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PRESS STATEMENT: FOR IMMEDIATE RELEASE

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RWC-340B and 340B Grantee Plaintiffs File Lawsuit to Protect 340B Contract Pharmacy Program from Manufacturer Attacks That Are Undermining Patient Care and Public Health

Washington, D.C. – On October 9, 2020, Ryan White Clinics for 340B Access (RWC-340B) and two 340B grantee clinics filed a lawsuit in the United States District Court for the District of Columbia to protect 340B entities' longstanding right to dispense their drugs through contract pharmacies under the federal 340B drug pricing program as mandated by statute and regulation.

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.

The Complaint for Declaratory and Injunctive Relief was filed to compel action by the U.S. Department of Health and Human Services (HHS) and its Health Resources and Services Administration (HRSA). The complaint asserts that four pharmaceutical manufacturers have flouted the 340B statute and regulation by openly refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements. The drug manufacturers cited in the complaint are Eli Lilly and Co., Sanofi-Aventis US LLC, AstraZeneca PLC, and Novartis Pharmaceuticals.

Cempa Community Care in Chattanooga, Tennessee is one of the plaintiffs in the lawsuit. Shannon Stephenson, CPA, MBA, CEO of Cempa, and president of RWC-340B said, "We are filing this lawsuit because these drug manufacturers' unilateral policies will decimate the ability of HIV clinics and other safety net providers to care for vulnerable patients." Just this week, RWC-340B released "Value of Ryan White Providers and Impacts Associated with Resource Reduction," a [white paper](#) and [fact sheet](#) detailing the long-term consequences for patient care and public safety of any reductions in resources to Ryan White clinics.

Another named plaintiff in the complaint is Matthew 25 AIDS Services. Inc, a Ryan White service provider with three locations in Kentucky and one in Indiana. According to Cyndee Burton, R.N., CEO of Matthew 25, "We need HHS to take immediate action against these companies because, if it does not, our organization will be forced to cut services vital to the health of our patients and community."

The 340B program's stated intent 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.

The complaint calls for a declaration that covered entities are entitled to purchase covered outpatient drugs through contract pharmacies at 340B discounts. It also asks the U.S. District Court to direct HHS Secretary Alex Azar to:

- promulgate dispute resolution regulations within 60 days of the Court's order;
- enforce the covered entities' rights to purchase covered outpatient drugs via contract pharmacies at 340B discounts by ordering them to refund overpayments owed to the covered entities;
- 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 emphasizes that inaction by HHS and HRSA has deprived the nation's most vulnerable individuals of crucial health services in a manner that causes irreparable harm contrary to the public interest at a time when our country is in the middle of a national public health emergency.

Unless the Secretary acts to protect the 340B safety net, the complaint alleges, these manufacturer actions 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.

The filed complaint can be found on the RWC-340B website and by clicking [HERE](#).