IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, *et al.*, *Plaintiffs*, v. ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*, *Defendants*.	Civil Action No. 1:20-cv-03531-CCB

BRIEF OF AMERICAN SOCIETY OF CLINICAL ONCOLOGY AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Jonathan R. Ference-Burke
D. Md. Bar No. 20824
Margaux J. Hall
Stephanie A. Webster
Douglas Hallward-Driemeier
Scott J. Falin
ROPES & GRAY, LLP
2099 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 508-4731
Jonathan.Ference-Burke@ropesgray.com

Attorneys for Amicus Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

STATEMENT OF INTEREST

As the nation's second leading cause of death and with an estimated 1.8 million new cases projected for this year alone, cancer has far-reaching consequences for health care delivery, communities, and families across the country.[1] *Amicus curiae*—the American Society of Clinical Oncology ("ASCO")—represents nearly 31,000 U.S. health care professionals leading the charge in cancer treatment, diagnosis, and prevention. ASCO's members serve alongside many other professionals who prescribe and administer lifesaving pharmaceutical treatments to U.S. cancer patients every day. Unfortunately, due to a hasty and sweeping administrative action, taken without adequate notice or comment or consideration of its effects, cancer patients' ability to access critical cancer treatments will be seriously jeopardized.

In late November, the Centers for Medicare & Medicaid Services ("CMS") issued the Most Favored Nation ("MFN") "interim final rule with comment period" (the "MFN Rule"), 85 Fed. Reg. 76,180 (Nov. 27, 2020) (to be codified at 42 C.F.R. pt. 513), which the plaintiffs seek to enjoin. The MFN Rule fundamentally overhauls how Medicare Part B reimburses prescription drugs by mandating a new, seven-year, nationwide program that begins on January 1, 2021—only a few weeks after its announcement. In one fell swoop, it entirely replaces Congress' carefully designed statutory regime for Part B drug reimbursement, which ties payments to a drug's average *domestic* sales price, with an untested policy based on the *lowest* price for that drug in a set of other countries.[2] In establishing a "transformative" new program that will

---

[1] *See* Jiaquan Xu et al., National Center for Health Statistics, *Mortality in the United States, 2018*, NCHS Data Brief No. 355, https://www.cdc.gov/nchs/data/databriefs/db355-h.pdf (last visited Dec. 16, 2020); Rebecca Siegel et al., *Cancer Statistics, 2020*, 70 CA: Cancer J. for Clinicians 7-30, https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21590 (last visited Dec. 16, 2020).

[2] A fixed add-on amount also will apply to drugs reimbursed under the MFN program.

"completely restructure the prescription drug market,"[3] CMS exceeded its authority to test new payment delivery models and did so without even consulting, through notice and comment, the health care professionals and Medicare beneficiaries who stand to be harmed.

The MFN rule's sudden, sweeping changes will disproportionately hurt vulnerable cancer patients, and the oncology practitioners who serve them. An overwhelming majority of drugs targeted by the MFN Rule are products used to treat cancer. 85 Fed. Reg. at 76,194, tbl. 2. There is a fundamental misalignment between the agency's purported policy goal of demanding lower drug prices and the actual operation of the MFN Rule. The MFN Rule guts reimbursement for drugs that oncology professionals must continue to buy for their patients at the prevailing market rate—rates that the MFN Rule leaves unaltered. In this manner, the MFN Rule perilously interacts with the existing Medicare Part B "buy-and-bill" reimbursement system, under which an oncology professional assumes the financial risk of purchasing a drug and then seeks Medicare reimbursement for it and the cost of its administration. Whereas current law ties a health professional's Part B drug reimbursement to U.S. commercial market prices,[4] the MFN program will reimburse at a rate based on the lowest qualifying international price for the drug—irrespective of the cost of acquiring the drug. This change will dramatically reduce reimbursement to oncology practices, resulting in the permanent closure of many practices—especially clinics that are smaller and in rural and underserved areas, and the many practitioner groups already financially strained due to the COVID-19 pandemic. The consequences to cancer

[3] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices (last visited Dec. 16, 2020).

[4] Under the Medicare statute, reimbursement is based on average sales price, taking into account various commercial market discounts, *plus* a six percent add-on fee to defray ancillary costs that many practices incur. 42 U.S.C. § 1395w-3a.

patients will be dramatic, as patients endure delays in and disruptions to care, and must seek out less effective treatment alternatives or potentially forgo care altogether. *Id.* at 76,237. CMS itself projects that this new scheme will lead to one in five Medicare beneficiaries forgoing care. *Id*. at 76,237, tbl. 11. For cancer patients unable to access therapies, this means irreversible harm and, in tragic instances, loss of life.

ASCO has a substantial interest in this case because the MFN Rule directly threatens substantial and irreparable harm to its members, their patients, and Medicare beneficiaries with cancer. ASCO thus offers the Court its perspective through this brief as amicus curiae.

ARGUMENT

ASCO strongly supports Plaintiffs' request that the Court enjoin application of the MFN Rule. The MFN Rule will restrict Medicare beneficiaries' access to lifesaving cancer therapies, lowering quality of care as it financially devastates oncology practitioners.

First, the agency bypassed proper notice and comment to the severe detriment of cancer patients and their practitioners. Had the agency not rushed forward with a hastily- and poorly-designed program that lacked the benefit of public input required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. § 1395hh(b), it could have understood and, one hopes, avoided these unlawful and discriminatory harms. Moreover, the agency lacked a valid reason for dispensing with notice and comment. In fact, CMS's basis for hastily effecting the MFN Rule—the COVID-19 pandemic—overwhelmingly points in favor of *not* pursuing such a sweeping change to the Part B reimbursement regime, especially without consultation with cancer care patients, professionals, and other members of the public.

Second, Congress put clear limits on CMS's authority to conduct demonstration projects precisely to prevent these kinds of disruptions and harms to oncology patients and practitioners. The MFN program will overhaul Medicare Part B drug reimbursement across the nation, without

the statutorily required "testing" or expert consultation, causing inevitable and irreversible harm to cancer patients. Such a program is not an authorized "demonstration" and thus cannot stand.

I. The Lack of Proper Notice and Comment Dooms the MFN Rule

A. Proper Notice-and-Comment Rulemaking Would Have Revealed that the Transformative Cuts Would Cause Substantial and Lasting Harm to America's Oncology Programs and Their Patients.

If there had been an opportunity to comment, the cancer community would have made clear to CMS the MFN Rule's severely adverse consequences for oncologists, who rely heavily on adequate Medicare Part B reimbursement, and their patients. Thirty-eight of the fifty drugs identified by CMS in the MFN Rule relate to oncology care. 85 Fed. Reg. at 76,194, tbl. 2. Under the program design, these drugs are selected on the basis of having some of the highest utilization of all drugs in the Part B program. *Id.* at 76,190-94. By tying reimbursement for these critical, heavily utilized cancer therapies to the *lowest* international price—drawn from a set of reference countries with health care systems, reimbursement regimes, and intellectual property laws entirely distinct from those in the United States—the MFN Rule will slash reimbursement rates for the oncology practitioners who purchase these drugs for patient use and furnish care associated with the medications. Over seven years, CMS projects the MFN Rule will reduce Part B fee-for-service expenditures—and thus revenues for practitioners administering the drugs affected by the MFN Rule—by nearly $65 billion. *Id*. at 76,238, tbl. 12.

Irreversible harm to oncology practices serving cancer patients. The MFN program's foundational structure perilously places health professionals and the patients they serve in the cross-fire of the government's purported attempt at a blunt-force drug pricing policy change. Oncology practices vary significantly with respect to size, financial health, and patient and payer mix. Many practices, especially in rural, underserved, and low-income areas that already are struggling to deliver care, will be irreparably harmed by cuts in reimbursement rates, and many

will have to close their doors altogether. These practitioners do not control drug prices and few, if any, have the bargaining power to lower acquisition prices to the degree necessary to compensate for the MFN Rule's staggering cuts in Medicare reimbursement. Instead, the professionals rely on the current reimbursement rate of a drug's average domestic sales price, plus a six percent add-on fee, to cover not just the costs of acquiring the drug, but other costs related to administering the drug for which the Medicare program does not specifically reimburse. For example, many cancer treatments are toxic substances that require resource-intensive handling, storage, preparation, and disposal. Any margin also might be used to operate practice pharmacies that enable safe storage, mixing, administration, and disposal of drugs, or to compensate for purchases where actual acquisition costs exceed the average sales prices or when drugs are lost due to breakage and thus not reimbursable. The MFN Rule will leave many oncology practices unable to afford these expenses or offer essential services.

If the cost of acquiring a particular cancer therapy remains above the MFN reimbursement rate, oncology providers can only continue to provide the medication at a financial loss, which is simply unsustainable for many practices. Moreover, in CMS's hurry to implement the MFN program, the agency has given manufacturers, distributors, physicians, and patients only a few weeks to prepare—nowhere near enough time for the many moving parts in the drug distribution system to adjust to such drastic changes. Many oncology practices, for example, are locked into multi-year contracts that will be difficult to renegotiate to mitigate the lost revenue. Regardless, CMS expects that some manufacturers will maintain their current prices despite the drastic reductions in reimbursement. 85 Fed. Reg. at 76,237, which would create crippling financial challenges for practitioners who would lose money on each drug under the MFN program administered to a Medicare beneficiary. Yet, without any assurance that

practitioners' acquisition costs will ever be competitive with the new MFN reimbursement rates, CMS has rushed to implement a seven-year demonstration that begins just weeks after its announcement. Moreover, as of December 16th, the agency has yet to release any instructions or guidance to manufacturers and practitioners on how to implement required new systems, or conduct additional record-keeping and reporting, creating further burdens on oncology practices.

By the time CMS recognizes its policy misstep, the consequences will be catastrophic and irreversible for patients and professionals. ASCO projects that the vast majority of oncology practices will suffer significant financial losses under the MFN Rule due to the substantially-reduced MFN price (taking into account the fixed add-on fee). Independent community oncology practices will see an average loss of Medicare drug revenue of 52% and hospital outpatient oncology departments will see an average loss of 50% by year four of the MFN program.[5] This will jeopardize their ability to stay in business and could disrupt the network of independent and hospital-based oncology practices built over decades that ensures adequate access to care. It will drive smaller practices and satellite clinics of larger practices out of business, especially in rural and other underserved areas. By the end of the seven-year program, this cancer care infrastructure could be permanently and irreparably destroyed. While CMS established a financial hardship exemption for adversely affected practitioners, the MFN Rule sets forth highly restrictive criteria to receive the post hoc payments. The agency expects "few, if any," will be able to qualify and, in a revealing statement, conceded that those who do qualify

[5] ASCO PracticeNET Report, *ASCO PracticeNET Analysis of the Medicare Most Favored Nation Interim Final Rule,* Am. Society of Clinical Oncology, https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-PracticeNET-MFN-Report.pdf (last visited Dec. 16, 2020).

may already be "insolvent and therefore unable to obtain retrospective hardship payments." 85 Fed. Reg. at 76,242-43.

Lasting harm for cancer patients. The financial losses and disruptions to oncology practitioners will harm patients by reducing their access to cancer care. CMS acknowledges that "beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." 85 Fed. Reg. at 76,244. Any of these impacts may have life-and-death consequences for cancer patients, who can ill afford to experience delays in care, disruptions in long-standing relationships with trusted oncology professionals, or restricted access to treatment. The MFN program forces cancer patients to navigate a new labyrinth in order to access urgently needed care—all while suffering from a life-threatening disease. CMS expects that some patients will never escape this labyrinth. In fact, the government estimates that a significant portion of the MFN Rule's estimated savings will come from a nineteen percent *decline in utilization* of this critical care. *Id.* at 76,237, tbl. 11. The Rule will have particularly detrimental impacts on beneficiaries in rural and other, already-underserved areas, where practices are most likely to close with adverse patient impact. As just one example of real-life impact, the MFN Rule includes four immune checkpoint inhibitors commonly used to treat advanced and metastatic lung and other cancers on the MFN drug list. Based on CMS's own projections on forgone care, ASCO estimates that 87,556 years of life will be lost due to loss of access to these four drugs alone over the duration of the program.[6]

[6] Elizabeth Garrett-Mayer and Brian Bourbeau, *ASCO Estimates that 87 Thousand Years of Life for Non-Small Cell Lung Cancer Patients Are at Risk Due to the Most Favored Nation Model*, https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-MFN-NSCLC-Analysis.pdf (last visited Dec. 16, 2020).

CMS's expectations about how patient harm will be mitigated are fundamentally misguided and reveal a lack of understanding of cancer care. The agency expects some patients to transition to "alternative therap[ies]," if they cannot access needed drugs. 85 Fed. Reg. at 76,244. This is not realistic for many cancer patients. Cancer patients have multifaceted medical needs and are sensitive to changes in treatment, especially as cancer treatments have become increasingly complex in an era of targeted therapies, immunotherapy, and personalized medicine. Delays and other disruptions in care and switching between therapies can be dangerous for many patients. Additionally, the cancer drugs included in the MFN rule have significantly improved survival for cancer patients and most simply do not have medically appropriate substitutes.

Even if the MFN Rule succeeds at lowering drug prices, the benefits for Part B beneficiaries are limited. Because the vast majority of Part B beneficiaries have supplemental coverage, one study concluded that less than one percent of Medicare patients will see reduced out-of-pocket costs in any given year of the demonstration.[7] Any savings accrue to the benefit of the government but come at the direct expense of cancer patients obtaining appropriate medical care. This violates 42 U.S.C. § 18114, which prohibits the agency from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; impedes timely access to health care services . . . or limits the availability of health care treatment for the full duration of a patient's medical needs."

In sum, oncology practitioners and their patients should not be victims of a slapdash mandatory "demonstration" purportedly intended to address drug prices, but which has the effect of unlawfully depriving Medicare cancer patients of life-saving care. As the agency would have

[7] Milena Sullivan et al., *Most Favored Nation Rule's Impact on Medicare Beneficiaries OOP Costs*, Avalere, https://avalere.com/insights/most-favored-nation-rules-impact-on-medicare-beneficiaries-oop-costs (last visited Dec. 16, 2020).

understood if it had engaged in proper notice and comment, there are many more efficient vehicles to achieve lower drug prices and beneficiary cost-sharing without such devastating consequences for cancer care providers and patients, who bear no responsibility for drug prices. If CMS had acted consistent with the procedural requirements of the APA and the Medicare Act, oncology practitioners and their patients would have had the opportunity to alert the agency to the terrible costs of the program before CMS rushed forward with an interim final rule set to take effect just a few weeks after its publication.

B. The Covid-19 Pandemic Not Only Fails to Give CMS "Good Cause" for Bypassing Notice and Comment, But in Fact Underscores Why the Agency Should Not Pursue Such a Devastating Program for Cancer Care at This Time.

Notwithstanding the agency's assertions to the contrary, there is no "good cause" to waive notice and comment. Indeed, the U.S. Department of Health and Human Services ("HHS") has a longstanding policy that "[good cause] exceptions [to the APA notice and comment procedures] should be used sparingly, as for example in emergencies and in instances where public participation would be useless or wasteful because proposed amendments to regulations cover minor technical matters." 36 Fed. Reg. 2,469, 2,532 (Feb. 5, 1971). *See, e.g.*, 73 Fed. Reg. 80,302 (Dec. 31, 2008) (asserting good cause to bypass notice and comment in order to "merely correct[] typographical and technical errors" in the Medicare physician fee schedule final rule, since those "corrections are consistent with, and do not make substantive changes to, the payment methodologies and policies adopted in the [] final rule with comment period"). While HHS's policy allows for the exception to be invoked in certain "emergencies," those emergencies are limited to instances in which "'delay [on account of pursuing the notice and comment process] would do real harm' to life, property, or public safety," *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 777 (9th Cir. 2018) (quoting *United States v. Valverde*, 628

F.3d 1159, 1164-65 (9th Cir. 2010)); *see also E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1278 (9th Cir. 2020). Courts have rejected past HHS attempts to use the good cause exception absent an emergency. *See, e.g., Vista Health Plan, Inc. v. U.S. Dept. of Health and Human Services,* No. 1:18-CV-824, 2020 WL 6380206, at *10 (W.D. Tex. Sept. 21, 2020), *appeal filed*, No. 20-50963 (5th Cir. filed Nov. 24, 2020); *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *4 (E.D. Tex. Jan. 25, 2017).

The existence of a public health emergency does not make every HHS action an emergency. *See, e.g., Itserve All., v. Scalia*, No. 20-14604 (SRC), 2020 WL 7074391, at *4-8 (D.N.J. Dec. 3, 2020) (holding that hardships caused by the COVID-19 pandemic were insufficient to waive public comment, particularly when the rule itself "might instead lead to the exact problem that [other cases successfully invoking the "good cause" exception] tried to avoid — a shortage of necessary products or services"). In fact, the MFN Rule's timeline reveals that the agency does not view it as an emergency action. The agency waited nearly ten months after the onset of the pandemic, and until right before the first vaccines are set to become available, to issue the MFN Rule, establishing a program that will be in effect for seven years, long after the pandemic is expected to subside. Tellingly, the MFN rule excludes drugs to treat patients with suspected or confirmed COVID-19 to allow for "maximum flexibility" in distribution of such drugs. 85 Fed. Reg. at 76,189. CMS makes no such accommodations for lifesaving oncology drugs, acknowledging the MFN Rule will restrict their access.

Applying the rubric of HHS and the courts to the case at hand reveals that there is no "good cause." Allowing the oncology community and rest of the public to participate in this rulemaking would certainly not be "useless or wasteful," nor does the MFN Rule address a "minor technical matter." Moreover, delaying the implementation of this rule in order to provide

for notice and comment unequivocally would not result in "real harm to life, property, or public safety." In fact, the opposite is true: the COVID-19 pandemic provides strong reason *not* to pursue this program absent public comment and careful deliberation.

For the agency to assert that it has taken such sudden action *on account of COVID-19*, without providing an opportunity for public comment, is contrary to reason, common-sense, and basic notions of good policy. A public health emergency is precisely the time for actions to minimize disruptions to the health care system and ensure patients have access to the care they need. The experiences of the oncology community highlight the continuing adverse impacts of COVID-19, which only will be made worse by the MFN Rule. Due to COVID-19, Medicare beneficiaries have deferred cancer screenings and treatments, which will increase patients' cancer health needs for years to come.[8] The downturn in utilization also has financially hurt oncology practices, many of which already operated on the thinnest of margins.[9] With COVID-19 continuing to generate unmet medical needs, backlogs in care, and financial strain on oncology professionals, CMS's hasty and sweeping change will further impair patient care. Among other harms, the MFN Rule risks bankrupting oncology practices, making it even more difficult for cancer patients to safely access care. Some patients will forgo care altogether, and others will seek care in hospital settings, exposing immunocompromised cancer patients to

[8] *See, e.g.*, Debra Patt et al., *Impact of COVID-19 on Cancer Care: How the Pandemic Is Delaying Cancer Diagnosis and Treatment for American Seniors*, 4 JCO Clinical Cancer Informatics 1059-71, https://ascopubs.org/doi/full/10.1200/CCI.20.00134 (last visited Dec. 16, 2020).

[9] *See, e.g.*, Nathan A. Pennell et al., *American Society of Clinical Oncology Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care*, J. of Clinical Oncology, https://ascopubs.org/doi/10.1200/JCO.20.02953 (last visited Dec. 16, 2020).

COVID-19 and further burdening hospitals already overwhelmed by the rise in COVID-19 cases. Rather than mitigating harms of COVID-19, the MFN Rule will gut providers and hurt patients.

II. The MFN Rule's Devastating Effect on Oncology Care Underscores Why Congress Placed the Statutory Limits on CMS's Demonstration Authority that the Agency Has Clearly Exceeded Here.

The MFN Rule's adverse consequences for cancer care providers and patients illustrate precisely why Congress circumscribed CMS's demonstration authority with parameters and guardrails in the first place. Section 1115A of the Social Security Act authorizes CMS to "test innovative payment and service delivery models" within a two-phase process for "testing" models first and then "expand[ing]" them if the results merit it. 42 U.S.C. § 1315a. The MFN Rule, however, is not a "test" within the contours of the statute. The rule exceeds anything Congress envisioned when it passed Section 1115A, as well as any regulatory initiative that CMS has taken since the enactment of Section 1115A a decade ago.[10] A mandatory, nationwide "demonstration" goes well beyond the plain meaning of a "test." A "test" refers to an experiment limited in scale that allows the agency to study the impact of a certain intervention against a control or comparison group that is not subject to the mechanism under investigation. Yet by applying the program nationwide, the MFN Rule lacks a control or comparison group against which to study the impact of the sweeping changes it makes to the Part B reimbursement system. Without first testing in a smaller, more measured manner with a control group, CMS cannot ascertain the MFN Rule's impact on particular categories of oncology providers and cancer patients (especially those in rural locations or who receive care from smaller clinics).

[10] A list of CMS demonstrations under Section 1115A is available at Centers for Medicare & Medicaid Services, *Innovation Models*, https://innovation.cms.gov/innovation-models#views=models (last visited Dec. 16, 2020).

In addition, CMS has disregarded Congress' clear directive that the agency consult stakeholders and experts prior to moving forward with demonstrations under Section 1115A. The statute requires CMS to "consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management" and to "use open door forums or other mechanisms to seek input from interested parties." 42 U.S.C. § 1315a(a)(3). By forgoing notice and comment, CMS has failed to carry out its duties under Section 1115A in an open manner and with the input of organizations, such as ASCO, that have relevant clinical and analytical expertise and could have ensured the agency fully understood the MFN Rule's severe consequences for the oncology community.

Most importantly, Section 1115A limits CMS to testing models "to reduce program expenditures…*while preserving or enhancing the quality of care*." 42 U.S.C. § 1315a(a)(1) (emphasis added). By driving oncology and other practitioners out of business and restricting access to care, the MFN Rule directly harms beneficiaries and diminishes the quality of care in violation of the statute. Astonishingly, the MFN Rule's detrimental effects for patients are not just some *potential* unintended consequence that third parties fear *might* occur. CMS openly acknowledges that patients will have reduced access to care under the MFN Rule. 85 Fed. Reg. at 76,237. That reduced utilization underlies the MFN Rule's ability to achieve its projected savings.

Cancer patients simply are not appropriate subjects for such a radical experiment in Medicare reimbursement policy, especially when CMS expects the MFN Rule to restrict this vulnerable population's access to treatment. Experiments with cancer treatment in particular are fraught with peril, considering the highly sensitive needs of cancer patients and the lack of suitable alternatives for many therapies. Additionally, the MFN Rule inappropriately mandates participation, forcing Medicare beneficiaries battling a life-threatening disease to "participate" in

a misguided experiment that CMS rushed through without the benefit of public input and for which the agency admits there are "significant[ly] uncertain[]" effects. 85 Fed. Reg. at 76,244. Studies have shown that different reimbursement systems can result in significant variations in access to drugs.[11] Nonetheless, CMS has required all Medicare Part B fee-for-service beneficiaries to participate in this experiment, despite not knowing its effects and leaving no safety net or protection for adversely impacted patients. When an experiment involving human subjects could result in different treatment experiences and outcomes, potential participants generally are afforded protections, including informed consent and the right not to participate.[12] CMS has denied any such protections here under the guise of a "test" of reimbursement policy.

Rather than testing a model, the administration seeks, in essence, to rewrite the Medicare Part B statute, jettisoning the carefully designed market-based reimbursement regime enacted by Congress with CMS's own policy judgment. This asserted power far exceeds the statute, which only authorizes the HHS Secretary to waive provisions of laws pertaining to Medicare "solely for purposes of carrying out" phase one "testing models." 42 U.S.C. § 1315a(d)(1). This limited power to waive does not encompass, and was never intended to include, the power to rewrite the law wholesale. Yet that is precisely what the administration has done here with respect to how Medicare pays for cancer and other drugs under Part B.

The Medicare Part B program is essential to oncology practices and millions of cancer patients. With the majority of U.S. cancer patients being over 65 years of age, and almost half of

---

[11] *See, e.g.*, Milena Sullivan et al., *Medicare Covers More Part B Therapies for Breast Cancer than NHS England*, Avalere, https://avalere.com/insights/medicare-covers-more-part-b-therapies-for-breast-cancer-than-nhs-england (last visited Dec. 16, 2020).

[12] Lokesh P. Nijhawan et al., *Informed Consent: Issues and Challenges*, J. Advanced Pharmaceutical Tech. & Res. 4(3): 134–40, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3777303/ (last visited Dec. 16, 2020).

all Part B drug spending involving cancer care,[13] any changes to the Medicare Part B program stand to significantly impact cancer patients and, as such, should be carefully considered with respect to safety, access, and quality of care before being implemented. Congress never intended to give the HHS Secretary a blank check to unilaterally overhaul Medicare, including how it pays for cancer care, through the back door of a "demonstration." A policy change of this magnitude—with its devastating consequences for cancer care providers and patients—cannot lawfully be done by administrative fiat, without public input or congressional approval.

CONCLUSION

The court should grant Plaintiffs' request to enjoin application of the MFN Rule.

Respectfully submitted,

Date: December 16, 2020

/s/ Jonathan R. Ference Burke
Jonathan R. Ference-Burke
D. Md. Bar No. 20824
Margaux J. Hall
Stephanie A. Webster
Douglas Hallward-Driemeier
Scott J. Falin
ROPES & GRAY, LLP
2099 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 508-4731
Jonathan.Ference-Burke@ropesgray.com

Attorneys for Amicus Curiae

[13] Am. Cancer Society, Comment Letter on CMS-5528-ANPRM – Medicare Program; International Pricing Model for Medicare Part B Drugs; Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 54,546 (Dec. 20, 2018), https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Comment%20Letter%20International%20Pricing%20Index%20Model%20FINAL.2.pdf.