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PRESS STATEMENT: FOR IMMEDIATE RELEASE

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RWC-340B and 340B Covered Entity Plaintiffs Ask Secretary of HHS to Immediately Enforce Covered Entities' Rights Under 340B Statute

Washington, D.C. – On November 23, 2020, Ryan White Clinics for 340B Access (RWC-340B) and five 340B providers filed a motion in the United States District Court for the District of Columbia asking the Court to order the Secretary of Health and Human Services (HHS), Alex Azar, to immediately enforce covered entities' longstanding right to dispense their drugs through contract pharmacies under the federal 340B drug pricing program. This motion is the next step in the lawsuit filed in October against HHS and the Health Resources and Services Administration (HRSA) for failing to take action against Eli Lilly and Co., Sanofi-Aventis US LLC, AstraZeneca PLC, and Novartis Pharmaceuticals for flouting the 340B statute and regulation by refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements.

The same day, an amended complaint was filed to add three additional covered entity plaintiffs to the lawsuit: Little Rivers Health Care Inc. (Wells River, Vermont), FamilyCare Health Center (Scott Depot, West Virginia), and Springhill Medical Center (Springhill, Louisiana).

Shannon Stephenson, CPA, MBA, CEO of Cempa, and president of RWC-340B, both plaintiffs in the lawsuit said, "HHS and HRSA's inaction opens the door for other drug manufacturers to implement similar policies and refuse to provide 340B pricing at contract pharmacies. I am deeply concerned that other manufacturers will follow suit, which would be devastating to the operations of HIV clinics and other safety-net providers, jeopardizing the health of our vulnerable patient population."

The temporary restraining order and preliminary injunction asks the U.S. District Court to direct Secretary Azar to:

- promulgate administrative dispute resolution regulations within 60 days of the Court's order; and
- enforce the covered entities' rights to purchase covered outpatient drugs via contract pharmacies at 340B discounts.

The Plaintiffs rely on 340B savings to provide drugs to financially needy patients at little or no cost. For example, Plaintiff Springhill Medical Center offers a drug discount program that allows eligible patients to purchase retail, self-administered drugs at low prices at its contract pharmacies. If a patient qualifies for the program, the patient pays Springhill's 340B cost for the drug plus a modest dispensing fee to the pharmacy. The motion recounts examples of

patients leaving the pharmacy without a medication produced by one of the four drug manufacturers because the drug was no longer offered at the 340B price, and the patient could no longer afford it. This problem will only be exacerbated without immediate action by HHS.

For many covered entities, the loss of 340B discounts threatens their ability to provide critical health services, which is harmful to their patients and threatens their financial viability. The motion emphasizes that inaction by HHS and HRSA has deprived the nation's most vulnerable individuals of crucial health care and is contrary to the public interest at a time when our country is in the middle of a national public health emergency. Without 340B savings, the Plaintiffs will need to scale back on important and life-saving health care and support programs currently offered to patients. For Plaintiffs Matthew 25, Little Rivers, and FamilyCare, examples of these services include case management services, transportation assistance, insurance enrollment, linkage to affordable housing, food access, patient care advocacy, in-home support, and education for chronic health care conditions. These services are generally not paid for by insurance or through grant funds but are critical in preventing patients' health from deteriorating.

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 covered entities to dispense drugs to patients through contract pharmacies is a critical component of the 340B program, allowing them to make medications more affordable to patients, offer services not otherwise covered by payers, and to offset the costs of uncompensated or under-compensated care. All of this is accomplished without relying on increased taxpayer support. The motion points out that the harm to covered entities and their patients is already occurring and will only worsen unless the Secretary acts immediately to enforce the contract pharmacy guidelines.

The [amended complaint](#) and [motion for immediate temporary relief](#) can be found on the RWC-340B website and by clicking [HERE](#).