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Statement

of the

American Hospital Association

before the

Health Subcommittee of the Committee on Energy & Commerce

of the

U.S. House of Representatives

"Examining the Drug Supply Chain"

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On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments on the drug supply chain and the cost of medications.

America's hospitals rely on innovative drug therapies to save lives every day. Without them, more lives would be lost to diseases like cancer and AIDS, and others who now can live comfortably while managing their chronic conditions would see their quality of life deteriorate. In short, modern pharmaceuticals play a critical role in getting patients healthy and helping them maintain health. Hospitals primarily interact with the drug supply chain in their role as purchasers and dispensers of pharmaceuticals. They also play a crucial role in the development of new drug therapies.

Spending on pharmaceuticals has increased dramatically over the past several years. The burden of this increase falls on all purchasers, including patients and the providers who treat them. For example, hospitals frequently see patients show up in the emergency department or return for follow up care sicker than when they left because they were unable to afford their medications. Just as many patients face difficult choices when considering purchasing medications, hospitals, as drug purchasers, face significant resource constraints and trade-offs as spending on drugs increases.

The primary driver behind increased drug spending is higher prices, not increases in utilization. Within the health care field, "pharmaceuticals" was "the fastest growing category" in terms of pricing for every month of 2016 and for most months of 2017.[1] We see both higher launch prices for new drugs and increases in prices for existing drugs. Limited competition and drug shortages have facilitated this price growth.

Hospitals work with manufacturers and group purchasing organizations (GPOs) to negotiate the best prices for the drugs they use. However, for many drugs, the starting point for the negotiation is high, with some new drugs hitting the market at $55,000,[2] $475,000,[3] and even $750,000[4] for a course of treatment. This price does not include the cost of managing and delivering the drug, or any of the ancillary services required to support the patient undergoing treatment.

We explore these challenges in more detail below.

HOW HOSPITALS AND HEALTH SYSTEMS INTERFACE WITH THE DRUG SUPPLY CHAIN

The drug supply chain is complicated, with a number of steps between the development and the delivery of a drug. America's hospitals and health systems did not design the supply chain, but they do interface with it. At the very beginning of the chain, academic medical centers are responsible for a significant amount of the research used to develop and test new drugs. Closer to the end of the chain, all hospitals are major purchasers of drugs used in clinical settings. Below we provide more information on our members' roles in the drug supply chain.

Research & Development. Academic medical centers play a leading role in both the development of the underlying science supporting new drug therapies (basic science research), as well as the development and testing of new therapies (applied or translational research). A combination of public and private funding supports this work, including grants from the National Institutes of Health, philanthropy and biopharmaceutical companies.

A report from Tufts University underlined that "a close and synergistic relationship between [the biopharmaceutical and academic medical center] sectors is critical to ensuring a robust national capacity."[5] The report noted that more than 50 percent of researchers at academic medical centers contribute to drug and device medical trials, and partnerships between biopharmaceutical companies and academic hospitals have increased in recent years.

A *New England Journal of Medicine* report underscored the benefits provided by public-sector research institutions (PSRI), which include academic medical centers and their affiliated universities. Specifically, the study's authors found that PSRI were responsible for 153 drugs, vaccines or new indicators for existing drugs approved by the Food and Drug Administration (FDA) between 1970 and 2009. They also found that hospitals and PSRIs were predisposed to discover drugs that have a disproportionately important clinical effect[6] and those that could be used for widespread public health concerns, including the treatment of cancer and infectious diseases, as well as vaccination development.[7]

Role as Purchasers and Providers. Hospitals purchase drugs that clinicians use to treat patients in their facilities. Hospitals use several different approaches to acquire drugs. Nearly all hospitals work with GPOs to negotiate prices with manufacturers and to contract with wholesalers for delivery. GPOs enable hospitals to reduce administrative expenses by precluding the need to maintain the staff it would take to negotiate contracts for thousands of drugs. Instead, by relying on GPOs, this contracting function, which is not insignificant, is shared across hundreds or thousands of hospitals. This also often enables hospitals to achieve the best price, as they benefit from the negotiating power the GPO has as a result of aggregating purchasing volume. GPOs can save hospitals 10 to 18 percent on the cost of drugs.[8] Hospitals pay GPOs in different ways, which may include a combination of upfront administrative fees, transaction fees and/or a percentage of discount obtained. One report found that GPOs save the health care system between $25 billion and $55 billion per year.[9]

Most hospitals do retain some direct contracting with drug manufacturers. This is primarily true for branded therapies for which there is no competition. In these instances, manufacturers are not compelled to negotiate with GPOs. In those instances, hospitals may directly negotiate with the manufacturer and contract with the wholesaler for delivery. Only a handful of hospitals directly contract for all of their drug supply. These are larger organizations that have both the patient volume and the staff capacity to make one-on-one negotiations worthwhile. A significant challenge arises for small hospitals that have neither the staff capacity nor the volume to enter into direct negotiations with manufacturers. In some instances, small, rural hospitals have been unable to obtain access to certain therapies.

Whether hospitals are contracting directly or relying on GPOs, the pharmaceutical manufacturers set the starting price in negotiations. The ability of the GPO or hospital to obtain a discount off this initial price largely has to do with volume and whether, and how much, competition for such a therapy exists. In instances where no competition exists, such as for many of the new, high-cost specialty drugs, large discounts are not available.

Once a hospital acquires a drug, it manages the supply in hospital-based pharmacies. Hospital pharmacists work with prescribing clinicians to develop and manage the formulary and follow standards for formulary development, which takes into account "evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety and economic factors that result in optimal patient care."[10] Pharmacists also manage the dispensing of medications to the appropriate clinical staff, who then deliver the drug to the patient.

HOSPITAL EXPERIENCE WITH DRUG SPENDING

Purchasers of prescription drugs have faced significant increases in spending over the past several years. Last week, the Centers for Medicare & Medicaid Services (CMS) released updated National Health Expenditures (NHE) data that showed that retail drug spending increased by 1.3 percent in 2016. While this level of growth may appear low, it follows two consecutive years of expansive growth in retail drug spending: 12.4 percent in 2014 and 8.9 percent in 2015. In other words, the lower growth comes on top of a much higher spending base for drugs. In addition, these figures capture *retail* drug spending only; they do *not* include spending on drugs purchased by providers, such as hospitals.

Detailed non-retail drug spending data is not publicly available, as it is not easily collected. Nearly all payments to hospitals for inpatient care are made on a per discharge (Diagnostic Related Group or DRG) or per diem basis, which means that all input costs are rolled into a single payment. Hospitals are responsible for managing input costs within that fixed payment amount and not all input costs are systematically reported publicly.

In order to explore the experience of non-retail drug purchasers, the AHA and the Federation of American Hospitals worked with the NORC at the University of Chicago last year to collect and evaluate data on inpatient drug spending (see Appendix A). The NORC found that increases in drug spending for inpatient care outpaced what the NHE reported for retail drug spending. ***Specifically, the NORC found that while retail spending on prescription drugs increased by 10.6 percent between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7 percent per admission during the same period.***[11] [12]

Price, not volume, is the primary driver of this increased spending. After examining data from two GPOs that collectively purchase drugs for more than 1,400 hospitals, the NORC was able to track changes in price, utilization and total spending for a select group of drugs. Consistently, changes in pricing drove increases in spending. These price increases, from the hospitals' perspective, appeared to be random, inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.

Our members were not surprised to learn that their purchasing experience differs from what the NHE reports for retail drugs. In testimony to the Committee on Oversight and Government Reform of the U.S. House of Representatives, one drug manufacturer acknowledged targeting hospital-administered drugs for price increases. Howard Schiller, then-interim CEO and director of Valeant Pharmaceuticals, stated: "Because these drugs are hospital-administered, and not purchased by patients directly, increasing the cost of the drugs to hospitals would affect the hospital's profits on these procedures, but it should not reduce patient access."[13]

While the NORC study supports Mr. Schiller's admission that manufacturers target hospitals for price increases, we challenge his assessment that such practices do not reduce patient access. Researchers at the Cleveland Clinic found that patient access to Valeant drugs nitroprusside and isoproterenol declined after the company increased the prices for both substantially. From 2012 to 2015, 53 percent fewer patients were treated with nitroprusside and 35 percent less were treated with isoproterenol.[14] This is because hospitals bear a heavy burden when the cost of drugs increases, in large part due to how hospital reimbursement it structured, and this has direct implications for the availability of certain drug therapies. Medicare, which is one of the largest payers for most hospitals and on which many commercial insurers base their rates, cannot keep up with new and frequently changing drug prices. The program relies on drug pricing data collected and reported by the Bureau of Labor Statistics, which does a full "refresh" of drug pricing information only every five to seven years. This data lag means that hospital reimbursement does not necessarily increase proportionally to drug price increases. As a result, hospitals must divert other resources to cover higher drug costs, forcing difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions

facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs.

A number of factors contribute to the increase in drug spending, and those factors have evolved over time. In the past several years, hospital have faced widespread price increases on existing drugs. While drug manufacturers have increased some prices by multiple hundreds or even thousands of percent, hospitals report that the 10 to 20 percent increases on widely used generic drugs often have a greater impact on their budgets given the high volumes of these drugs that hospitals purchase. Increasingly, our members report that high *launch* prices and increased spending due to drug shortages are new challenges they face, as well as budget pressures associated with the ancillary service costs associated with highly complex and potent drugs.

High Launch Prices. Drug manufacturers are increasing the launch prices for new drugs. These prices are the basis for negotiations with purchasers. Examples of recent launch prices include:

- Talz (Eli Lilly), used for treating psoriasis, costs $50,000 a year.[15]
- Keytruda (Merck), used for treating melanoma, costs $152,400 a year.[16]
- Kymriah (Novartis), used for treating leukemia, costs $475,000 for a course of treatment.[17]
- Spinraza (Biogen), used to treat spinal muscular atrophy, costs $750,000 for the first year of treatment and $375,000 per year thereafter.[18]

Drug Shortages. Drug shortages also are a major contributor to increases in drug spending. Medications that experience shortages are largely injectable products that are off patent and have few suppliers; shortages typically arise from quality concerns that cause a halt to production. If a product has few competitors, this disruption cannot be absorbed by other companies and demand outpaces supply. This not only results in a shortage, but also causes prices to rise. For drugs with a sole manufacturer, shortages are exacerbated – since there is no alternative, clinicians must scramble to find the drug or compound the drug in cases where it is possible. They also may recommend an alternative (often less effective) therapy, if one exists. This, in turn, can result in higher spending because manufacturers often capitalize on the situation by increasing the price of the alternative therapy. For example, a 2017 study that examined how drug prices change during supply disruptions[19] found that after quality-control issues forced a manufacturer of glycopyrrolate – an injectable agent commonly used before surgery to reduce secretions – to suspend production, the remaining manufacturer increased the price of its product by 855 percent. The list price remained at the new level even after production capacity was restored.

Ancillary Costs. Many new drug therapies are highly potent and come with significant side effects. A recent example is Kymriah, a new blood cancer drug using "CAR-T cell therapy" through which patients' own genes are extracted, modified and reinjected to kill leukemia cells. The potential side effects require extensive ancillary services to monitor patients and prevent infections and other adverse events for a prolonged period of time.

According to the FDA, "Treatment with Kymriah has the potential to cause severe side effects. It carries a boxed warning for cytokine release syndrome (CRS), which is a systemic response to the activation and proliferation of CAR T-cells causing high fever and flu-like symptoms, and

for neurological events. Both CRS and neurological events can be life-threatening. Other severe side effects of Kymriah include serious infections, low blood pressure (hypotension), acute kidney injury, fever, and decreased oxygen (hypoxia). Most symptoms appear within one to 22 days following infusion of Kymriah. Since the CD19 antigen is also present on normal B-cells, and Kymriah will also destroy those normal B cells that produce antibodies, there may be an increased risk of infections for a prolonged period of time"[20] (emphasis added).

While these services do not directly increase the cost of the drug, they do impact the overall cost of care.

HOSPITALS' APPROACH TO REDUCING DRUG COSTS

Hospitals and health systems are committed to ensuring patients receive high-value care. Hospital pharmacists continually work to reduce the costs of drug therapies in order to maintain and expand access to care. Specific examples of approaches taken by hospitals include:

- Identifying equally effective and safe alternative therapies that may be less costly;
- Ongoing monitoring of pricing changes to anticipate upcoming needs;
- Improving inventory management, including by changing how and where medicines are stocked and how they are delivered to clinicians;
- Reducing waste by identifying safe approaches to splitting excessively large single dose vials into multiple doses; and
- Compounding therapies in-house.

Despite these efforts, increased drug spending remains a challenge and one which we believe requires legislative and regulatory intervention. We urge Congress and the Administration to support patients and providers by taking immediate action to reign in the rising cost of drugs, including by passing the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) and protecting the 340B Program. We also offer a broader set of comprehensive solutions in Appendix B.

The CREATES Act. Generic drugs are one tool for reducing drug prices, as they increase competition after the monopoly enjoyed by drug manufacturer ends when a drug's patent expires. The CREATES Act targets two forms of anticompetitive behavior that are being used to block and delay entry of generic drugs. The first is known as sample-sharing. This occurs when brand-name drug companies refuse to sell samples of their product to potential generic competitors so the generic company cannot perform testing to show that its product is bioequivalent to the brand-name product, a prerequisite for approval by the FDA. The second involves participation in a shared safety protocol. This occurs when brand-name manufacturers whose products require a distribution safety protocol refuse to allow generic competitors to participate in that safety protocol, which is needed to gain FDA approval. The CREATES Act allows a generic drug manufacturer facing the sample-sharing delay tactic to bring an action in federal court for injunctive relief, such as to obtain the sample it needs. The bill also authorizes a judge to award damages to deter future delaying conduct. **We urge Congress to pass the CREATES Act.**

The 340B Program. Congress created the 340B program to permit safety-net hospitals that care for communities with a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[21] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to these health care organizations. For 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to communities across the country with a high number of low-income and uninsured individuals, *at no cost to the federal government.*

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build healthy communities. In 2015, the 340B program accounted for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S. However, hospitals were able to use those savings to support many programs that are improving and saving lives.[22]

Thirty percent of the hospitals that serve 340B communities are located in rural communities. Nearly 50 percent of those hospitals' communities significantly exceeded the minimum Medicare disproportionate share hospital (DSH) adjustment percentage of 11.75 percent, which is the qualifying threshold for the 340B program. In fact, one-fifth of these hospitals have a Medicare DSH adjustment percentage of more than 25 percent. Many 340B hospitals are financially vulnerable, and in 2015, one out of every four hospitals had a negative operating margin.[23]

The 340B program enables these hospitals to serve their communities by reinvesting savings from reduced drug pricing into programs that benefit their patients, particularly their vulnerable patients. In 2015, 340B hospitals provided $23.8 billion in uncompensated care.[24] Examples of programs provided by 340B hospitals include:

- Financial assistance programs for patients unable to afford their prescriptions;
- Provision of clinical pharmacy services, such as disease management programs or medication therapy management;
- Increased access to other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establishment of additional outpatient clinics to improve access to care;
- Community outreach programs; and
- Free vaccinations for vulnerable populations.

In addition, an examination of hospital services illustrates that 340B hospitals provide access to essential services to their communities: [25]

- Nearly two-thirds of 340B hospitals provide **trauma care**.
- Three-quarters of 340B hospitals provide **pediatric medical surgical services**.
- Nearly all 340B hospitals have **obstetrics (OB) units**.
- Approximately two-thirds of 340B hospitals provide **psychiatric services**.
- 42 percent of 340B hospitals provide **substance abuse or dependency services**.

- 58 percent of 340B hospitals have **Neonatal Intensive Care Units (NICUs)**.
- Nearly all 340B hospitals provide **breast cancer screening**.

The 340B program is under threat, especially as a result of a recent change in Medicare payment policy that reduces by nearly 30 percent, or $1.6 billion, Medicare payments to certain hospitals for outpatient drugs purchased under the 340B program. Cuts of this magnitude will negate the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities. **We urge Congress to pass H.R. 4392, which would prevent these cuts from going into effect and reducing critical health care resources in vulnerable communities.**

CONCLUSION

We appreciate the opportunity to provide these comments and support the Committee's efforts and attention to examining the issue of the drug supply chain and the cost of medications. We remain deeply committed to working with Congress, the Administration and other health care stakeholders to ensure that all Americans can access the drug therapies they need to lead healthy, happy and productive lives.

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