & Co. v. United States HHS, 385 F.Supp.3d 81, 84 (D.D.C. 2019)
\(^d\) Merck, 962 F.3d at 534
treatment with] [name of prescription drug or biological product] is [insert list price]. If you have insurance that covers drugs, your cost may be different.

The drug manufacturers and the marketing trade association filed a complaint only five weeks after the publication of the final rule. The pharmaceutical industry alleged that HHS lacked authority for the rule and the rule risked misleading and confusing consumers. The plaintiffs incorporated the industry objections within their complaint stated three theories of violations. They argued that the rule exceeds the HHS’s statutory authority; it is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law; and it is contrary to the First Amendment of the U.S. Constitution. The district court held that HHS exceeded its rulemaking authority and struck the rule down; HHS appealed.

III. Analysis

HHS argued that it had power to make the Disclosure Rule under the Social Security Act (“SSA”), specifically sections 42 U.S.C. § 1302(a) and 42 U.S.C. § 1395hh(a)(1). These provisions give the Secretary of HHS similar powers to make rules and regulations necessary for the “administration” of the Medicare and Medicaid programs. As such, the Court resolved this case by deciding whether HHS had the power to promulgate the Disclosure Rule based on these provisions. Both the appeals court and the district court applied the *Chevron* standard to this question, despite protests from HHS that a pre-*Chevron* standard based on *Mourning v. Family Publication Services, Inc.* should apply. The *Mourning* standard gives more agency deference than *Chevron*, so HHS asserted

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* Merck, 385 F. Supp. 3d at 86-87.
that it should control, without much reason. However, both courts were quick to conclude that *Chevron* applies. Interestingly, the courts diverged in their *Chevron* analysis. The district court focused exclusively on the first step of *Chevron* to find that the HHS lacked power to issue its Disclosure Rule under the SSA.

On the other hand, the appeals court invalidated the Disclosure Rule as unreasonable under step two of *Chevron*. Under this framework, the court “need not decide whether [the SSA] unambiguously foreclose[d] any regulation of pharmaceutical advertisements or price disclosure requirements” (i.e. the appeals court assumed step one held, for the sake of argument) (emphasis in original). Instead, the Court scrutinized whether the Disclosure Rule was a reasonable interpretation of the HHS’s governing statute. This statute allowed HHS to promulgate rules “necessary to the efficient administration of the functions with which [the Secretary] is charged.” Here the Court focused in on the idea of “administration” and looked to the dictionary definition of the word at the time when the SSA was enacted. “Administration” in this context meant the “practical management and direction of” the Medicare and Medicaid programs. In the Court’s view, this word was key; administration meant operations and management, not tangential change that could lower costs. To illustrate this distinction, the Court said that “the Secretary would be hard pressed to defend as necessary to program administration a rule forbidding vending machines or smoking breaks at businesses that employ Medicare or Medicaid recipients just because those measures could promote healthier living and thereby reduce program costs.”

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19 Id. at 537 (citing 42 U.S.C. § 1302(a)).
20 Id. (citing BLACK’S LAW DICTIONARY 58 (3d ed. 1933)).
21 Id. at 538.
After laying out how HHS has the power under these SSA provisions to promulgate only *administrative* regulations, the Court elaborated four reasons why HHS’s Disclosure Rule was not administrative in nature. First, the wholesale acquisition cost of prescription drugs (as required to be disclosed) bore little resemblance to what Medicare and Medicaid beneficiaries actually pay. At a minimum, beneficiaries will only pay a copay for these drugs, not the full price. Medicare and Medicaid don’t pay the full price either. For instance, if a drug company wants Medicaid to cover its drugs, the drug company must first sign an agreement with the program agreeing to give Medicaid a rebate on all drugs purchased through the program. Because few if any Medicare or Medicaid beneficiaries would pay the wholesale acquisition price disclosed in advertisements, the Court held that the rule had no connection to the administration of these programs.

Second, HHS failed to show how the Disclosure Rule would improve consumer behavior to reduce prices. The theory behind the price disclosure is that, armed with pricing information, consumers can make rational decisions that would make the market more competitive and bring down prices. But here, consumers are unlikely to actually be better informed. As the Court noted, “informing consumers about a price that Medicaid and Medicare customers will almost never pay, and that they are unlikely to understand, unlashes the disclosure from its claimed administrative mooring.”

Third, the Court leaned into what was supposedly being administered (the Medicaid and Medicare programs). The Court reasoned that if this rule was really about administering these programs, then the rule would target beneficiaries of these programs. However, the Disclosure Rule applies to all advertisements generally.

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22 *Id.* at 539-40.
instead of being limited to advertisements targeted to Medicare and Medicaid beneficiaries. This again goes beyond the more limited idea of administration to which the HHS is confined.

Fourth and lastly, the “sweeping ‘nature and scope of authority being claimed by the’ Department underscored the unreasonableness of the Department’s claim that it is merely engaged in general ‘administration.’” The Disclosure Rule would affect a huge market; Medicare and Medicaid are the single largest payer of pharmaceuticals in the country, spending over $238 billion on prescription drugs in 2016 alone. Although the Court didn’t mention it, spending on pharmaceutical advertisements is astronomical as well. The Court held that HHS attempted too great of a power grab in the face of statutory silence on the issue of regulating advertisements for prescription drugs.

Despite such strong arguments against the Disclosure Rule, the Court left the door open for some alternative regulation of pharmaceutical advertisements by HHS under its powers from the SSA. When concluding its opinion, the Court wrote that “nothing in this opinion h[e]ld that the Secretary is categorically foreclosed from regulating pharmaceutical advertisements.” This statement leaves open the possibility that a regulation more in line with administering the Medicare and Medicaid programs could be upheld. But the Court left the specifics of that allowance for a future case.

IV. Going Forward

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23 Id. at 540 (citing Loving v. I.R.S., 742 F.3d 1013, 1021 (D.C. Cir. 2014).
24 Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 84 Fed. Reg. 20,733 (June 10, 2019).
26 Merck, 385 F.3d at 541.
a. State Level Changes

The Court concluded that HHS exceeded the authority granted by Congress. Congress might have the power to direct the HHS to regulate the WAC Disclosure Rule as it has with respect to direct-to-consumer advertising of pharmaceutical products under the Food, Drug, and Cosmetic Act (FDCA). In the absence of additional federal authority, many States have introduced price transparency laws. State laws control multiple areas of the pharmaceutical industry, and more recent efforts have included price transparency laws. State transparency laws target manufacturers, wholesalers, pharmacy benefit managers (PBM), pharmacies, insurers. Of the thirty-five recent laws passed from 2015-2018, only two states (Vermont and Maine) required that the insurers or manufacturers report the net price paid by consumers.

States have also turned to balanced billing laws to address the consumer audience more directly. Balanced billing is the patient’s cost when the provider is an out-of-network provider and does not get reimbursed through the consumer’s insurance company. Thirty-one states have enacted a partial or comprehensive balanced billing law to address the cost information made available to consumers and the providers. State governments focus on balanced billing in many states to better inform consumers of out-of-pocket costs and how they will financially be impacted by out-of-network providers. Ultimately, many balanced billing laws have a direct impact

on the consumer and offer greater benefits than disclosure rules focused on wholesale drug prices.

b. Alternatives to the Disclosure Rule

The Disclosure Rule may not benefit the intended consumer audience because it does not consider third-party reductions in the price, so consumers never learn what they will actually pay. As a result, wholesale price transparency fails to increase competition and bring down the price of prescription drugs. However, transparency regulations could effectively be implemented for specific types of advertisements and upstream transactions to better inform consumers.

One of the biggest problems with the Disclosure Rule is that it applied to general advertisements like newspaper and broadcast TV ads; these ads are presented to everyone watching, regardless of their insurance plan, so a particular list price would not apply to the majority of people who see a disclosure. But advertising has changed a great deal over the last two decades to solve this exact problem. Search, social, and streaming ads (ex. Hulu) are presented to users based on a user’s specific profile, and ads are even customized based on that information. For instance, two people could be viewing the same ad for a fast-food restaurant in different cities, but see different addresses in the ad based on the closest restaurant. This principle could be used to ensure that consumers only see prices that are relevant for them. Although it is unlikely that advertisers have the individualized insurance information needed to make these customizations, a future regulation could give consumers the ability to release insurance information and require pharmaceutical corporations to use that information. That way, when a particular user sees a pharmaceutical ad on Hulu or on Google, the disclosed price would be the price applicable for that consumer. Given the shift in
advertising dollars towards customized online advertising, such a regulation seems not only possible but potentially effective and informative.

Another promising variation on the Disclosure Rule could be to increase the transparency of upstream transactions. The pharmaceutical distribution system is extremely complex and opaque. Drug manufacturers, insurers, government agencies, pharmacy benefits managers, wholesale distributors, pharmacies, and patients all play roles as buyers or sellers (and many of these players play both roles). Each intermediary in these transactions takes a share of the profit. In theory, fewer intermediaries would equate consumers to receive greater savings. If a regulation required the disclosure of the chain of sales of prescription drug, a consumer might see how unnecessary layers of intermediaries translate into higher prices. This information might lead a consumer to buy the drug through a seller that relied on fewer unnecessary buyer/sellers upstream.

The exorbitant cost of pharmaceuticals is taking a toll on patients’ wallets and health. Although classic economics suggest that improving consumers’ knowledge of prices could help drive prices down, this case highlights how HHS currently lacks the authority to improve consumer knowledge by requiring drug price disclosures in advertisements. Even if HHS had the legal authority to promulgate this specific rule, the realities of the pharmaceutical and insurance world make it unlikely that this rule would have much impact on drug prices. A more thoughtful policy approach with respect to transparency is necessary to lower pharmaceutical prices.