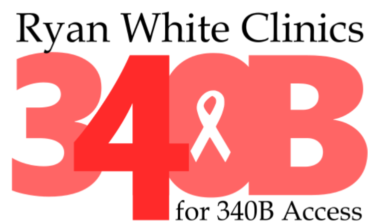

September 21, 2022

Federal and State Policymakers: Beware of Drug Companies' Disinformation Campaign

A spate of recent articles attacking the 340B program, some under the guise of research studies and some funded by drug manufacturers and their allies, were published in recent weeks and sent to Capitol Hill and state legislators. One article erroneously concludes that physicians participating in the 340B program prescribe certain medications for patients living with HIV/AIDS solely to increase "profits" from the 340B program. Other articles distort the intent and value of the 340B program. Still others falsely assert that the 340B program is harmful to communities of color.

"RWC-340B will not stand idle while the pharmaceutical industry attacks safety net providers in the 340B program," said Shannon Stephenson, president of RWC-340B and CEO of Cempa Community Cares. She noted, "[w]e are calling them on their disinformation and educating the public and policymakers to be aware of drug manufacturers' true goal – to cripple the 340B program in an effort to increase their profits at the expense of patients and communities."

Congress established the 340B program in 1992 to lower the cost of prescription drugs for federal grantees and other tax-supported safety net providers to enable them "to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."[1] Program eligibility was carefully crafted by Congress to target the clinics and hospitals that serve as the backbone of this nation's health care safety net for uninsured, underinsured and other vulnerable populations. Because these safety net providers generally treat anyone regardless of their ability to pay, they often receive no or inadequate compensation for their services. Among the "covered entities" eligible to participate are: Ryan White Program HIV/AIDS clinics (RWCs) and other specialty clinics that offer services typically unavailable in traditional settings, community health centers operating in underserved areas, and hospitals serving a disproportionate share of uninsured or underinsured patients.[2]

<u>Unfounded Attack: Physicians Prescribing for Profit</u>

One recent article in the New England Journal of Medicine focuses on PrEP medications and falsely asserts that 340B providers promote the use of brand drugs over generics to increase 340B "profits."[3] This claim not only ignores physicians' legal and ethical responsibility to "place patients' welfare above the physician's own self-interest or obligations to others,"[4] it essentially accuses PrEP prescribers of malpractice by suggesting that they care more about drug profits than their patients – an accusation that is as insulting as it is fallacious. Prescribing the right PrEP medication is a clinical matter left to the physician and patient to decide, taking into consideration the patient's needs and unique medical risk factors. Contrary to critics' assertions, PrEP drugs are not interchangeable and have differing short and long-term effects. For example, Truvada has been shown to have negative long-term effects on kidney function and bone density.[5] In accordance with their ethical obligations, physicians' decisions on a patient's medical treatment are guided by clinical indications, not 340B discounts. It is ironic that allegations about financial motivations are being made against safety net providers when manufacturers

have enjoyed record profits in recent years.[6] Notably, some of the authors of the NEJM article have received grant funding from drug manufacturers and insurers, calling into question their objectivity.

Unfounded Attack: Work of 340B Safety Net Providers Not Aligned with Program's Intent

Several recent articles inaccurately state that the work of 340B safety net providers does not align with the original intent of the program.[7] These articles also mischaracterize and vilify the relationships that covered entities have with contract pharmacies.[8] They do so by misrepresenting the intent of the 340B program. They falsely claim that Congress enacted the 340B statute to pass prescription drug savings to patients. If Congress had really intended to make 340B a patient entitlement program, why would the statute have directed manufacturers to give discounts to a group of carefully defined safety net providers rather than to patients themselves? Congress realized that the best way to support underserved and medically vulnerable patients was to provide more resources to the clinics and hospitals that care for them. The articles attempt to ascribe a new purpose to the 340B program that Congress never intended, a purpose that deliberately ignores the vital role 340B entities play in their communities.

In many communities – particularly low-income rural and urban areas – safety net providers and the contract pharmacies they rely on for dispensing medications offer the only pathway to affordable health care for individuals within those communities. Most covered entities do, in fact, provide medications to needy patients at little or no cost, often below the covered entity's 340B acquisition cost. But using the program for the sole purpose of lowering patient drug costs would do a grave injustice to patients. The high cost of drugs is just one of a myriad of obstacles that vulnerable patients face in accessing clinically appropriate health care in the U.S. The strength of the 340B program is that it allows a covered entity to use drug savings to address and mitigate the barriers to care that are unique to patients within that entity's service area. Safety net providers use 340B savings for direct health care services, drug adherence and management programs, and education and prevention programs, among many others, to benefit their patients and the communities they serve.[9]

Congress deliberately permitted safety net providers to determine the most effective use of their 340B program savings so that local safety net providers can address each community's unique needs rather than establishing a federally determined, one size fits all, federal discount to patients. Stephenson said, "[e]ven if the law directed the discounts to be given directly to patients, the cost of many drugs, even with a large discount, would be unaffordable to most of Ryan White patients."

Unfounded Attack: The 340B Program Does Not Help Underserved Communities

Some recent articles falsely claim that 340B entities, including RWCs and community health centers, do not use their savings to help patients in underserved areas.[10] There are at least two good reasons why these claims should not be taken seriously. First, RWCs and community health centers are subject to strict grant requirements mandating the delivery of care to medically underserved populations. Second, patient outcomes data demonstrate that they are clearly meeting these requirements.

The federal grants that enable RWCs to participate in the 340B program require RWCs to use their income, including the resources available to them through the 340B program, to support "core medical and support services, clinical quality management, and administrative expenses."[11] RWCs are required to serve only low-income patients without health care insurance.[12] Community health centers are subject to similar standards. They are required to develop fee schedules based on a sliding scale

approach that gives patients discounts on care according to their ability to pay. Those under 100 percent of the federal poverty level receive services free of charge.[13] Community health centers are also required by statute "to invest *every penny* of 340B savings into activities that expand access for their patients."[14]

Critics of the 340B program use a common tactic to discredit the program. Namely, they focus on narrow and statistically insignificant data to support broad generalizations that, while appearing empirically based, are actually unsubstantiated and misleading.[15] For example, by using data from only certain 340B entities but applying it to all 340B entities, detractors of the 340B program conclude that the program is flawed and in need of reform. A case in point is a recent article by the American Action Forum. The article cites a 2014 Office of the Inspector General study that was based on a small sample of covered entity types. The study itself warned that it was "not generalizable to other covered entities."[16] Despite this admonition, the American Action Forum article, and similar anti-340B studies, do exactly what the OIG warned against – overgeneralize narrow information to criticize the program.[17] Several of these authors argue that 340B grantees are not the intended target of 340B reform, but their publications say otherwise.[18] Under the guise of "reforming" the program to address so-called "bad actors," these articles belie the authors' true intent which is to attack the program and to chip away at the entire health care safety net.[19]

There is much more reliable data to assess the true value of the 340B program. Widely accepted patient outcomes data show that the 340B program is working exactly as Congress intended. The 340B program allows RWCs to leverage their 340B savings to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression. RWCs achieve viral suppression rates far above the average national viral suppression rate. This success in viral suppression rates results in fewer transmissions of the HIV/AIDS virus and is instrumental in helping to achieve the national goal to end the HIV/AIDS epidemic by 2030.[20] Eighty-nine percent of community health centers report that the 340B program has improved medication adherence, and 86 percent report that the program has improved clinical outcomes.[21] Almost half of community health centers have reported a decrease in emergency department utilization because of the program.[22]

Unfounded Attack: The 340B Program Harms Communities of Color

Perhaps the most egregious misinformation currently being propagated by industry-supported critics is that the 340B program harms communities of color.[23] The facts show that the opposite is true. The vast majority of patients served by RWCs and community health centers are racial and ethnic minority groups, low-income populations, or the uninsured.[24] Of RWC clients, 73.7 percent are from racial/ethnic minority groups.[25] RWCs work to decrease disparities in health care outcomes between demographic groups, showing a reduction in disparities in viral suppression rates.[26] Empirical evidence also indicates that any reduction of resources in the 340B program could have negative long-term consequences for these minority populations, including disruptions in care and treatment, adverse health outcomes, or increased health care expenses.[27]

One author, using suspiciously similar language to drug industry rhetoric, asserts that: "[t]he 340B program is not improving access to health care for communities of color because participating pharmacies are often not located where these communities live."[28] This is a baffling assertion given that a growing number of drug companies – eighteen as of today – are attempting to limit patient access to the 340B drugs by restricting the use of contract pharmacies. These restrictions are directly undermining

the ability of 340B safety net providers to care for their patients, most of whom are vulnerable and from communities of color. Ironically, the same author contends, "[w]hen programs – such as the 340B program – that are designed to help vulnerable communities and communities of color fail, it is those same communities who bear the burden."[29]

Another author, also borrowing common anti-340B messaging and supported financially by drug manufacturers, lauds Massachusetts lawmakers for fighting to end discrimination and tells them to "look no further" than the 340B program. He said, "[o]utdated, unregulated, and growing exponentially, the 340B Drug Pricing Program has steered off its original path to help vulnerable patients access their care in Massachusetts and around the country." Statements like this are reckless and without merit. Stephenson said, "[t]he drug industry is working in earnest to make the 340B program fail by disseminating half-truths and false narratives about the program and its impact on communities of color."

A large number of opinion pieces and so-called "studies" criticizing the federal 340B drug pricing program have been published in 2022. Almost all of the authors of these anti-340B publications have financial ties to the pharmaceutical industry, calling into question the objectivity and integrity of their work. Listed below are a few examples:

- One of the authors of a New England Journal of Medicine article entitled "Perverse Incentives: HIV Prevention and the 340B Drug Pricing Program," accepted research grant funds from Gilead, the largest manufacturer of HIV prevention drugs, to write the article.
- The authors of Temple University's "Patient Affordability and Debt Collection at 340B Hospitals" credit PhRMA with funding their work. PhRMA is the trade association for brand name drug manufacturers. One of PhRMA's top advocacy goals is to scale back the 340B program.
- Both authors of "340B Drug Discounts: An Increasingly Dysfunctional Federal Program," previously worked for Pfizer and are consultants for drug companies.

A complete list of financial interest information on select publications/authors that are funded either directly or indirectly by the drug industry is available at https://rwc340b.org/wp-content/uploads/2022/09/Verified-Author-Bias-Claims-for-Rebuttal-Article.pdf

PhRMA's Thinly Veiled Motive: Increase Profits at the Expense of Marginalized Communities

By targeting the 340B program and RWCs, the pharmaceutical industry is trying to divert public attention away from the real problem afflicting vulnerable populations – the high cost of prescription drugs. From 2019 to 2020, manufacturers increased the price of 23 of the 25 most expensive drugs covered by Medicare Part D at rates higher than the rate of inflation.[30] Indeed, almost one-third of 340B discounts can be attributed to the higher discounts that drug manufacturers must pay, called the inflationary penalty, when they increase the price of their drugs greater than the inflation rate.[31]

Since its inception, the 340B program has acted as a check on PhRMA's profit-focused pricing decisions that way too often make drugs unaffordable for low-income and underserved communities. In the early 1990s, to offset the prescription drug discounts that drug manufacturers were required to give the Medicaid program as part of the Medicaid drug rebate program, manufacturers increased prices for other purchasers, including the health care safety net. Drug manufacturers "promptly cancelled discount contracts, terminated special-price contracts, and raised the prices they charged public hospitals."[32] As a consequence, the cost of drugs for safety net hospitals increased an average of 32 percent.[33] Congress created the 340B program as a necessary measure to constrain pharmaceutical pricing behavior, explaining "the Federal government simply cannot continue to allow [covered entities] and their patients to remain unprotected against manufacturer price increases."[34]

The 340B program has been helping safety net providers tackle the high cost of rising drug prices for three decades.[35] Stephenson said:

> The 340B program helps RWCs and other safety net providers that work with underserved populations keep their doors open despite these rising drug costs. The 340B program is imperative to sustain these organizations' safety net care initiatives. For Ryan White clinics, this means fighting to stop the HIV/AIDS epidemic.

Stephenson contends that concerns with the program are motivated by drug companies' inherent interest in protecting drug profits, not by their often-stated contention that the program does not support vulnerable patients.

<u>Industry's 340B Reform Proposals Would Harm Patients, State and Local Government, and Public Health</u>

Safety net participants in the 340B program often furnish very different services and treat very different populations, but they all suffer from the same problem of providing care that is uncompensated or under-compensated. The high rate of uncompensated care in the U.S. is a serious national problem that falls disproportionately on the shoulders of 340B clinics and hospitals. The diverse range of charity care and other community benefits that safety net providers provide – such as care coordination or enabling services, drug adherence and management programs, and education and prevention programs – are desperately needed by low-income and other vulnerable patients but too often are unaffordable in absence of the 340B program because the services are not reimbursed by private insurers or public funding mechanisms.[36]

If essential 340B discounts were eliminated or scaled back as some drug companies are recommending, RWCs anticipate having to cut "case management and dietician services, clinic infrastructure and quality improvement . . . [and] administering vaccines and services for substance use disorders," examples of common activities supported by 340B program discounts.[37] RWCs provide drugs at little or no cost to patients who cannot afford them, but also use the 340B program more broadly to provide the comprehensive care that is so important to controlling new HIV/AIDS infections. For many individuals living with HIV/AIDS, access to non-pharmacy services made possible by 340B discounts – *i.e.*, primary and specialty care, case management, housing, transportation, nutrition, and other support services – is equally as important to achieving desired health outcomes as access to low-cost drugs.[38]

Ryan White Clinics 340B for 340B Access

340B discounts allow RWCs, like other 340B safety net providers, to furnish and augment the health care and related services needed by their patients, without cost to taxpayers.[39] Any diminution in 340B savings will be borne by state and local governments, and the taxpayers that support them, because the care needed by low-income populations would continue to be uncompensated. Manufacturers' self-interested assault on the 340B program will cripple the ability of RWCs and other safety net providers to care for vulnerable patients, undermining their use of the 340B program to protect public health.[40]

If drug manufacturers' relentless crusade against the 340B program succeeds, it will come at the expense of patients and communities in need. Most insidiously, these attacks disguise themselves as genuine concern for vulnerable patients when the reality is that such "reform" would come at the expense of these patients.

While Congress works to preserve and support the 340B program, manufacturer-backed groups undermine its efforts by spreading misinformation and inaccurate generalizations.[41] PhRMA recently published an article titled, "*Study after study after study: Contract pharmacy expansion is not aligned in communities 340B is meant to serve*."[42] What it fails to mention is that these "studies" criticizing the 340B program can all be traced back to the same source: drug manufacturers. Their sponsorship of numerous articles framed as objective research are nothing more than an effort to trick Congressional members and the public into believing that the 340B program is harmful to divert resources away from RWCs and other safety net providers to line their own pockets.[43]

Stephenson said, "RWC-340B strongly urges the public and policymakers to 'consider the source' and think twice before believing attacks on the 340B program." She added, "[i]t is imperative that the 340B program remains strong and protected from disinformation, misinformation, and lies distorting the true value of the program to our communities."

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[1]H.R. Rep. No. 102-384, pt. II (Sept. 22, 1992); *Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight,* GAO (May 15, 2018).

[2] 42 U.S.C. § 256b(a)(4) (2018).

[3] Julia L. Marcus, Amy Killelea, & Douglas S. Krakower, *Perverse Incentives—HIV Prevention and the 340B Drug Pricing Program,* NEJM (June 2, 2022).

[4] AM. MED. ASS'N, *Patient-Physician Relationships in* AMA CODE OF MEDICAL ETHICS.

[5] Michelle Llamas, *Truvada Side Effects,* DRUGWATCH (Jan. 27, 2021). There have been lawsuits filed by individuals and class actions against Gilead alleging kidney and bone density problems from Truvada. *See* Complaint, Lujano v. Gilead Sciences, Inc.; Complaint, Martinez v. Gilead.

[6] For example, Pfizer realized $81.3 billion in profits in 2021, a growth of over 94 percent from $41.9 billion in 2020. Pfizer, *Pfizer Reports Fourth-Quarter and Full-Year 2021 Results* (Feb. 8, 2022). Similarly, Johnson and Johnson realized $93.8 billion in profits in 2021 (an increase of 13.6 percent) and Gilead realized $27.3 billion in profits in 2021 (an increase of 11 percent). Johnson & Johnson, *Johnson & Johnson Reports Q4 and Full-Year 2021 Results* (Jan. 22, 2022); Gilead Sciences, Press Release, *Gilead Science Announces Fourth Quarter and Full Year 2021 Financial Results* (Feb. 1, 2022).

[7] WILLIAM SMITH & JOSH ARCHAMBAULT, 340B DRUG DISCOUNTS: AN INCREASINGLY DYSFUNCTIONAL FEDERAL PROGRAM 4 (2022); Brian Nyquist, *Viewpoint: Cost-Saving Drug Program Needs Transparency* (April 18, 2022); Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, USC SHAEFFER CENTER (Oct. 2021).

[8] The American Action Forum's June 16th article inaccurately states that covered entities give contract pharmacies a percentage of their 340B savings as profit. This harmful language conflates profit sharing with the necessary dispensing and administrative fees that covered entities pay to contract pharmacies to distribute their 340B medications. *See PRIMER: The 340B Drug Pricing Program,* AMERICAN ACTION FORUM (June 16, 2022). *See also* Karen

Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, USC SHAEFFER CENTER 9 (Oct. 2021).

[9] Letter from RWC-340B to Speaker Ryan, Leader Pelosi, Leader McConnell & Leader Schumer (May 14, 2018).

[10] *See* Nicole Longo, *New Research Finds Gaps in Charity Care Provided by 340B Hospitals*, PHRMA (June 2, 2022); Nicole Longo, *340B Program Remains Second Largest Federal Drug Program, Yet Little Solid Evidence of Benefits to Patient*, PHRMA (June 30, 2022); Jonathan K. Larsen & Sabrina Ruchelli, *Patient Affordability and Debt Collection Policies at 340B Program Hospitals*, TEMPLE UNIV. (May 2022); Ekemini Isaiah et. al, *340B Hospital Child Sites and Contract Pharmacy Demographics*, AVALERE (April 18, 2022); Sally Greenberg, *340B Program Isn't Working for Patients*, REALCLEAR HEALTH (May 6, 2022).

[11] RWC-340B, VALUE OF RYAN WHITE PROVIDERS AND IMPACTS ASSOCIATED WITH RESOURCE REDUCTION 4 (2020).

[12] 42 U.S.C. § 300ff-15(e) (2018).

[13] *Chapter 9: Sliding Fee Discount Program*, HRSA.

[14] NAT'L ASSOC. OF CMTY. HEALTH CENTERS, 340B, A CRITICAL PROGRAM FOR HEALTH CENTERS 2018.

[15] *See* Nicole Longo, *New Research Finds Gaps in Charity Care Provided by 340B Hospitals*, PHRMA (June 2, 2022); Jonathan K. Larsen & Sabrina Ruchelli, *Patient Affordability and Debt Collection Policies at 340B Program Hospitals*, TEMPLE UNIV. (May 2022); Ekemini Isaiah et. al, *340B Hospital Child Sites and Contract Pharmacy Demographics*, AVALERE (April 18, 2022); Sally Greenberg, *340B Program Isn't Working for Patients*, REALCLEAR HEALTH (May 6, 2022); *Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program*, AIR 340B (Nov. 2019).

[16] Department of Health and Human Services, Office of the Inspector General, Memorandum Report, *Contract Pharmacy Arrangements in the 340B Program* (Feb. 4, 2014).

[17] Citing the 2014 OIG study, the American Action Forum article concludes, "Patients and taxpayers are therefore not necessarily benefiting from the mandated discounts." *PRIMER: The 340B Drug Pricing Program*, AMERICAN ACTION FORUM (June 16, 2022).

[18] For example, an Avalere article mentions the need for "targeted reform" that utilizes "guardrails that protect access for populations that are the intended recipients of 340B benefits." However, pharmaceutical manufacturers such as Gilead and others have implemented blanket policies restricting access to 340B drugs for all 340B entities, with no exceptions for RWCs, which use their grant funds exclusively to serve low-income patients. *Compare* Ekemini Isaiah et. al, *340B Hospital Child Sites and Contract Pharmacy Demographics*, AVALERE (April 18, 2022), *with* Letter, *RWC-340B Follow-Up Letter to Gilead Regarding Contract Pharmacy Policy*, RWC 340B.

[19] For example, some pharmaceutical manufacturers have refused to honor 340B contract pharmacy arrangements for all 340B entities, rather than so-called "bad actors." *See, e.g., Astra-Zeneca Announces It Will No Longer Offer 340B Discounts At Most Contract Pharmacies*, RWC 450B; Eli Lilly Announces New Limited Distribution Plan, RWC 450B; Robert King, Drugmaker 340B Contract Pharmacy Restrictions Continue with Bausch Health (July 5, 2022).

[20] Letter from RWC-340B to Ranking Member Walden and Chairman Alexander, Response to Request for Input Regarding the 340B Program (Oct. 30, 2020).

[21] NAT'L ASSOC. OF CMTY. HEALTH CTRS., 340B: A CRITICAL PROGRAM FOR HEALTH CENTERS 2022.

[22] *Id.*

[23] Rev. K.W. Tulloss, *Loophole, Lack of Transparency Allows California Communities of Color to be Exploited as Part of Federal Drug Program*, LOS ANGELEES SENTINEL (Apr. 14, 2022).

[24] Americas-Health-Centers-March-2016.pdf (nachc.org);

[25] Letter from RWC-340B to Ranking Member Walden and Chairman Alexander, Response to Request for Input Regarding the 340B Program (Oct. 30, 2020).

[26] *Id.*

[27] *Id.*

[28] Rev. K.W. Tulloss, *Loophole, Lack of Transparency Allows California Communities of Color to be Exploited as Part of Federal Drug Program*, LOS ANGELEES SENTINEL (Apr. 14, 2022).

[29] *Id.*

[30] Juliette Cubanski & Tricia Neuman, *Prices Increased Faster Than Inflation for Half of All Drugs Covered by Medicare in 2020*, KFF (Feb. 25, 2022). In January 2022, drug manufacturers raised prices on 791 brand name drugs by an average of over five percent. So far in July 2022, 57 drug manufacturers have increased prices on 108 brand

name drugs. Jon Conradi, *CSRXP: Big PhRMA Brazenly Increases Prices on More Than 100 Drugs to Start July Price-Gouging*, THE CAMPAIGN FOR SUSTAINABLE RX PRICING.
[31] 340B HEALTH, 340B DOES NOT INCREASE DRUG PRICES.
[32] H.R. REP. 102-384, 10.
[33] *Id.*
[34] *Id.* Pharmaceutical manufacturers attempt to frame the pricing they provided safety net providers before the Medicaid Drug Rebate Program and the 340B program as voluntary "charitable giving." They fail to mention that it was their unchecked price increases that led to the need for Congressional intervention. *See PRIMER: The 340B Drug Pricing Program*, AMERICAN ACTION FORUM (June 16, 2022).
[35] Letter from RWC-340B to Chairman Pallone, Chairwoman Eshoo & Representative Matsui, Thank You (Oct. 28, 2019).
[36] NAT'L ASSOC. OF CMTY. HEALTH CENTERS, 340B, A CRITICAL PROGRAM FOR HEALTH CENTERS 2018.
[37] RWC-340B, VALUE OF RYAN WHITE PROVIDERS AND IMPACTS ASSOCIATED WITH RESOURCE REDUCTION 7 (2020).
[38] Letter from RWC-340B to Chairman Pallone, Chairwoman Eshoo & Representative Matsui, Thank You (Oct. 28, 2019).
[39] *Id.*
[40] *Id.*
[41] For example, Representatives Spanberger, McKinley, Johnson, Axne, and Kato recently circulated a letter to members of Congress requesting signatures to express support for the 340B program, to be sent to the Department of Health and Human Services. AIR340B encouraged members of Congress to withhold their name from this letter to "instead focus on working with stakeholders to develop real policy changes." This blanket discredit of the 340B program in the name of reform is dangerous and will harm patient access to care.
[42] Nicole Longo, *Study after study after study: Contract pharmacy expansion is not aligned in communities 340B is meant to serve*, PHRMA (June 24, 2022).
[43] For example, when running a search for "340B" generally, the first website listed does not direct the reader to the Health Resources and Services Administration's official resources for the program, but instead to a misleading PhRMA-sponsored ad decrying a "broken" 340B system. *Id.*