IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEEMA VERMA, in her official capacity of Administrator of the Centers for Medicare and Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; BRAD SMITH, in his official capacity as the Director of the Center for Medicare and Medicaid Innovation; CENTER FOR MEDICARE AND MEDICAID INNOVATION, Defendants.	CIV. NO. 1:20-cv-03531

DECLARATION OF DR. MICHAEL SEIDEN

I, Michael Seiden, M.D., PhD, declare as follows:

1. I am the President of The US Oncology Network ("USON" or the "Network"). Prior to assuming that position, I was Senior Vice President and Chief Medical Officer for McKesson Specialty Health and The US Oncology Network. I received my bachelor's degree from Oberlin College and my medical and Ph.D. degrees from Washington University. I completed my

residency at Massachusetts General Hospital, my fellowships in medical oncology and bone marrow transplant at Dana Farber Cancer Institute, and my post-doctoral fellowship at Brigham and Women's Hospital, Department of Pathology.

2. I have extensive experience treating patients and researching cancer treatment. Previously, I served as the CEO and President of Fox Chase Cancer Center, a National Cancer Institute-designated Comprehensive Cancer Center research facility and hospital in Philadelphia, PA. Prior to that, I spent many years practicing at Massachusetts General Hospital, where I served as Chief of the Clinical Research Unit, Cancer Science Division, and as an Associate Professor in Medicine at Harvard University.

3. The US Oncology Network provides a wide range of comprehensive oncology practice management solutions to the largest nationwide network of community oncologists in the United States. The Network supplies its more than 1,300 network physicians with industry-leading technologies to support all core clinical, operational and financial aspects of their practices, such as drug inventory management, electronic health record management, and online patient portal development and maintenance, as well as recruitment, marketing, and community outreach.

4. The US Oncology Network serves approximately 70 oncology practices. The top priority for USON and the Network practices is to provide patient care. Collectively, these practices operate more than 480 oncology care sites across 25 states, and they serve more than 1.2 million patients per year. The Network's cancer care sites are served by more than 1,300 affiliated physicians and hundreds of advanced practice nurses and physicians' assistants. In addition to providing medical oncology treatment, these centers provide a variety of non-medical support services to help patients and their families, including assistance with nutrition, exercise, financial management, advance care planning, and documentation of patients' treatment preferences. Nearly

100 of the Network's 480 sites are considered integrated cancer centers, which provide comprehensive cancer care.

5. I provide this declaration, on behalf of The US Oncology Network, in support of Plaintiffs' motion to prevent implementation of the Most Favored Nation rule (the "MFN Rule") issued by the Centers for Medicare & Medicaid Services' Center for Medicare and Medicaid Innovation, 85 Fed. Reg. 76,183 (Nov. 27, 2020).

6. The MFN Rule imposes a new payment methodology aimed at substantially reducing Medicare reimbursement for 50 single source drugs and biologicals covered by Medicare Part B. 85 Fed. Reg. 76,194, Table 2. Of those, CMS identified 38 as drugs administered for oncology (the "Affected Oncology Drugs"). The MFN Rule requires mandatory, nationwide participation of Medicare participating providers, which includes the Network's oncology centers.

7. This declaration is based on my personal knowledge of facts regarding The US Oncology Network and oncology practices, as well as analysis of CMS's own modeling.

8. In my considered judgment, the MFN Rule will cause immediate and irreparable harm to Medicare patients across The US Oncology Network whose treatment includes the Affected Oncology Drugs. The MFN Rule puts lives at risk and jeopardizes the health of patients seen by the Network practices.

9. Of the 1.2 million patients that the Network practices serve annually, roughly 625,000 are Medicare beneficiaries, and roughly 425,000 are Medicare fee-for-service (FFS) beneficiaries.

10. In 2019, the Network practices administered approximately 1.75 million Medicare Part B pharmacological treatments to more than 100,000 Medicare FFS beneficiaries.

Approximately 70% of these Medicare FFS beneficiaries received one or more of the Affected Oncology Drugs.

11. The Network practices, like most providers, purchase Medicare Part B drugs and administer them to patients before receiving reimbursement. This approach is commonly known as "buy and bill." The Network practices have set negotiated contracts in place, based on market prices, that dictate the price they pay for the drugs they administer. When reimbursement rates are higher or lower than those negotiated prices, the Network practices will either earn a margin or incur a loss.

12. The Network practices have binding contracts that set prices for oncology drugs affected by the MFN Rule, and the contracts extend for months at a time and even for a year or more. Nearly half of the Network practice contracts regarding the Affected Oncology Drugs extend to at least March 31, 2021; of those, more than 75% extend to June 30, 2021 or later.

13. Hence, the price of drugs that the Network practices will administer under the MFN Rule in January 2021 will be set by pre-existing contracts. It would be extremely difficult, if not impossible, to renegotiate these contracts before the MFN Rule begins to reduce reimbursement rates beginning on January 1. Moreover, the Network practices will have to continue to purchase drugs under the pre-existing contracts in order to maintain drug inventory.

14. Because the MFN Rule will reimburse providers at below-market rates, it will force the Network practices to absorb substantial losses for Affected Oncology Drugs that have been purchased on the market (according to market prices) but qualify only for MFN Rule reimbursement rates. With drug acquisition costs substantially higher than reimbursement rates, the MFN Rule means that an oncology practice is guaranteed to incur a financial loss every time it provides an Affected Oncology Drug to a patient.

15. Most branded oncology drugs are costly; indeed, that is why 38 of the 50 drugs governed by the MFN Rule (which targets the most expensive drugs in the Medicare program) are cancer drugs. The Network practices typically spend $10,000 to $15,000 (or more) per administration for their patients, and the losses posed by the MFN Rule are enormous. Because the Network practices cannot administer the Affected Oncology Drugs at a staggering financial loss per administration, patient care will be jeopardized under the MFN Rule.

16. For example, pembrolizumab, which is one of the Affected Oncology Drugs (and for which there is no generic or biosimilar), was administered to Medicare FFS beneficiaries by the Network practices more than 20,000 times during 2019. When the MFN Rule reimbursement rates take effect beginning January 1, those practices will receive nearly $2,000 less in Medicare reimbursement per administration. Assuming similar demand going forward (that is, roughly the same usage of the drug in 2021), this translates to an anticipated loss of over $41 million in revenue across the Network practices during just the first year of the MFN Rule.

17. Additionally, nivolumab, which is another of the Affected Oncology Drugs (and for which there is no generic or biosimilar), was administered to Medicare FFS beneficiaries by the Network practices approximately 20,000 times during 2019. When the MFN Rule reimbursement rates take effect beginning January 1, those practices will receive roughly $1,900 less in Medicare reimbursement per administration. Assuming similar demand going forward (that is, roughly the same usage of the drug in 2021), this translates to an anticipated loss of over $38 million in revenue across the Network practices during just the first year of the MFN Rule.

18. When the Affected Oncology Drugs are considered as a group, the magnitude of these revenue losses across the Network practices grows nearly four-fold. We estimate those revenue losses to total roughly $300 million across all of the individual practices in the Network

in just 2021 alone. This will force many individual practices to operate at a deficit, which is not sustainable for any significant period of time.

19. The risk that the MFN Rule presents to Network practices and patients is immediate and profound. Given the number of Medicare beneficiaries that the practices treat and the volume and cost of Affected Oncology Drugs at issue, the MFN Rule will deprive vulnerable patients of the Affected Oncology Drugs. Under the MFN Rule, it will not be sustainable for the Network practices to continue to provide the Affected Oncology Drugs to the same number of Medicare patients as they currently serve; they will incur staggering losses within days after the Rule's January 1, 2021 effective date.

20. The MFN Rule will therefore cause immediate and irreparable harm to vulnerable Medicare patients, many of whom will lose access to life-saving cancer treatments beginning in January 2021. The Network practices (and other oncology practices) will have no choice. They will be forced by the MFN Rule to decline treatment for numerous Medicare patients beginning in January 2021.

21. The Network practices' inability to provide the Affected Oncology Drugs to patients will have significant negative health impacts, and puts doctors in the impossible position of forgoing the treatment they deem necessary in their medical judgment. Many of the Affected Oncology Drugs have been developed in the last ten years and have dramatically improved care for patients diagnosed with the indicated cancers. The failure to administer the Affected Oncology Drugs will result in a reduction in care for cancer patients, and a corresponding reduction in favorable outcomes and life expectancies.

22. The Affected Oncology Drugs are far superior to existing alternative treatments. The Affected Oncology Drugs include immunotherapy and biologics options that are far more

innovative and effective than existing alternative treatments. In fact, the list of Affected Oncology Drugs represents clinical standards of care according to the National Comprehensive Cancer Network (NCCN) guidelines, which are widely recognized and used as the standard for clinical treatment in oncology by clinicians and payors. For example, 58% (22 out of 38) of the Affected Oncology Drugs are used to treat advanced cancers with the goal of extending patient lives. Collectively, they result in improvements in survival and quality of life. In lung cancer, for example, use of drugs such as pembrolizumab has doubled median survival.[1] Accordingly, an oncologist cannot stop using these drugs and continue to provide the same level of care to a patient.

23. Significantly, 82% of the Affected Oncology Drugs do not have generic or biosimilar alternatives and are thus available only from the brand-name manufacturer, which means that there is no alternative source for the drugs.

24. It is no answer to suggest that Medicare patients denied treatment at the Network practices could seek treatment elsewhere, perhaps at one of the 340B hospitals,[2] which are subject to the MFN Rule but can acquire the Affected Oncology Drugs at a much lower cost, or one of the 11 Prospective Payment System (PPS)-exempt cancer centers, which are also exempt from the MFN Rule. Promptly assigning, transferring, or closing practices to Medicare patients is not straightforward especially during this extraordinary health emergency caused by the COVID-19 pandemic.

a. Many of the Network's oncology care sites are located in suburban, exurban, or rural areas, rather than in the urban areas where major hospital centers are

[1] *See* Gadgeel, S. *et al.*, "Updated Analysis From KEYNOTE-189: Pembrolizumab or Placebo Plus Pemetrexed and Platinum for Previously Untreated Metastatic Nonsquamous Non-Small-Cell Lung Cancer," J Clin Oncol 38(14):1505-1517 (May 10, 2020).

[2] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell drugs at discounted prices to certain health care organizations (known as "340B hospitals") that serve uninsured or low income patients.

typically located. For instance, of the 11 PPS-exempt cancer centers in the United States, only two (American Oncologic Hospital in Philadelphia and MD Anderson in Houston) are within a 90-minute drive of a small portion of the Network's 480 facilities. Many Medicare patients served by the Network practices have no readily available alternatives for their cancer care. Asking Medicare recipients, most of whom are seniors, to drive several hours for treatment that can be as frequent as weekly – in the midst of the COVID-19 pandemic – is simply not viable and will result in numerous patients forgoing the recommended treatment.

b. Even if a 340B hospital or PPS-exempt cancer center were accessible, it likely would not have the staffing and other capacity to take on these displaced patients, particularly in the magnitude that the MFN Rule will trigger, and particularly during the COVID-19 pandemic, with its impact on hospitals across the country. Importantly, many 340B hospitals are also safety net hospitals, operating at capacity. They have had to re-purpose hospital facilities and staff to take care of COVID-19 patients. During the COVID-19 pandemic many hospitals have reassigned nursing and physician staff to ICUs and emergency departments. During this public health emergency, I do not believe that either 340B hospitals or PPS-exempt cancer centers will be in a position to take on a wave of new patients seeking cancer care. Even if these facilities and their staffing could be modified to take additional patients, they could not do so on a timetable that accommodates the urgency with which cancer patients must obtain critical treatment.

c. The dislocation of a large collection of cancer patients to alternative sites on short notice during a national health emergency enhances the risk of lapses in appropriate care and increased medical errors. Transitioning cancer patients to distant sites will interrupt their relationship with their primary oncology team, with whom many of these patients have worked with during a long and arduous cancer journey, which in many cases has spanned years. This will create significant anxiety and stress along with additional logistic challenges for this vulnerable population. In addition, if patients need to travel to more distant sites, it risks jeopardizing coordinated care they might receive from multiple co-located community-based physicians involved in managing the patients' co-morbid illnesses, such as chronic heart, kidney or pulmonary disease. Establishing appropriate input from these needed medical specialists will be difficult to coordinate in new clinical settings especially with the demands posed by the pandemic.

25. CMS's own analysis confirms the threat to Medicare patients and to providers like the Network practices. CMS's Economic Analysis of the MFN Rule concedes that Medicare "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. 76,244.

26. In fact, CMS predicts that 9% of Medicare patients who receive the 50 drugs subject to the MFN Rule will lose access to care in the first year of the program. That number will increase to 14% in the second year and 19% in years 3-6. *See* 85 Fed. Reg. 76,237, Table 11. Based on

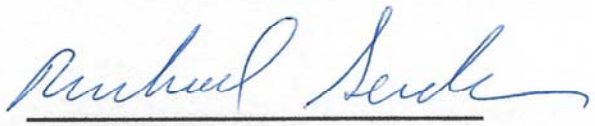
these estimates, CMS acknowledges that both "lost utilization" and "beneficiaries not accessing their drugs through the Medicare benefit" will account for some of the projected $85.5 billion in savings stemming from the MFN Rule. *Id*. at 76,237. In other words, under CMS's own analysis, the MFN Rule's financial savings come in part from patients losing access to these life-saving and life-extending drugs.

27. Under CMS's own projections, at facilities administered by The US Oncology Network alone, the MFN Rule will lead to loss of access to medically necessary and potentially life-saving care for more than 6,000 Medicare patients in the first year, more than 10,000 in the second year, and more than 14,000 per year in years 3-6.

28. Attached to this declaration is a true and correct copy of a letter from Network oncology practices providing further support for my conclusions.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 10th day of December, 2020.



Dr. Michael Seiden