



Submitted Testimony of Dr. Debra Patt on
Opportunities to Improve the 340B Drug Pricing Program
Energy and Commerce Health Subcommittee Hearing
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Chairman Burgess and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology and the Community Oncology Alliance (COA) before the Energy and Commerce Subcommittee on Health on proposed opportunities to improve the 340B Drug Pricing Program. The Members of the Health Subcommittee have demonstrated commitment to the nation's cancer patients and care providers over the years and many of the Members on this Committee can take credit for policies that have shaped our world-class cancer care delivery system. Thank you for your dedication and support for Americans and their families fighting cancer and for those of us who deliver that care.

I am Dr. Debra Patt and I am honored to appear before the Committee today. For the last 15 years I have spent the majority of my time taking care of cancer patients as a practicing medical oncologist in the great state of Texas. On an average day I treat around 30 patients in a 12 hour day. I also donate my free time in different capacities including serving as a leader in cancer research, informatics, health care policy, and various leadership roles in my practice, The US Oncology Network, COA and ASCO. While I am a community oncologist in a private practice, I also volunteer my time and work collaboratively with Seton, my local 340B hospital, and their

medical school affiliate. As a Professor at The University of Texas Dell Medical School I direct breast health services and co-chair the access to care working group and serve on other committees to collaboratively improve access to cancer care for the uninsured and underinsured patients in my community. These complimentary roles allow me to see care delivery concerns for vulnerable patients from multiple perspectives.

I am proud to be a part of community oncology—the most effective and successful cancer care delivery system in the world, and the highest value site of service in the United States. After nearly 100 years of increasing cancer death rates in the US, we have turned the corner in the fight against cancer. Cancer mortality has fallen by more than 20 percent from a 1991 peak and there are now nearly 15.5 million cancer survivors alive in the US alone. This number of survivors continues to increase as cancer treatment paradigms transform cancer to a chronic disease that is more akin to diabetes than a rapidly lethal entity. The reasons for this success are due in large part to earlier detection through screening programs, scientific breakthroughs such as immunotherapies and the dedication of the nation’s oncology providers.

Sadly, not all Americans have had access to these improved cancer outcomes. Vulnerable patients without access to health care have almost 50 percent higher mortality for the 10 most deadly cancers, in comparison to their insured counterparts.¹ The 340B program was created to facilitate qualifying entities to stretch limited resources to improve care for vulnerable patient populations in critical access areas. Unfortunately, the lack of transparency, oversight, and accountability within the 340B program has led to unintended consequences including excessive

¹ Walker GV, Grant SR, Guadagnolo BA, Hoffman KE, Smith BD, Koshy M, Allen PK, Mahmood U. “Disparities in stage at diagnosis, treatment, and survival in nonelderly adult patients with cancer according to insurance status.” J Clin Oncol. 2014 Oct 1;32(28):3118-25

growth of the program, expansion of its reach, closure of private oncology practices, and the shift to a much more expensive site of service in hospitals. When cancer care is shifted from private practices to the hospital outpatient department, the cost of care doubles. I share this committee's commitment to maintain the 340B drug discount program by re-imagining it to include meaningful enhancements to the program, including reforms to enhance program oversight, transparency, and accountability. While there may be differences between Members' approach to program reform, I think we can all agree that we want to see the program preserved with transparency, integrity, and accountability.

In my time before you today, I would like to focus on two aspects of the 340B program: The natural consequences of its excessive growth on the cost of health care, and the total lack of clarity regarding the use of the program to directly help underserved patients.

Growth of the 340B Program

When Congress established the 340B Drug Pricing Program in 1992, it was to give covered entities access to price reductions so that they could stretch scarce federal resources to reach eligible patients and provide more comprehensive services. Since then the program has grown substantially from a few hundred participating entities in 2005, to more than 12,000 qualifying entities in 2017. In 2017, 340B program drug purchases amounted to more than \$19 Billion. This rapid growth of the program suggests powerful economic incentives are at work. A substantial increase in new hospital qualifying entities and 340B hospital-contract pharmacy relationships have accounted for the majority of growth of the program in recent years. This allows hospitals to contract with many pharmacies to implement the 340B discount through

additional, unaffiliated pharmacy partners in the community. The rapid growth of 340B hospital-pharmacy relationships have changed some of the dynamics of the program. Pharmacies with new margin based contracts have substantial economic benefit from program participation. In cancer care, we have many oral drugs that cost \$10,000 a month that patients take for many years. A 5-15 percent margin on a \$10,000 drug is a substantial economic benefit. An entire business of post-hoc split fee billers have emerged to adjudicate participating pharmacy scripts to identify potential hospital patients that qualify for the 340B discount and transfer additional funds to the qualifying hospital entity. As opposed to a community practice that pays nearly \$10,000 for a \$10,000 drug that they sell for \$10,000 with a minor ASP increment, hospital contract pharmacies may purchase the drug for \$5,000 then sell the drug for \$10,000 with a small ASP increment. There were more than 16,000 contract pharmacy arrangements between covered entities and a pharmacy as of January 1, 2017.¹²

This growth has translated into incremental revenue for all participating entities. Based on the Energy and Commerce report on the 340B program, some of these programs enjoyed more than \$100 Million in drug savings in 2016. The tremendous economic opportunity the 340B program provides for hospital systems has been a contributor to hospitals seeking to grow their outpatient cancer service line. When 340B qualifying hospitals treat privately insured patients and prescribing these \$10,000 drugs, each time they purchase the drug for \$5,000 and keep nearly \$5,000 in additional profits. Commonly 340B hospitals have acquired private oncology clinics in their market to leverage the incremental revenue opportunity they can see from the program. When this site of service shift occurs, costs double. Any CFO of any corporation in the world

² Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. On Energy and Commerce, 115th Cong, at footnote 19 (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, GAO)

would embrace the opportunity to purchase a drug for \$5,000 and sell it for \$10,000. Hospitals are no different. This arbitrage opportunity on drugs (to buy low and sell high) affords a clear market advantage and allows them to acquire community oncology practices. A recent Community Oncology Alliance report indicates that 658 private community oncology clinics have closed or aligned with hospital systems since 2008.³ When hospitals acquire community oncology practices, the cost of care doubles and everyone in the country pays more for healthcare. A recent study published in JAMA Oncology confirmed that by disease type and by episode of care, outpatient cancer care costs at least twice as much in the hospital outpatient department in comparison to a private practice.⁴

Hospitals qualify for 340B status based on their inpatient DSH rates, though this does not guarantee that vulnerable patients will have access to their outpatient departments. In fact, qualifying hospitals sometimes refuse to see these patients. To make matters worse, it is not clear how an entity defines a qualifying patient. With the exponential growth of the post hoc vendor market, laxity in patient definition allows for expansion of the program as it becomes more likely that “hospital patients” are being identified who aren’t being directly managed by the hospital entity.

Is there evidence that revenues from the 340B program are being used to enhance the care of vulnerable patients?

This is a tough question and hard to answer with limited data the lack of transparency provides us. Clearly there are hospitals that use incremental revenue to stretch their limited resources to

³ 2018 Community Oncology Alliance, Practice Impact Report. Full Report available at: <https://www.communityoncology.org/downloads/pir/COA-Practice-Impact-Report-2018-FINAL.pdf>.

⁴ Winn AN, Keating NL, Trogdon JG, Basch EM3, Dusetzina SB, “Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014.” JAMA Oncol. 2018 Apr 1;4(4):580-581.

enhance care for vulnerable patients. Parkland Hospital in Dallas is a great example of a hospital that is using this program in alignment with its original intent. While Parkland Hospital's drug savings exceeded \$100 Million, the hospital is almost at 50 percent DSH, far exceeding the required 11.75 percent. Parkland requires this funding and actually needs far more to provide the services it needs to serve its high volume of vulnerable patients, but Parkland hospital is not a typical 340B hospital. In a report by the National Academies Press there is discussion that nonprofit hospitals are increasingly displaying characteristics of for profit hospitals.⁵ Many 'nonprofit' hospital executives have seven or eight figure annual salaries.⁶

The most important challenge that I would like to discuss is the lack of responsibility to care for vulnerable patients in some 340B qualifying entities. Because of the lack of transparency, oversight, and accountability, we can observe tremendous variability across the country in the philanthropic commitment of 340B hospitals in using additional revenue to enhance care for vulnerable patient populations. Because spending incremental 340B revenue on vulnerable patients is not mandated, some hospitals use these funds to build lavish new towers and enhance executive compensation.

As of 2015, there was only a 1 percent difference in the amount of uncompensated care provided by 340B qualifying hospitals in comparison to non-340B qualifying hospitals, and participating hospitals were no more likely to offer low profit services.⁷ A 2016 report by Avalere Health

⁵ National Academies Press, Making Medicines Affordable: A National Imperative, Pre publication copy (Nov. 2017)

⁶ "The Million-Dollar Club: About 2,700 individuals employed by organizations legally classified as charities earned at least \$1 million during 2014" The Wall Street Journal, 2017.

⁷ Nikpay, S, Buntin, M, Conti, R, "Diversity of Participants in the 340B Drug Pricing Program for US Hospitals" JAMA Intern Med. 2018 May 21

found that 24 percent of 340B hospitals provide 80 percent of all charity care, despite representing less than half of the beds in the program.

No one knows exactly how the incremental revenue of the 340B program is used without appropriate oversight and transparency, though data that we do have is troubling. As a clinician, working in close proximity to 340B hospitals in my market, across my state, and across the country there are pervasive and deep access to care issues for vulnerable patients like I see every day in clinic. I want to share with you some of my experiences and the experiences of some of my colleagues across the state and across the country.

In Texas, where we have about 9 percent of the US population and rates of poverty are higher than the national average at 15.6 percent in comparison to 12.7 percent. Across the state there are grave challenges in caring for vulnerable patients with cancer. As cancer care for vulnerable patients is complex and dependent on many factors, not just 340B funding, I limited my examples to misses and near misses that have involved 340B entities.

In Longview, Texas, about 2 hours East of Dallas, a 340B qualifying hospital declines to provide care for uninsured or underinsured patients for systemic chemotherapy. They require cash payments for this group of patients prior to administering therapy.

In Austin, I and my partners work collaboratively with our local 340B entity and with the its medical school affiliate. There are widespread deficiencies, delays, and detours in care for uninsured patients that impact care effectiveness and efficiencies across the system. There are multiple uninsured patients with cancer who are county residents who are placed on a queue for months to be seen. Last year, I saw a 50 year old Austin musician who had a clinical stage III

breast cancer found in March of 2017. She had a mammogram at the hospital outpatient unit, and was even connected to a navigator. She was referred to the 340B hospital outpatient department for oncologic evaluation but sat on a queue for 3 months while her aggressive Her 2 amplified locally advanced breast cancer progressed. In June, she presented to my private clinic with a locally advanced stage III breast cancer and scared to death. We were able to evaluate her and get some of her expensive chemotherapy drugs donated from the pharmaceutical manufacturer. The remaining services were billed to her, which ultimately resulted in bad debt. The patient received appropriate care. She ultimately was found to have a breast cancer in each breast, and a genetic predisposition to getting breast cancer as we discovered she carried the BRCA gene. After receiving chemotherapy, she was able to successfully undergo surgery and remains disease free in follow up. The same month, a 26 year old massage therapist presented to my office with a stage II aggressive breast cancer. She was uninsured and a young county resident but was refused services at our local 340B institution. We were able to see her in our private clinic, help her apply for Medicaid, and she was able to have chemotherapy and surgery and remains disease free today. We also were able to preserve her fertility by harnessing embryos so that when she is older and a many year cancer survivor, she will have the option of becoming a mother as she survives cancer. These stories are near misses, as these patients ultimately received appropriate care and we believe will have a good outcome.

Many of the stories however, don't have happy endings. My partner's patient, a 61 year old man, was seen in South Austin with a new metastatic colon cancer with brain metastasis in December 2017. He was referred to the 340B entity for treatment where they have a contract for radiation services with another cancer provider, but was told that they needed to wait for social security determination before he could qualify for treatment in the county system. He was

ultimately admitted to the hospital 5 months later with a complication and had not yet started treatment for his cancer. A few weeks after his April admission he qualified for Medicaid and ultimately was able to start chemotherapy. A partner had a 34 year old pregnant woman with stage IV colon cancer. During her pregnancy we had to start her on FOLFOX chemotherapy. We treated her for five cycles as a hospital inpatient under emergency care because the 340B hospital took 8-10 weeks to get her an appointment in clinic. Another 16 patients sat on a gynecologic oncology queue last year for more than 6 months while they waited to be given appointments in the 340B qualifying entity. Some of these patients had curable advanced cervical cancer, and many represented to the emergency room while they waited on the queue. Additionally, the lack of ability to give timely access leads to alterations in care delivery that raise the cost of care. Patients who cannot get adequate follow up have disproportionately longer hospital stays and inpatient as opposed to outpatient management.

The lack of commitment to services also extends to a near absence of cancer screening efforts. This absence removes the opportunity to cure cancer cheaply and effectively. There is minimal current availability for uninsured county residents to have screening mammography, and screening colonoscopy is only minimally available through a program run by a local private practice. More so, the 340B entity has recently decreased already limited screening services. In our community there is a pervasive lack of screening in uninsured patients that contribute to late stage diagnosis and higher mortality rate. Lack of breast and colon cancer screening rates among the uninsured are staggering. Early stage breast cancer and colon cancer is virtually undiagnosed in my community amongst the uninsured because of failure of screening. Higher stage of cancer and substantially higher mortality afflict the vulnerable population across the state.

Across the Country these are also similar recurring stories of lack of access to care for vulnerable patients with a 340B hospital in their area. In Kentucky, a patient was diagnosed with a locally advanced but still curable Non Small Cell Lung Cancer in late February 2018, and in follow up he saw a 340B hospital based oncologist in March with further work up. In follow up in April and May the patient still had not started treatment for his curable cancer as he had an application to insurance denied. The 340B hospital plan was to wait to start chemotherapy when insurance was approved. Ultimately the patient sought care outside of the hospital system to initiate definitive chemotherapy and radiation in June. For this patient, a three month delay in diagnosis is the difference between life and death. It is these misses and near misses to treat curable cancer that are so devastating. In Boulder, one of our oncologists was seeing a patient with aggressive lymphoma who had Medicare part A but was waiting on part B and was delayed in getting Medicaid. He was referred to the local 340B hospital to receive therapy or for evaluation for a clinical trial. They would not see or schedule the patient until he got part B. He died several weeks later without ever being seen by the qualifying entity or given the opportunity.

Just because qualifying entities choose not to use the profit from the 340B program to evaluate and manage uninsured cancer patients, it does not necessarily imply that they are not stretching limited resources to serve vulnerable patients in other ways. Without transparency and oversight, it remains unclear. For hospitals that choose not to spend additional funds towards the care of vulnerable patients, there is no statutory obligation that prevents hospital systems from directing these additional funds to other strategic initiatives including building physical plants or enhancing executive compensation. We see troubling examples in community oncology where vulnerable patients have no ability to even be evaluated for treatment, and executive

compensation within those systems exceeds millions of dollars. If a hospital administrator chooses to direct funds towards other priorities instead of increasing care delivery for vulnerable patients there is no way to know because there is no transparency and it is not illegal. They are simply following their fiduciary duty to their organization. If there were transparency and accountability within the 340B program, the policy would reinforce actions in alignment with the initial intent of the program.

On behalf of oncologists nationwide, I appreciate the Committee's leadership and dedication to our nation's health care system in examining the 340B program. When community cancer clinics close their doors, access to care is compromised for all cancer patients. The continued shift to hospital-based care doesn't just reduce access to care for cancer patients, especially in rural areas, but it also increases healthcare costs for all Americans.

I urge the Committee and Congress to act to protect the integrity and viability of the 340B program. Without your action, continued growth of the program will render it susceptible to abuse, vulnerable patients will not see a maximal benefit of the program and community cancer clinics will continue to close and care will continue to shift to the more expensive, less-accessible hospital outpatient setting. Americans fighting cancer will experience diminished access to care, and patients, payers, and taxpayers will pay more.

My oncology colleagues across the country and I are doing our very best to help patients fight cancer, and win. In order to do that effectively we need the 340B program to be implemented optimally. To do that, we need your help. Once again, thank you for the opportunity to address the Committee. I am happy to answer any questions the Committee has regarding my testimony.
