

**TESTIMONY OF
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**Before the
UNITED STATES CONGRESS
HOUSE COMMITTEE ON ENERGY AND COMMERCE
Health Subcommittee**

**Hearing on
Lowering Prescription Drug Prices:
Deconstructing the Drug Supply Chain**

May 9, 2019

**Testimony for the Record
Submitted to the
U.S. House Committee on Energy and Commerce
Health Subcommittee**

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I. Introduction

Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee, thank you for the opportunity to testify before you today. My name is Lynn Eschenbacher and I currently serve as Chief Pharmacy Officer and Vice President of Medication Management at Ascension. I want to start by thanking the full Committee and this Subcommittee for your ongoing, bipartisan, and thoughtful work to address the important issue of high and rising drug prices. I appreciate you calling today's hearing to look more closely at and better understand how the drug supply chain works, particularly the role it plays within the broader context of the drug pricing debate. Ascension appreciates these efforts and we are honored to be here today testifying before the Subcommittee.

II. Background

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2018, Ascension provided nearly \$2 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 156,000 associates and 34,000 aligned providers. The national health system operates more than 2,600 sites of care – including 151 hospitals and more than 50 senior living facilities – in 21 states and the District of Columbia, while providing a variety of services including physician practice management, venture capital investing, investment management, biomedical engineering, facilities management, clinical care management, information services, risk management, and contracting through Ascension's own group purchasing organization.

In my current role, I am responsible for developing and implementing pharmacy services that positively impact patient safety and quality. I am also responsible for improving operational efficiencies through the standardization and optimization of pharmacy services while demonstrating the value of pharmacy. I spend the vast majority of my time thinking about, developing, and rolling out new programs and processes that allow Ascension to be a better steward of patient, public, and system finances, while improving the health and wellness of our patients and communities.

Before coming to Ascension, I worked in a wide array of settings – including academic medical centers, community hospitals, and county hospitals, as well as with systems that run physician practices and infusion centers. I have also worked in a variety of roles – including medication safety, clinical services, operations, and process improvement. Immediately prior to joining Ascension, I served as Assistant Director of Clinical Services for Pharmacy for WakeMed Health & Hospitals in Raleigh, NC. Before that, I was the Medication Safety Officer for Duke University Hospital in Durham, NC. I completed a pharmacy practice residency at Parkland Health & Hospitals in Dallas, TX, and hold a bachelor’s degree in biology from Indiana University in Bloomington, a doctorate of pharmacy from The University of Texas at Austin, and a master’s of business administration from The Fuqua School of Business at Duke University with a focus in Health Sector Management. I am currently a fellow of the American Society of Health-System Pharmacists (ASHP) and was awarded the national Distinguished Service Award by ASHP.

These positions and experiences total almost 20 years in this field and have provided me with substantial knowledge about how the medication supply chain works, where it delivers significant value for patients, and where there are opportunities for improvement. I am honored to be asked to testify, and I am pleased to share some of my insights with you. In particular, I want to highlight some potential opportunities that Congress, the Administration, and industry can leverage to improve the functioning of the supply chain and pharmaceutical market.

III. Overview: Price Increases and Supply Chain Abuses Have a Meaningful Impact on Providers

The Committee has asked me to provide input regarding the impact of rising drug prices on the supply chain. To that end, my testimony will address in three ways how high and rising drug prices reorient how we deliver the best quality of care and how we operate as a system: first, I will outline how, in the context of varying reimbursement structures, escalating costs are directly and indirectly impacting patients and the providers who care for them; then, I will discuss the efforts we undertake to mitigate the impact of these additional costs on patients, both immediately through care process adjustments and over the longer term through various targeted assistance programs – all focused on the ultimate goal of ensuring patients do not experience gaps in access to therapies as a result of price escalations; and finally, I will offer some observations from the hospital supply chain perspective on where we see market failures driving inappropriate price increases, as well as recommended solutions that we believe will have meaningful impacts, such that our ability to invest the maximum amount of resources into delivering high quality care and community benefit becomes less encumbered by the very real implications of unforeseeable and excessive cost increases.

First and foremost, the most critical goal for Ascension is providing the highest quality care for the patients we are privileged to serve, while having a special focus on caring for the poor and vulnerable. This is our Mission and it shapes everything we do. As healthcare providers, Ascension and our counterparts in healthcare delivery cannot provide the quality care that our patients deserve and need without the partnership of the pharmaceutical industry. We wholeheartedly believe it is important to maintain protections for intellectual property and reward innovation. At the same time, however, we need to balance these innovations with access.

We understand that in certain, very specific circumstances the price of a drug may be justified by the research and development investment, manufacturing cost, and true clinical value of the treatment; however, most price increases are not predicated on this creation of value. While we understand there may be rational increases in prices that reflect market dynamics, we are nevertheless concerned about

the sudden, unfounded, unpredictable, and cumulatively burdensome price spikes and launch prices that divert our finite resources away from our ability to care for patients both in and out of the hospital. While pharmaceutical price inflation is nothing new, the increases that we have seen over the last several years are unprecedented. These price increases are among the largest and most unpredictable drivers of increased hospital costs. Not only do price increases create significant financial burden, they also place serious constraints on our ability to carry out an essential part of our Mission through special focus on serving the poor and vulnerable.

A. Drug Pricing Increases and Impacts as Experienced by Ascension

Recent Aggregate Price Inflation Has Been Significant

To navigate the vast and complex health care supply chain, Ascension has established our own group purchasing organization (GPO) – The Resource Group. In general, The Resource Group helps our hospitals and other providers realize savings and efficiencies by aggregating purchasing volume and negotiating discounts with manufacturers, distributors, and other vendors. The Resource Group does not purchase or procure products, nor do they determine which products the GPO participants can or should buy – they ingest input from participants about their clinical needs and preferences, then negotiate contracts that those providers can use when making *their own* purchases in line with *their own* decision-making process.

Establishing a GPO through Ascension has allowed us to better control our systemwide approach to procurement. Through both The Resource Group and other direct contract negotiations, we have gained unique insights into the functioning of the hospital supply chain. From this perspective, we have seen the positive impact that competition and appropriate negotiating leverage can have on prices in similar product areas, such as the implantable device market. In that market, we have seen a steady decline in prices over time, as competitive products come to market.

In the prescription drug market, however, the lack of meaningful competition driven by an overabundance of sole-source branded products, patent and Food & Drug Administration (FDA) exclusivity abuses, and other factors, means manufacturers have almost no incentive to offer negotiated price concessions or other contracting accommodations to providers. **As a result, in the span of only four years, Ascension alone has had to mitigate against a 34% increase in drug costs, totaling \$564 million in additional costs for providing care to the patients we serve.**

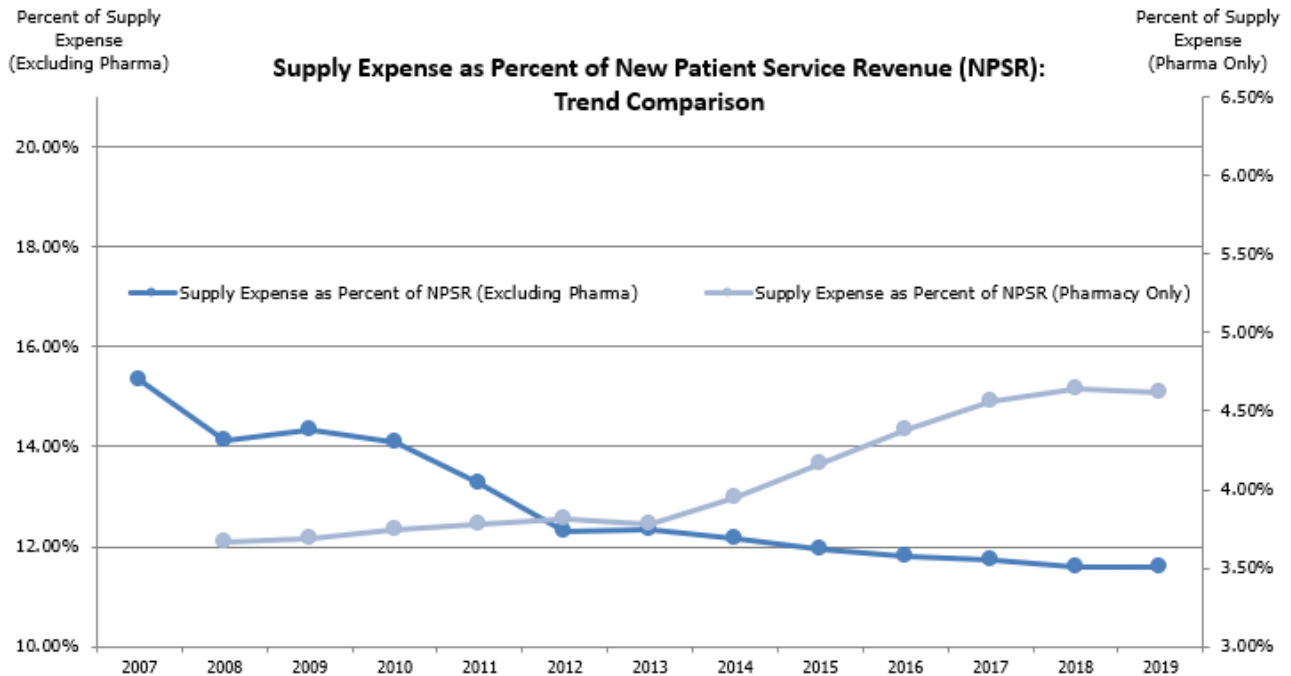
Price Increases Are Frequent, Unpredictable, and Difficult to Protect Against

Contrary to popular belief, very few manufacturers are willing to enter into a contract for their product(s) or offer volume-related discounts or accommodations for even the largest of health systems, like ours. Just over half of our pharmaceutical spending comprises products that are “on contract”. Across those contracts, only 18.6% provide for a full year of firm – or steady – pricing, and only 4.8% provide for two years of firm pricing. As a result, **we typically experience up to 40 new price increases each week**, with the greatest number of increases experienced during the weeks of January 1 and July 1 each year – when we can see upwards of several hundred product price increases. In January 2019, the number of drug price increases reached the thousands. While we fervently seek to mitigate the impacts of these increases, the frequency at which price increases occur and the unwillingness of many manufacturers to negotiate consistent, long-term contracts with providers collectively create significant uncertainty and administrative burden.

Contracting Practices and Price Trends for Drugs are Distinct from Other Segments

These practices are not the norm for other areas of procurement across healthcare providers. In the implantable device space, we have entered into contracts under which hip and knee supply pricing is set for up to three years. This kind of certainty and stability allows us to accurately predict and manage budgets, which creates efficiency across the system.

Furthermore, it remains unclear what distinct and measurable value the additional revenues derived from higher pricing adds to the system. Our top 10 pharmaceutical companies show an average research and development (R&D) expense of 16.7% of total revenue as of 2017; reported selling, general, and administrative expense (SG&A) during that year was 25.2% of total revenue. On the supply side, our hip implant costs have *decreased* by 37.0% and knee implant costs have *decreased* 51.8% from 2009 to 2018. At the same time, our top three (public) hip and knee companies with which we contract show an average R&D expense of 15.7% of revenue in 2017 and an average SG&A expense of 41.1%. Thus, despite similar research and development costs generally borne by manufacturers in both sectors, and higher manufacturing and sales costs often associated with implantable devices, there is a marked divergence in our observed price trends – many drug prices have grown at rapid, unpredictable, and unsustainable rates over time, as overall implantable device prices have declined.



High and Rising Drug Prices Directly Impact Patients and Providers

As I discuss in greater detail here, the frequent, unexplained, and unpredictable price increases have proven extremely difficult to prevent in the normal course of business. They are the result of market imbalances and supply chain abuses that I will highlight below and, in turn, suggest corresponding proposed solutions. However, as they exist today and in the context of provider reimbursement and care delivery structures, these practices have a direct impact on our ability to direct finite resources towards patient care, charitable services, and community benefit. At best, we are able to mitigate the impacts to

our system and our patients through a variety of operational modifications and charitable programs. For these reasons, I would again applaud you for the work this Committee and Congress has undertaken to promote competition and create a more robust and balanced market for pharmaceuticals.

Drug Pricing Implications Vary Across Care Settings and Payment Systems

a. Acute Care

In the inpatient setting, insured patients are substantially shielded from the direct financial impact of high drug costs as hospitals are typically paid a bundled payment covering most, if not all, of a hospital stay. This is true across most payers – from Medicare to commercial insurance. The result of this structure, however, is that the cost of drugs used during a hospital stay is built into that bundled payment. These bundles are generally recalibrated on an annual basis to adjust for increases in the market basket of items and services covered in an inpatient stay. As a result, payment for the inpatient stay eventually increases to reflect the higher drug cost. As a general rule, however, within Medicare and with commercial payers, this bundled payment amount is set and remains unchanged throughout the year. So, generally, when the price of a drug goes up in a given week or month, that newly added cost must be immediately absorbed by the hospital. At the same time, hospitals also treat patients who are self-pay (or uninsured) or underinsured through charity or uncompensated care. Within Ascension, we cover the out-of-pocket costs for patients with incomes below 250 percent of the federal poverty level (FPL) and cover the out-of-pocket costs on a sliding scale for patients with incomes from 250 percent to 400 percent of FPL. Any time the cost of delivering care to these patients goes up, we bear the vast majority of that cost directly.

So while patients may not feel the immediate impact of higher drug costs during an inpatient stay, these cost increases nonetheless have a real and measurable impact on the patient. In the longer term, an increase in pricing will be felt by all patients as increased costs will eventually contribute to higher insurance premiums or higher out-of-pocket costs for patients as the bundles are recalibrated. More immediately, and discussed further below, the diversion of our resources to cover these added costs affects our ability to provide other patient-centered services that we deliver as part of our Mission.

b. Outpatient and Physician Offices

Unlike the inpatient setting, most drugs that are administered by practitioners in the outpatient setting or in a physician's office are reimbursed on a standalone basis. By way of example, the Medicare program typically pays providers directly for these drugs (*i.e.*, Part B drugs) at a fixed rate of Average Sales Price (ASP) plus six percent (or 106% of ASP)¹ to cover acquisition and carrying costs associated with procuring product and maintaining a necessary level of supply. A manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to the Centers for Medicare & Medicaid Services (CMS) within 30 days of the close of the quarter.

This system presents its own set of unique challenges: ASP is based on self-reported pricing information that incorporates a wide swath of purchasers, so that each provider's reimbursement might vary in terms of the degree to which the payment covers the provider's costs; the validity of ASP reporting has been called into question by federal government watchdogs², raising uncertainty about the accuracy of the

¹ This rate of payment is established in statute, but in practice the rate of reimbursement is actually 104.3% of ASP as a result of sequestration.

² <https://www.gao.gov/assets/680/678175.pdf>

resulting payments; and there is a built-in lag between a manufacturer's implementation of a price increase and the reflection of that new data in the ASP. As a result, providers might be underpaid for a given drug (depending on the price at which they are able to purchase a product (relative to ASP)), as well as for any changes in that price not immediately accounted for in the ASP and any additional associated costs. And because beneficiaries are generally responsible for 20 percent of the payment rate for these Part B drugs, they are likely to experience an increase in out of pocket costs more immediately than they do with respect to drugs administered in the inpatient setting.

Here too, many Medicare beneficiaries are shielded from this out of pocket cost because they have also purchased a Medicare supplemental policy that covers coinsurance and copayment expenses, while lower income patients may qualify for assistance with these out-of-pocket costs through Medicaid or other Medicare assistance programs. But many beneficiaries nevertheless see these increased costs – and those who are not eligible for or able to afford additional assistance will experience these rising costs and struggle to afford those medications. **If medications are not properly managed due to unaffordability or lack of access, the risks increase for diminished health and even hospital admissions.** In the long run, these outcomes are costlier to patients and the program overall – to say nothing of the impact they can have on quality of life.

c. Retail

In the retail setting (or, for drugs covered under Medicare Part D), the patient feels the immediate impact of any increase in price for a product in the form of higher coinsurance. The patient is also directly impacted when his or her plan's Pharmacy Benefit Manager (PBM) plays a role in excluding a particular product (or pharmacy) from coverage. We have seen this example play out recently in the biosimilar space, where innovator biopharmaceutical manufacturers often offer steep rebates to PBMs that incent the exclusion of competitor biosimilars from a formulary. This practice is costly for patients: "patients usually pay a coinsurance percentage (for example, 20%) for high-cost brand-name and specialty drugs; however, because the coinsurance percentage is calculated based on the price of the prescription drug before the application of rebates, patients often pay a greater share of the true cost to the health insurer than the listed coinsurance percentage."³

However, retail exclusions and price increases do not divorce providers. When patients' out of pocket costs for retail pharmaceuticals go up, our pharmacists and physicians are on the front line of helping patients mitigate the impact of such added costs, to ensure there are no downstream health consequences from a patient going off their medications, changing doses inappropriately, or sacrificing other aspects of their health and well-being to afford their prescriptions.

Legacy Reimbursement Structures Evidence the Need for Health System Transformation

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. Accordingly, we strongly support the movement towards innovative, value-based care and payment models that support population health. Today's highly complex system of billing and reimbursement for drugs under Medicare, which represents only a fragment of the delivery system, has helped to perpetuate the persistence of a siloed and outdated

³ Milliman, *A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices*, May 2018. Available at: <http://www.milliman.com/insight/2018/A-primer-on-prescription-drug-rebates-Insights-into-why-rebates-are-a-target-for-reducing-prices/>

fee-for-service reimbursement system. The complexity of the structures described above is exacerbated by the specialty supply chain, which changes how certain drugs are reimbursed – regardless of the site of administration. For infusion services, some medications are reimbursed through PBMs, while some are reimbursed through the applicable medical specialty, causing fragmentation and administrative burden.

These and other legacy reimbursement structures – such as cost-to-charge ratios used by some commercial payers and Medicaid programs – undermine the move to value-based care models. They also create distortions in perceived behavior that can appear, without diving under the surface, unfounded. For example, reports released last year by the pharmaceutical industry suggested that some hospitals may be marking up charges to private payers for certain separately billable drugs at a rate of nearly five hundred percent. While briefly noting that “Hospitals are generally not paid 100% of charges,” the report fails to examine the actual payment percentages provided to hospitals. If a hospital “charges” 500% of the acquisition cost for a given drug, but a contract pays only 20% of the amount charged, that hospital would break even against acquisition cost – without addressing costs related to storage, waste, dispensing, and administration.

When reimbursement is paid as a percentage of charge, and charge is the **only** known piece of information, actual reimbursement cannot be deduced. Because they are the result of proprietary negotiations, other factors remain privately held, including: actual acquisition costs, percent(s) of charges paid, and additional discounts negotiated. Just as list prices are not a true measure of what a manufacturer is ultimately paid for a drug, hospital charges are merely a single factor among many that are used in the complicated process of establishing any final payment. And for uninsured patients, Ascension – like many other non-profit and safety net hospitals – offers charity care programs and discounts, to help ensure patients are able to access care, regardless of their ability to pay.

To better promote integrated care, decrease complexity, and reduce administrative burdens and expenses, it is essential that the healthcare delivery system quickly move away from these kinds of reality-distorting legacy reimbursement structures toward value-based models that drive us toward whole-person care across populations.

B. Existing Options to Mitigate the Impact of Price Increases on Our Patients and System

When price increases begin to prove overly burdensome to either our hospitals or our patients, there are a variety of protocols and programs we rely on to mitigate the impact, always with the overarching goal of protecting patient safety and ensuring the best possible health outcomes.

Immediate Mitigation: Substitution, Education, and System Updates

As noted above, pharmaceutical price increases are not limited to only a few drugs. Ascension tracks cost changes on a weekly basis, and we are currently budgeting a six percent year-over-year rate of inflation for fiscal year 2020.

In an effort to mitigate such increases in cost, Ascension turns to a national Therapeutic Affinity Group (TAG). This group consists of pharmaceutical leaders and physicians from across our system. In addition to medication safety initiatives that improve outcomes and increase patient safety, these leaders feel it is imperative in instances of drug shortages or significant drug price increases to also look for alternate therapies that provide effective care and also steward our system resources and achieve savings for those who ultimately pay for healthcare. The TAG’s primary objective is first and foremost to conduct clinical

evaluations that ensure quality of care and patient outcomes are not compromised. This work is not easy. It takes much time and effort to gather the data, create potential alternatives, socialize the potential options, move through an approval process and then implement. We will not compromise patient safety and will not recommend switching to a therapeutic equivalent – regardless of costs borne by our system – unless we are convinced that the switch is evidence-based and will not have an adverse impact on patients. But to accomplish any appropriate switching requires at a bare minimum: physician engagement, negotiation and contracting efforts with a new manufacturer or supplier, purchase and procurement of product, physical stocking of product in the appropriate locations across facilities, modifications to electronic medical records processes, and education and information dissemination to protect against medication errors as new therapies are rolled out. Each of these discrete steps in the process represents significant time, personnel resources, and additional expenses for any impacted facility – when scaled up across a whole system, one significant price increase can effectively mobilize a small revolution in our care delivery processes.

Ongoing Patient Impact Mitigation: 340B Drug Pricing

The growth in pharmaceutical spending highlighted above – a 34% net increase, totaling an additional \$564 million in costs over four years – is calculated *after* taking into account the 340B discounts that a number of our safety net facilities qualify for. **The 340B program is a vital tool with which hospitals are able to stretch our scarce resources to provide care to the poor and vulnerable by mitigating against the immediate and long-term impacts of high and rising drug prices.** The program is critically important because the pharmaceutical market and supply chain are not collectively incentivized to set and maintain drug prices at levels that ensure sustained and meaningful access to medications for hospitals and their patients. Instead, year-over-year growth in prices becomes embedded into *today's* pharmaceutical costs; the ongoing price increases effectively compound onto themselves. In other words, last year's price increase will continue to impact the cost of delivering care this year and next – and will continue to divert and consume additional resources going forward, as compared to years prior. The 340B program allows our qualifying safety net facilities to obtain pharmaceutical products at more predictable and manageable prices. Absent this program, our patients and qualifying hospitals would feel more of the brunt of myriad price increases. The 340B program instead allows qualifying Ascension hospitals and other covered entities to implement and maintain investments in community- and patient-tailored programs that offer patients access not only to affordable medications, but to health care and community services that are critical to the poor and vulnerable. And while low government payer reimbursement rates coupled with rising drug prices can constrain the ability of Ascension safety net hospitals to carry out our Mission to provide compassionate and personalized care to the communities we serve, 340B discounts help address this shortfall so that we are able to continue to serve the poor and vulnerable in these communities and invest in programs to improve their health.

Across Ascension, 50 of our hospitals participate in the 340B Drug Discount Program. Of these, 21 are critical access hospitals (CAHs), 23 are disproportionate share hospitals (DSHs), and the remaining hospitals fall into a variety of other categories, including sole community hospitals, children's hospitals, and rural referral centers. Ascension's 340B hospitals were able to invest roughly \$200 million last year in charity care and community benefit programs as a result of the current 340B program. Our 340B savings allow us to stretch scarce resources, allowing us to invest in a multitude of programs designed to increase access to prescription medicines and other health services for low-income patients. These include the following, among others: providing medications at low or no cost; operating primary and specialty care clinics in urban and rural communities; providing clinical and ambulatory pharmacy services and oncology services; providing free medical care; embedding nurse services in local school districts; and operating

Medical Missions at Home, as discussed further below. Our 340B savings also fund programs to address a wide variety of healthcare conditions among our most vulnerable populations, including diabetes, cancer, and behavioral health conditions.

There are many examples throughout Ascension of how the reduced drug costs resulting from the 340B program enable us to stretch our resources to expand services for the poor and vulnerable, several of which are outlined in detail in Appendix A. In sum, the 340B program – when leveraged as intended – enables safety net providers to not only mitigate against high and rising drug prices, but to be good stewards of finite patient, program, and provider resources. To that end, Ascension has signed on to the American Hospital Association’s 340B Stewardship Principles.⁴ We strongly believe in the value of transparency and rigorous internal oversight, to ensure that the program meets the Congressional objective: “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

Ongoing Patient Impact Mitigation: Ascension Medical Missions at Home

As noted above, Ascension has undertaken a national commitment to running Medical Missions at Home, which deliver healthcare and social and support services in places of worship, schools, community centers, homeless shelters, and food pantries at no cost to those who might not otherwise have access to these services. The program was launched in 2008 in Davidson County, TN, which had approximately 87,000 uninsured at that time. Medical Mission at Home day-long events now provide free services such as primary care, dental care, no-cost prescriptions, eye exams and eyeglasses, social services referrals, flu shots and follow-up to those who need it most.

One of the most in-demand services provided through this program is access to medications. Prescriptions dispensed at our Medical Missions at Home are provided through the Dispensary of Hope, which is discussed further below. With each Medical Mission at Home, processes have improved, more services have been added, and more patients have benefitted from these events.

In 2019 alone, we have been able to assist hundreds of patients with access to no-cost medications. The data we have seen includes the following examples, though these are just a small sample of the Missions carried out⁵:

- Our 2019 Florida Medical Mission at Home in one day dispensed 304 prescriptions, serving 177 patients. In the year prior, Florida’s Medical Mission at Home dispensed 294 prescriptions, serving 173 patients.
- Our 2019 Oklahoma Medical Mission at Home on a single day served 180 patients, filling 76 prescriptions at no cost. Attendees who did not require medical treatment received donated items such as diapers, wipes, shoes, socks, formula, and fresh fruits and vegetables.
- The 2019 Rutherford County, Tennessee Medical Mission at Home filled 123 prescriptions and served 370 patients.
- The 2019 Davidson County, Tennessee Medical Mission at Home filled 327 prescriptions and served 667 patients.

⁴ <https://www.aha.org/press-releases/2018-09-18-aha-hospital-leaders-announce-340b-good-stewardship-principles-0>

⁵ Additional Medical Missions at Home for 2018 – 2019: <https://www.medicalmissionathome.org/get-involved>

Ongoing Patient Impact Mitigation: Dispensary of Hope

Dispensary of Hope started in 2003 as a collaborative effort – today hosted and funded by Ascension – with the collaborative comprised of medication manufacturers, health systems, free clinics, and charity pharmacies. Dispensary of Hope distributes medications through more than 180 partnering sites across the country. During fiscal year 2018, the Dispensary of Hope network of about 50 Ascension locations filled 137,245 (30-day) prescriptions. The Dispensary of Hope works with community programs that are licensed to dispense medication by supplying inventories of the most needed medications. Patients are given medication free of charge and may return for unlimited medication fills as long as their prescription remains valid and the patients continue to qualify for the program. To be eligible for Dispensary of Hope medication, patients must have a valid prescription, must be self-identified as uninsured, and must be earning 200 percent or less of FPL.

All medication at the Dispensary of Hope is donated through the generosity of prescription drug manufacturers and distributors, and no medication is purchased. Currently, more than two dozen pharmaceutical manufacturers – including 24 generic manufacturers and one branded manufacturer – donate medication to the program each month.

The national program is unique in its goal to create a stable medication list, pre-positioned in clinics and pharmacies close to the uninsured low-income U.S. residents. One of the most exciting recent developments has been the addition of insulin to this medication list.⁶ There are currently 16 Dispensary of Hope sites ordering insulin with 1090 vials distributed. As of March 30, 2019, 155 vials have been dispensed to patients in need. By 2024, the Dispensary of Hope expects to distribute 2.7 million scripts annually.

Patient Impact Mitigation: Leveraging Pharmaceutical Patient Assistance Programs

In addition to Ascension-sponsored programs, providers across our system will work with patients in-need to help navigate and secure discounted or free medications through pharmaceutical patient assistance programs (PAPs). We often find that these programs are imperfect and the market distortions that they create are well-documented – including delays in access due to eligibility processing, the brand-adherence (rather than generic substitution) that they promote, and resulting increased insurance premiums and overall costs to the healthcare system.⁷ Regardless of these downsides, the reality is that PAPs are an existing mechanism that can sometimes help patients access life-sustaining medications – and we do our best to help patients maintain adherence to their therapies however possible.

IV. Market Failures and Supply Chain Abuses That Are Driving Price Increases and Proposed Corresponding Solutions

The implications of frequent, unexplained, and unpredictable price increases are vast, as I hope has become evident. Our efforts to mitigate against them can often present their own challenges in terms of how we are able to best use finite resources to care for patients in fulfillment of our Mission. As noted above, however, we at Ascension believe this current reality is largely the result of market failures and

⁶ See <https://www.dispensaryofhope.org/news/posts/eli-lilly-partners-with-the-dispensary-of-hope>

⁷ See, e.g., Catherine Starner et al., "Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums," Health Affairs, vol. 33, no. 10 (October 2014), pp. 1761-1769.

supply chain abuses that persist unchecked. We believe the following represent some of the most significant supply chain issues and corresponding proposed options to address them.

A. Market Failures and Supply Chain Abuses

Market Failures: Insufficient Competition, Patent Abuses

As the generic marketplace has largely demonstrated, and as we've seen in other supply chains, competition for prescription drugs should generally result in increased options for lower cost therapies, particularly through the introduction of one or more generic or biosimilar competitors. Manufacturers understand this and have long manipulated patent and exclusivity protections in creative ways to maintain monopolies where they exist, or to otherwise delay, hinder, or limit competition. As more entrants are introduced to the market, increased pressures flow through the system putting downward pressure on manufacturer list prices, incentivizing PBMs to cover more product options, and providing alternative therapeutic options for providers to utilize when necessary.

Potential Solutions to Increase Competition

Given the current realities of the branded drug market, which is plagued by a lack of competition and a resulting imbalance of negotiating leverage, hospitals and other purchasers can undoubtedly stand to benefit from Federal efforts that incent against market abuses and failures in order to create a more appropriately level playing field. These potential solutions include:

- **Promoting faster FDA approval of generic and life-saving drugs.** We recognize and applaud the efforts that the FDA has taken to reduce the backlog of generic drug applications. Nevertheless, the FDA still faces a backlog of nearly 4,000 generic drug applications, and approval times can be three or more years. We would urge Congress to provide FDA the necessary resources to clear this backlog and prioritize generic drug approval applications. Several FDA programs have been implemented to date with the goal of expediting review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and should encourage second or third market entrants to truly spur price competition and access. Again, we applaud the FDA's efforts in this area and would encourage Congress to provide this needed funding for approval of generic drugs on an expedited basis.
- **Creating and Restoring Access to Equivalent Samples (*i.e.*, the CREATES Act).** Currently, FDA requires manufacturers to submit detailed Risk Evaluation and Mitigation Strategies (REMS) to weigh a drug's risks and benefits. While this type of information can create additional safety information for patients and safeguards for providers, manufacturers often manipulate REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice can stifle the introduction of generic competition, thus preventing lower price options from being available. We applaud the Committee's action on this legislation to date and urge Congress to move it forward.
- **Promoting the uptake of biosimilars.** Statutory and regulatory policies should encourage both market entry and the uptake of biosimilars, which have significant potential to expand treatment options and reduce costs of expensive biologics through increased competition. Today, we see payors and PBMs hesitating to put biosimilars on their formularies, which may be the result of rebate-driven incentives. Policies that promote the uptake of biosimilars should consider the impacts of such rebate structures and address them as necessary, including through increased

transparency where appropriate. In addition, as biosimilars become more available, it is critical for the FDA to educate drug manufacturers and physicians on the availability of interchangeability designations in order to effectively increase competition.

- **Limiting application of exclusivity protections to truly innovative products.** Pharmaceutical manufacturers are currently able to extend market exclusivity protections by seeking approval for a “new” product that is essentially the same as the initial innovator product. Prohibiting these tactics will allow more competitors to come to market faster.

Market Failures: Year-over-year Price Increases and High Launch Prices

The steady weekly, monthly, and annual increases in prices for products that have often been on the market for extended periods of time may not have the same immediate and notable impact as a high one-time spike or an extremely high launch price, but they nonetheless consume significant resources when evaluated cumulatively. These year-over-year price inflations often occur without any added demonstration of quality or value. On the other end of the spectrum, shockingly high launch prices continue to threaten the financial stability of the safety net and public programs. While new blockbuster drugs may in fact offer demonstrably improved outcomes, our current system lacks or prevents the use of innovative financing mechanisms to support the availability of such next generation pharmaceuticals.

Potential Solutions to Incent Appropriate Launch Prices and Prevent Unwarranted, Year-Over-Year Price Increases

Policy options to incent appropriate launch prices and prevent unwarranted, year-over-year price increases and exceedingly high launch prices that divert resources away from direct patient care and community benefits include:

- **Increase funding for public and private research on drug pricing and value.** Increase funding for private and public research efforts like the Institute for Clinical and Economic Review (ICER), a non-profit organization that evaluates evidence on the value of medical tests and treatments. Investments in objective information is critical for physicians, patients, and payers as more high-priced and potentially high-value drugs are launched.
- **Require manufacturers to demonstrate alignment of increased costs with improved outcomes across new versus existing drugs.** Through comparative effectiveness research (CER) studies, manufacturers should be required to demonstrate how their product is better than others, so that physicians and patients can make informed decisions about the value of different therapies. This will be particularly important for those new products with very high costs.
- **Expand value-based pricing in public programs.** Federal programs like Medicare and Medicaid are not currently well-positioned to accommodate value-based payment models for pharmaceuticals. Steps should be taken to ensure these programs can leverage recent developments in value-based purchasing to ensure all segments of the healthcare system can benefit from market-based efforts to lower drug prices.
- **Pursue the International Pricing Index (IPI) Model Only with Adequate Safety Net Protections.** Given the persistence of price increases in the current market, we think it would be worthwhile to test – through an appropriately sized and scoped demonstration model – an approach to U.S. drug pricing that provides new tools to enhance providers’ negotiating leverage. However, any model should include adequate protections to ensure no safety net providers, including 340B entities, are inadvertently harmed (*e.g.*, exclude 340B covered entities).

Supply Chain Abuses: Coverage Design Limitations and Fragmentation of Care

We have increasingly observed that payors and PBMs are denying claims based on the site of care, rather than for want of medical necessity. Claims denials and site-specific coverage limitations can have serious consequences for patients, especially those with limited mobility or access to transportation, including diminished continuity of care. Continuity of care and whole person treatment is particularly critical for patients with multiple chronic illnesses. Similarly, payors and PBMs have been hesitant to include biosimilars on their formularies, thereby limiting access to branded biopharmaceuticals that may offer rebate incentives or other arrangements. While some of these design limitations and practices have the effect of limiting competition, they also diminish patient access to the full array of therapies and sites of care that may be necessary to provide appropriately comprehensive and innovative care.

This also results in increased burden and confusion for the patient, as some patients might have to seek out care in different settings to ensure coverage. For example, a patient may need to obtain their prednisone from a retail pharmacy, go to an infusion center for infusion therapy, and then get a specialty medication from an entirely separate specialty pharmacy. This approach to coverage creates a lack of continuity of care and fragmentation, as well as burden for the patient who must navigate this complex system. In addition, the medications might fall under differing reimbursement streams (*e.g.*, coverage through a plan/PBM or medical specialty benefit), creating more confusion and complexity. This kind of fragmentation can also act as a barrier to population health and whole-person care.

Potential Solutions to Promote Appropriate Coverage

Policies to promote appropriate coverage of competitive innovators and ensure care continuity that best manages a patient's health outcomes could include:

- **Promoting the expansion of any willing provider requirements.** Allow providers or facilities to provide or dispense medications to their own patients, regardless of the site of service, to ensure adherence, compliance, and improved outcomes for those patients for whom we are care.
- **Promoting the uptake of biosimilars.** As noted above, statutory and regulatory policies should encourage both market entry and the uptake of biosimilars, which have significant potential to expand treatment options and reduce costs of expensive biologics through increased competition. Today, we see payors and PBMs hesitating to put biosimilars on their formularies, which may be the result of rebate-driven incentives. Policies that promote the uptake of biosimilars should consider the impacts of such rebate structures and address them as necessary, including through increased transparency where appropriate.

Supply Chain Abuses: Hidden, Unpredictable Fees

Our pharmacies have seen a marked increase in the use of direct and indirect remuneration (DIR), a term used as a catch all for many types of fees applied by plan sponsors and their pharmacy benefit managers to pharmacies participating in Medicare Part D networks. DIR fees can include the following:

- Fees for network participation, also called "pay to play fees." These can be a flat fee per claim or a percentage of each claim.
- The "true-up" between the Maximum Allowable Cost (MAC)/adjudicated rate and the contract rate. This is a reconciliation process that results in the difference between those rates being assessed to the pharmacy. This generally occurs quarterly or annually.

- Reconciliation for the lower reimbursement rates from pharmacies that don't score well on PBM-established quality measures or "Performance Metrics."

These fees are assessed after the point of sale transaction, sometimes several months after. This makes it extremely difficult for the pharmacy to determine if they are receiving the correct reimbursement. As a result, recent research suggests that patients are likely to pay more out of pocket costs, as many PBMs will charge a co-pay that is higher than the drug's price without insurance. PBMs will subsequently 'clawback' the difference from the pharmacy, but there is no evidence that the clawback obtained from the pharmacy is ever credited back to the patient.

Potential Solutions to Prevent Hidden, Unpredictable Fees

Policy options to prevent the use of hidden, unpredictable, and retroactive fees that increase overall costs to providers and patients could include:

- **Requiring all DIR fees to be accounted for upfront.** This proposal would effectively eliminate retroactive pharmacy DIR fees by requiring all price concessions be accounted for at the pharmacy counter.

V. Conclusion

Thank you again for the opportunity to testify before the Committee. Ascension appreciates the Committee's continued bipartisan efforts to fully assess and address these important issues and we are honored to serve as a resource to you, both today and in the future.

Appendix A

Examples of 340B-enabled Patient Services and Assistance Programs

There are many examples throughout Ascension of how the reduced drug costs resulting from the 340B program enables us to stretch our resources to expand services for the poor and vulnerable. One example is Ascension's Our Lady of Lourdes Memorial Hospital in Binghamton, New York. Lourdes Hospital has provided compassionate care to those in need since 1925 and has participated in the 340B program since April 2016. In 2017, Lourdes provided approximately \$79.6 million in uncompensated care to the community. The hospital's 340B savings support programs to help uninsured and underinsured patients receive needed care and medications, including Lourdes' Patient Financial Assistance Program (PFAP). This program helps patients who meet income guidelines with payment of bills for services provided by and billed by Lourdes. In 2014, Lourdes expanded the PFAP to include prescription medications. This prescription component of the program is especially important in efforts to help the working poor. These patients are unable to afford the care they need because they are faced with high deductibles or co-pays but may not be eligible for other programs. In 2017, Lourdes enrolled 13,018 individuals in the PFAP, an increase of 24 percent from the year before. Pharmaceutical access impacted more than 80,000 prescriptions, which accounted for \$1.2 million in co-pay assistance to vulnerable patients. If the 340B program was scaled back or eliminated, Lourdes' ability to provide care and assistance to these needy patients would be in jeopardy.

Another example of how the 340B program enables us to expand services to the poor and vulnerable is at Ascension Indiana. St. Vincent Health in Indiana relies on 340B to provide medications to its rural, poor and vulnerable patients. Without the program, the hospital's Joshua Max Simon Primary Care Center (PCC) would not be able to provide its patients with the prescription medications they need at a cost they can afford. Patients served at the Center are charged on a sliding scale for drugs based on their income. Most of those served pay only 20 percent of the 340B discounted price; the remainder of the cost is covered by St. Vincent. In 2017, the PCC served more than 101,000 patients and filled more than 41,000 prescriptions that were all eligible for 340B pricing.

In Tennessee, Ascension's Saint Thomas Hickman Hospital, a 25-bed CAH, has provided personalized care to those in Centerville and Hickman County since 1964. The hospital was the first in Tennessee to qualify as a CAH, serving roughly 10,000 people each year. Nearly 20 percent of the hospital's patients do not have health insurance, and the next closest hospital is about 30 miles away. Without the 340B program, Hickman Hospital would not be able to provide patients the prescription medications they need at a price they can afford. In FY17, Hickman saved \$476,035 through 340B discounts, which was used to improve patient care through the provision of vital medications and services to the poor and vulnerable. In high-poverty, rural areas such as Hickman County, which has one of the highest suicide rates in the state, many patients face several obstacles to receiving the care they need. The 340B program allows Saint Thomas Hickman to improve access to care for the most vulnerable members of the community by: sponsoring a Medical Mission at Home health event that provides mental health, medical, vision, and dental services; creating both an Alzheimer Caregiver and a Diabetic Education Support Group that meets monthly; offering a Behavioral Health Screening Day; expanding the campus clinic to provide expanded behavioral health services and hiring a behavioral health nurse practitioner and a clinical therapist; and opening a charity pharmacy.

Ascension Kansas provides yet another example. Via Christi Health in Kansas has participated in the 340B program since 2012. In FY2016, Via Christi received \$4.3 million in 340B benefit and provided \$77.8 million in community benefit, which included \$44.5 million in charity care, and \$7.9 million in unpaid costs of Medicaid services. Among other programs offered, Via Christi uses its 340B savings to offset the cost of patients' prescription drugs, annually providing more than 5,500 prescriptions to 2,000 patients at no cost.