December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4187-P: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency

Dear Administrator Verma,

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,100 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. With more than 12,000 establishments, California's life sciences industry generates nearly $317 billion in annual economic output, boosts the state's total gross product by $171.4 billion, supports more than 1.1 million jobs, and increases labor income by $92 billion per year.[i]

In our mission of providing feedback and communication between regulators and industry, we are writing in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the proposed rule Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency ("proposed rule"). The proposed rule would require direct-to-consumer (DTC) television advertisements (including broadcast, cable, streaming, or satellite) of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC or "list price") of that drug or biological product.

Biocom acknowledges CMS' efforts to provide patients with greater transparency regarding their prescription drug costs but respectfully urges the agency to withdraw the proposed rule. DTC advertising plays a vital role in making patients aware of medical conditions and treatments available to them. We believe that a government-mandated disclosure of product prices would not only violate drug manufacturers' first amendment rights but also create consumer confusion by providing patients with misleading and incomplete information about their drug costs.

Misleading Consumer Information

The proposed rule would require DTC television advertisements for prescription drugs and biological products covered by Medicare and Medicaid to include the list price if it is greater than $35 for a monthly supply or a course of therapy.

Mandating list prices in DTC television advertisements would be misleading to patients because list prices do not reflect patients' actual out-of-pocket costs, which may vary based on rebates, negotiated discounts, and individual health plans. The price of prescription drugs paid by the consumer is determined by a combination of rebates and negotiated discounts between manufacturers, pharmacy benefit managers (PBMs), wholesale distributors, pharmacies, and plan sponsors. Therefore, using the list price would provide consumers with misleading and incomplete information about their actual drug cost.

Additionally, the list prices could cause confusion due to the variance in patients' individual health plans, which have different deductible/co-pay, formulary status, treatment protocol, and availability of similar drugs, resulting in a wide range of possible out-of-pocket costs. Biocom is concerned that DTC advertisements using the list price will not provide patients with enough information to fully understand their drug costs.

According to the Department of Health and Human Services (HHS), list prices for the top ten prescription medicines advertised on television range from $535 to $11,000 for a month or course of treatment.[ii] Biocom is concerned that advertising high list prices without additional information as to what the actual out-pocket-costs would be may discourage patients from taking life-saving treatments. This could result in patients foregoing treatment or having poor medication adherence.

Violation of First Amendment

Biocom believes that the proposed rule encroaches on drug manufacturers' right to free speech under the First Amendment by compelling companies to speak to convey a particular message mandated by the government. The First Amendment protects commercial speech that is not false or misleading and that does not advertise illegal or harmful activity. The First Amendment also provides equivalent protection for both the right to speak and the right not to speak. The U.S. Supreme Court has long held that the First Amendment limits the government's ability to regulate commercial speech by forcing companies to communicate particular pricing information to consumers. The agency's proposed rule requiring drug manufacturers to disclose list prices in direct-to-consumer television advertisements infringes on companies' protected First Amendment interests because the disclosures do not meet all the requirements to pass constitutional muster, as explained below.

In *Zauderer v. Office of Disciplinary Counsel,*[iii] the Court held that a requirement that goods or services disclose "factual and uncontroversial" information is constitutional so long as the requirement is not unduly burdensome, and the requirement is "reasonably related to the State's interest in preventing deception of consumers.[iv]" CMS asserts that the proposed rule mandates purely factual and uncontroversial information about a firm's own product, namely the list price of the drug or biological product. While the compelled disclosure of a drug's list price is abstractly "purely factual", the list price is misleading to consumers and therefore controversial. Courts have taken a narrow view of what constitutes as a factual, uncontroversial disclosure. In *American Beverage Ass'n v. City and County of San Francisco,*[v] the court reviewed a required warning that drinking sugary beverages contributes to obesity, diabetes, and tooth decay. The Court held that because the disclosure did not state that overconsumption of beverages was the problem, it was "misleading and, in that sense, untrue." Likewise, the list price is not an accurate representation of what drug costs are for most patients, and the disclosure omits key information to inform patients of their prescription drug cost.[vi]

In *Central Hudson Gas & Electric Co. v. Public Service Commission,*[vii] the U.S. Supreme Court decided that a regulation of the New York Public Service Commission, which completely banned an electric utility from advertising to promote the use of electricity, violated the First Amendment. The Court held that the government could regulate commercial speech under the First Amendment if there is substantial government interest that is directly advanced by the regulation, and if the regulation is not broader than necessary to achieve that goal. The case established the *Central Hudson* test, a four-part test to determine whether government regulation of commercial speech is constitutional. Under the *Central Hudson* test, commercial speech is protected by the First Amendment if (1) it concerns lawful activity and is not misleading; (2) the asserted government interest is not substantial; (3) the regulation does not directly advance the asserted governmental interest; and (4) the regulation is more extensive than is necessary to serve that interest.

Biocom believes that the proposed rule does not meet the *Central Hudson* test's four requirements to lawfully compel manufacturers to include list prices in DTC television advertisements. The *Central Hudson* asks whether the government has a substantial interest that is directly and materially advanced by the speech restriction and whether the restriction is narrowly tailored to achieving that goal. The proposed rule does not satisfy the material-advancement requirements[viii] because there is no substantial evidence that supports the agency's claim that advertising list prices would reduce the cost of prescriptions. Courts have held that the government is required to provide evidence that a disclosure will effectively address the problem it targets.[ix] CMS does not provide any evidence that supports its claim that advertising list prices would reduce the cost of prescriptions.

Enforcement Concerns

Biocom also believes that enforcement concerns would render the rule ineffective. CMS plans to only list violators on its website and rely on drug companies to sue each other over violation of the rule using the Lanham Act, which prohibits false or misleading representations in advertising or promotion. Using the Lanham Act to enforce the rule has significant limitations.

Enforcement of this proposed rule may be restricted due to the standing requirements and elements of a Lanham Act claim. Under the Lanham Act, consumers do not have standing, and challenges would need to be brought by competitors or others who can demonstrate commercial harm caused by the defendant's advertising. Competitors may also lack standing if they are not harmed by a particular advertisement's omission of the list price. Omissions do not qualify as falsities under the law unless they create an erroneous belief among consumer. Furthermore, competitors must prove that the falsity caused it to lose a sale, which could be challenging considering there are a number of reasons why patients and prescribers may prefer one drug over another.

Scope of CMS Authority to Issue Rule

Biocom argues that CMS lacks the legal authority to issue rules regarding prescription drug advertising. The agency does not cite any statute that expressly authorizes CMS to issue the proposed rule.

In 1962, Congress specifically granted the Food and Drug Administration (FDA) statutory authority to regulate prescription drug labeling and advertisement through an amendment to the Federal Food and Drug Cosmetic Act (FFDCA). [x] However, the proposed rule was issued by CMS, not FDA. The FDA issued final regulations for prescription drug advertising, which stipulated that ads must (1) not be false or misleading, (2) present a "fair balance" of information describing both the risks and benefits of a drug, (3) include facts that are "material" to the product's advertised uses, and (4) include a "brief summary" that mentions every risk described in the product's labeling.[xi] The FFDCA does not authorize price disclosures in prescription drug advertising because the disclosures would not meet the "fair balance" standard, as prices are unrelated to drug safety and efficacy.

CMS is issuing the proposed rule pursuant to sections 1102 and 1871 of the Social Security Act, which authorizes HHS to issue regulations "for the efficient administration of function" under the Act and "as may be necessary to carry out the administration of the insurance programs." The agency claims that the rule would enhance the efficient administration of the Medicare and Medicaid programs and reduce expenditures for the government programs and their beneficiaries. This interpretation of the law does not clearly define CMS' authority to issue regulations on matters outside of which drugs are covered under Medicare and Medicaid and how they are reimbursed.

Alternative Models

Biocom would like to recommend that CMS consider alternative models that would provide patients with voluntary, comprehensive information about their medicine cost to help them make informed healthcare decisions. Under such an approach, DTC ads could direct patients to where they can find comprehensive information about medicine costs, including list prices, out-of-pocket costs or other context about the potential cost of the medicine, how to access company-specific patient assistance and other forms of cost-sharing support, and resources to help patients navigate their insurance coverage. The Pharmaceutical Research and Manufacturers of America (PhRMA) has designed a similar model that would have member companies voluntarily direct consumers to a company-developed website in their DTC ads.

Biocom is dedicated to improving patient access to innovative therapies and thanks you again for the opportunity to provide these comments. We look forward to a continued dialogue with CMS. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom

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[i] *Biocom 2017 Economic Impact Report Databook*. 2017, issuu.com/biocom0/docs/biocom-2017-economic-impact-report-_9995632bde2e0c?e=30611789/53618285.
[ii] U.S. Department of Health and Human Services. (2018, October 15). What You Need to Know about Putting Drug Prices in TV Ads. Retrieved from https://www.hhs.gov/about/news/2018/10/15/what-you-need-to-know-about-putting-drug-prices-in-tv-ads.html
[iii] 471 U.S. at 651, 105 S.Ct. 2265
[iv] Mason, A. (2017). Compelled Commercial Disclosures: Zauderer's Application to Non-Misleading Commercial Speech. *U. Miami L. Rev.*, 72, 1193.
[v] 871 F.3d 884 (9th Cir. 2017)
[vi] Dusetzina, S. B., & Mello, M. M. (2018). Disclosing Prescription-Drug Prices in Advertisements — Legal and Public Health Issues. *New England Journal of Medicine*. doi:10.1056/nejmp1814065
[vii] 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980)
[viii] Dusetzina and Mello
[ix] 696 F.3d 1205 (D.C. Cir. 2012)
[x] 21 U.S.C 352
[xi] Ventola C. L. (2011). Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?. *P & T : a peer-reviewed journal for formulary management*, *36*(10), 669-84.