THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al., Plaintiffs, v. XAVIER BECERRA, Secretary of Health & Human Services, et al., Defendants.	Case No. 1:21-cv-81-SEB-MJD

BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs seek to eviscerate the 340B drug discount program ("340B Program"), which provides discounts to safety-net providers known as "covered entities," many of which cannot afford to operate their own pharmacies or cannot fulfill their patients' pharmaceutical needs through their own pharmacies. Contract pharmacies are the only way that many covered entities—including Amici Little Rivers Health Care, Inc. ("Little Rivers") and FamilyCare Health Centers ("FamilyCare") and many of the members of the National Association of Community Health Centers ("NACHC") and Ryan White Clinics for 340B Access ("RWC-340B")—can obtain 340B discounted drugs. Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively "Lilly") attempt to create a boogeyman of for-profit contract pharmacy companies by misrepresenting how covered entities' 340B contract pharmacy arrangements actually work. No party to this litigation is a 340B covered entity, and Amici, which are covered entities and their membership organizations, submit this brief to inform the Court of how contract pharmacy arrangements enable safety-net health care providers to receive critically necessary discounts on outpatient drugs. If Lilly succeeds in this litigation, covered entities that operate on narrow margins and serve low-income, rural, and medically fragile patients will be shut out of the 340B Program because they will have no way to distribute drugs to their patients. This is Lilly's endgame—to increase its profits by excluding from the 340B Program the very health care providers Congress intended to benefit when it enacted the 340B Program.

Plaintiffs are obligated to sell discounted drugs to nonprofit covered entities, and covered entities have relied on contract pharmacy arrangements for over twenty years to distribute drugs to their patients. Many covered entities do not operate in-house pharmacies because the requirements to obtain and maintain a pharmacy license are complex and operating a pharmacy

is expensive. One of the largest costs of opening a pharmacy—acquiring the initial drug inventory at standard prices—is precisely the type of expenditure the 340B Program is designed to reduce. Many covered entities wisely choose not "to expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("Contract Pharmacy Notice").

Both the longstanding history of the 340B Program and the welfare of safety-net providers were compromised when Lilly unilaterally advanced a self-serving reinterpretation of the 340B statute and led other drug companies on a campaign to undermine the 340B Program by cutting off discounts on drugs shipped to covered entities' contract pharmacies. After having failed to convince the Department of Health and Human Services ("HHS") to bless its unlawful and unprecedented acts,[1] and with both houses of Congress evidently against it,[2] Lilly turned to the judiciary to condone its unlawful behavior.[3] Lilly currently seeks to gut this vital federal drug pricing program by asking the Court to vacate the 340B Administrative Dispute Resolution ("ADR") regulations, which provide the sole forum for covered entities to challenge drug company overcharges, and override a clear and well-reasoned HHS cease-and-desist letter finding that Lilly is in violation of the 340B statute and commanding it to cease its unlawful

[1] *See, e.g.*, Letter from Robert P. Charrow to Anat Hakim (Sept. 21, 2020), ECF No. 19-5 at 60–61; HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, ECF No. 19-5 at 38–45 ("Advisory Op.").

[2] *See* Letter from Members of Congress to Alex M. Azar II at 1 (Sept. 14, 2020), ECF No. 19-5 at 47–48; Letter from United States Senators to Alex M. Azar II at 1 (Sept. 17, 2020), https://www.baldwin.senate.gov/imo/media/doc/20200917%20Letter%20to%20HSRA_340B%20Enforcement_Final.pdf; Letter from House Committee on Energy & Commerce to Alex M. Azar II at 1 (Sept. 3, 2020), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/HHS.2020.9.3.%20Final.pdf.

[3] Lilly's litigation strategy is not limited to this suit. *See, e.g.*, Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1, *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020) (stayed).

behavior.[4]

The nation's healthcare safety-net and countless underserved communities will continue to be significantly harmed if the Court ratifies Lilly's refusal to sell its 340B drugs to covered entities that dispense through contract pharmacies. This case impacts *thousands* of covered entities delivering health care to *millions* of Americans, many of whom are among our most medically underserved and vulnerable. To divert attention from its own profit motive, Lilly attempts to villainize large chain pharmacies and mischaracterizes them as de facto covered entities. But contract pharmacies are not covered entities, do not function as covered entities, and do not purchase 340B discounted drugs. Contract pharmacies are simply the sites where patients pick up drugs prescribed and purchased by covered entities. Lilly cannot dismiss covered entities and their patients by shining the spotlight on for-profit retail pharmacies any more than it can hide the true motivation behind this suit in meritless arguments against the legality of over twenty-four years of well-recognized practice within the U.S. drug distribution system and regulations that were ten years in the making and crucial for covered entities to vindicate their rights under the 340B statute. The truth is that Lilly's unlawful acts damage covered entities that treat the most vulnerable patients and are motivated by Lilly's desire to increase profits.

Lilly would have the Court rewrite the 340B statute to exclude many covered entities from participating in the 340B Program and simultaneously deprive covered entities of their one and only statutory remedy against Lilly. In essence, Lilly wants the lucrative benefit of its Pharmaceutical Pricing Agreement with HHS—having its products covered under Medicare and Medicaid—without the associated burden of offering 340B pricing to covered entities. Without access to 340B pricing and contract pharmacy distribution systems, covered entities will

[4] Letter from Diana Espinosa to Derek L. Asay (May 17, 2021) ("May 17 letter"), ECF No. 103-17.

inevitably be forced to cut services and staff that are supported by 340B discounts, and patients will lose access to low-cost medications, leaving many to face the potentially life-threatening choice of forgoing their prescriptions altogether.

No covered entity is a party to this action, but all covered entities will be negatively impacted if the Court grants Lilly's motion to vacate HHS's May 17 cease-and-desist letter and the ADR Rule. Amici have a significant interest in the continued viability of the 340B Program, including the ADR process, because three of the Amici have ADR petitions currently pending, several Amici have filed suit to compel the Secretary to implement ADR, and one court has held that ADR provides the sole forum for covered entities to challenge drug company overcharges.[5] Amici therefore support the Defendants' motion to dismiss and motion for summary judgment, ECF No. 88, and oppose Plaintiffs' cross-motion for summary judgment ECF No. 89 ("Lilly Mot. SJ"). Simply put: Amici urge the Court to protect the nation's safety-net as Congress intended.

ARGUMENT

I. Lilly Misrepresents Contract Pharmacy Relationships, Which Have Been a Critical Component of the 340B Program for More Than Two Decades

Lilly mischaracterizes the contract pharmacy model as a massive forced giveaway to large, corporate chain pharmacies. Lilly Mot. SJ at 25, 29, 34-35. But contract pharmacies do not purchase 340B drugs. The covered entity buys drugs at 340B discounts and directs the drugs to be shipped to a contract pharmacy, which stores and dispenses the drugs to the covered entity's patients, and, importantly, remits third-party payments and/or patient co-payments to the

[5] NACHC filed ADR claims on behalf of 225 federally qualified health centers ("FQHCs") on January 13, 2021; Little Rivers filed its petition on February 4, 2021; and FamilyCare filed its petition on February 12, 2021. On November 23, 2020, Little Rivers and FamilyCare filed suit to compel promulgation of ADR regulations. *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020) (stayed). NACHC filed a similar suit on October 21, 2020. *NACHC v. Azar*, No. 1:20-cv-03032 (D.D.C. filed Oct. 21, 2020) (stayed).

covered entity, minus the pharmacy's fee, while providing needed pharmaceutical and convenience to often underserved communities.

Lilly asserts that HHS "commands" it "to sell outpatient drugs at 340B discounts to contract pharmacies" and "provide discounts to an unlimited number of for-profit retail chains." Lilly Mot. SJ at 12, 15. HHS has not required Lilly to "sell" drugs or "provide discounts" to contract pharmacies. The sale is to the covered entity, which is the entity that receives savings and revenue contemplated by the 340B statute. Lilly cites a 2014 HHS Office of Inspector General ("OIG") report on contract pharmacies several times but neglects to mention that OIG confirmed that "the *covered entity purchases* . . . the drug at the discounted 340B price and has it delivered to the contract pharmacy." HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014) ("2014 HHS-OIG Report") (emphasis added)[6]; *see also* Contract Pharmacy Notice, 61 Fed. Reg. at 43,552 ("The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity."); Lilly Mot. SJ 28 n.4, 32, 40 (discussing 2014 HHS-OIG Report). The contract pharmacy is merely the dispensing location, contrary to Lilly's characterization.

Typically, health care providers purchase a pharmaceutical manufacturer's drugs from third-party wholesalers. A covered entity will establish a 340B account with the wholesaler, under the covered entity's name, enabling the covered entity to purchase 340B discounted drugs. If the covered entity has one or more contract pharmacies, the wholesaler creates a "bill-to, ship-to" arrangement in which the drugs are billed to the covered entity and shipped to the contract pharmacy. *See* HRSA, *FAQs, What is a "ship to bill to" arrangement?*[7] Wholesalers do not establish 340B accounts for contract pharmacies, which are not eligible for these discounts.

[6] https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp
[7] https://www.hrsa.gov/opa/faqs/index.html/

Lilly also takes issue with the "replenishment model" in which a contract pharmacy dispenses a non-340B drug to a covered entity's patient from the pharmacy's inventory, and the covered entity then places a replenishment order for the same drug at 340B discounted prices. Lilly mischaracterizes replenishment orders as "demands for 340B drugs from manufacturers . . . made by a contract pharmacy." Lilly Mot. SJ at 28 n.4 (citing 2014 HHS-OIG Report, at 5), 32. But any "demand" comes from the covered entity ordering the replenishment drug. The replenishment model is merely an accounting tool, which reconciles all 340B and non-340B sales after the fact and thereby ensures that 340B discounted drugs are dispensed only to 340B-eligible patients. Far from causing diversion to ineligible patients, the replenishment model's reconciliation process serves as an accurate and effective means to protect *against* diversion.

The alternative to the replenishment model is for the pharmacy to maintain a supply of drugs that the covered entity has pre-purchased at 340B discounts. *See* 2014 HHS-OIG Report at 5 (discussing "pre-purchased inventory model"). The pre-purchased inventory model, however, is a poor fit for most 340B contract pharmacy arrangements for at least two reasons. First, a pre-purchased inventory is just that—an expense to the covered entity in advance of a potential prescription. Such inventory would go to waste if it expires and is never dispensed. Second, the pharmacy often does not know whether the individual who presented the prescription is a patient of a covered entity at the time the prescription is dispensed. Without that real-time information, the pharmacy cannot effectively use a pre-purchased 340B inventory. Even if that information were available, a pre-purchased inventory model introduces an element of risk because it requires a busy pharmacist or technician to select the correct inventory when dispensing. In contrast, under the replenishment model, the pharmacy fills all prescriptions from its inventory, and that inventory is replenished with 340B drugs purchased by the covered entity only to the

extent that the contract pharmacy filled prescriptions for the covered entity's own patients, as determined outside the bustle of the pharmacy environment.

The replenishment model also helps prevent duplicate discounts. The 340B statute protects manufacturers from providing a 340B discount and a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). To comply with this requirement, some covered entities "carve out" Medicaid patients, which means that these covered entities do not dispense 340B discounted drugs to any Medicaid patients. *See* HRSA, *Duplicate Discount Prohibition*.[8] Patients are often retroactively enrolled in Medicaid, and an individual's Medicaid status may not be known at the time the prescription is filled. By the time replenishment occurs, the covered entity will have updated information on its patients' Medicaid status. The replenishment model thus helps ensure that manufacturers are protected from paying duplicate discounts.

There is nothing nefarious or unusual about replenishment inventory systems. As the HHS OGC explained, replenishment is a common inventory management tool in many enterprises. Advisory Op. at 6 n.6. Moreover, the Supreme Court has endorsed an inventory replenishment system as compliant with a statutory scheme analogous to 340B. In *Abbott Laboratories v. Portland Retail Druggists Ass'n, Inc.*, the Supreme Court analyzed whether hospital purchases through group purchasing organizations are consistent with federal antitrust law, which permits certain health care providers to purchase discounted drugs for some patients (as does 340B). *Abbott Laboratories v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 3-4 (1976). The Supreme Court *recommended* a replenishment system in which providers manage their inventories according to general accounting principles by adjusting inventories at a later

[8] https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html. Other covered entities "carve in" Medicaid patients by furnishing 340B discounted drugs to Medicaid patients and then informing the state Medicaid program of the 340B purchases. *Id.*

date. *Id*. at 20-21.

II. Lilly Seeks to Undo a Statutorily Required Program In which It Participated for More Than Two Decades

Lilly not only asks this Court to reverse the HHS May 17 letter, but also to shield its unlawful conduct by vacating the ADR Rule. Such an outcome would upset more than two decades of practice, free Lilly from its legal and contractual obligations, run counter to Congress's intentions for covered entities, and significantly damage the viability of the nation's health care safety net. Until Lilly and other drug companies unilaterally violated federal law and their contracts with HHS, covered entities relied on contract pharmacies to best serve their patients' pharmaceutical needs, consistent with Congress's intent and HHS's longstanding interpretations of both Sections 330 and 340B of the Public Health Service Act.[9] Congress intended drug manufacturers to honor their statutory and contractual obligations to provide discounted drugs to covered entities, allowing covered entities to rely on 340B savings and revenue to fund crucial aspects of their safety-net operations.

Despite honoring contract pharmacy arrangements for at least twenty-four years, in the summer of 2020, Lilly led the charge in cutting off covered entity access to 340B pricing by either refusing outright to honor contract pharmacy arrangements or imposing onerous conditions that effectively eliminated covered entities' access to drugs at 340B pricing. HRSA, *Manufacturer Notices to Covered Entities* (July 2020);[10] Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020) ("Lilly LDP").[11] Other drug

[9] FQHCs receive, or are eligible to receive, federal grant funding under Section 330 of the Public Health Service ("PHS") Act to serve four general patient populations: residents of federally-designated medically underserved areas; homeless populations; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1).

[10] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

[11] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf

companies took strikingly similar actions to halt 340B pricing on drugs shipped to contract pharmacies, effective during September and October 2020. *See* Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020);[12] Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020); [13] Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[14] Three months later, Novo Nordisk, Inc. and United Therapeutics Corporation likewise adopted limitations similar to Lilly's. *See* Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020);[15] Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[16] Hundreds of other drug company participants continue to honor their contract pharmacy obligations, consistent with established practice, but these drug companies may be emboldened to follow Lilly's and its compatriots' lead if the May 17 letter and ADR Rule are invalidated.

HHS, through its Health Resources and Services Administration ("HRSA"), has consistently interpreted the 340B statute to require drug companies to sell discounted drugs for shipment to covered entities' contract pharmacies. *See, e.g.*, Contract Pharmacy Notice, 61 Fed. Reg. at 43,549–50 ("There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. . . . Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities."); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed.

[12] https://www.rwc340b.org/wp-content/uploads/2020/12/Sanofi-340B-Program-Integrity-Initiative-Notification-7.2020.pdf.
[13] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.
[14] Novartis has since retreated, in part, by shipping to federal grantees' contract pharmacies and to hospital contract pharmacies within a 40-mile radius. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020).
[15] https://bit.ly/2NQlzpc.
[16] https://bit.ly/3pNrfgZ.

Reg. 10,272, 10,275 (Mar. 5, 2010). HHS confirmed this longstanding interpretation in its May 17 letter to Lilly, noting that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities."[17]

In 1996, HRSA acknowledged that covered entities were already using contract pharmacies to dispense 340B drugs. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550 ("[A] number of large organizations" were using a contract pharmacy model, which was developed "as early as 1993"). At that time, HRSA explained why contract pharmacies are essential for the "many covered entities" that "do not operate their own licensed pharmacies":

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Contract Pharmacy Notice, 61 Fed. Reg. at 43,549.

When Congress created the 340B Program in 1992, it had every reason to anticipate that FQHCs, Ryan White Clinics ("RWCs"), and other covered entities would use pre-existing authority and flexibility to provide drugs to their patients through contracts with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy. As community and patient-based providers, FQHCs necessarily have flexibility to determine how best to meet the needs of their patients and communities, but FQHCs must—and do—use any 340B savings and revenue (as well as any other income generated from grant-supported activities) to further their health center projects. 42 U.S.C. § 254b(e)(5)(D). FQHCs have long

[17] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf.

had an express grant of authority to provide their services, including pharmacy services, either directly through their own staff or through contracts or cooperative arrangements with other entities, or a combination thereof. *See*, *e.g.*, Public Health Service Act, Pub. L. 78-410, § 330(a), 58 Stat. 682, 704 (1944) ("For purposes of [Sec. 330], the term 'health center' means an entity that serves a population that is medically underserved . . . either through the staff an (sic) supporting resources of the center or through contracts or cooperative arrangements"); Special Health Revenue Sharing Act of 1975, Pub. L. 94-63, § 501, 89 Stat. 304, 342–43 (1975) (amending § 330(a) of the Public Health Service Act to read: "For purposes of this section, the term 'community health center' means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides" health care services, including "pharmaceutical services").

Lilly argues that the agency relationship between covered entities and their contract pharmacies is a fiction. Lilly Mot. SJ at 27-32. But Lilly and other manufacturers are currently selling drugs to covered entities to be distributed through their contract pharmacies, albeit at much higher prices than the 340B discounted price. Most covered entities have discontinued purchasing drugs through their contract pharmacies from Lilly and other manufacturers that have adopted policies similar to Lilly's. Other covered entities continue to purchase drugs from Lilly and other manufacturers with similar policies through contract pharmacy arrangements, but the covered entities are buying those drugs at much higher prices. Lilly, therefore, recognizes that an agency relationship exists when it is able to sell drugs to a covered entity through its contract pharmacy at non-discounted prices.

Contract pharmacy arrangements are not unique to the 340B Program. They are a well-established means for non-profit health care providers to dispense drugs to their patients. In

2010, the Federal Trade Commission ("FTC") recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies to dispense discounted drugs within the parameters of the Robinson-Patman Antidiscrimination Act ("Robinson-Patman Act") and the Non-Profit Institutions Act ("NPIA").[18] *See* Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[19] Both the 340B statute and NPIA provide for the purchase, and restrict the resale, of discounted drugs by non-profit healthcare entities. 15 U.S.C. § 13c; 42 U.S.C. § 256b(a)(5)(B). The NPIA provides an exemption from antitrust laws for certain resales of discounted drugs purchased by a non-profit hospital. The FTC examined and approved the exact contract pharmacy model at issue here, with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the NPIA, not the 340B statute. *Id.*

The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). When HHS formally recognized the contract pharmacy model in 1996, it acknowledged that drug manufacturers were already, either directly or through wholesale distributors, shipping 340B drugs purchased by covered entities to contract pharmacies. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550. All but a handful of the hundreds of drug manufacturers participating in the 340B Program continue to do so.

Covered entities have long used 340B Program savings and revenue as Congress

[18] Congress enacted the Robinson-Patman Act to protect small businesses from larger businesses using their size advantages to obtain more favorable prices and terms from suppliers and to prohibit discrimination in the sale of fungible products, including drugs. 15 U.S.C. §§ 13–13b. The Robinson-Patman Act added the NPIA, which permits manufacturers to sell discounted medical supplies, including drugs, to certain non-profit entities by exempting "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" from the Robinson-Patman Act's prohibitions against price discrimination. *Id*. § 13c.

[19] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

intended: to enable and expand health care services to populations desperately in need of care, including populations affected by a public health crisis or to serious chronic conditions. Money saved or generated by covered entities through the 340B Program covers the cost of medications for uninsured or underinsured patients, and funds expanded access to necessary medical and crucial enabling services. These services include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

Lilly attacks the ADR Rule and HHS's May 17 cease-and-desist letter to prolong its unprecedented and self-serving refusal to provide covered entities access to drugs at 340B discount pricing in violation of federal law. Lilly ignores that, for decades, covered entities have, as Congress intended, structured their safety-net operations in reliance on 340B discounts, which are often accessible only through contract pharmacies.

III. Granting Lilly's Motion for Summary Judgment Will Inflict Significant Harms on Covered Entities and Their Patients and Compromise Vital Safety-Net Services Throughout the Nation

Nowhere in Lilly's court filings does Lilly discuss the vast uncompensated or undercompensated safety-net services provided by covered entities by virtue of 340B savings and revenue, much of which is attainable only from contract pharmacy arrangements. Covered entities are on the front lines of caring for our nation's most vulnerable patients and use 340B discounts to support their missions of increasing access to care, improving health outcomes, and fortifying the nation's safety net. Lilly seeks to upend the 340B Program by removing access to discounted drugs for covered entities that must rely on contract pharmacies. Denying 340B pricing is antithetical to Congress's design of the 340B Program, which is intended to expand care to patient populations served by safety-net providers. Without 340B savings, covered

entities cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services" to those patients. H.R. Rep. No. 102–384(II), at 12 (1992). Indeed, Lilly's deprivation of 340B Program benefits has already harmed covered entities, their patients, and their broader communities, because covered entities have had to reduce critical services supported with 340B-derived funding. Eliminating 340B contract pharmacy arrangements will directly and indirectly harm our nation's most vulnerable communities by denying them affordable medications, critical health care, and related services that covered entities are able to provide through 340B Program participation. Other drug companies will likely believe the Court has broadly authorized drug manufacturers to stop shipping covered entity-purchased drugs to contract pharmacies. Such an outcome could cause many safety-net providers to shut their doors. These outcomes would be tragic at any time, but after over a year of covered entities serving on the front lines of the COVID-19 pandemic, they are unconscionable.

A. Covered Entities Use 340B Contract Pharmacy Savings to Provide Deep Discounts on High-Cost Medications to Eligible Patients

The 340B Program enables covered entities to offer discounted drugs to financially needy patients. For example, FamilyCare, a West Virginia-based FQHC, has a drug discount program that allows indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17.[20] Because 340B discounted prices are significantly lower than non-340B prices, patients who relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30. Vermont-based FQHC Little Rivers operates a similar drug discount program that

[20] The following declarations are included in the record as exhibits in Amici's Brief in Support of Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, ECF No. 75 (Mar. 9, 2021): Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (ECF No. 75-3, "Glover Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (ECF No. 75-4, "Dickerson Aff."). The declarations were originally submitted as exhibits in a lawsuit by three Amici against HHS, Mot. for TRO and Prelim. Inj., RWC-340B v. Azar, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24, (stayed Jan. 13, 2021).

subsidizes the costs of drugs for financially needy patients. Auclair Aff. ¶ 18[21] (patients pay a percentage of costs, including $0, on an income-based sliding scale). Little Rivers, and other covered entities, or their patients, are now bearing the increased cost of Lilly's drugs for prescriptions filled at contract pharmacies. Auclair Aff. ¶¶ 23, 27, 30, 31–34 (Little Rivers will struggle financially if forced to continue incurring these increased costs).

The inability of financially needy patients to access drugs at 340B prices is particularly problematic for insulin-dependent diabetics, whose survival depends on daily access to insulin and who are faced with increasing insulin prices. The astronomical increase in the price for insulin products in recent years is well documented. *See, e.g.*, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Senate Report, 6 ("The WAC [wholesale acquisition cost] prices of long- and short-acting insulins have risen steeply.")[22]; American Diabetes Association, Diabetes Care, Insulin Access and Affordability Working Group: Conclusions and Recommendations, Jan. 2018 ("The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013").[23] For example, between 2009 and 2019, the list price for a 10-milliliter vial of Humalog, a fast-acting insulin produced by Lilly, rose from $93 to almost $275, a 295% increase. Rachel Gillett & Shayanne Gal, *One Chart Reveals How the Cost of Insulin Has Skyrocketed in the US, Even Though Nothing About it Has Changed*, Business Insider (Sept. 18, 2019).[24] During the same period, U.S. inflation was only 22%. U.S. Bureau of Labor Statistics, *CPI Inflation Calculator*.[25]

Little Rivers reviewed the difference in the 340B and non-340B price for one of Lilly's

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[21] The Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. is submitted as Exhibit A to this brief (Ex. A, "Auclair Aff.").
[22] *Available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL).pdf
[23] *Available at* https://care.diabetesjournals.org/content/41/6/1299.
[24] https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9.
[25] https://www.bls.gov/data/inflation_calculator.htm ($1 in January 2009 for buying power in December 2019).

insulin products, Humalog® KwikPen. On May 23, 2021, the 340B price for this product was only $0.16, but the average wholesale price was $636.48 and the wholesale acquisition cost was $636.48. Auclair Aff. ¶ 35. Under the patient assistance programs provided by FamilyCare and Little Rivers, and prior to Lilly's new policy on contract pharmacies, a financially needy diabetic patient was able to fill a prescription for Humalog® KwikPen based on the 340B pricing, but now faces a price that is thousands of times higher and will continue to rise if insulin prices continue on their current trajectory. Lilly is increasing the price for insulin at the same time it refuses to offer 340B discounts to covered entities that choose to dispense insulin to their patients through contract pharmacies. Lilly's policy is not only financially harmful; it can impact a patient's health. The American Diabetes Association has reported that the high cost of insulin may impact patients' health because patients faced with these high costs "may be less adherent to recommended medication dosing and administration, resulting in harm to their health." American Diabetes Association, Diabetes Care, Insulin Access and Affordability Working Group: Conclusions and Recommendations, Jan. 2018.[26] Covered entities like Little Rivers have absorbed these increased costs to date, but they cannot afford to do so indefinitely.

Through contract pharmacies, uninsured and under-insured covered entity patients fill prescriptions at convenient locations, often at a greatly reduced or no cost. FQHCs and RWCs care for increasing numbers of patients with chronic conditions that are managed primarily through prescription drugs. From 2013 through 2018, the number of FQHC patients with HIV increased 66% (from 115,421 to 191,717), patients with substance use disorders increased 80% (from 506,279 to 908,984), and patients with depression, mood and anxiety disorders increased by 72% (from 2,740,638 to 4,724,691). Sara Rosenbaum et al., *Cmty. Health Ctrs. Ten Years*

[26] *Available at* https://care.diabetesjournals.org/content/41/6/1299.

After the Affordable Care Act: A Decade of Progress and the Challenges Ahead, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020).[27]

With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients lost access to lifesaving medications. Lilly has made a tiny concession to allow covered entities to use *one* contract pharmacy if they do not operate their own in-house pharmacies, but Lilly's policy does little to aid many indigent covered entity patients who cannot access that one pharmacy.[28] Covered entities serving remote or rural areas in particular have lost access to discounted drugs over large geographic areas, making it nearly impossible for their patients to access affordable medications.[29] *See, e.g.*, Simila Aff. ¶ 27 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles."); Francis Aff. ¶ 19 ("Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships."); Chen Aff. ¶ 21 ("NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel [35-180 miles] (one-way trip), to reach the closest of NCHC's in-house pharmacies").

FamilyCare serves a very large area in rural West Virginia and uses contract pharmacy arrangements across its service area to meet its patients' pharmaceutical needs. Glover Aff. ¶ 19 (noting that its contract pharmacy network enables FamilyCare to provide patients discounted

[27] https://www.rchnfoundation.org/wp-content/uploads/2020/03/FINAL-GG-IB-61-ACA-CHC-3.4.20.pdf.
[28] Moreover, implementation of this exception has taken several months for some covered entities.
[29] The record contains affidavits from an ADR petition filed by Amicus NACHC, on behalf of 225 FQHC covered entities, against Lilly and other manufacturers for unlawful overcharging. The following NACHC declarations were submitted as part of Exhibit D to Plaintiff's Motion for PI, ECF No. 19-5: Declaration of Donald A. Simila, Upper Great Lakes Health Center, Inc. ("Simila Aff."); Declaration of Lee Francis, Erie Family Health Center ("Francis Aff."); Declaration of Kimberly Christine Chen, North County HealthCare, Inc. ("NCHC") ("Chen Aff."); Declaration of Ludwig M. Spinelli, Optimus Health Care Inc., ("Spinelli Aff."); Declaration of J.R. Richards, Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus ("Richards Aff."); Declaration of Heather Rickertsen, Crescent Community Health Center ("Rickertsen Aff."); and Declaration of Jackson Mahaniah, Lynn Community Health Center ("Mahaniah Aff.").

drugs near their homes); *see also* Simila Aff. ¶ 26 ("a single pharmacy for all our patients would severely limit our patients access to life saving medications"). Hudson Headwaters Health Network ("HHHN"), an FQHC based in upstate New York, provides care to over 90,000 patients across a 7,000 square-mile area that HHS designated as a Health Professional Shortage Area. Slingerland Aff. ¶ 10. HHHN's service area has only one major road that traverses from North to South, other roads are often impassable in the winter, and the service area is generally not served by public transport. Slingerland Aff. ¶ 10.[30] HHHN uses contract pharmacies to minimize the many "geographic and logistical barriers" that its patients face to access affordable medications. Slingerland Aff. ¶ 10. FQHCs have an obligation to ensure that all patients have equal access to services. 42 U.S.C. § 254b(k)(3)(A). Meeting that obligation is logistically impossible if only one pharmacy serves a large service or "catchment" area.

Lilly has also made a meaningless exception to allow contact pharmacies to offer insulin through contract pharmacies, subject to several conditions not stated in the 340B statute:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;
- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
- No insurer or payer is billed for the Lilly insulin dispensed; and,
- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Lilly LDP. However, these four requirements make the exception completely unworkable and legally suspect. Lilly's exception requires that the pharmacy not charge a dispensing fee for providing the drug. This requirement could subject Amici to violations of the federal law that

[30] The Declaration of D. Tucker Slingerland, M.D. is submitted as Exhibit B to this brief (Ex. B, "Slingerland Aff.")

prohibits offering financial inducements to patients.[31] Moreover, it is entirely impractical to expect a pharmacy to fill a prescription for free. Thus, Amici cannot use Lilly's insulin "exception" for their patients.

The affidavit from Optimus Health Care Inc. provides just a few examples of the negative impact Lilly's actions have already had on covered entity patients. Spinelli Aff. ¶ 12. One Optimus patient, who is visually impaired and does not speak English, previously paid only $15 a month for Lilly insulin prior to Lilly's new policy. Spinelli Aff. ¶ 23. When she attempted to refill her prescription on September 4, 2020, the price was $270. *Id*. An Optimus patient with gestational diabetes relied on Lilly insulin to help manage her high-risk pregnancy, but twenty-seven weeks into her pregnancy, Lilly's new policy resulted in a price of $320 for her insulin, which she could not afford. Spinelli Aff. ¶ 24. These patients are left without these crucial safety-net protections due to Lilly's policy.

Moreover, in response to Lilly's actions, covered entities have generally struggled to switch patients' medications to affordable alternatives, especially given that certain medications do not have an approved generic formulation. Chen Aff. ¶ 34; Francis Aff. ¶¶ 24, 26. Many patients want to continue taking familiar medications or are fearful of the negative health impact of changing to a new medication. Richards Aff. ¶ 23; Francis Aff. ¶ 26. Additionally, before a patient can change medications, a medical provider must "review the patient chart, consider comorbidities, and assess the appropriate dosing for the substitute medication." Francis Aff. ¶ 26. If the new drug treatment has different dosing, this could require significant patient education

[31] Offering inducements to Medicare or Medicaid beneficiaries can subject a provider or supplier of services that are payable by Medicare or Medicaid to Civil Monetary Penalties. 42 U.S.C. § 1320a-7a(a)(5). Routinely providing drugs free of charge to all patients, regardless of ability to pay is not an exception to the inducement prohibition. 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1003.110. Such a scheme could also be viewed as a violation of the antikickback statute insofar as it causes Medicare or Medicaid beneficiaries to "self-refer" to the participating pharmacy. 42 U.S.C. § 1320a-7b(b)(1).

and "provider troubleshooting" to avoid adverse health outcomes. *Id*. The administrative and clinical burden of largescale shifts in patient medication regimes presents an unanticipated strain on covered entity staffing, removing resources from day-to-day patient care.

Another distressed covered entity, Crescent Community Health Center (Crescent Community Health) in Dubuque, Iowa, notes that Lilly's and other drug companies' actions will cause many patients to lose access to diabetes, hypertension, asthma/chronic obstructive pulmonary disease ("COPD"), and heart disease medications. Rickertsen Aff. ¶ 30. Crescent Community Health's clinical pharmacy director determined that approximately thirty-two uninsured patients will be unable to afford asthma/COPD medications, seventy-six diabetic patients will lose access to critical oral medications to treat diabetes, fifty-one patients will lose access to their insulin, and forty patients will lose access to medications to treat other acute and chronic conditions. Rickertsen Aff. ¶ 30. These patients have no choice but to ration their medications, leading to a decline in their health and increased uninsured hospital costs just as rural hospitals cope with the COVID public health emergency. Rickertsen Aff. ¶ 12, 19, 30.

B. Covered Entities Rely on 340B Contract Pharmacy Savings to Pay for Necessary and Required Health Care and Related Services

Covered entities use 340B Program savings to subsidize the cost of important and life-saving health care services. For insured patients, covered entities benefit from the difference between the 340B price and the insurer's payment for the drug. Covered entities use these funds to supplement their federal grants and other program income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992). Many of the programs and services that covered entities support with 340B savings are critical to treating the whole patient, but are not reimbursed by public or private insurance, and are often most needed by patients who lack insurance altogether. Auclair

Aff. ¶¶ 21-22; Glover Aff. ¶ 15; Simila Aff. ¶ 18; Slingerland Aff. ¶ 7. Congress designed the 340B Program to provide a funding stream for just these sorts of programs and services. And for decades, FQHCs have structured their operations in reliance on 340B funding, just as Congress intended. *See, e.g.*, Auclair Aff. ¶¶ 6-7; Glover Aff. ¶¶ 11, 25; Slingerland Aff. ¶ 11.

FQHCs and RWCs provide, among other services, case management to assist patients with transportation, insurance enrollment, links to affordable housing resources, food access, patient care advocacy, in-home support, and education for chronic health care conditions. Auclair Aff. ¶¶ 12–16, 22 (noting provision of behavioral health services at local public schools for students and families); Glover Aff. ¶¶ 11, 14–15; Slingerland Aff. ¶ 7 (noting that 340B savings are used to "improve infrastructure, renovating facilities, and expanding services into underserved communities in Northeastern New York who otherwise would have limited or no local access to care."). Case management and care coordination are particularly critical for homeless and indigent individuals, who require these services to encourage their use of necessary primary and other health care services. Auclair Aff. ¶ 17; Glover Aff. ¶ 26; *see also* 42 U.S.C. § 254b(a)(1) (designating the homeless as one of four patient populations served); RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020) (Ryan White patients are more likely to be homeless than general HIV/AIDS population). Education and in-home assistance for patients with chronic health conditions are also vitally important for disease management and the prevention of exacerbation or deterioration that would require more costly care. Glover Aff. ¶¶ 15, 27; *see also* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-11 (number of health center patients diagnosed with a chronic health condition grew 25% from 2013 to 2017), 1-10 (21% of FQHC patients have

diabetes compared to the national rate of 11%).[32]

Covered entities also rely on 340B funding to provide a range of other critical services responsive to serious ongoing public health crises, such as medication assisted treatment programs and other treatment options for opioid use disorder, and fighting the COVID-19 pandemic. *See* Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 5; Francis Aff. ¶ 9; Slingerland Aff. ¶ 7; *see also* HRSA, Bureau of Primary Health Care, *2018 Health Center Data: National Data, Other Data Elements* (2019) (FQHCs are "the first line of care in combatting the Nation's opioid crisis," screening and identifying nearly 1.4 million people for substance use disorder, providing medication-assisted treatment to nearly 143,000 patients, providing over 2.7 million HIV tests, and treating 1 in 5 patients diagnosed with HIV nationally).

Lilly's deprivation of 340B discounts has already resulted in cuts and reductions to critical FQHC and RWC services supported in whole or in part with 340B-derived funding. *See, e.g.*, Auclair Aff. ¶ 23 (Little Rivers will lose approximately $44,860.35 annually in 340B savings as a result of the decision by Lilly not to honor contract pharmacy arrangements); Glover Aff. ¶ 22; Dickerson Aff. ¶ 6; Spinelli Aff. ¶¶ 28–30 (estimating annual revenue loss of over $560,000 from drug manufactures refusal to offer 340B pricing, which risks vital primary care services including dental, podiatry, clinical nutrition, and others); Richards Aff. ¶¶ 24, 25 (estimating annual loss of $350,000 due to 340B restrictions, forcing reduction in services); Rickertsen Aff. ¶¶ 34, 36 (estimating annual loss of $1 million in revenue and $500,000 to $2 million in increased cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program). HHHN estimates that it will lose $8,400,000 in revenue due to manufacturer actions to cut off

[32] http://www.nachc.org/wp-content/uploads/2020/01/Chartbook-2020-Final.pdf.

access to 340B drugs at contract pharmacies. Slingerland Aff. ¶¶ 20-23. Community HealthCare System in St. Marys, Kansas recently announced that it is closing its emergency room and reducing its inpatient beds due, in part, to manufacturers' restrictive 340B contract pharmacy policies. WIBW, *Community HealthCare System in St. Marys to close emergency room doors, adjust services* (Apr. 28, 2021).[33]

Without preventive and enabling services, patient health will undoubtedly suffer. Patients will require additional, more expensive health care visits at the Amici's locations and more expensive hospital and specialist care. Auclair Aff. ¶¶ 28–29; Glover Aff. ¶¶ 26–27; *see also* Robert S. Nocon, et al., *Health Care Use and Spending for Medicaid Enrollees in Fed. Qualified Health Ctrs. Versus Other Primary Care Settings*, Am. J. Public Health (Sep. 15, 2016) ("Medicaid patients who obtain primary care at FQHCs had lower use and spending than did similar patients in other primary care settings"). The cost of providing additional health care visits will further strain Amici's and other covered entities' resources.

Lilly's and other drug companies' refusal to offer drugs at 340B discount pricing has also already resulted in covered entities reducing staff. *See, e.g.*, Simila Aff. ¶ 29 (health center forced to reduce staffing for OB/GYN services and planning other major service reductions—including service delivery site closures, employee terminations, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services); Mahaniah Aff. ¶ 20 (health center preparing to permanently eliminate 5% of employees); Chen Aff. ¶ 42 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations); Richards Aff. ¶ 25 (significant financial loss will result in reduction in clinical and patient services); Slingerland Aff. ¶ 23 (noting that HHHN may be forced to close its Women's

[33] https://www.wibw.com/2021/04/28/community-healthcare-system-in-st-marys-to-close-emergency-room-doors-adjust-services/.

Health Center). FQHCs and RWCs will also have to divert remaining staff to attempt to provide alternative or palliative services to vulnerable patients and seek out additional federal grants or other sources of funding to make up for lost 340B funding. *See, e.g.*, Chen Aff. ¶ 40; Auclair Aff. ¶ 30; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9; Slingerland Aff. ¶ 21. Expending already scarce financial and human resources will further burden tight budgets and cause additional and unbearable operational expenses. Auclair Aff. ¶ 27-28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

Many covered entities, including numerous NACHC and RWC-340B members, as well as Amici Little Rivers and FamilyCare, rely entirely on contract pharmacies to dispense covered outpatient drugs to their patients. *See, e.g*, Auclair Aff. ¶ 19; Glover Aff. ¶ 18; Slingerland Aff. ¶ 10. For some covered entities, 340B Program revenue has meant the difference between remaining in operation and closing their doors. For FamilyCare, revenue from its contract pharmacy arrangements is comparatively almost half of the funding it receives from federal grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici would be even more "devastating" to their operations and the patients they serve. Auclair Aff. ¶ 34; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; Slingerland Aff. ¶¶ 19-23. Little Rivers currently operates at a loss and FamilyCare's revenue barely exceeds its operating expenses. Dickerson Aff. ¶ 7. In 2019, Little Rivers' average cost per patient was $1,270.64; FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*.[34] Per patient costs will increase dramatically if these providers are burdened with covering the full price of Lilly's drugs. Many covered entities, including Amici Little Rivers and FamilyCare, lack the financial resources necessary to bear the additional costs of drugs for indigent patients. Auclair Aff. ¶ 38.

[34] https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited June 11, 2021).

CONCLUSION

Granting Lilly's motion would significantly harm covered entities, their patients, their staff, and the health care safety-net community by freeing Lilly and other drug companies from their obligations under the 340B statute, upending an over two-decades-long status quo on which FQHCs and RWCs depend, and leaving covered entities with no remedy. HHS's May 17 letter describes what Lilly has understood for decades—drug companies that choose to participate in the 340B federal drug pricing program are required to offer to covered entities 340B pricing, regardless of where the drugs are dispensed to the covered entity's patients. The ADR Rule provides covered entities with the administrative proceeding they need to correct the harms Lilly and other manufacturers have caused by flouting their obligations under the 340B statute. For the above reasons, Amici respectfully request that the Court grant HHS's motion to dismiss and motion for summary judgment and deny Lilly's cross-motion for summary judgment.

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