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“More Cures for More Patients: Overcoming Pharmaceutical Barriers”

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Chairman Doggett, Ranking Member Nunes, and members of the Subcommittee, thank you for devoting your valuable time to seeking legislative solutions that address various pharmaceutical barriers. It is my honor to participate in today’s hearing. Thank you for giving me the opportunity.

I am Ge Bai, a Certified Public Accountant, Associate Professor of Accounting at The Johns Hopkins Carey Business School, and Associate Professor of Health Policy and Management (joint) at The Johns Hopkins Bloomberg School of Public Health. I am affiliated with the Johns Hopkins Drug Access and Affordability Initiative and I serve on the Consumer Standing Advisory Committee of the Maryland Health Services Cost Review Commission. My research expertise is in the interdisciplinary area of health care and accounting. I have published many research articles in leading academic journals regarding the pricing of hospital and physician services, hospital finance, cost control, and risk management, as well as pharmaceutical supply chain and drug manufacturer behavior. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University or any of its subsidiaries or affiliated entities.

The focus of my testimony today is drug manufacturers’ financial contributions to independent patient assistance programs (IPAPs) and patient advocacy organizations (PAOs), and drug manufacturers’ provision of free drug samples to clinicians. Although these programs improve drug access and the well-being of some patients to some extent, they often lead to market distortions, price increases, and inefficient prescription drug spending. Congress should design tax and disclosure policies to contain spending and improve affordability and market efficiency for prescription drugs.
Section I: Drug Manufacturers’ Financial Contributions to Independent Patient Assistance Programs

Background
IPAPs are independent patient assistance programs operated by 501(c)(3) nonprofit organizations unaffiliated with drug manufacturers. These nonprofit organizations are exempted from federal income tax on the basis that they are operated exclusively for charitable purposes. Most states exempt these organizations from state income tax, sales tax, and property tax. Charitable contributions from donors to these organizations are deductible for federal income tax purposes.

The independent nonprofit organizations operating patient assistance programs receive cash donations, primarily from drug manufacturers, and use them to provide financial subsidies to eligible patients by covering their deductibles, copays, coinsurance, and/or premiums for their prescription drugs. Patients or their providers and pharmacists (on the patient’s behalf) can apply for financial assistance from IPAPs. Financial assistance is delivered through either claim submission by providers and pharmacies at the point of sale or by post-sale reimbursement to patients.

IPAPs differs from manufacturer PAPs (MPAPs), which are also 501(c)(3) organizations but are owned by manufacturers. Most MPAPs receive donated prescription drugs from the manufacturer and distribute them to eligible patients, a process that involves no cash transaction. In contrast, IPAPs are unaffiliated with manufacturers, receive cash donations from manufacturers, and cover out-of-pocket expenditures for patients. Manufacturers claim a tax deduction for their charitable drug donations (to MPAPs) and cash donations (to IPAPs). The scale of operation has declined since 2013 for MPAPs but has grown consistently and rapidly for IPAPs.2

Coverage provided by IPAPs also differs from prescription drug coupons. Coupons are offered by manufacturers to directly offset patients’ out-of-pocket expenditure for a specific drug made by the manufacturer. For accounting and tax purposes, the coupon amount applied is treated as a reduction in gross revenue for the drug manufacturer. Coupons cannot be used with federal health benefits as per the federal anti-kickback statutes.

The first IPAP, Patient Services Incorporated, was established in 1989.1 IPAPs started experiencing rapid growth in the early 2000s, when the Medicare Modernization Act added the coverage of prescription drug benefits to the Medicare program. In 2006, the combined financial assistance provided by the top five largest IPAPs totaled $50 million. In 2015, it grew to $1.4 billion, representing an annualized growth rate of 39%.2

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IPAPs are regulated through a special advisory bulletin by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS), issued in 2005 and updated in 2014. Maintaining independence from manufacturers is critical for IPAPs used in federal health benefits to mitigate legal risks under the federal anti-kickback statute; the bulletin states that IPAPs “must not function as a conduit for payments by the manufacturers to patients and must not influence beneficiaries’ drug choices.” For example, the disease applicable to an IPAP cannot be narrowly defined; the provision of assistance cannot be applied inconsistently across drugs, and manufacturers cannot receive sensitive data from IPAPs.

**Implications**

Financial assistance provided by IPAPs has important implications for patients, insurance plans, and drug manufacturers. Insurance plans design cost-sharing tiers with varying out-of-pocket expenditure to influence drug utilization and spending. For example, expensive brand-name drugs generally entail higher out-of-pocket expenditure than their more affordable generic alternatives, encouraging utilization of the generics. By defraying patients’ out-of-pocket expenditure for a specific drug, IPAPs eliminate patients’ exposure to price, desensitize them from the drug’s affordability, and enhance the utilization of the drug.

The benefit design for beneficiaries’ out-of-pocket expenditure is the primary tool used by insurance plans to influence drug utilization and contain spending. When patients no longer have exposure to price due to IPAPs’ intervention, this tool is blunted, leading to inefficient drug utilization by patients and higher spending by insurance plans. Outside of the prescription drug space, waiving patients’ out-of-pocket expenditure by healthcare facilities and clinicians is considered a form of insurance fraud.

IPAPs’ coverage of patients’ out-of-pocket expenditure, by making patients insensitive to cost-sharing and making insurance plans unable to influence utilization, boosts drug utilization and revenue (from insurance plans) for manufacturers of the covered drugs. A $10 financial contribution to an IPAP was estimated to generate between $6 and $30 in incremental profit. The financial contributions from drug manufacturers to IPAPs also generate tax savings for the manufacturer, assuming the 10% taxable income limitation has not been reached. Moreover, because out-of-pocket costs are reduced, patient demand for the product becomes more inelastic, which encourages drug manufacturers to raise prices.

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Taken together, financial contributions to IPAPs generate significant return for drug manufacturers and reduce barriers for price increases. Recently, multiple IPAPs and drug manufacturers settled with the Department of Justice for allegedly violating the federal anti-kickback statute for their drug coverage for Medicare beneficiaries.\textsuperscript{7,8,9,10,11} My coauthored study published in the Journal of the American Medical Association (JAMA) in 2019 found that major IPAPs only covered insured patients, did not design their eligibility criteria to favor low-income patients, and disproportionately covered expensive drugs and off-patent brand-name drugs.\textsuperscript{12} The evidence suggests that policy actions are needed to address the anti-kickback concerns involved in drug manufacturers’ financial contributions to IPAPs and IPAPs’ uses of the financial contributions.

**Policy Recommendations**

On the surface, assistance provided by IPAPs mitigates the financial burden for patients who take the specific drugs covered by the IPAP. In essence, however, it distorts drug demand, enhances drug manufacturers’ revenue from insurance plans, and reduces barriers for raising prices. IPAPs are not only the wrong solution to high drug prices, but they contribute to inefficient drug spending and high drug prices. Policy effort should focus on (1) eliminating or reducing the tax deduction for contributions from manufacturers; (2) improving oversight of IPAPs; (3) mandating disclosure by manufacturers, and (4) mandating disclosure by IPAPs.

**Eliminating or Reducing the Tax Deduction for Contributions from Manufacturers**

Currently, drug manufacturers are allowed to deduct all of their financial contributions to eligible charitable organizations, including IPAPs, up to 10% of taxable income. Financial contributions above the limit may be carried over to five succeeding years, subject to the 10% limitation each year. Within the 10% limit, financial contributions to IPAPs generate business returns in the forms of enhanced revenue (from insurance plans) and tax benefit (reduced tax payment). Eliminating the eligibility of financial contributions to IPAPs for tax deduction would remove the tax benefit and thus discourage such financial contributions.

This policy approach does not affect drug manufacturers’ enhanced revenue attributable to a given amount of financial contributions to IPAPs, nor does it prevent such contributions. Currently, gifts to customers above $25 are not tax deductible due to anti-bribery and corruption concerns. The IRS could be authorized to take a similar approach and establish that financial contributions to IPAPs


above $25 per patient are not tax deductible, with the $25 per patient counted toward the annual 10% charitable contribution limit.

Another option is to allow a 50% tax deduction for financial contributions to IPAPs, that is, 50 cents of each $1 contribution would be tax deductible. This tax treatment would be the same as the tax treatment of business meals, except for one consideration—the full amount of the contribution (not 50%) should be applied to the annual 10% charitable contribution limit.

**Improving Oversight of IPAPs**

The special advisory bulletin by HHS OIG has the following requirements: manufacturers should not exert influence or control over IPAPs; IPAPs should be truly independent, severing any link between manufacturers’ funding and the beneficiaries; IPAPs should have no regard to manufacturers’ interests or beneficiaries’ choice of product; IPAPs should provide assistance based upon a reasonable, verifiable, and uniform measure of financial needs that is applied consistently; manufacturers should not solicit or receive data from IPAPs to correlate the donation with their products, and IPAPs should not define a particular disease narrowly or cover a limited group of drugs, such as a subset of available drugs or the drugs of a major donor.

Recent research findings and settlements of IPAPs with the Department of Justice suggest that non-compliance is common, such as preferential coverage of expensive brand-name drugs. To deter non-compliance, policy makers may consider linking compliance with the tax-exempt status of IPAPs as 501 (c)(3) organizations, which requires that they do not operate for the benefit of private interests. The IRS could be authorized to impose an exercise tax on non-complying IPAPs on the basis that they have engaged in excess benefit transactions with the drug manufacturer. An excess benefit transaction occurs when the economic benefit provided by a tax-exempt organization to the donor is greater than the value of the donation received by the organization, which may be the case for some transactions between IPAPs and manufacturers.

Besides the existing requirements, HHS may consider imposing the same requirements that are applicable to IPAPs operating outside of the Medicare Part D program on all IPAPs used with federal health benefits, that is, IPAPs should provide assistance for the whole coverage year and the assistance should remain available even if the beneficiaries’ use of the subsidized drug is periodic during the coverage year. HHS should also specify that not covering generic drugs or less expensive drugs for any disease will be treated as covering limited drugs and not covering uninsured patients will be treated as using an unreasonable measure of financial needs. In addition, IPAPs operated by the same charity should be required to maintain the same eligibility criteria that remain unchanged in each fiscal year. IPAPs that expect to terminate coverage should notify affected patients at least eight weeks in advance of termination. IPAPs’ failure to fulfill any of the existing and proposed new

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requirements should increase the risk of violating the anti-kickback statute, jeopardizing the tax-exempt status, and being required to pay the exercise tax for excess benefit transactions.

**Mandating Disclosure of Drug Manufacturers**
To improve the transparency of financial relationships between drug manufacturers and IPAPs, manufacturers should be required to report all financial relationships with IPAPs to HHS, which will collect and publish the data to the public. This policy option would be an amendment to the Physician Payments Sunshine Act of 2010, which requires applicable manufacturers of drugs, medical devices, and biological and medical supplies to report all financial relationships with clinicians and teaching hospitals to CMS. CMS publishes this information on its Open Payment Program website.

**Mandating Disclosure of IPAPs**
To improve the transparency of financial relationships between drug manufacturers and IPAPs, IPAPs should be required to report the names, addresses, and donated amounts of major donating entities on their websites. Alternatively, this information may be collected by HHS and subsequently made available to the public.

Moreover, the amount of restricted contributions from major donating entities—for example, contributions earmarked for a specific disease or limited to any restrictive uses—and the details of the restrictions should be made available to the public annually, on IPAPs’ websites or through filings with IRS or HHS filing. Distinguishing restricted donations from unrestricted donations is an existing accounting and reporting practice. For example, Financial Accounting Standard Board Accounting Standard Codification 958-205-45, pertaining to accounting and reporting issues for nonprofit entities’ endowments, distinguishes between restricted endowments and unrestricted endowments.¹⁴

The actual uses of financial assistance for various drugs should also be disclosed to the public annually, on IPAPs’ websites or through filings with IRS or HHS filing. The information on donors combined with information on the uses of funds will facilitate monitoring and oversight by regulatory agencies and the public to reduce the risk that IPAPs’ actions are misaligned with their charitable mission.

**Section II: Drug Manufacturers’ Financial Contribution to Patient Advocacy Organizations**

**Background**
Patient advocacy organizations (PAOs) are 501(c)(3) nonprofit entities with the primary mission to improve the well-being of a particular patient population.¹⁵ These organizations educate patients,

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provide social support, and raise public awareness about diseases or medical conditions. In the meantime, PAOs exert substantial influence on pharmaceutical policy by advocating for biomedical research and drug development, promoting drug approvals, suggesting pricing policies, and encouraging insurance coverage for drugs, among other activities.\(^{15}\)

An important revenue source of PAOs is financial contributions from drug manufacturers. Drug manufacturers are allowed to deduct their financial contributions to PAOs and other eligible tax-exempt organizations, up to 10% of their taxable income. The contributions above this limit may be carried over for five years, subject to the annual 10% limit.

Besides the exemption requirements in section 501(c)(3) of the Internal Revenue Code and state-level regulations applicable to all 501(c)(3) organizations, PAOs are not subject to legislative or regulatory constraint specifically applicable to them, except for PAOs that advocate on behalf of patients or fund medical research in Nevada. Nevada’s drug transparency law (SB539), which received bipartisan support and was enacted in 2017, requires PAOs in Nevada that have received monetary considerations from manufacturers and other entities to annually post the transaction information on their website (or submit it to the Nevada Department of Health and Human Services if websites are not maintained). The disclosure includes the amount and donor information for each contribution and the proportion of the PAOs’ total gross income in that year attributable to the contributions from each entity.\(^{16}\)

**Implications**

PAOs, by combating a particular disease or condition, bring value to patients and improve their well-being. However, some PAOs have advocated for drug policies that appear inconsistent with patients’ welfare but are more closely aligned with the financial interest of drug manufacturers—for example, supporting expensive drugs with questionable clinical benefit and opposing automatic biosimilar substitution that would improve drug affordability.\(^{15,17,18}\)

A study published in the New England Journal of Medicine in 2017 found that more than 80% of large PAOs in the U.S. received funding from the pharmaceutical, medical device, and biotechnology industries. My coauthored study published in the American Journal of Public Health in 2019 found that in 2016, some major drug manufacturers’ financial contributions to PAOs in the U.S. ($88 million) were 2.8 times their financial contributions to PAOs in Canada, UK, Italy, France, Germany,

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Spain, and Japan combined ($31 million), substantially higher than would be allocated to the U.S. based on population size, drug sales revenue, or Gross Domestic Product across these countries.\(^\text{19}\)

The financial relationships between drug manufacturers and PAOs in the U.S. raise the concern that PAOs supported by financial contributions from drug manufacturers and other medical products suppliers might have conflicts of interest that affect the policy agendas they pursue and positions they take.

Transparency is crucial for maintaining the public’s trust in PAOs and deterring potential activities that would undermine PAOs’ patient-oriented mission. Currently, both PAOs’ voluntary disclosure of financial contributions they received from drug manufacturers and drug manufacturers’ voluntary disclosure of their financial contributions to PAOs is limited and varied; PAOs rarely self-regulate conflicts of interest.\(^\text{15, 20}\) Therefore, policy intervention is warranted to maintain a high level of transparency of the financial relationships between drug manufacturers and PAOs.

**Policy Recommendations**

Financial relationships between drug manufacturers and PAOs exhibit conflicts of interest. Policy effort to address these conflicts should focus on (1) mandating disclosure by manufacturers, and (2) mandating disclosure by PAOs.

**Mandating Disclosure by Drug Manufacturers**

To improve transparency of financial relationship between drug manufacturers and PAOs, manufacturers should be required to report all financial relationships with PAOs to HHS, which would collect and publish the data to the public. This policy option would be an amendment to extend the Physician Payments Sunshine Act of 2010, which requires drug manufacturers and other medical products suppliers to disclose all financial relationships with clinicians and teaching hospitals.

**Mandating Disclosure by PAOs**

PAOs should be required to disclose financial relationship with drug manufacturers. Nevada’s drug transparency law (SB539) offers a reference for potential federal legislative action. Congress may consider requiring all PAOs that receive monetary considerations from manufacturers and other entities to annually post on their websites the amount of and donor information for each contribution and the proportion of the PAOs’ total gross income that is attributable to the contributions from each donating entity. Alternatively, this mandatory disclosure could be fulfilled by PAOs reporting to HHS, which can make the information publicly available.

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Section III: Drug Manufacturers’ Provision of Free Samples to Clinicians

Background
Providing free drugs samples to clinicians, often called sample closets, is the main marketing tool used by drug manufacturers. Most promoted drugs are new and expensive brand-name drugs that have less expensive but clinically equivalent alternatives on the market. In 2016, drug manufacturers spent $13.5 billion on free samples, distributed by salespeople (including online requests), accounting for 69% of professional marketing for prescription drugs. These expenditures are classified as promotion expenses for accounting purposes and are fully tax-deductible.

Although some states restrict clinician office visits by pharmaceutical salespeople, provision of free drug samples to clinicians is not subject to legislative or regulatory constraints. The Physician Payments Sunshine Act of 2010 exempted free drug samples from the mandatory disclosure of clinician-industry financial relationship. While some hospitals limit free drug samples, the magnitude of drug manufacturers’ spending on free drug samples ($13.5 billion in 2016) indicates that it is not uncommon for clinicians to receive free drug samples. A study published in JAMA Internal Medicine in 2020 found that 60% of primary care practices received free drug samples.

Implications
The majority of free drug samples provided to clinicians are distributed to patients at no cost. The access to free samples allows patients to try a new medication before committing to it. Patients usually receive prescriptions for the same promoted drug after exhausting the free sample. Since free drug samples are generally new and expensive brand-name drugs that have equally effective, older, and more affordable alternatives on the market, both the patients’ out-of-pocket expenditure and their insurance plans’ prescription drug spending are likely to be higher as a result of the provision of free drug samples to clinicians.

Clinicians’ prescription behavior and quality are influenced by free drug samples. Besides distributing free samples to patients, approximately one-third of the samples are used by physicians and their family and staff, financially benefiting them directly. Receiving free drug samples, therefore, raises conflicts of interest concerns for clinicians. The position paper by the Ethics and Human Rights Committee of the American College of Physicians states that “it is unethical for physicians to accept any industry gift or subsidy that is predicated on recommending a particular product or taking a particular clinical action.”

The effect of free drug samples on clinicians’ prescribing behavior and the resultant higher utilization and spending on the promoted drugs suggest that a free sample is a powerful marketing tool that generates lucrative returns for drug manufacturers. The high spending on free drug samples and their prevalence in clinician practice indicates that this tool is being actively utilized by drug manufacturers.

**Policy Recommendations**
Free drug samples given to clinicians by pharmaceutical salespeople affect clinicians’ prescribing behavior and increase drug expenditure for patients and their insurance plans. To encourage cost-effective drug prescription and moderate drug spending, policy effort should focus on improving transparency of drug manufacturers’ spending on free samples to clinicians.

**Mandating Disclosure of Drug Manufacturers**
Drug manufacturers should be required to disclose the transaction details of free drug samples provided to clinicians. This policy option has been proposed in the Sunshine for Samples Act of 2019, a bipartisan proposal introduced by Representatives Judy Chu (CA-27) and Devin Nunes (CA-22). The Act would require drug manufacturers and other medical products suppliers to report to HHS the number and value of free drug samples given to clinicians each year, to be posted on the Open Payment Database.

**Section IV: Conclusion**
Drug manufacturers play a critical role in drug discovery and development, advancing clinical treatment, and improving population health. However, their financial contributions to IPAPs may violate the federal anti-kickback statute and motivate future drug price increases. Their financial contributions to PAOs and provision of free drug samples to clinicians also raise important concerns of conflicts of interest that might affect the policy position of PAOs and the prescribing practices of clinicians. Overall, these financial transactions can undermine the best interests of patients and their insurance plans while benefiting drug manufacturers financially. Congress should recognize the implications of these transactions and design tax and disclosure policies to influence the behaviors of the drug manufacturers, IPAPs, PAOs, and clinicians with the goal to contain spending and improve affordability and market efficiency for prescription drugs.

Thank you again for giving me the opportunity to participate in this hearing. I would be pleased to answer any questions you may have.

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