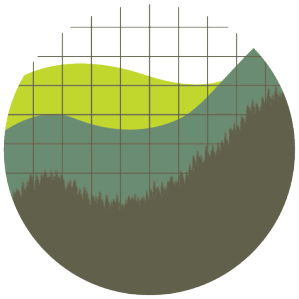

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

December 17, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn:	Centers for Medicare and Medicaid Services
Re:	Regulation to Require Drug Pricing Transparency, 83 Fed. Reg. 52,789 (proposed Oct. 18, 2018)
Docket ID:	CMS-4187-P

The Institute for Policy Integrity at New York University School of Law ("Policy Integrity")[1] respectfully submits the following comments to the Centers for Medicare and Medicaid Services ("CMS") on the proposed Regulation to Require Drug Pricing Transparency ("Proposed Rule"), which would require disclosure of the wholesale acquisition cost, or "list price," on televised direct-to-consumer ("DTC") advertising for certain pharmaceutical and biological products.[2] Policy Integrity is a nonpartisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Our comments focus on flaws in the Regulatory Impact Analysis accompanying the Proposed Rule. Specifically, we urge CMS to:

- more clearly identify a market failure that would be addressed by the Proposed Rule;
- more thoroughly assess the Proposed Rule's costs;
- more thoroughly review the available literature on the effects of mandatory price disclosure in pharmaceutical markets; and
- conduct its own studies of the Proposed Rule's potential effects on consumer and manufacturer behavior.

[1] No part of this document purports to present New York University School of Law's views, if any.
[2] *See* Regulation to Require Pricing Transparency, 83 Fed. Reg. 52,789 (proposed Oct. 18, 2018).

I. CMS should more clearly identify a market failure that would be addressed by the Proposed Rule

Although CMS states that the purpose of the Proposed Rule is to "reduce the price to [Medicare] beneficiaries of certain prescription drugs and biological products,"[3] the agency has not persuasively explained why current prices are the product of a market failure or how the Proposed Rule would address that failure.

CMS has not shown that consumers lack adequate information about list prices for prescription drugs

Executive Order 12,866 states that agencies should issue discretionary regulations only when there exists some "compelling public need, such as material failures of private markets to protect or improve . . . the well-being of the American people."[4] In the Proposed Rule, CMS purports to address an informational market failure, arguing that because consumers do not have access to drug prices, they are unable to price shop, leading to inefficiently high drug prices.[5]

In some situations, inadequate or asymmetrical information may cause parties to misallocate resources, such as paying too much or too little for a good. Providing the relevant information at the right moment, often at the time of purchase, can be a relatively inexpensive way to prevent this market failure.[6] Here, though, many pharmaceutical prices, including the list price and pharmacy price, are already available online.[7] As a result, the Proposed Rule does not provide consumers information that they could not already find. Additionally, CMS has not explained why providing the price in the advertisement is the proper time to disclose this information. Because CMS believes that purchasing decisions are made during physician-patient discussions,[8] providing information in advertisements is arguably just as disconnected from the decision process as providing information online. As a result, the agency has failed to show that price disclosures in DTC advertisements are necessary to address an informational market failure.

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[3] 83 Fed. Reg. at 52,789.
[4] Exec. Order No. 12,866 § 1(a), 58 Fed. Reg. 51,735 (Oct. 4, 1993).
[5] 83 Fed. Reg. at 52,790.
[6] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, 2010 ANNUAL REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS 55 (2010).
[7] 83 Fed. Reg. at 52,793.
[8] *Id.* ("[W]hile consumers make many critical decisions that bring about the ultimate writing of the prescription—making the appointment, asking the doctor about particular drugs, etc.—the physician, rather than the patient, ultimately controls the writing of the prescription, and the patient may not even know exactly which drug is prescribed.").

CMS has not shown that more prominent disclosure of list prices will lead to price declines

Under longstanding OMB guidance, a Regulatory Impact Analysis must explain how the actions required by a proposed rule would lead to the promised benefits.[9] Here, CMS does not make a persuasive case for why the Proposed Rule would serve the agency's ultimate goal of reducing prescription drug prices.

As CMS acknowledges, consumers' ability to choose between different treatment options based on price is constrained, because physicians, not patients, are responsible for making the final decision in prescribing pharmaceuticals.[10] The agency nevertheless maintains that disclosing the list price of drugs in DTC advertising will lead patients to discuss prices with their doctors before prescribing decisions are made and that those discussions will cause physicians to take price into account when deciding between treatment options. [11] This analysis fails to account for many of the unique features in the healthcare market.

Patients do not have a strong incentive to price shop and thus have little incentive to discuss pricing with their doctors. CMS acknowledges that "[t]hird-party payment, a dominant feature of health care markets, is not a prominent feature of other markets and causes distortions, such as the absence of . . . the information and *incentives that prices provide*."[12] Most Americans rely on prescription drug coverage provided to them by their employer or the federal government. Because patients are not directly responsible for pharmaceutical costs, they have little incentive to bear the additional costs associated with price shopping. As a result, "pharmaceutical manufacturers tend not to compete based on list price."[13]

Even when patients do pay out of pocket for medications, most do not pay the full list price. Instead, they pay a price negotiated by their insurance company. Depending on the terms of their health insurance plans, different patients may pay dramatically different prices for the same medication.[14] Therefore, it is unclear whether including the list price in DTC advertising would be of much informational benefit to consumers.

CMS argues that the list price is still relevant because over 40% of those with private health insurance are in high deductible health plans (HDHPs), which requires them to pay the full list price until they meet their deductible.[15] However, this statistic is misleading for a variety of reasons. First, it is drawn from a study that surveyed only individuals under the age of 65.[16] Second, it does not include the almost 30% of Americans under 65 who have

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[9] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB CIRCULAR A-4 ON REGULATORY ANALYSIS 2 (2003) [hereinafter "Circular A-4"].
[10] 83 Fed. Reg. at 52,793.
[11] *Id.*
[12] *Id.* at 52,790 (emphasis added).
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] Although CMS did not provide a citation, the 40% statistic appears to be drawn from this CDC report: MICHAEL MARTINEZ ET AL., NAT'L CTR. HEALTH STATISTICS, HEALTH INSURANCE COVERAGE: EARLY RELEASE OF ESTIMATES FROM THE NATIONAL HEALTH INTERVIEW SURVEY, JANUARY–SEPTEMBER 2017 (2017).

government health insurance plans, including Medicaid, which do not offer HDHPs.[17] In reality, less than a third of the US population under 65 is enrolled in a HDHP.[18] Third, HDHPs often completely cover certain "preventative" prescription drugs and exempt them from deductible requirements.[19] Fourth, those with HDHPs account for a disproportionately small share of total pharmaceutical expenditures.[20] Thus, the list price is relevant only for a small share of pharmaceutical purchases.

Even if disclosing list prices in DTC advertising did somehow prompt patients to discuss pricing with their physicians, it is not clear that physicians are well-positioned to help their patients compare prices. Doctors are currently incentivized to provide the highest quality care, not the most cost-effective care.[21] As a result, physicians are often both unaware of and bad at estimating the cost of treatment.[22] Thus, even if a patient were to mention the advertised list price of a particular drug, that patient's physician may be unaware of the list prices of alternative treatments, let alone what the *actual* cost of the treatments would be for the patient..

For all these reasons, CMS's contention that the Proposed Rule would lead to lower drug prices is unpersuasive.

II. CMS should more thoroughly assess the Proposed Rule's costs

Executive Order 12,866 requires agencies to assess the costs and benefits of any economically significant regulatory action, including, but not limited to, "any adverse effects on the efficient functioning of the economy . . . health, safety, and the natural environment."[23] This assessment should be based "on the best reasonably obtainable scientific, technical, economic, and other information," and effects should be quantified "to the extent feasible."[24]

Separate from the requirements of Executive Order 12,866, courts have held that "[w]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable."[25] In weighing a possible

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[17] JESSICA C. BARNETT & EDWARD R. BERCHICK, U.S. CENSUS BUREAU, 2017 HEALTH INSURANCE COVERAGE IN THE UNITED STATES 4 (2017).
[18] *Id.* This estimate extrapolated from the fact that 70% of Americans have a private health insurance plan and 40% of those are HDHP.
[19] Joanne Wojcik, *IRS' Lack of Definitive Drugs List has Firms Fully Covering Maintenance Meds*, BUSINESS INSURANCE (Nov. 9, 2014), https://www.businessinsurance.com/article/20141109/NEWS03/311099985/irs-lack-of-definitive-drugs-list-has-firms-fully-covering
[20] Buntin M. Beeuwkes et al*., Healthcare Spending and Preventive Care in High-Deductible and Consumer-Directed Health Plans*, 17(3) AM. J. MANAGED CARE 222 (2011)(demonstrating that families enrolled in HDHP spent 14% less than similar families with conventional health insurance plans).
[21] J. Bauer Horton & Larry Hollier, *The Current State of Health Care Reform: The Physicians' Burden*, 32(2) AESTHETIC SURGERY J. 230 (2012).
[22] Allan G Michael et al., *Physician Awareness of Drug Cost: A Systematic Review*, 4(9) PLOS MED. e283 (2007).
[23] Exec. Order No. 12,866 § 6(a)(3)(C).
[24] *Id.* §§ 1(b)(7), 6(a)(3)(C).
[25] *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (arbitrary and capricious standard requires agency to

action, an agency "cannot tip the scales . . . by promoting [the action's] possible benefits while ignoring [its] costs."[26] Furthermore, the Supreme Court has made clear that "'cost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost."[27] Such disadvantages include "harms that regulation might do to human health or the environment."[28]

In its analysis of the Proposed Rule's costs and benefits, CMS overlooks several ways in which the proposed disclosure requirements might harm both consumers and pharmaceutical manufacturers. Finalizing the Proposed Rule in reliance on this materially incomplete analysis would be arbitrary and capricious.

CMS overlooks costs to consumers

The Proposed Rule provides no substantive discussion of the costs that consumers could incur as a result of mandatory list price disclosures. CMS admits that consumers may misinterpret list prices, believing they are being "asked to pay the list price rather than a co-pay or co-insurance."[29] As a result, CMS believes the Proposed Rule "could discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care" as they are intimidated by the high list prices.[30] Despite recognizing the potential for such adverse effects, CMS makes no effort to assess their likelihood and magnitude, either quantitatively or qualitatively.

The costs incurred by consumers could take a variety of forms and would depend upon consumer and firm responses to the Proposed Rule. Consumers may face costs due to misinterpreting the information provided in the disclosures, leading to undesirable treatment decisions. Additionally, firm responses may lead to a decrease in treatment. Accordingly, CMS should assess the following potential costs to consumers:

1. Costs may result from consumers misinterpreting the disclosed prices

Disclosure of list prices may lead consumers to make less efficient healthcare decisions, whether by dissuading them from pursuing a treatment or causing them to ignore more important characteristics of a treatment option, such as its side effects.

"examine the relevant data" and "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made" (internal quotation marks omitted)).

[26] *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983); *see also California v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (vacating a delay where agency relied "on precisely the same Regulatory Impact Analysis that it had previously relied on" to support its findings regarding the suspended rule's costs, but ignored that analysis's findings regarding the rule's benefits).

[27] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015).

[28] *Id.*; *see also Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.,* 956 F.2d 321, 326–27 (D.C. Cir. 1992) (holding that the agency should have considered costs in the form of safety risks associated with the smaller size of more fuel-efficient cars).

[29] *See* Fed. Reg. at 52797.

[30] *See id*. at 52797-98.

a. Consumers may misinterpret the list price as the price they are expected to pay and, as a result, forgo seeking treatment

Americans are highly sensitive to the costs of healthcare. Fifty-five percent of Americans "worry a great deal" about the availability and affordability of healthcare.[31] Not surprisingly, concerns over affordability often lead consumers to avoid treatment. Studies have indicated that as much as 40% of Americans forgo recommended treatments due to cost[32]; between 24%[33] and 44%[34] forgo doctor visits altogether due to cost. The Proposed Rule would result in advertisements highlighting prices that are unrepresentative of the prices consumers actually pay. If consumers mistakenly conflate list prices with the prices they will be required to pay, they may forgo seeking medical treatment due to cost concerns.

b. Consumers who associate price with quality of care may request the most expensive treatment advertised

In traditional product markets, it is well understood that price is one of the most common proxies people use in estimating the quality of a product.[35] The literature on this phenomenon in the pharmaceutical market is not conclusive; studies have reached opposing conclusions as to whether consumers use price as an indicator of quality when making healthcare choices.[36]

The Proposed Rule presents a risk that consumers presented with list prices in DTC advertising will begin assuming that the drug with the highest disclosed price is the drug with the highest quality. Such a result would be problematic as, generally speaking, price serves as a poor indicator for whether a drug is the best option for a given patient.[37] Consumers might begin specifically requesting drugs that are less beneficial than other alternatives, either because of individual health needs or due to overall quality. This risk is compounded by the fact that physicians have been observed to be far more likely to

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[31] Jeffrey M. Jones, *U.S. Concerns About Healthcare High; Energy, Unemployment Low*, GALLUP (Mar. 26, 2018).
[32] WEST HEALTH INST. AND NORC AT THE U. OF CHICAGO, AMERICANS' VIEWS OF HEALTHCARE COSTS, COVERAGE, AND POLICY (2018) *available at* https://s8637.pcdn.co/wp-content/uploads/2018/03/WHI-Healthcare-Costs-Coverage-and-Policy-Issue-Brief.pdf.
[33] Jennifer M. Taber, Bryan Leyva, and Alexander Persoskie, *Why Do People Avoid Medical Care? A Qualitative Study Using National Data*, 30 J. GEN. INTERNAL MED. 290 (2015).
[34] WEST HEALTH, *supra* note 32.
[35] *See, e.g.,* Akshay R. Rao, *The Quality of Price as a Quality Cue*, 42 J. MARKETING RES. 405 (2005); Ronald B. Larson, *Psychological Pricing Principles for Organizations with Market Power*, 16 J. OF APPLIED BUS. & ECON. 11 (2014).
[36] *Compare* Alberto J. Espay et al., *Placebo Effect of Medication Cost in Parkinson Disease*, 84(4) NEUROLOGY 794 (2015) (finding test patients are significantly more likely to associate greater drug effects with medications that have significantly higher costs) *with* Kathryn A. Phillips et al., *Most Americans Do Not Believe That There is an Association Between Health Care Prices and Quality of Care*, 35 HEALTH AFF. 347 (2016) (using survey results to find that Americans do not explicitly associate price with healthcare quality).
[37] *See* Roger Bate, Ginger Zhe Jin, & Aparna Mathur, Does Price Reveal Poor-Quality Drugs? Evidence From 17 Countries (Nat'l Bureau of Econ. Research, Working Paper No. 16854, 2011) (finding that price is often a poor indicator of drug efficacy and that consumers are often better served by choosing the cheaper drug).

prescribe a drug if patients request it by name.[38] Additionally, if the Proposed Rule drives consumers to seek out the most expensive drugs, firms will have no incentive to lower prices and may instead raise them in an effort to signal higher quality.

c. List price disclosures may crowd out more useful information and thus lead to less efficient treatment choices

Providing all available information is not necessarily beneficial for consumers. Because consumers can process only a limited amount of data, excessive information may cause consumers to make suboptimal choices.[39] In these situations, consumers often take short cuts, which lead to less complete analysis.[40] As a result, mandating list price disclosures may cause consumers to disregard more useful information, like that on potential side effects.[41] Additionally, assimilating new information into a consumer's analysis inevitably takes extra time, which may cause inefficient delays in decision-making. Consumers may, for instance, delay seeking treatment while they try to analyze how the list price affects their cost of treatment.

2. A decrease in DTC advertising may present costs to consumers due to a reduction in disease and treatment awareness

DTC pharmaceutical advertising is pervasive in American life; one estimate finds that television alone, the sole medium targeted by the Proposed Rule, exposes the average American to 16 hours of pharmaceutical advertising per year.[42] There is evidence that DTC advertising has some positive effects on consumers. For instance, the FDA has found that 53% of doctors believe DTC advertising leads to better discussions with patients[43] and 88% of patients who inquired about a drug were diagnosed with a condition treated by that drug.[44] While these trends have raised some concerns regarding physicians over-

[38] *See* John B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of A Factorial Experiment*, 52 MEDICAL CARE 294 (2014) (finding that physicians are significantly more likely to prescribe a variety of medications when the patient asks for them by name).
[39] *See, e.g.* Kevin Lane Keller & Richard Staelin, *Effects of Quality and Quantity of Information on Decision Effectiveness*, 14 J. CONSUMER RES. 200 (1987), Jacob Jacoby et al., *Brand Choice Behavior as a Function of Information Load*, 11 J. MARKETING RES. 63 (1974), N.H. Lurie, *Decision Making in Information-Rich Environments: The Role of Information Structure*, 30 J. CONSUMER RES. 473 (2004).
[40] J. Hibbard, & E. Peters. *Supporting Informed Consumer Health Care Decisions: Data Presentation Approaches That Facilitate the Use of Information in Choice*, 24 ANN. REV. PUB. HEALTH 413, 416 (2003).
[41] O. Ben-Shahar, C. E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647 (2011).
[42] C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic*, 36 PHARMACY & THERAPEUTICS 669, at 671 (Oct. 2011).
[43] U.S. FOOD & DRUG ADMIN., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS – SUMMARY OF FDA SURVEY RESEARCH RESULTS, at 59 (2004), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM600276.pdf.
[44] *Id.* at 4.

diagnosing illnesses and over-prescribing medications,[45] the possible benefits they present should not be overlooked.

CMS has acknowledged these possible consumer benefits of DTC advertising.[46] However, despite recognizing the possibility that pharmaceutical companies will reduce advertising in response to the Proposed Rule,[47] CMS has made no effort to assess the potential costs of such a reduction to consumers in the form of reduced awareness of treatment options.

CMS overlooks costs to pharmaceutical manufacturers

CMS's Regulatory Impact Analysis for the Proposed Rule includes only direct compliance costs for pharmaceutical manufacturers—specifically, the costs of employee time needed to add list price disclosures to DTC advertisements and to adjust firms' overall marketing strategies.[48] But CMS fails to recognize or quantify any costs that manufacturers could incur as a result of reduced sales. For example, if, as discussed above, list price disclosures intimidate some consumers into forgoing medical treatment altogether, manufacturers would suffer a cost in the form of lost producer surplus from forgone drug purchases. Both OMB guidance and relevant case law obligate CMS to include such ancillary costs in its analysis.[49]

III. CMS should more thoroughly review available literature on the effects of mandatory price disclosure in pharmaceutical markets

As noted previously, Executive Order 12,866 instructs agencies to base their regulatory decisions "on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."[50] Yet CMS relies on only two sources to support its argument that mandatory list price disclosures will decrease pharmaceutical prices: an article by John F. Cady[51] and a

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[45] *See, e.g.,* Ben Harder, *Pushing Drugs: How Medical Marketing Influences Doctors and Patients*, 168 SCI. NEWS 75 (2005) (finding that physicians are five times more likely to prescribe a medication when asked for it by name rather than being only presented with relevant symptoms).

[46] *See* 83 Fed. Reg. at 52,798 (admitting "some studies indicate direct-to-consumer advertising increases disease awareness, and that if this rule decreases disease awareness such that untreated illness occurs, there may be other impacts").

[47] *See id.*

[48] *Id*. at 52,797. CMS neither explains the reasoning behind nor cites any sources to support its estimates of how much time each of the specified tasks will take. If CMS is basing these calculations on in-house expertise regarding the pharmaceutical advertising process, the agency should make this clear and provide at least a minimal discussion of that process.

[49] *See, e.g.,* Circular A-4, *supra* note 9, at 26 ("Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks."); *U.S. Telecom Ass'n v. FCC*, 290 F.3d 415, 424–25 (D.C. Cir. 2002) (remanding a rule for failure to consider indirect costs).

[50] Exec. Order No. 12,866 §§ 1(b)(7).

[51] John F. Cady, *An Estimate of the Price Effects of Restrictions on Drug Advertising*, 44 ECON. INQUIRY 493 (1976).

Congressional Research Service (CRS) report.[52] Neither source supports the agency's assertion that "data indicate that [list price disclosures] will likely motivate manufacturers to be less willing to raise prices."[53]

The Cady article focuses on state restrictions on advertising by pharmacies, not pharmaceutical manufacturers. Pharmacies set retail prices for pharmaceuticals based on a variety of factors, including the individual pharmacy's acquisition cost, which may vary based on the pharmacy's negotiations with the pharmaceutical manufacturer. As a result, drug prices often vary between different pharmacies, even if they are in the same city.[54] A consumer without coverage for prescriptions thus has an incentive to determine which pharmacy will fill a particular prescription for the lowest price.

The regulations Cady analyzed prevented pharmacies from competing based on price—for example, by banning outdoor signs with information identifying the products and prices offered by the pharmacy, or by prohibiting promotional schemes that offered discounts to certain segments of the market.[55] Cady concluded that there was a difference in the *retail* price of pharmaceuticals between states that banned such price advertisements and states that did not. The study did not claim that these regulations affected the manufacturer's list price.

The modern pharmaceutical manufacturing market looks significantly different than the 1970s pharmacy market that Cady examined. First of all, competing pharmacies sell the same products and therefore compete primarily on price. Competing pharmaceutical manufacturers, on the other hand, sell different products, with different efficacy rates and side effects. Secondly, while consumers are ultimately responsible for deciding which pharmacy to use, they are less responsible for determining which medication to take (which is typically determined by a physician's prescription). These differences explain why pharmacies had the incentive to advertise their prices in the first place, while pharmaceutical manufacturers do not. [56]

Additionally, pharmacies today are less likely to compete on price than their 1970s counterparts. In 1975, over 75% of prescription costs were paid out of pocket; by 2015, only 14% were.[57] Since most patients no longer bear the bulk of the cost of their prescription medications, they have lost the incentive to price shop. Thus, even if the examined regulations were still in place today, it is unlikely Cady's results would be replicated.

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[52] D. ANDREW AUSTIN & JANE G. GRAVELLE, CONG. RESEARCH SERV., RL34101, DOES PRICE TRANSPARENCY IMPROVE MARKET EFFICIENCY? IMPLICATIONS OF EMPIRICAL EVIDENCE IN OTHER MARKETS FOR THE HEALTHCARE SECTOR (2008) [hereinafter "CRS Report"].
[53] 83 Fed. Reg. at 52,790.
[54] Brenda Breslauer et al., *Want Cheaper Prescription Drugs? You Better Shop Around*, NBC NEWS (Dec. 19, 2017), https://www.nbcnews.com/health/health-news/want-cheaper-prescription-drugs-you-better-shop-around-n830066.
[55] Cady, *supra* 51, at 498.
[56] 83 Fed. Reg. at 52,790.
[57] NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2016: WITH CHARTBOOK ON LONG-TERM TRENDS IN HEALTH tbl. 95 (2011).

The CRS report cited by CMS also fails to support the agency's conclusion that a mandatory list price disclosure regime will lead to lower pharmaceutical prices. Although the CRS report concluded that advertising generally led to lower prices for various goods, it distinguished between voluntary advertising and mandatory price disclosures.[58] It also repeatedly cautioned against applying the conclusions of the Cady article, which examined advertising by pharmacies, to advertising by pharmaceutical *manufacturers*.[59]

A number of other studies, not cited by CMS in the Proposed Rule, have analyzed the effects of disclosure regimes in the healthcare and other markets. Many of these studies suggest that consumer-focused disclosures will have little or no effect on healthcare, due in large part to the fact that consumers are particularly bad at analyzing relevant information in the healthcare market. Some suggest that disclosure could increase prices under certain circumstances by aiding collusion between pharmaceutical companies. The following are a list of studies and papers analyzing the effects of mandatory disclosures on price:

- Morgan A. Muir et al., *Clarifying Costs: Can Increased Price Transparency Reduce Healthcare Spending*, 4 Wm. & Mary Pol'y Rev. 319 (2013).
    - The authors look at price transparency in the healthcare market and conclude that legislative or regulatory efforts to promote price transparency may result in increased healthcare costs, depending on market conditions. They suggest price transparency initiatives need to include a plan to decrease economic inefficiencies that would prevent them from being effective. They also argue that initiatives targeting insurers, providers, and employers would be more effective than those targeted at consumers.

- Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 Am. J. L. & Med. 7 (2009).
    - The authors conclude that mandated disclosures are unlikely to result in good care at good prices due to the barriers consumers in the healthcare market face when making decisions.

- Martin N. Marshall et al., *The Public Release of Performance Data: What Do We Expect to Gain? A Review of the Evidence*, 283 J. Am. Med. Ass'n 1866 (2000).
    - The authors find, based on a review of empirical studies, that disclosing performance data for health care providers and organizations does not have a substantial effect on consumer behavior. The authors believe this is due to difficulty understanding the information, lack of trust in the data, problems with timely access, and a lack of choice.

- Lauren E. Willis, *Decisionmaking and the Limits of Disclosure: The Problem of Predatory Lending: Price*, 65 Md. L. Rev. 707 (2006)

[58] CRS Report, *supra* note 52, at 39.
[59] *See, e.g.*, *id.* at 41 ("This result would not necessarily apply to drug manufacturers' current advertising to consumers that promotes potential benefits of drugs, but does not advertise prices.").

- The author analyzes why home loan disclosures, including price-related disclosures, have been ineffective at preventing predatory lending. Factors she identifies include logistical and timing issues, incomplete information, and financial illiteracy.

- U.S. Federal Trade Commission, Letter to Assemblyman Greg Aghazarian, (September 7, 2004)
  - In this letter, the FTC analyzes a proposed California Assembly Bill that would require pharmacy benefit managers to disclose information on their revenues and drug formularies to purchasers. The agency concludes that the legislation would most likely increase costs.
  - The proposed legislation was eventually vetoed by Governor Schwarzenegger.

- P.B. Ginsburg, *Shopping for Price in Medical Care*, 26 Health Aff. 208 (2007):
  - The author argues that government transparency initiatives designed to provide price information for uninsured or out-of-network patients may actually increase costs, in part because the information helps hospitals coordinate their pricing decisions.

- David Cutler & Leemore Dafny, *Designing Transparency Systems for Medical Care Prices*, 364 New Eng. J, Med. 894-5 (2009).
  - The authors note that the competitive effect of price transparency is similar to "most-favored nation" (MFN) clauses, under which a supplier formally agrees not to charge a lower price to other providers. The effect of MFN clauses in the health care industry resulted in higher prices.

- Svend Albaek et al., *Government Assisted Oligopoly Coordination? A Concrete Case*, 45 J. L. & Econ. 429 (1997).
  - A Danish antitrust order required ready-mix companies to disclose their prices. After publication, there was a 15-20% price increase. The authors argue that mandatory price disclosure made collusion easier.

- Hongyan Li & Jin Xu, *The Consequences of Mandated Compensation Disclosure* (2017). Available at SSRN: https://ssrn.com/abstract=2756533.
  - The authors find that, after the SEC mandated the disclosure of Chief Financial Officer (CFO) compensation in 2006, CFO pay increased significantly relative to CEO pay, particularly in firms most affected by the mandate.

IV. CMS should conduct its own studies of the Proposed Rule's potential effects on consumer behavior

According to OMB guidance on regulatory analysis,"[w]hen uncertainty has significant effects on the final conclusion about net benefits," agencies "should consider additional

research prior to rulemaking."[60] Here, most of the potential costs of the Proposed Rule are functions of uncertain consumer behavior; their magnitude depends upon consumers' interpretation and use of new pricing information. Given this fundamental uncertainty about the Proposed Rule's likely effects, CMS should, in addition to reviewing the literature discussed in the prior section, consider conducting its own studies into how consumers are likely to interpret and respond to list price disclosures in DTC advertising.

In conducting such studies, CMS should consider the following methodologies:

- Individual Interviews[61]
    - One research option for CMS would be to conduct standardized interviews with individual consumers regarding their perception of and behaviors in the healthcare market. While such interviews are helpful in identifying conscious consumer behaviors (e.g., "do you avoid seeking out treatment due to healthcare costs?"), they provide less information on unconscious behaviors.

- Focus Groups[62]
    - Group conversations led by a researcher could also be a valuable tool for CMS. The researcher could ask probative questions, show drug advertisements, and encourage debate among participants to uncover misconceptions and preferences. This method can be fairly costly and time-consuming. Additionally, the results from multiple focus groups may not provide easily comparable opinions, especially if conducted by different interviewers.

- Questionnaires[63]
    - Questionnaires would likely be the easiest and most cost-efficient way for CMS to gather standardized data from a large sample of consumers. CMS should recognize, however, that questionnaires are very easily misunderstood by participants. A questionnaire administered by CMS should be clear and designed to reveal a specific response, like sticker shock from higher list prices.[64]

Assuming appropriate sample demographics, data collected using any or all of these methods could inform estimates of consumer responses to the information provided under the Proposed Rule. CMS could, for example, estimate rates at which consumers would forgo

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[60] Circular A-4, *supra* 9, at 45-46 ("When uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.")
[61] *See* Fatimah Furaiji & Malgorzata Latuszynska, *Methods for Gathering Data for the Study of Consumer Behavior*, 58 STUD. & PROC. POLISH ASS'N FOR KNOWLEDGE MGMT. 77 (2012) (discussing the benefits and weaknesses of the most common methodologies used for assessing consumer behavior).
[62] *See id.*
[63] *See id.*
[64] Given the anonymity of questionnaires, this method could also be used to collect data from pharmaceutical and marketing professionals on their likely responses to the Proposed Rule.

healthcare due to "sticker shock" from high prices, or favor one medication over another because of its higher price. CMS could then calculate the costs of those behavioral changes using available information on the cost of forgone treatment or the cost to Medicare and Medicaid for pricier drugs.

CMS should also look to the following studies for insights into methodologies for estimating consumer behavior:

- Valarie A. Zeithaml, *Consumer Response to In-Store Price Information Environment*, 8 J. Consumer Res. 357 (1982).
    - Through a laboratory experiment, researchers presented consumers with the price of an item in a variety of ways. They then tracked how individuals processed this information throughout the cognitive, affective, and behavioral stages. This methodology provided information about how consumer decisionmaking is affected when prices are removed or presented, and what steps the consumer takes to make a purchasing decision.
    - CMS could undertake a substantially similar study, presenting consumers with list price disclosures and tracking how this information is processed by asking similar questions of the participants. The study would allow the agency to determine the likelihood of consumers misinterpreting the information and how the disclosures could be most effective in fully informing the public.

- Eric N. Berkowitz & John R. Walton, *Contextual Influences on Consumer Price Responses: An Experimental Analysis*, 17 J. Marketing Res. 349 (1980).
    - Researchers provided participants with fake newspapers; these papers contained real stories from around the city, but also had fake ads for fake products. The participants were asked to read through the papers without being told the research was on the advertisement. The researchers then asked a variety of questions to understand how the participants processed the advertisements.
    - Because the DTC advertisements targeted by the Proposed Rule are shown within the context of television programming, CMS could use a similar study to determine how consumers pick up on and perceive the new disclosures.

- Donald R. Lichtenstein, Nancy M. Ridgway & Richard G. Netemeyer, *Price Perceptions and Consumer Shopping Behavior: A Field Study*, 30 J. Marketing Res. 234 (1993).
    - Researchers interviewed shoppers at a grocery store to determine the level of "recall" for the products they just bought and assess the positive and negative effects that product prices had on the decision to buy.
    - CMS could conduct a similar survey of pharmaceutical consumers to determine their understanding of what the "list price" is. Additionally, the consumers could be asked about the effects drug prices have on their choice of treatment for a medical condition.

CMS has provided no evidentiary support for its conclusion that the benefits of mandatory list price disclosures in DTC advertisements would justify the likely costs to manufacturers and consumers. Accordingly, further scientific study is crucial before the agency moves forward with this or any similar disclosure rule. In addition to the aforementioned research methods, CMS could consider engaging in real-world regulatory experimentation, such as a small-scale pilot program, to gain further knowledge of the Proposed Rule's likely effects before rolling it out on a national scale.[65]

Respectfully submitted,

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[65] ZACHARY J. GUBLER, REGULATORY EXPERIMENTATION FINAL REPORT, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, at 3 (2017), *available at* https://www.acus.gov/sites/default/files/documents/ZGubler%20ACUS%20Final%20Report%2811-17%29.pdf (recommending the use of regulatory experimentation to produce more data, and thus certainty, when dealing with regulatory methods that present a substantial amount of uncertainty).