No. 22-3054

**IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

DANIEL HALLER and LONG ISLAND SURGICAL PLLC,

Plaintiffs-Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 INDEPENDENCE AVENUE SW, WASHINGTON, DC 20201,

Defendants-Appellees,

(See inside cover for continuation of caption)

On Appeal from the United States District Court for the
Eastern District of New York, No. 2:21-cv-07208-AMD-AYS

BRIEF AMICI CURIAE OF THE AMERICAN CANCER SOCIETY AND AMERICAN CANCER SOCIETY CANCER ACTION NETWORK SUPPORTING DEFENDANTS-APPELLEES' OPENING BRIEF

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Defendants-Appellees.

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure:

Amicus curiae **American Cancer Society** states that it is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Amicus curiae **American Cancer Society Cancer Action Network** states that it is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

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INTEREST OF *AMICI CURIAE*1

The mission of the American Cancer Society (ACS) is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer. ACS-funded research has helped make possible almost every major cancer breakthrough since 1946, including funding research conducted by 50 investigators who went on to win the Nobel Prize, considered the highest accolade any scientist can receive. Ongoing in-house research identifies factors at the patient, provider, health system, and policy levels that can be modified to improve access to and receipt of affordable cancer prevention, screening, treatment, survivorship, and end-of-life care. This work includes studies on the economic burden of cancer and the financial hardship it causes.

The American Cancer Society Cancer Action Network (ACS CAN) is the non-partisan advocacy affiliate of ACS that seeks to end suffering and death from cancer. This work included strong support of the patient protection provisions of the No Surprises Act whi le the measure was being debated in the U.S. Congress, as well as submission of comments to federal agencies during the regulatory

[1] Under Local Rule 29.1 and FRAP 29(a)(4), ACS and ACS CAN certify that this brief was authored in whole by counsel for ACS and that no part of the brief was authored by counsel for any other party. No party, nor any other person, counsel, or entity, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

proceedings implementing the law. ACS CAN did not take a position on the independent dispute resolution (IDR) provisions of the statute in either of those phases, and likewise declines to do so in this litigation.

SUMMARY OF ARGUMENT

The No Surprises Act (NSA) created new protections for over 170 million Americans with private health insurance. Before Congress passed this law in December 2020, millions of patients faced crippling, unexpected bills when they received emergency and other care from "out of network" providers. In an emergency, patients often have no control over where they receive medical care. And in non-emergencies, patients who select facilities in their network may unknowingly receive care—at in-network facilities—from out-of-network providers. A patient might, for example, have surgery at an in-network hospital but be treated by an out-of-network anesthesiologist. Historically, such patients would then receive surprise bills, or "balance" bills, from the out-of-network facilities and providers, often for amounts far greater than what those patients would have owed had they been treated only by in-network providers.

Patients diagnosed with cancer are especially susceptible to this type of surprise billing, because they depend heavily on several of the specialties most likely to send surprise bills, such as diagnostic and interventional radiology,

pathology, anesthesiology, and emergency medicine. Surprise billing exacerbates financial hardship, which empirical data show negatively impacts patient outcomes and is associated with increased mortality in patients with cancer. Several studies, which ACS and ACS CAN will discuss below, document the real world consequences of financial hardship on health outcomes in general, and for patients with cancer in particular. These data support the district court's rulings in two important respects.

First, the financial hardship and related adverse impact on patient outcomes demonstrate the substantial public interest underlying the No Surprises Act's ban on balance billing. Plaintiffs did not and cannot prove one of the four requisites of an injunction, namely, that enjoining the balance billing provisions would be in the public interest.

Second, the demonstrable financial hardship to which balance billing contributes provides compelling support for Congress' decision to create a new public right, protecting patients from surprise billing while creating a mechanism for out-of-network providers to seek compensation from insurers, as part of a comprehensive statutory framework to promote fairness in the health care system and to enhance health care itself. The legitimacy and importance of that new public right, disputes over which Congress had the power to commit to something other than Article III courts, show both that Plaintiffs were unlikely to succeed on

the merits of their constitutional challenges and that the district court was correct to dismiss their Takings Clause and Seventh Amendment claims.

ARGUMENT

A. **Surprise billing causes financial hardship, which in turn limits care due to costs, harms health outcomes and increases mortality risk among patients with cancer.**

Surprise billing has affected millions of consumers each year, including patients with cancer. Many patients have little or no control over whether they are treated by an out-of-network provider. Patients needing emergency care may be transported by an out-of-network air ambulance, taken to an out-of-network emergency room ("ER"), or treated by out-of-network physicians even when taken to an in-network ER. *See* H.R. Rep. No. 116-615, pt. I, at 51. Even patients who schedule non-emergency procedures at in-network facilities may, without their consent or even knowledge, receive treatment from out-of-network providers, which could result in surprise bills in the thousands of dollars.

The statistics bear this out. Between 18-20 percent of emergency visits and 16 percent of in-network hospital care resulted in at least one out-of-network charge for enrollees of large group health insurance plans. Karen Pollitz *et al.*, *An Examination of Surprise Medical Bills and Proposals to Protect Consumers from Them* (2020), https://jamanetwork.com/journals/jama/fullarticle/2760721 and Zack

Cooper & Fiona Scott Morton, *Out-of-Network Emergency Physical Bills—An Unwelcome Surprise* New England J. of Medicine 2016; 375:1915-1918 (2016), https://www.nejm.org/doi/full/10.1056/NEJMp1608571. Out-of-network charges billed to consumers before the No Surprises Act often reached into thousands of dollars, ranging from average bills of $20,000 for air ambulances, $3600 for surgical assistants, and $1200 for anesthesiologists. Karan Chhabra *et al*., *Most Patients Undergoing Ground and Air Ambulance Transportation Receive Sizable Out-of-Network Bills*, Health Affairs 39(5): 777-82 (2020); Karan Chhabra, *et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery with In-Network Primary Surgeons and Facilities,* J. of the Am. Med. Ass'n 323(6): 538-47 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7042888/.

Surprise billing is an especially salient concern for patients with cancer, a consistently growing population that experiences ongoing care access and affordability challenges. Nearly two million Americans are expected to be diagnosed with cancer in 2023. American Cancer Society, *Cancer Facts & Figures: 2023*, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf. An additional 20 million Americans are cancer survivors who are living with a history of cancer. *Id*. Affordable health care is essential to preventing cancer, to early diagnosis, and to improving long-term survivorship.

The National Cancer Institute estimated that cancer-related medical costs in the U.S. were $208.9 billion in 2020, which is likely an underestimate, because it does not account for the growing cost of treatment. *Id*. For example, the list price for many prescription medicines is now more than $100,000 annually. Cancer-related costs to patients are estimated at $21.1 billion, including $16.2 billion in total out-of-pocket costs and $4.9 billion in patient time costs (travel to/from treatment and waiting for and receiving care). *Id*. High out-of-pocket costs cause hardship to many cancer patients and survivors, including delaying or skipping needed medical care, problems paying bills, depletion of savings, and potential bankruptcy. K. Robin Yabroff, *et al., Understanding Financial Hardship Among Cancer Survivors,* J. Clinical Oncology 38(4): 292-94 (2020).

Because patients with cancer often see different physicians with different specialties at multiple facilities for different types of care during their course of treatment (*e.g*., surgery, radiation therapy, chemotherapy), they are particularly vulnerable to surprise billing. Patients with cancer are also frequent users of emergency care, with one study finding that 35.9% of such patients visited the emergency department an average of 1.79 times during the one-year study period. L. Panattoni, *et al*., *Costs of Potentially Preventable Emergency Department Use During Cancer Treatment: A Regional Study* (2017), https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.8_suppl.2.

When ACS CAN surveyed cancer patients and survivors before the passage of the No Surprises Act, it found that 24% of respondents said they had received a surprise bill. American Cancer Society Cancer Action Network, *Survivor Views: Surprise Billing and Prescription Cost and Coverage Survey Findings Summary* (2019), https://www.fightcancer.org/policy-resources/survivor-views-surprise-billing-and-prescription-cost-and-coverage-survey-findings. Sixty-one percent of these surprise bills were over $500, and 21% were $3000 or more. Surprise bills negatively affected the behaviors of patients with cancer, making them less likely to follow up with a recommended specialist who may be out of network and less likely to call an ambulance or visit the emergency room when experiencing a serious cancer-related issue. *Id*. These findings are corroborated by another study, in which 77% of cancer patients had to be urged by providers (most commonly oncologists) or caregivers to seek emergency care. R. Lash, *et al., A Systematic Review of Emergency Department Use Among Cancer Patients,* Cancer Nurs. 40(2):135-144 (2017).

Although surprise billing can cause financial hardship to patients of all income levels, these effects are especially detrimental to lower income patients and survivors. Patients diagnosed with cancer who have annual incomes below $30,000 reported a higher prevalance of each of these negative behavioral impacts than did their higher-income counterparts. *Survivor Views, supra,*

https://www.fightcancer.org/policy-resources/survivor-views-surprise-billing-and-prescription-cost-and-coverage-survey-findings. These concerns are consistent with survey data of all insured adults, 65 percent of whom, according to a 2020 poll, were at least "somewhat worried" about unexpected medical bills. Lunna Lopes, *et al, Data Note: Public Worries about and Experience with Surprise Medical Bills* (2020), https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.

The financial hardship associated with surprise billing would be more than enough to justify Congress' judgment in passing the No Surprises Act. But such hardship is not limited merely to the financial. Hardship caused by unexpected medical bills harms not only patients' financial well-being, but their use of healthcare and their health outcomes as well. Not only is this phenomenon intuitive—one would expect that fear of crippling medical bills might cause consumers to defer or forego care—it is borne out by the data.

Medical financial hardship, including problems paying medical bills, financial distress, and delaying or altogether skipping medical care, "is a common and lasting effect of cancer diagnosis and treatment for cancer survivors and their families." Xuesong Han, *et al., Medical Financial Hardship Intensity and Financial Sacrifice Associated with Cancer in the United States*, American Ass'n for Cancer Resarch Cancer Epidemeology, Biomarkers & Prevention 29(2):308

(2020). A 2022 study in the Journal of the National Cancer Institute focused on the long term health consequences of medical financial hardship among cancer survivors. *See* K. Robin Yabroff, *et al., Association of Medical Financial Hardship and Mortality Among Cancer Survivors in the U.S.*, J. Nat'l Cancer Inst. 114(6) 863 (2022). The authors defined "medical financial hardship" as problems affording care or delaying or forgoing any care because of cost, and they studied cancer survivors aged 18-64 years and 65-79 years. *Id.* Cancer survivors who reported financial hardship were statistically significantly more likely to be younger, female, members of racial and ethnic minority groups, and unmarried, and to have more health conditions and lower educational attainment compared with cancer survivors without financial hardships in both age groups. *Id*. at 864.

The results of the mortality study were sobering: cancer survivors with financial hardship had higher mortality risk than survivors without financial hardship in both age groups. *Id*. Those mortality findings were recently corroborated by a 2023 study by researchers at the Emory University School of Public Health and the American Cancer Society. *See* Xin Hu, *et al., Association of Medical Debt and Cancer Mortality in the U.S*., American Society of Clinical Oncology (2023), https://ascopubs.org/doi/abs/10.1200/JCO.2023.41.16_suppl.6505. By way of background, those researchers noted that medical debt is associated with both

medical and non-medical financial hardship, such as delaying or forgoing recommended medical care and food and housing insecurity. *Id.* The study looked at levels of medical debt and age-adjusted mortality rates for all malignant cancers, using county-level data, throughout the U.S. *Id*. The study concluded that medical debt is associated with "significantly higher cancer mortality rate at the county level" and that policies "increasing access to affordable health care may improve cancer outcomes." *Id*.

In sum, before Congress passed the No Surprises Act, surprise billing was pervasive, it added to medical financial hardship, and that hardship, in turn, limited use of recommended healthcare due to cost concerns and worsened health care outcomes, including increased cancer mortality.

B. <u>The financial hardship and harm to patient outcomes caused by surprise billing mean that Plaintiffs cannot prove that an injunction would be in the public interest.</u>

In order to obtain a preliminary injunction, the Plaintiffs were required to show that the public's interest weighs in favor of granting an injunction. *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011). This standard is elevated when seeking injunctive relief against government action taken in the form of a statutory scheme for the express purpose of furthering the public interest. *Sussman v. Crawford*, 488 F.3d 136, 140 (2d Cir. 2007). In passing the No Surprises Act, Congress balanced the interest of protecting patients from surprise

medical bills against that of allowing providers to sue those patients directly for potentially ruinous medical bills.

Ample empirical data support Congress' judgment that patients should be protected from the financial hardship caused or worsened by balance billing, and that disputes over payment should be resolved between providers and insurers. Taking patients out of the middle of payment disputes between providers and payors has resulted in changes of operational processes that mitigate risk of exposure to disputes between their insurance and medical providers. Jack Hoadley, *et al.*, *No Surprises Act: Perspectives on the Status of the Consumer Protections Against Balance Billing*, Urban Institute & Robert Wood Johnson Foundation, at 2 (April 2023), https://www.urban.org/sites/default/files/2023-04/No%20Surprises%20Act%20Perspectives%20on%20the%20Status%20of%20the%20Consumer%20Protections%20Against%20Balance%20Billing.pdf.

The passage of time also argues in favor of protecting patients from potentially ruinous surprise medical bills and allowing out-of-network providers to sue their patients. In the first two months after the No Surprises Act took effect, the act prevented two million surprise medical bills and was projected to prevent 12 million more throughout the rest of 2022. AHIP & Blue Cross and Blue Shield, *New Study: No Surprises Act Prevented Over Two Million Potential Surprise Bills for Insured Americans* (May 24, 2022), https://www.ahip.org/news/press-

releases/new-study-no-surprises-act-protects-9-million-americans-from-surprise-medical-bills.

Also during that time, medical facilities, providers, and payors adjusted their processes to clarify and strengthen cost-sharing protections, notice and consent standards, complaint processes, and enforcement. Hoadley, *supra*, at 5. Both providers and payors have made significant capital investments into coding, billing, and other operational processes to streamline how insurers and administrators process claims for services covered by the Act. Id. at 8. Many have introduced specialized billing codes and have employed vendors to automate compliance in their claims processing systems. *Id*.

The consequences of an injunction against enforcement of the Act would be more severe now than they would have been immediately after the law went into effect. The millions of balance bills that were diverted to alternate resolution, some of which may have been sold on a secondary market or written off by collection agencies, would immediately become eligible for attempts to collect. The district court rightly concluded that the public interest and balance of the equities argue against enjoining this system that providers, payors, and government agencies have implemented, and which they and patients have come to rely on.

C. Medical Financial Hardship and Resulting Harm to Patient Outcomes and Increased Mortality Support Congress' Decision to Create a New Public Right that Protects Patients from Surprise Billing and Gives Out-of-Network Providers the Right to Payment from Insurers.

Likewise, data showing the harms caused by medical financial hardship supports Congress' decision to protect patients against surprise billing while giving out-of-network providers the right to seek payment from insurers, with disputes over payments being adjudicated through the IDR process.

A key "public rights" case is *Thomas v. Union Carbide*, in which the Supreme Court approved of a statutory scheme requiring that disputes between private parties be decided by arbitration. There, pesticide manufacturers challenged a provision in the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA") that required disputes about compensation under a data-sharing arrangement to be decided by binding arbitration. 473 U.S. 568, 585 (1985). Pesticide manufacturers argued that because FIFRA conferred a "private right" to seek compensation from a private company, it required "either Article III adjudication or review by an Article III court sufficient to retain the essential attributes of the judicial power." *Id*. at 585. The Court disagreed. It concluded that because the data-sharing provision was an integral part of a program safeguarding the public health, Congress had the power, under Article I, to authorize an agency to assign costs without providing an Article III adjudication. *Id*. at 571-75.

The same is true with the No Surprises Act. The Act is part of a highly technical statutory scheme to regulate the health care industry nationwide. The rights of patients, providers and health plans under this statutory scheme are quintessential public rights, of the same character as those approved of in *Thomas*. Congress chose to protect patients from the financial hardship caused by surprise billing, while creating a mechanism for out-of-network providers to be compensated by insurers. Plaintiffs offer no compelling reason to second-guess that balancing of interests.

CONCLUSION

For these reasons, ACS and ACS CAN respectfully submit that the judgment of the district court should be affirmed.

Dated: August 2, 2023

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CERTIFICATE OF COMPLIANCE

Under Federal Rule of Appellate Procedure 32(g), I certify that:

This brief complies with the type-volume limitation of Second Circuit Rule 29.1, which sets the length of amicus briefs as one-half the maximum authorized length of the supported party's brief.

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because it contains 2855 words, excluding the parts of the brief exempted by Rule 32(f).

This brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 in Times New Roman 14-point font.

Dated: August 2, 2023

/s/ Thomas W. Curvin
Thomas W. Curvin

CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2023, I caused the foregoing brief to be served on all registered counsel through the Court's CM/ECF system.

/s/ Thomas W. Curvin
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