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PRESS STATEMENT: FOR IMMEDIATE RELEASE

Contact: Peggy.Tighe@PowersLaw.com

**Dozens of Attorneys General and Hundreds of Members of Congress Agree with RWC-340B:
Manufacturers' Actions Against 340B Undermine the Safety Net**

RWC-340B commends the 28 state attorneys general who sent a [letter](#) to Health and Human Services' Secretary Alex Azar on December 14, 2020 demanding action against several drug manufacturers that are restricting access to drug discounts required under the federal 340B program. The letter condemns the manufacturers' actions, calling them an "unlawful refusal to provide critical drug discounts to covered entities."

We couldn't agree more.

The letter states that HHS has the authority and legal basis to "prohibit drug manufacturers from dictating whether and how a covered entity can access 340B pricing for their contract pharmacies." It explains how Congress requires HHS to regulate and oversee compliance of the 340B program.

Shannon Stephenson said, "Hundreds of members of Congress and now dozens of Attorney's General have joined the fight to ensure that manufacturers cannot continue to 'brazenly' undermine the 340B program, a program that has always been critically necessary for the communities we serve, even more so during this pandemic and its aftermath."

In clear and certain language, the AG letter summarizes many of our views,

Each day that drug manufacturers violate their statutory obligations, vulnerable patients and their healthcare centers are deprived of the essential healthcare resources that Congress intended to provide. Drug manufacturers are, without justification, flouting discounted pricing requirements for low-income patients and/or unreasonably conditioning 340B pricing on data demands, depriving such patients of affordable medications to the detriment of the health centers and hospitals that serve these vulnerable communities. During a national public health crisis, these actions are especially egregious and cannot be ignored.

The AG letter applauds HHS for publishing a long-overdue rule for resolving disputes within the 340B program, but notes that, because the rule won't go into effect until January 14, 2021, it cannot remedy the harm that has already occurred. The AGs urge HHS to exercise its existing authority to issue civil monetary penalties against the non-compliant manufacturers.

We completely agree with the AGs. Publication of the alternative dispute resolution rule will neither cure the harms that stem from HRSA's inaction against manufacturers nor deter RWC-340B from continuing to seek relief on behalf of safety net providers and their patients.

The AG letter describes the timing of these drug companies' actions to be especially egregious because "millions of Americans in our respective States are already reeling from the grave health and financial consequences caused by a historic pandemic and unprecedented economic crisis." Stephenson said, "It is especially gratifying that these AGs recognize the 'insult to injury' aspect of these actions. We are on the frontlines of the COVID-19 pandemic and HIV/AIDS epidemic and drug manufacturers do this to us now? It's unconscionable."

The 340B program's stated intent, echoed in the AG letter, is for safety net providers to use their 340B savings to serve more patients and to provide more comprehensive services. The ability of 340B grantees to serve patients through contract pharmacies is a critical part of the 340B program, allowing them to offer services not otherwise covered by payers, to offset the costs of uncompensated or under-compensated care, and to make medications more affordable to patients. The savings and revenue generated through contract pharmacy arrangements enable covered entities to maximize their resources to address the unmet health care needs of their communities without relying on increased taxpayer support.

On October 9, 2020, RWC-340B filed a lawsuit and subsequent motion for a temporary restraining order and preliminary injunction in the United States District Court for the District of Columbia, calling on the U.S. Department of Health and Human Services (HHS) and its Health Resources and Services Administration (HRSA) to require pharmaceutical manufacturers to honor 340B contract pharmacy arrangements.

We asked the court to enforce the covered entities' rights to purchase covered outpatient drugs via contract pharmacies at 340B discounts by ordering the agency to refund overpayments owed to the covered entities; order the Secretary to use his authority to impose civil monetary penalties upon the named drug manufacturers; revoke the pharmaceutical pricing agreement (PPA) of any pharmaceutical manufacturer that does not offer drugs at 340B discounts when ordered via contract pharmacy arrangements; and exclude such manufacturer from the Medicaid and Medicare Part B programs.

The complaint and subsequent filings call on the Secretary to protect the 340B safety net against these manufacturer actions that could force safety net providers to scale back or eliminate services when these front-line health care providers are fighting both the HIV/AIDS epidemic and COVID-19.

RWC-340B is a national association of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the 340B program. Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS. Many of the association's Ryan White members are also Federally Qualified Health Centers (FQHCs), FQHC "look-alikes", sexually transmitted disease clinics, and safety net hospitals.