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

ELI LILLY AND COMPANY, *et al.*,

Plaintiffs,

v.

NORRIS COCHRAN, *et al.*,

Defendants.

Case No: 1:21-cv-81-SEB-MJD

BRIEF OF AMICUS CURIAE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTERESTS OF AMICUS CURIAE

The National Association of Community Health Centers (NACHC), a nonprofit and tax-exempt organization, is the national membership organization for federally-funded community health centers, known as Federally-qualified health centers, or FQHCs.[1] Founded in 1971, NACHC's primary objective is to further—through extensive education, training, and advocacy—FQHCs' mission and purpose.

FQHCs are predominantly community-based, patient-directed nonprofit organizations that play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations in all fifty states, the District of Columbia, Puerto Rico, and other U.S. territories, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs receive or are eligible to receive federal grant funding under Section 330 of the Public Health Service 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). In addition to providing comprehensive primary care to approximately one in twelve Americans who fall into one or more of these categories, FQHCs serve on the front lines in preventing, treating, and containing serious, nationwide public health threats such as the HIV epidemic, the opioid addiction crisis, and the ongoing COVID-19 pandemic.

[1] No counsel for any party authored this brief in whole or in part and no person, party, or entity other than NACHC and its counsel made a monetary contribution to its preparation or submission.

FQHCs treat a population that is disproportionately poor: ninety-one percent of health center patients are under 200 percent of the Federal Poverty Line ("FPL"); sixty-nine percent of patients are at or below 100 percent of the FPL. *See* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-8, 2-9 and 2-11, https://www.nachc.org/research-and-data/research-fact-sheets-and-infographics/chartbook-2020-final/ (hereinafter "NACHC Chartbook"). Eighty-two percent of FQHC patients are either publicly insured (e.g. Medicare and Medicaid beneficiaries) or lack health insurance entirely. *See id.*, Fig. 1-5. For decades, FQHCs have relied on 340B Program savings and revenue to meet the needs of their vulnerable patient populations, which in 2020 included approximately one in three people living in poverty, one in five residents of rural areas, one in every nine children , one in eight people of a racial or ethnic minority, and one in every six Medicaid beneficiaries. *Id.*, Fig. 1-1.

As the Court well knows, this case concerns an important program administered by the Department of Health and Human Services ("HHS"), the 340B Drug Discount Program ("340B Program"), which allows certain healthcare providers (known as "covered entities") serving uninsured and under-insured patients to purchase outpatient drugs at significant discounts. 42 U.S.C. § 256b. Since the 340B Program's 1992 inception, FQHCs have appeared first on the 340B statute's list of provider types that qualify as "covered entities" eligible to purchase drugs at 340B discount pricing. 42 U.S.C. § 256b(a)(4)(A).

NACHC submits this amicus brief to apprise the Court of the broad-based and far-reaching legal, social, and economic implications inherent in any change to the 340B Program, as well as the impact of such change on FQHC covered entities and their patients. No FQHC covered entity is a party to this action, but all FQHC covered entities will be significantly impacted if the Court grants Lilly's motion. FQHC covered entities have a significant interest in the continued viability of the 340B Program, including the availability of HHS's Alternative Dispute Resolution ("ADR") process, which provides the sole forum for covered entities to challenge drug manufacturer overcharging.

Although Lilly presents this case as a challenge to HHS's Final ADR Rule, 85 Fed. Reg. 80,632, the case is, in reality, one front in the broader war Lilly, in conjunction with other major drug manufacturers, is waging against its statutory obligation to provide drugs to covered entities at 340B discount pricing. In the latter half of 2020, Lilly advanced a self-serving reinterpretation of Section 340B, and took sweeping action in accordance with that interpretation, despite HHS's clear refusal to endorse Lilly's actions and the agency's pointed warnings that Lilly's conduct risked triggering False Claims Act liability. *See* Letter from Robert P. Charrow, Gen. Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and Gen. Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/de-fault/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf. ECF No. 19-5 at 60–61. Lilly has not relented despite subsequent condemnation by

bipartisan coalitions in both houses of Congress,[2] and an HHS's General Counsel Advisory Opinion that, in keeping with longstanding agency guidance and practice, forcefully reiterated Lilly's obligations under the 340B statute. ECF No. 19-5 at 38–45 (HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program).

Lilly asserts that the balance of equities and the public interest weigh in favor of enjoining the final ADR Rule. Not so. FQHCs would be severely damaged if the Court were to enjoin the ADR Rule and process.[3] An injunction would strip FQHCs of the *only* process available to them to seek relief from unlawful drug manufacturer overcharging for critical drugs that, drug manufacturers are required to offer to covered entities for purchase at or below statutory ceiling prices. An injunction would also indefinitely suspend the pending ADR claims NACHC (on behalf of 225 FQHCs) filed against Lilly and other manufacturers for ongoing unlawful overcharging.[4] Such a suspension would compound the harms FQHCs, their patients, staff members, and broader communities are already suffering due to Lilly's unlawful upending of a decades-long status quo.

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[2] *See* Letter from Members of Congress to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1 (Sept. 14, 2020), ECF No. 19-5 at 47–48 (Mem. In Supp. of Pls.' Mot. Prelim. Inj.); Letter from United States Senators to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1 (Sept. 17, 2020); Letter from House Committee on Energy & Commerce to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1 (Sept. 3, 2020).

[3] NACHC brought suit in October 2020 to compel the promulgation of the mandated ADR rule and process. *NACHC v. Azar,*, No. 20-cv-3032-KJB (D.C.C. filed Oct. 21, 2020); s*ee also Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121–22 (2011) (citing 42 U.S.C. § 256b(d)(1)(A);. *see also Astra* (only option available for resolving disputed between manufacturers and covered entities).

[4] NACHC filed those claims on January 13, 2021—the first day the ADR process became available. On its second day, NACHC filed a motion for immediate relief, as HHS has all but decided the underlying issue, which is purely legal and has been already thoroughly reviewed by the agency.

ARGUMENT

Having failed to convince HHS to bless its unlawful acts, and with both houses of Congress evidently against it, Lilly has turned to the Judiciary to condone Lilly's clearly unlawful behavior.[5] Here, with covered entities' overcharging claims currently pending in the newly established ADR process, Lilly primarily seeks to delay an almost certain ruling against it. To avoid the inevitable for perhaps another quarter or two of increased profits, Lilly advances a radically revisionist history in which the current state of affairs—brought about mere months ago by Lilly's own unsanctioned self-help—erase a nearly twenty-five-year course of conduct to become the "status quo" Lilly insists this Court must preserve.

Significant harm to the public interest will result if this Court grants the extraordinary relief Lilly requests. This case impacts *thousands* of FQHC covered entity sites delivering health care to *millions* of Americans, many of whom are among the most medically underserved and vulnerable in our nation. To divert attention from its own profit motive, Lilly attempts to villainize large chain pharmacies and mischaracterizes them as de facto covered entities. But Lilly cannot erase covered entities and their patients by shining the spotlight on CVS and Walgreens any more than it can hide the true motivation behind this suit in

[5] 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 at 19–21, *Ryan White Clinics for 340B Access v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020). Two other major drug manufacturers are also acting in close concert with Lilly. *See, e.g., Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Human Servs.*, 3:21-cv-00634 (D.N.J. Jan. 12, 2021); *AstraZeneca Pharm. LP v. Azar*, No. 1:21-cv-00027 (D. Del. Jan. 12, 2021); Mem. in Supp. Of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1 at 3, *Ryan White Clinics v. Azar*, Case No. 1:20-cv-02906; Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1 at 15, *Ryan White Clinics*, No. 1:20-cv-02906J (Nov. 24, 2020).

meritless constitutional arguments against a Rule that finally established a process in which Lilly knows it will almost certainly lose.

The truth is that Lilly's unlawful acts damage health centers that treat the most vulnerable. Weakening a significant portion of the health care safety net runs counter to the public interest in the best of times; here, Lilly boldly asks this Court to ratify its anti-social actions during the worst public health crisis in a century.

I. The Status Quo Lilly Seeks to Preserve is the Result of Unsanctioned and Unlawful Conduct and Reverses More Than Two Decades of Practice

As a threshold matter, the status quo Lilly asks this Court to preserve pending final resolution of its claims is the result of Lilly's own unsanctioned and unlawful conduct, upsets more than two decades of policy and practice, violates Lilly's legal and contractual obligations, and runs counter to Congress' plans for how FQHCs would operate even before it created the 340B Program.

The *true* status quo is a state of affairs in which, consistent with Congress' intent and HHS's longstanding interpretations of both Sections 330 and 340B of the PHS Act, FQHC covered entities rely on contract pharmacies to dispense their 340B purchased drugs and otherwise best serve their patients' pharmaceutical needs. It is also a state of affairs in which drug manufacturers' honor their obligation to provide discounted drugs to FQHC covered entities as Congress intended. Finally, it is an environment in which FQHC covered entities rely on 340B savings and revenue to fund crucial aspects of their operations.

In 1992, when Congress listed FQHCs as the first type of provider in its enumerated list of covered entities eligible to participate in the 340B Program, it

had every reason to anticipate that FQHCs would use pre-existing authority and flexibility to provide covered outpatient drugs to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through a pharmacy owned, controlled, and operated by the health center.

As community and patient-based providers, FQHCs necessarily have flexibility in determining how best to meet the needs of their patients and community, but FQHCs must—and do—use any 340B savings and revenue (as well as any other income generated from grant-supported activities) in furtherance of their health center projects. 42 U.S.C. § 254b(e)(5)(D). FQHCs have also long 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 PHS 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" primary and supplemental health services, including "pharmaceutical services"); Health Centers Consolidation Act of 1996,

Pub. L. 104-299, 110 Stat 3626 (1996), *codified at* 42 U.S.C. § 254b(a) (consolidating and reauthorizing provisions of Public Health Service Act relating to health centers).[6]

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). For nearly 25 years in the long life of that program—from 1996 until mid-2020—drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' contract pharmacies, *i.e.*, third-party pharmacies with which FQHCs contract to dispense drugs to FQHC patients. All but a handful of the hundreds of drug manufacturers participating in the 340B Program continue to do so.

FQHC covered entities use 340B Program savings and revenue to provide additional services in their federally designated service areas. Money saved or generated through 340B Program participation is used to cover the cost of medication for uninsured or underinsured patients who could not otherwise afford it, 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

[6] The FQHC designation was first established in Medicaid in 1989, along with a special cost-based payment right, to "ensure that health centers receiving funds under [Section 330] would not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." *Three Lower Cties. Cmty. Health Servs. v. Maryland*, 498 F.3d 294, 297–98 (4th Cir. 2007) (citing H.R. Rep. No. 101-247, at 392–93, *reprinted in* 1989 U.S.C.C.A.N. 2118–19).

services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

II. The Public Interest is Not Served by Incapacitating HHS's ADR Process

The public interest will not be served by disabling the remedial scheme Congress mandated to deter and remedy drug manufacturer overcharging. Quite the opposite. Without such a process, drug manufacturers are free to deny FQHC covered entities a crucial funding stream Congress intended they receive to supplement federal grant funding.

FQHCs are a lynchpin of the U.S. health care safety-net, serving as the primary source of care for tens of millions of Americans who are overall poorer and sicker than the general population. Health Res. & Servs. Admin., Bureau of Primary Health Care, Health Center Program: Impact and Growth, https://bphc.hrsa.gov/about/healthcenterprogram (last visited Feb. 21, 2021); Peter Shin et al., *A Profile of Community Health Center Patients: Implications for Policy*, Kaiser Family Foundation (Dec. 23, 2013) (FQHC patients more likely to present known health risks than general population); NACHC Chartbook, Fig. 1-10 (FQHC patients present with higher rates of chronic conditions such as diabetes, hypertension, and asthma than general population). More than 1,350 FQHCs care for residents of every state and federal territory at over 11,700 unique sites. NACHC Chartbook, Fig. 2-1. In some communities, FQHCs may be the only primary care providers available to certain vulnerable populations. U.S. Gov't

Accountability Office, *Health Centers: Trends in Revenue and Grants Supported by the Community Health Center Fund*, Report 19-496 (May 2019) at 1.

As required by Section 330 of the PHS Act, 42 U.S.C. § 254b, FQHCs provide a comprehensive array of health care and related services, including, among others: family and internal medicine, pediatrics, obstetrics and gynecology, diagnostic laboratory and radiologic services, preventive health screenings, immunizations against vaccine-preventable diseases, emergency medical services, and pharmaceutical services. 42 U.S.C. § 254b(b)(1)(A). FQHCs must provide these services to all service area residents, regardless of any individual patient's ability to cover associated costs. 42 U.S.C. § 254b(a)(1); 42 U.S.C. § 254b(k)(3)(G)(iii) ("no patient will be denied health care services due to an individual's inability to pay for such services"). In addition to covering costs for patients who cannot afford to pay for services, FQHCs "have emerged as a health care backbone for state Medicaid programs." Peter Shin et al., *Keeping Community Health Centers Strong During the Coronavirus Pandemic is Essential to Public Health*, https://www.healthaffairs.org/do/10.1377/hblog20200409.175784/full/ (April 10, 2020) ("Nationally nearly one in five Medicaid patients obtains care at a community health center; in 10 states and the District of Columbia, this figure stands at one in four.").

Year over year, FQHCs see more patients presenting with serious health risks, conditions, and complications. *See* NACHC Chartbook, Fig. 1-11 (number of health center patients diagnosed with a chronic health condition grew twenty-five

percent from 2013 to 2017). Many of these chronic conditions are managed primarily through prescription medications. Data for the 2013 to 2018 period indicates that the number of health center patients with HIV has increased sixty-six percent from 115,421 to 191,717; patients presenting with alcohol and other substance use disorders increased eighty percent from 506,279 to 908,984; and patients with depression and mood and anxiety disorders increased by 72 percent, from 2,740,638 to 4,724,691. Sara Rosenbaum *et al.*, *Community Health Centers Ten Years After the Affordable Care Act: A Decade of Progress and the Challenges Ahead* at 9, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020), https://www.rchnfoundation.org/wp-content/uploads/2020/03/FINAL-GG-IB-61-ACA-CHC-3.4.20.pdf (hereinafter "Rosenbaum Retrospective"). FQHC patients present with diabetes at more than double the rate of such patients in the general population. NACHC Chartbook, Fig. 1-10 (twenty-one percent of FQHC patients have diabetes compared to national rate of eleven percent).

These figures speak to inherent need and the continually expanding reach of FQHCs, which deliver high-quality care and achieve better health outcomes versus other primary care settings. Robert S. Nocon, *et al.*, *Health Care Use and Spending for Medicaid Enrollees in Federally Qualified Health Centers Versus Other Primary Care Settings*, Am. J. Public Health (Sep. 15, 2016) (finding "Medicaid patients who obtain primary care at health centers had lower use and spending than did similar patients in other primary care settings"); U.S. Dep't of Health & Human Servs.,

Health Res. & Servs. Admin., Bureau of Primary Health Care, 2018 Health Center Data: National Data, Other Data Elements (2019) (noting increase in behavioral health services, medication-assisted opioid use disorder treatment, and telehealth capabilities for specialist consultations and primary health delivery); Rosenbaum Retrospective at 8.

FQHCs are also at the forefront in addressing major public health crises. HRSA, Health Center Program. They are, for example, "the first line of care in combatting the nation's opioid crisis" and "an essential component in the [federal] *Ending the HIV Epidemic* initiative, serving as a key point of entry for detection and diagnosis of people living with HIV." *Id.* (noting health centers screened and identified nearly 1.4 million people for substance use disorder, provided medication-assisted treatment to nearly 143,000 patients, provided over 2.7 million HIV tests, and treated 1 in 5 patients diagnosed with HIV nationally).

During the ongoing COVID-19 public health emergency, FQHCs continue to play a critical role in providing testing and care, and are "a first line of defense" against the virus due to their role in caring for the most at-risk populations. U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Press Release: *HHS Awards More than Half Billion Dollars Across the Nation to Expand COVID-19 Testing* (May 7, 2020)[7] (quoting HRSA Administrator Tom Engels) (internal quotation marks omitted). FQHCs are currently performing a vital role in ensuring

[7] https://www.hhs.gov/about/news/2020/05/07/hhs-awards-more-than-half-billion-across-the-nation-to-expand-covid19-testing.html#:~:text=Today%2C%20the%20U.S.%20Department%20of,to%20expand%20COVID%2D19%20testing

that COVID-19 vaccines reach "underserved and most vulnerable communities." White House, Press Release, *FACT SHEET: President Biden Announces Community Health Centers Vaccination Program to Launch Next Week and Another Increase in States, Tribes, & Territories' Vaccine Supply* (Feb. 9, 2021),[8] (announcing launch of Community Health Center Vaccination Program, whereby FQHCs directly receive vaccines); *see also* White House, Press Release, *Fact Sheet: President-elect Biden Outlines COVID-19 Vaccination Plan*,[9] (announcing then-President-elect Biden's intent to partner with FQHCs in vaccine distribution and to request Congress allocate additional funds to FQHCs "[g]iven the critical role that these providers play in their communities").

Lilly seeks here to prolong a self-serving and self-created "status quo" in which it is blocking FQHCs' access to Lilly's drugs at 340B discount pricing, while simultaneously attacking the process that exists to prevent that precise unlawful behavior. As explained *supra*, FQHCs use savings and revenue generated by participation in the 340B Program, as Congress intended, to expand health care and enabling services to populations desperately in need of such care, whether due to an acute public health crisis or to serious chronic conditions.

Many of the programs and services FQHCs support with 340B funding are critical to treating the whole patient, but are not reimbursed by public or private

[8] https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/09/fact-sheet-president-biden-announces-community-health-centers-vaccination-program-to-launch-next-week-and-another-increase-in-states-tribes-territories-vaccine-supply/

[9] https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/15/fact-sheet-president-elect-biden-outlines-covid-19-vaccination-plan/

insurance, and regardless are often most needed by patients who lack insurance altogether. 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, as Congress intended.

Denying FQHCs 340B funding is antithetical to Congress' 340B Program design—without 340B funding, FQHCs cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). Indeed, Lilly's deprivation of FQHCs' access to 340B Program benefits has already resulted cuts and reductions to critical services supported in whole or in part with 340B-derived funding. *See, e.g.,* ECF No. 19-5 at 356 ¶ 24, 25 (Decl. of J.R. Richards) (estimating that covered entity will lose approximately $350,000 in annual net revenue as result of 340B restrictions, forcing reduction in services), 361 ¶ 28–30 (Decl. of Donald A. Simila) (estimating annual revenue loss of approximately $600,000 from *Lilly's actions alone*, resulting in "major reductions in services" and "significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community"), 372–73 ¶¶ 34, 36 (Decl. of Heather Rickertsen) (estimating annual loss of approximately $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program). Lilly's refusal to offer its drugs to FQHCs at 340B discount pricing has also already resulted in FQHCs reducing staff. *See, e.g.,* ECF No. 19-5 at 361 ¶ 29 (Simila Decl.) (forced to reduce staffing for

OB/GYN services and currently planning other major reductions in services—including closure of service delivery sites, termination of employees, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services), 395 ¶ 20 (Decl. of Kiame Jackson Mahaniah) (currently preparing to permanently layoff 5 percent of its employees due to loss of 340B revenue), 403–04 ¶ 42 (Decl. of Kimberly Christine Chen) (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations due to manufacturers' restrictions).

The 340B Program was not designed to allow Lilly—or any drug manufacturer—to place profits over the patients and providers that 340B discounts were designed to benefit. The longer Lilly is able to shirk its 340B Program obligations to covered entities, the greater and more permanent the harm to the public interest.

CONCLUSION

In deciding Lilly's motion for extraordinary relief, the Court should consider the significant harm to FQHC covered entities, their patients, their staff members, and their broader communities that, as described above, Lilly's unlawful actions in upsetting a decades-long status quo have caused and will continue to cause—without any available remedy—if the Court grants Lilly's motion. For the foregoing reasons and those stated by Defendants, the Court should deny Lilly's motion.

Dated: February 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **February 23, 2021**, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's ECF. Parties may access this filing through the Court's system:

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