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The Honorable Frank Pallone
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20510

RE: Subcommittee on Health Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

Dear Chairman Pallone:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to follow-up questions as part of the hearing before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health titled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain." The AMA remains strongly committed to advancing public policies that will increase access to affordable and medically necessary prescription medication by increasing competition, promoting transparency, reducing administrative burdens, and lowering costs for patients.

I have attached the AMA's responses to the committee's follow-up questions. We look forward to continuing to work with you on solutions to lower prescription drug prices and ensuring access to necessary medications for our patients.

Sincerely,

Jack Resneck, Jr., MD

Attachment

cc: Honorable Greg Walden, Ranking Member
Committee on Energy and Commerce

Honorable Anna G. Eshoo, Chairwoman
Subcommittee on Health

Honorable Michael C. Burgess, Ranking Member
Subcommittee on Health

The Honorable Michael C. Burgess, MD

1. **Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?**

The AMA agrees that strategic focus should remain on addressing the current persistent shortages as well as developing contingencies to address those that may arise due to unforeseeable events, such as natural disasters. The AMA remains actively engaged in discussions to address shortages. We strongly support the work of the U.S. Food and Drug Administration (FDA) in this area and continue to work with their staff along with the U.S. Department of Homeland Security (DHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), manufacturers, supply chain experts, as well as other members of the public and private sectors. The AMA has prioritized raising awareness that shortages must be addressed and all stakeholders must play a role in addressing current shortages and developing systematic contingencies. To address the drug shortage issue, the AMA supports policy, legislation, and/or regulation that:

- Encourages stakeholders in the drug supply chain to increase collaboration.
- Increases transparency along the pharmaceutical supply chain.
- Establishes plans for continuity of supply of vital medications, including the establishment of resiliency and redundancy in manufacturing capability.
- Reduces or removes regulatory hurdles and barriers while enhancing flexibilities.
- Incentivizes investment in expanded manufacturing production capacity for vital products.

Collaboration

The AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply. We urge stakeholders from the entirety of the drug supply chain and the FDA to work in a collaborative fashion to implement these recommendations.

Increase Transparency

The AMA strongly urges the FDA to require manufacturers to provide greater transparency regarding the drug manufacturing process from start to finish. Knowledge of the entire supply chain, including raw material suppliers, active pharmaceutical ingredient manufacturers and suppliers, distributors and distribution sites, as well as production locations of drugs, can provide the necessary metrics for much needed quality analysis and information regarding supply chain disruptions that contribute to medical product shortages and their causes. More information about the manufacturing process can inform the causes and anticipated duration of drug shortages and assist in shortage mitigation.

Continuity of Drug Supply

The AMA strongly supports conferring the FDA with enforcement authorities to ensure that drug manufacturers establish a plan for continuity of supply of vital medications and vaccines to avoid production shortages whenever possible. The continuity of supply plan should include the establishment of the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

The AMA strongly supports the designation of drug shortages as a national security priority and the inclusion of vital drug production sites in the critical infrastructure plan. Several manufacturers were impacted by cyber events over the past year and product shortages were worsened by the recent hurricanes impacting Puerto Rico which demonstrate the need to evaluate risk and hazard and disaster response for drug and medical product manufacturing. The AMA urges the application of critical infrastructure policies to the drug shortage challenges clinicians, their patients, and families face each day.

Reduction in Regulatory Burden

The AMA strongly supports the FDA's effort to provide increased flexibilities and engagement when manufacturers have notified the Agency of a potential or actual drug shortage. The AMA continues to specifically support expedited facility inspections and the review of manufacturing changes, drug applications, and supplements that would assist manufacturers in mitigating or preventing a drug shortage.

Federal Policies, Market Forces, Investment Incentives

The AMA strongly supports the development of a comprehensive report on the root causes that also analyzes current manufacturing capacity, the number of manufacturers, mergers and consolidations, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. The AMA also urges careful consideration of federal health care program payment rates for drugs that are vulnerable to shortage. The Government Accountability Office identified low profit margins for drugs in shortage as a relevant contributing factor to persistent shortages. Carefully targeted policies to address potential underinvestment in vital products subject to intractable shortages should be evaluated.

The AMA strongly supports collaboration between the Federal Trade Commission (FTC) and the FDA during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers and pharmacy benefit managers (PBMs). FTC consultation with the FDA can aid in determining the public health implications of mergers and acquisitions of manufacturers, including the potential impact on drug shortages. Likewise, careful attention to merger and acquisition activity that involves health plans and/or PBMs would be prudent, as consolidation of PBMs can limit contracting opportunities for pharmaceutical manufacturers. Where opportunities to sell products are limited, manufacturers may be pushed out of the space for certain drugs, sometimes leaving only one manufacturer in production for some drug products and increasing potential for drug shortages. Related to the foregoing, the AMA has expressed support for expanded resources and capacity at the FTC to more fully assess and evaluate the impact of mergers and consolidations in both the manufacturer and PBM spaces on competition as well as consumer access as part of the FTC's charge to advance consumer protection. Without oversight and intervention, drug shortages will exist into the foreseeable future if further consolidations occur reducing production capacity.

In support of the above recommendations, the AMA has presented at the National Academies of Science, Engineering, and Medicine (NASEM) as part of the drug shortages workshop, an American Society of Health-System Pharmacists (ASHP) drug shortages summit, an FDA listening session regarding their newly formed Drug Shortage Task Force, and in a public meeting hosted by the FDA, "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." We also submitted comments to the FDA public docket regarding the root causes of drug shortages and possible solutions outlining our policy and recommendations. Additionally, the AMA House of Delegates and members receives annual reports that update physicians on any current developments related to drug shortages and activities to address them.

2. **Dr. Resneck, you mention in your testimony that you support physician access to accurate, real-time formulary and drug cost data at the point of e-prescribing. Express Scripts and others have created programs that can present some of that information to physicians so that they can engage in informed decision making with their patients.**

   Do physicians face any barriers to utilizing these programs during their patient visits? How integrated are existing programs in the workflow?

Yes, physicians face barriers in utilizing these programs during patient visits. First, these programs result in requiring a series of different stand-alone products for each PBM or health plan. Physicians need a non-proprietary system that seamlessly integrates into electronic health records (EHRs). Unfortunately, any technology solutions that provide drug pricing data for every patient in a physician's practice panel are years away from being widely available. Second, these programs need access to accurate data on formularies, prior authorization requirements, step therapy requirements, patient copayments, and health plan drug costs so that physicians can get patients treatments quickly and be good stewards of resources. Currently, pharmaceutical manufacturers, PBMs, and health plans are putting up barriers to making that information available even to the limited Real Time Benefit Tools (RTBTs) that exist. Thus, physicians currently lack accurate, granular, patient-specific formulary data at the point-of-care.

Formulary and benefit data must be seamlessly integrated within EHR systems, as well as reliable and sufficiently detailed (unlike currently available Formulary and Benefit batch files), to be widely adopted by physicians. Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. Drug price transparency at the point-of-care has the potential to reduce drug costs for patients. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of prior authorization (PA) and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Transparency of coverage restrictions in EHRs can thus prevent medication nonadherence and treatment abandonment. The 2018 AMA Prior Authorization Physician Survey reveals the magnitude of this problem, with 75 percent of physicians reporting that PA can lead to treatment abandonment.

The AMA supports the Centers for Medicare & Medicaid Services' (CMS) efforts to expedite industry implementation of RTBTs to support drug pricing transparency. However, the AMA disagrees with the specific approach detailed in the Medicare Advantage and Part D Drug Pricing Final Rule, which merely requires Part D plans to support a single RTBT that integrates with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan to have access to prescription benefit information for every patient treated by the practice. As projected by CMS in the proposed rule, this will be an overwhelming, expensive, and burdensome proposition for vendors and physicians and will discourage adoption of this technology. Expenditures in these proprietary tools will be particularly wasteful if CMS mandates a standard RTBT within the next few years, since vendors, physicians, and Part D plans will have to rebuild technology to support the mandated RTBT.

The AMA recommends that CMS require plans to support a single RTBT standard that will integrate with all EHR systems when made available. The National Council for Prescription Drug Programs (NCPDP) has been developing an electronic standard for the communication of real-time prescription drug coverage and pricing information, including therapeutic alternatives, between payers and prescribers over the past few years. The AMA participates in the NCPDP group involved in this effort and expects that a RTBT standard will be published by NCPDP within the next year.

We believe that this approach will ensure that physicians have access to accurate, real-time formulary data across payers, without which this technology will not realize its full potential. We also note that in its current format, the draft NCPDP RTBT standard supports use of two different syntaxes (SCRIPT and Telecommunication standards). We have concerns that this will create interoperability challenges between EHR vendors and payers who are not using the same syntax. We therefore support a testing period after the initial publication of the NCPDP RTBT

standard to ensure seamless translation between the two different syntaxes and that any RTBT can provide physicians with accurate and complete prescription drug formulary and pricing data across all payers and patients.

a. **Follow-up: Are there any laws, regulations, electronic health record contracts, or other agreements that stand in the way of developers of these programs from sharing this information with physicians?**

As described above, current CMS regulations only require Part D plans to support a single RTBT that is required to integrate with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan to have access to prescription benefit information for every patient treated by the practice. Thus, while not a barrier for developers, the AMA is concerned about adding unnecessary administrative burden and costs to physician practices.

We are not aware of any legal or regulatory barriers to the provision of patient-specific formulary data, out-of-pocket costs, and therapeutic alternatives to physicians in their EHRs. These data are already provided to pharmacies in claim adjudication and should therefore be readily available to be disclosed in physician EHR systems. Additionally, several of the currently available proprietary RTBTs already offer this information to physicians in their EHRs, although we must again stress that these tools are of limited utility to physicians because they do not cover all payers or patients.

However, we have heard anecdotally from some industry stakeholders that the restrictions and protections in contracts and trade agreements between pharmacy benefit managers (PBMs) and pharmacies prohibit the disclosure of the amount paid by the PBM to the pharmacy for a patient's medication, as this would reveal proprietary contract information. We find this claim troubling at a time when our nation is transitioning to value-based care (VBC) and risk-based payment models. Under these newer payment systems, physicians are held accountable for the total costs of a patient's health care, including prescription drugs. Without access to a drug's overall costs, including the plan's responsibility, the physician will not be able to accurately assess true treatment costs. This will serve as a significant barrier to physicians' success in VBC arrangements. For a RTBT to be successful, it must not only provide information for every patient in a physician's care, regardless of PBM or other payer, but also report complete pricing data, including both patient and payer responsibilities for a particular drug. It is imperative that RTBTs display complete drug pricing data to physicians to support our nation's move to VBC. Without this capability, the full value of RTBTs will not be realized.

<u>The Honorable John Shimkus</u>

1. **Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?**

The health care system is moving to a world that pays health professionals to manage episodes of patient care in a more comprehensive way. However, this approach to payment can run afoul of the fraud and abuse laws. For example, even if the primary purpose of an arrangement is to improve patients' health outcomes, as long as one purpose of the arrangement's payments is to induce future referrals, the arrangement may violate the fraud and abuse laws (e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's

care among a hospital, physician specialists, and a primary care physician may induce future referrals to the primary care physician to avoid an unnecessary readmission to the hospital).

Fostering the shift to alternative payment models (APMs) has necessitated reviewing and, in some situations, updating fraud and abuse laws to ensure that they do not unduly impede the development of value-based payment. Through specific statutory authority, both the CMS and the Office of Inspector General (OIG) have deemed it necessary to waive the requirements of certain fraud and abuse laws to test the viability of innovative models that reward value and outcomes.

Outside of those models, however, the fraud and abuse laws may still pose barriers to initiatives that align payment with quality and improve care coordination. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of these laws. For example, the Stark law impedes sharing needed resources between multiple physicians caring for the patient which prohibits physicians from coordinating care on behalf of their patients. Instead, the patient, in addition to dealing with the physical and emotional aspects of a disease or condition, must also attempt to coordinate their own care in a fragmented and siloed system. Placing the obligation on the patient to know how to properly manage follow-up care without the assistance of their physician or care coordinator may have a negative impact on patient care and the physician-patient relationship.

With value-based contracting, the anti-kickback statute potentially prevents health industry companies from providing health care providers with a bundle of services to achieve a specific clinical outcome and from paying a rebate if the outcome was not achieved. For example, it may make perfect clinical and logical sense to bundle services such as technology, consulting, training, and patient monitoring that cover the different ways in which a company may contract with health professionals. Discounts in connection with a bundled sale, however, do not qualify under existing safe harbors because safe harbor protection only exists for services, which are reimbursed by the same federal health care program using the same methodology, which could exclude the type of value-based service bundle that a company wishes to offer in the example.

Moreover, the existing warranties safe harbor limits any warranty to the cost of the item itself. Thus, the current safe harbor does not cover, for example, payment for corrective services if the targeted clinical outcome under a value-based contract is not achieved. Nor does the existing safe harbor allow manufacturers flexibility in determining the types of warranties that could be offered for products that do not work as specified (e.g., reimbursement of copayments or new products in exchange for damaged or defective products).

To ensure that value-based reforms benefit patients and protect taxpayers, the AMA has urged Congress and the Administration to create a Stark exception and anti-kickback safe harbor to facilitate coordinated care and promote well-designed APMs. This exception should be broad, covering both the development and operation of a model to allow physicians to transition to an APM model, and provide adequate protection for the entire care delivery process to include downstream care partners, entities, and manufacturers who are linking outcomes and value to the services or products provided.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

The reforms outlined above along with the recommendations that the AMA has advanced to support competition, transparency, and reduction in administrative burdens, will drive value, costs savings and improved outcomes. How? Patients will receive medically appropriate medication when their conditions are less acute or advanced; patients will receive care in lower cost sites of care as medication adherence should correlate with reduction in emergency department visits and hospitalizations; care coordination costs will be reduced and clinical staff will be able to provide medical care instead of complete paperwork; and, duplication and redundancies will also be substantially reduced.

In addition to the broader value the policies AMA is advocating will bring, the AMA believes in the context of value-based pricing of pharmaceuticals, "value" should be regarded as a comprehensive assessment of a range of factors that truly determine a product's value to the marketplace, including patients. In addition to strong consideration of clinical outcomes as an indicator of value, the AMA encourages a value assessment that also weighs factors such as cost, comparative effectiveness research, toxicity/side effects, novelty, budgetary impacts, incremental cost-effectiveness, and impacts on patients such as long-term benefits, patient individual budget, impact on caregivers, variation of clinical response in different patient populations, and the ability of patients to return to work.

A comprehensive review of all factors relevant to determining a drug product's true value will help assure patient affordability, limit system-wide budgetary impact, and determine appropriate payment amounts for those products that incentivize innovation by pharmaceutical manufacturers, ensure that patients have access to the critical drug product they need, and avoid situations where a product's success justifies a price that patients and the system simply cannot afford. Importantly, value-based prices of pharmaceuticals should be determined by objective, independent entities. Ultimately, initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs and allow for patient variation and physician discretion.

The AMA recognizes that the concept of "value-based pricing" can mean different things to different players in the pharmaceutical marketplace. The AMA is concerned about conversations surrounding "value-based pricing" that really mean payment contracts negotiated on clinical outcomes only, without consideration of other important factors that impact the true value of a drug to the marketplace. Value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, post-marketing safety and efficacy data, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes. As such, clinical outcomes are an incredibly important piece of the value equation when discussing payment policies for pharmaceuticals. However, the AMA believes strongly that a number of other factors need to be considered in concert in order to determine the true "value" of a drug to physicians, patients, and the health care system and to arrive at an appropriate, value-based price for the product in question. Furthermore, it is not clear that purchasing contracts based on outcomes alone are achieving any measurable savings for those payers that have entered in to them, showing the need for additional transparency in this space.

In fact, in the case of products that successfully demonstrate clinical effectiveness, outcomes-based pricing could even be used to justify extremely high prices. Even for pharmaceuticals that do not meet outcomes metrics and warrant the payment of retrospective rebates, such outcomes-based contracts do not result in a lower list price for the drug in question. Importantly, patients do not reap the rewards of reduced out-of-pocket costs under outcomes-based contracts: patients incur costs at the point-of-sale, and outcomes-based contracts are not structured in a way to enable patients to enjoy savings up front. Overall, the AMA believes that federal drug

payment policies should be structured so that federal health programs do not pay the full amount for drugs that are not clinically effective for patients.