

Testimony of Inmaculada Hernandez

Professor, University of California, San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

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Drug Shortages: Examining Supply Challenges, Impacts, and
Policy Solutions from a Federal Health Program Perspective

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Key Points

- Drug shortages threaten patients' access to medications and constitute a public health risk of national priority.
- Drug shortages disproportionately affect low-cost generic products.
- Reimbursement rates are generally the same for all generic versions of a product; as a result:
 - Manufacturers compete solely on price.
 - Health care providers and pharmacies are incentivized to purchase drugs at the lowest acquisition cost.
- Prices of generic drugs are lower in the US than other countries.
- While aiming to create an efficient marketplace for generics, current policies have led to marked price compression, aggravated by the consolidation of purchasing entities. Price pressure interacts with the limited ability to raise prices in some generic segments, threatening sustainability.
 - Price erosion foments the adoption of cost-containment strategies, including off-shoring. Most generic drugs used in the US are currently produced overseas.
 - Cost-containment strategies create vulnerabilities that contribute to shortages.
 - Limited profitability may ultimately result in manufacturers' determination to discontinue production, increasing market concentration.
- Generic injectable drugs are particularly vulnerable to factors underlying shortages, which generate a "perfect storm":
 - Generic injectables have reduced profit margins due to small market sizes and high costs of manufacturing associated with specialized manufacturing processes.
 - Market entrants are limited, and rates of market exit are pronounced, resulting in particularly concentrated markets.
 - The requirement for specialized manufacturing and equipment makes supply redundancies uncommon and limits the ability to quickly ramp up production in response to shortages.
- Absent policy reform, drug shortages will continue to threaten medication access, as reimbursement models do not incentivize pharmacies and providers to purchase generics products from resilient supply chains.
- Mitigation of generic drug shortages requires intentional policy reform that:
 - Rebuilds the domestic manufacturing infrastructure of generic active ingredients and final dosage forms.
 - Revises generic reimbursement models to incorporate incentives for manufacturers to invest in resilient supply chains.
- Effective policy reform to address drug shortages will likely increase government spending. This spending is a necessary investment in our country's health and national security.

Chairman Wyden, Ranking Member Crapo, and Honorable Members of the Committee, thank you for the invitation to testify about drug shortages. My name is Inmaculada Hernandez, and I am a pharmacist and professor at the University of California, San Diego. My testimony is substantiated by the academic research I conduct on the drug reimbursement system in the US. The opinions I offer today are my own and do not reflect the opinions of the organization with which I am affiliated.

Mr. Chairman, I applaud you for holding this hearing. Drug shortages are an ongoing public health concern that threatens patients' access to essential medications. Drug shortages have devastating consequences, leading to delays or omission in the use of life-saving treatments or substitution with less effective drugs, all of which contribute to adverse health effects and even death in certain clinical circumstances.¹⁻³ As such, the development of policy reforms that address drug shortages is a national public health priority.

In the US, drug shortages are disproportionately seen in the generic product market—84% of the drugs experiencing a shortage in 2017-2023 were generics.⁴ Shortages of generic drugs are a complex interaction of many factors, including 1) the lack of adequate financial incentives for manufacturers to a) produce drugs with limited profit margins and b) invest in resilient and mature drug supply chains, and 2) the logistical and regulatory complexities associated with drug manufacturing.²

My testimony focuses on the economic factors underlying shortages of generic products rather than regulatory oversight. This does not mean, however, that reform of the regulatory oversight of the supply chain is not needed. To the contrary, effective policymaking to address drug shortages requires a combination of policy reforms that address both economic and regulatory drivers.

In what follows, I explain the generic supply chain and the reimbursement model under Medicare and Medicaid. I discuss how the generic reimbursement model generates a “race to the bottom” of prices, which reduces manufacturer profitability, jeopardizing sustainability. I outline the mechanisms through which limited profit margins for certain drugs contribute to drug shortages. Finally, I provide policy recommendations for addressing this major public health risk.

I. THE GENERIC DRUG SUPPLY CHAIN

Generic products make their way to patients through a complex, global supply chain. The supply chain involves manufacturers, wholesalers, group purchasing organizations, pharmacies, health care providers, and ultimately the patient. Below is a brief explanation of the major players in the supply chain. A resilient supply chain necessarily requires all players in the manufacturing, packaging, and distribution process to remain financially stable.

Manufacturing

Generic sponsors submit abbreviated new drug applications to the Food and Drug Administration (FDA). After approval, manufacturers may produce the active ingredient and the final dosage form or may outsource production. Increasingly, generic manufacturers purchase the active ingredient from a supplier and outsource the manufacture of the dosage form to

contract manufacturing organizations. Thus, generic manufacturers serve as a coordinating body of regulatory approval, distribution and sales, but may not actually perform any manufacturing.⁵

All generic products marketed in the US must adhere to the Current Good Manufacturing Practices. Current Good Manufacturing Practices are the minimum level of requirements for drugs to access the US marketplace but are not necessarily indicators of resilience and maturity of the supply chain, needed to ensure supply continuity.

The US heavily relies on foreign manufacturing of generic drugs, with 87% of active ingredients and 60% of final dosage forms produced overseas.⁶ Foreign manufacturing of drugs is associated with increased quality issues—an analysis of warning letters issued by the FDA in 2010-2020 found that the majority of letters reporting violations of Current Good Manufacturing Practices were issued to manufacturers based in Asian countries.⁷

Oral and Injectable Products

The market and manufacturing of generic drugs are markedly different for oral and injectable products. Oral products consist largely of tablets, capsules, and liquid dosage formulations. Injectables include products that are administered subcutaneously (under the skin), intramuscularly (into a muscle), or intravenously (into a vein). Injectable products require specialized manufacturing to ensure sterility, among other requirements that oral products are not required to meet.⁸

The market size of generic oral products, as measured in sales, is 200 times the market for generic injectable products.⁹ Additionally, the market for injectable products is considerably more concentrated—two years after loss of exclusivity, generics oral products in the highest third of sales had an average of 13 generic manufacturers, compared to two for those in the lowest third of sales. In comparison, injectable generics in the highest third of sales had an average of four manufacturers, and those in the lowest third, only one manufacturer.⁹

Purchasing of Generic Drugs by Pharmacies and Health Care Providers

Wholesalers purchase generic products from manufacturers and distribute them to pharmacies and health care providers, including physician offices, ambulatory clinics, and hospitals. The wholesaler market is highly concentrated, with over 90% of drugs distributed through only three wholesalers.¹⁰ Given the large volumes of purchases, when wholesalers design their lists of preferred generics, they consider the manufacturer's ability to supply sufficient volume to meet customer demand. This ultimately leads to the concentration of the manufacturer market, as only manufacturers who consistently produce large volumes of products are competitive enough to have preferred relationships with the primary wholesalers dominating the market. This highly concentrated market leaves limited room for smaller firms who might otherwise create competition and provide an alternative source of supply.

Pharmacies, health care providers, and the clinics or institutions they work for purchase drugs from wholesalers. Often, the prices at which pharmacies and providers purchase generic products are negotiated by group purchasing organizations. Group purchasing organizations are buying consortiums that, through the use of their aggregate purchasing power, achieve greater

discounts than individual members would on their own. The market of group purchasing organizations is highly consolidated, with the four larger group purchasing organizations accounting for 90% of the market.¹¹

II. GENERIC DRUG REIMBURSEMENT

Generic Drug Reimbursement under the Medicare Program

For reimbursement purposes, we distinguish between two types of drugs: a) drugs that patients receive from a pharmacy (“pharmacy-dispensed drugs”), and b) drugs that are administered to a patient in the clinical setting, incident to a provider service (“provider-administered drugs”). Injectable drugs are more likely to be administered in the clinical setting, as only selected injectable formulations are designed for self-administration. In what follows, I provide a simplified summary of the reimbursement of each type of product under Medicare.

Reimbursement of Pharmacy-Dispensed Drugs

Generic drugs are interchangeable by law as they are therapeutic equivalent versions of the same drug but manufactured by different companies. Thus, when a patient presents a prescription for a generic drug, the dispensing pharmacist selects among all generic versions approved by the FDA. Pharmacy-dispensed drugs are covered under Medicare Part D, which is administered through private insurers called Part D organizations. Pharmacy benefit managers administer prescription drug coverage on behalf of Part D sponsors or may act as Part D sponsors themselves, offering their own Stand-Alone Prescription Drug Plans. As part of their services, pharmacy benefit managers reimburse pharmacies for the submitted claims. Generic drug reimbursement is based on the rates specified on contracts between pharmacy benefit managers and pharmacies. Importantly, these rates are generally the same regardless of the manufacturer of the generic product dispensed. Since pharmacies are reimbursed the same amount regardless of the generic version selected, pharmacies are incentivized to purchase generic versions with low acquisition costs.

Reimbursement of Provider-Administered Drugs

The reimbursement of provider-administered generic drugs under Medicare depends on the clinical setting in which the drug is administered.

1. Medicare Part A payments for inpatient hospital services are bundles that cover all services provided under a hospitalization, including drugs. In other words, drugs administered during an inpatient admission are not separately reimbursed. The payments for bundles are based on Medicare severity diagnosis related groups (MS-DRG), which represent the average resources to care for cases that fall within the MS-DRG. This bundling of payments is meant to dissuade the provision of unnecessary care and improve efficiency. In some cases, there may be additional add-on payments for new high-cost technologies to correct for costs incurred before codes and payment rates are updated to reflect new technologies.
2. Drugs administered in hospital outpatient departments with an estimated per-day cost below the packaging threshold (\$135/day in 2023) are not reimbursed separately. Just

like in the case of inpatient admissions, hospital outpatient departments receive a bundled payment that accounts for all procedures and services delivered.

3. Drugs that qualify for coverage under Medicare Part B,¹² are administered in hospital outpatient departments, and have estimated per-day costs above the packaging threshold (\$135/day in 2023) are reimbursed separately. This reimbursement follows the “buy and bill model”, under which providers purchase the drug product and then bill Medicare using Healthcare Common Procedure Coding System (HCPCS) codes. Medicare reimburses such drug products at 106% of the average sales price.¹³ The average sales price is a statutory price benchmark net of manufacturer discounts. Importantly, multi-source products have a unique weighted average sales price that includes all branded and generic versions of a product. The average sales price is calculated quarterly, and there is a two-month lag in its application, meaning that reimbursement rates in Q4 2023 are based on Q2 2023 average sales price.
4. Drugs that qualify for coverage under Medicare Part B¹² and are administered in physician offices are reimbursed separately. This reimbursement also follows the “buy and bill model” and is calculated as 106% of the average sales price.¹³

Regardless of whether reimbursement for a generic provider-administered drug is based on a medical service bundle or a separate payment, providers are incentivized to procure drugs at the lowest acquisition cost. This allows them to maximize margin, as the reimbursement (if any) is the same for all generic versions of a drug. These reimbursement incentives are unlike those for single-source products, where providers are incentivized to select more expensive products, as the 6% mark up results in larger margins for more expensive drugs.¹⁴ The reimbursement model for generic drugs is also different from the reimbursement of biosimilar products, which have their own average sales price, separate from originator biologics.

As all generics marketed in the US must meet regulatory requirements for adherence to Current Good Manufacturing Practices, the partiality of pharmacies and providers towards less expensive generic versions should not compromise quality of the product dispensed.² However, as explained above, these regulatory requirements are considered a *minimum threshold* for accessing the US marketplace and do not necessarily reflect the resilience and maturity of the supply chain.

Generic Drug Reimbursement under the Medicaid Program

The reimbursement of generic drugs under the Medicaid program presents certain peculiarities:

1. State Medicaid agencies have flexibility in the administration of the pharmacy benefit and the reimbursement of both pharmacy-dispensed and provider-administered drugs. For example, some states “carve in” the coverage of pharmacy-dispensed drugs by including it as a benefit under Medicaid Managed Care Organizations, while others administer it on a fee-for-service basis.

When Medicaid directly administers the drug benefit on a fee-for-service basis, the reimbursement is estimated based on the ingredient cost and a dispensing fee. The ingredient cost is meant to reflect the pharmacy acquisition cost.

2. The Medicaid Drug Rebate Program requires manufacturers to enter a rebate agreement for covered outpatient prescription drugs in exchange for Medicaid coverage of the manufacturer's drugs (§ 1927(a)(1)). Rebates are defined by statute, and for generic drugs, are estimated as the sum of:
 - a. A base rebate, which equals 13% of the average manufacturer price. The average manufacturer price is the average price paid to the manufacturer by wholesalers for drugs sold to retail pharmacies.
 - b. An inflationary rebate, which penalizes increases in prices above general inflation. The inflationary rebate on generic drugs was implemented in January 2017 under the Bipartisan Budget Act of 2015. For drugs brought to market after April 1, 2013, the inflationary rebate is estimated using as baseline the average manufacturer price for the fifth full calendar quarter after which the drug was marketed. For drugs marketed before April 1, 2013, it is calculated based on the average manufacturer price in Q3 2014.
3. For provider-administered drugs to be eligible for manufacturer rebates under the Medicaid Drug Rebate Program, they need to be billed separately (§1927(k)(3)). This policy has strongly incentivized the separate reimbursement of outpatient provider-administered drugs, which states generally estimate using the average sales price.¹⁵ It should be noted that a 2023 CMS proposed rule would make drugs reimbursed as part of bundles eligible for rebates, as long as they are separately itemized in the invoice.¹⁶

The 340B Drug Pricing Program

Manufacturers that participate in the Medicaid Drug Rebate Program are required to offer covered outpatient drugs to safety net providers at a discounted price. The discounted price is estimated using the rebate calculated under the Medicaid Drug Rebate Program explained above. The 340B program has substantially expanded in recent years, driven by the expansion of contract pharmacy arrangements.^{17,18} In recently published work, I documented large variation across therapeutic classes in the share of drug sales that are subject to 340B discounts, highest for antivirals and anticancer agents.¹⁷

Reimbursement Practices and Contribution to Shortages

Downward Pricing Pressure

As generic drug reimbursement is the same across all therapeutically equivalent versions of a product, generic manufacturers solely compete to sell their product at the lowest price, generating a "race to the bottom". Price erosion is aggravated by the consolidation of purchasing entities.¹⁹ It should be noted that, unlike branded drugs, prices of generic products are generally lower in the US than other countries.²⁰

Limited Ability to Raise Prices

Inflation penalties under the Medicaid Drug Rebate Program and the 340B program limit manufacturers' ability to raise prices when manufacturing costs increase, especially for drugs

with a large share of sales under these two programs. This is particularly problematic for the subset of generic products marketed before April 1, 2013, for which inflation penalties are estimated based on an arbitrary period (Q3 2014) instead of the fifth full calendar quarter after marketing. Some manufacturers may have lowered their prices to near marginal cost by this arbitrarily-set baseline period, so any increase in production costs would generate a penalty.

The reimbursement of generic products by Medicare Part B puts manufacturers that raise prices at a competitive disadvantage. This is because there is a two-quarter lag in the application of the average sales price to Medicare reimbursement rates (for example, reimbursement rates for Q4 2023 are based on the average sales price in Q2 2023). As a result, providers would be less willing to purchase drugs that have recently raised prices, as reimbursement rates are not updated for two quarters.

Contribution to Shortages

Reimbursement practices that were meant to create an efficient marketplace for generics and keep costs down have led to marked price compression, threatening market sustainability and supply continuity:

1. According to experts, price pressure induces manufacturers to engage in cost-reduction strategies, such as reduced investments in factory maintenance, equipment upgrading and off-shoring,²¹⁻²³ which increase the risk of quality issues. Quality issues create vulnerabilities across the supply chain and ultimately contribute to shortages.^{23,24}
2. Limited profitability generates a lack of incentives for manufacturers to invest in drug supply redundancies and quality management systems.² Redundancies enable manufacturers to quickly ramp up manufacturing at the back-up line while resolving issues affecting the primary line, and thus prevent manufacturing issues from ultimately disrupting product supply. Quality management systems proactively identify issues before they lead to shortages.²
3. Reduced profitability may ultimately lead manufacturers to discontinue the production of less profitable drugs.²³ Market withdrawals increase the concentration of generic manufacturers,²⁵ which limits the market ability to respond to disruptions in the supply chain by a single manufacturer.

Generic Injectable Drugs – The Perfect Storm

The peculiarities of the manufacturing and marketing of generic injectable drugs generate a “perfect storm” that explains their vulnerability to drug shortages—67% of drugs on shortage in recent years were generic injectable products.⁴

1. Generic injectables have reduced profit margins due to the small market size⁹ and the requirements for specialized manufacturing, which make them costlier to manufacture than oral drugs.
2. Generic injectable markets have fewer entrants than generic oral markets.⁹
3. Rates of market exit are markedly higher for generic injectable products.⁹ An analysis of molecules that lost patent production in 2010-2013 found that, for generic products with

small markets, more than half of generic manufacturers had exited the market by the end of the fourth year after loss of exclusivity.⁹

4. The manufacture of generic injectable products is particularly vulnerable to maintenance cost-reduction strategies due to the requirement for specialized manufacturing processes that ensure sterility.²⁴
5. Supply redundancies are particularly uncommon for generic injectable drugs, which require specific facilities and rooms.^{23,24}
6. The requirement for specialized manufacturing lines limits the ability of other manufacturers to ramp up production in the setting of a drug shortage.

The time needed to establish production of injectable drugs is one of the factors that has limited the role of 503B outsourcing facilities in filling supply gaps for drugs on shortage.^{26,27} 503B compounding facilities, often denominated outsourcing facilities, compound drug products in large volume without the need for patient-specific prescriptions. 503B facilities are only allowed to compound products that include bulk drug substances for which the FDA has determined there is clinical need, or products that appear in the FDA drug shortage list. 503B facilities are required to follow Current Good Manufacturing Practices and to compound at least one sterile product.²⁸ The role of 503B facilities in the manufacturing of drugs on shortage has been limited.²⁷ This has been attributed to the unpredictability around the occurrence and duration of shortages, which generate uncertainty around the profitability associated with the re-assignment of production lines to products on shortage.²⁶

Other Shortcomings Associated with the Current Generic Drug Reimbursement Model

The failure to incentivize pharmacies and providers to purchase products with resilient supply chains is a major shortcoming of the generic reimbursement model, but not the only one. Earlier this year, Chairman Wyden brought attention to the provision of unjustifiably high reimbursements for certain generic drugs by Medicare Part D sponsors, an issue that I recently studied.²⁹ In collaboration with colleagues at the University of Washington, I evaluated reimbursement rates for the top 50 generic drugs by Medicare spending. I identified 16 generic drugs reimbursed in 2021 at a mark-up of 1000% or higher by at least one of the six leading Part D organizations. For instance, aripiprazole 5mg, an antipsychotic drug, was purchased by pharmacies at an average of \$0.17 per tablet in 2021. However, Rite Aid reimbursed pharmacies at point-of-sale at an average of \$11.7 per tablet (over 7000% mark-up), Cigna at \$4.6 per tablet (over 2700% mark-up), and CVS Health at \$4.5 per tablet (over 2600% mark-up).

Due to the confidential nature of post-sale adjustments, it was not possible to study to what extent these unjustifiably high reimbursements were offset by claw backs. Nevertheless, the described reimbursement practices are concerning because point-of-sale reimbursement rates are the basis for patient cost-sharing. As a result, it is likely that the provision of these unjustifiably high reimbursements rates resulted in increased out-of-pocket costs for Medicare beneficiaries.

III. POLICY RECOMMENDATIONS

The drug supply chain heavily relies on foreign manufacturing, which is a national public health risk. The drug reimbursement model fails to generate sufficient incentives for the manufacturing of certain drugs with limited profit margins, yet allows intermediaries to unjustifiably inflate costs of generic products covered under Medicare Part D. These major shortcomings warrant policy intervention to re-envision the way how we pay for generic drugs. In what follows, I focus on the aspects of the reform that more closely relate to drug shortages. These are not, however, the only reforms needed to the generic reimbursement model. The recommendations proposed below should be complemented by reforms to the Medicare Part D program to align patient and payer financial incentives, ensure fair pricing and reimbursement practices, prevent and penalize anti-competitive behavior, foster pharmacy sustainability, guarantee pharmacy access, and promote transparency. I applaud the efforts of the Committee in the drafting and passage of legislation to achieve these goals earlier this year.

Effective policymaking requires a combination of policy reforms that address both economic and regulatory factors underlying drug shortages. My discussion is limited to policy solutions that address economic drivers of drug shortages. These interventions should be accompanied by the strengthening of the FDA oversight of the supply chain.

Federal policy intervention is urgently needed to: 1) rebuild the domestic infrastructure for the manufacturing of generic drugs, 2) create incentivizes for manufacturers to invest in resilient supply chains to ensure long-term sustainability.

1. Government funding to rebuild the domestic manufacturing infrastructure.

The provision of government funding is a short-term solution to rebuild the domestic infrastructure for the manufacturing of both generic active ingredients and final dosage forms. Funds would be destined for the establishment or upgrading of domestic facilities, purchasing of equipment, development of supply chain redundancies, and development of quality management systems. As suggested by Wosińska and Frank, funds could be provided in the form of low-interest loans, which would be eligible for forgiveness based on performance. Performance would capture the manufacturer's ability to meet supply guarantees and the achievement of high levels of supply chain maturity and resilience, as monitored by the FDA.²¹ Funds destined to the establishment or upgrading of production lines for a list of eligible products would be fully forgivable. The list of eligible products would be assembled by the Department of Health & Human Services (HHS) based on prices per unit, market concentration, recent history of shortages, vulnerability of the existing supply chain, and criticality of the product.³⁰

2. Revision of generic reimbursement models to reward supply chain resilience and maturity.

I recommend a revision of generic drug reimbursement models to incentivize the selection of products manufactured in resilient and mature supply chains. Supply chain resilience and maturity are crucial for supply stability and continuity. Supply stability and continuity are elements of value because, when we initiate a patient on a treatment, we

not only value the product available for the initial dose, but also the continuity of supply so that a patient can complete the treatment course. The value of supply continuity differentiates the generic market from the common commodity market and justifies variable payment based on the resilience and maturity of the supply chain of the generic version selected.

The reform of the current generic reimbursement model to reward supply chain resilience and maturity would involve:

- a. Development of a rating system measuring supply chain resilience and maturity for each generic product. The rating system would be developed by the FDA and would measure key elements for supply chain resilience and maturity. Such elements may include factory maintenance, upgrading of equipment, presence of manufacturing redundancies, and monitoring of manufacturing variability.² This system would differentiate from the Current Good Manufacturing Practices in that it would measure attributes of the supply chain that are not needed to ensure minimum levels of quality but are relevant to supply stability and continuity.

The ratings would be measured at the manufacturer-generic product level, would be mandatory for all generic products marketed in the US, and would be made publicly available by the FDA. Measurement at the manufacturer-generic product level is preferred over manufacturer-level measures, as the latter would incentivize manufacturers to invest in resilient supply chains for high-utilization profitable products but not necessarily for generic drugs most vulnerable to shortages.

- b. Application of the rating as a value-based modifier to generic products reimbursed under Medicare Parts A and B. The manufacturer-generic product rating would be transformed into a value-based modifier applied to claims for generic products separately reimbursed by Medicare Parts A and B. Reimbursement would still be based on the weighted average sales price capturing all branded and generic versions of a product. The value-based modifier would be operationalized as the mark-up for the average sales price, with different tiers for different ratings. For instance, reimbursement could be calculated as 125% of the weighted average sales price for generic versions scoring three out of three stars, 115% for products with two out of three stars, and 106% for products with one out of three stars. (Note: these mark-ups are provided for illustration purposes; the incorporation of value-based modifiers would necessitate further research to identify the optimal magnitude of modifiers that incentivizes providers to purchase products with high ratings while limiting budget impact).

Claims would incorporate national drug codes in addition to HCPCS codes to enable identification of the generic version selected, as is currently done in Medicaid for rebate collection. The value-based modifier would be applied at the claim level. The alternative—the derivation of average value-based modifiers capturing product mix for a given provider—would disproportionately incentivize providers to purchase high rating generic versions for high-utilization drugs, but not necessarily for drugs most vulnerable to shortages.

The incorporation of value-based modifiers would increase provider reimbursement rates when selecting generic versions with high ratings, which would ultimately result into higher acquisition costs and higher profit margins for manufacturers of generic versions with resilient and mature supply chains.

- c. Establishment of eligible drugs with daily costs under the packaging threshold as separately payable products under Medicare Part A and Part B, independent of clinical setting. Drug shortages disproportionately affect low-priced generic injectable drugs, which are not separately reimbursed under Parts A or under Part B when administered in outpatient hospital departments, as further detailed above. The incorporation of value-based modifiers at the drug claim level would require the separate reimbursement of eligible drugs with daily costs under the packaging threshold under Medicare Parts A and B, independent of clinical setting. Eligible products would include those in a list elaborated by HHS based on prices per unit, market concentration, recent history of shortages, vulnerability of the existing supply chain, and criticality of the product.³⁰

I recognize that this proposal would only generate incentives for providers to purchase drugs with resilient and mature supply chains, and not pharmacies. The creation of similar incentives in Medicare Part D would necessitate legislation that requires pharmacy benefit managers to incorporate value-based modifiers into Part D reimbursement rates.

Other Policy Solutions to Generate Incentives for the Manufacture of Selected Generic Drugs

The incorporation of value-based modifiers to the reimbursement of generic provider-administered drugs is a major overtaking, yet the necessary step to reward supply chain resilience and maturity. In what follows, I offer less sophisticated policy solutions that would have a *limited* impact in generating incentives for the manufacture of selected generic products:

1. Creation of incentives for generic manufacturing through regulatory benefits. Regulatory benefits could be explored as incentives for investments in supply chain resilience and maturity and for the manufacture of less-profitable products. Examples of these benefits include:
 - a. Manufacturers could be rewarded for investments in supply chain maturity and resilience through the development of tiers for generic user fees based on supply chain maturity and resilience ratings.
 - b. Waiver of generic user fees, award of priority review vouchers, or conferral of extended market exclusivity periods could be considered as incentives for manufacturers who enter the market of eligible products and commit to supply guarantees. Eligible products would include those in a list elaborated by HHS based on prices per unit, market concentration, recent history of shortages, vulnerability of the existing supply chain, and criticality of the product.³⁰

2. Reform of the inflation penalty. Several reforms to the calculation of the Medicaid inflationary rebate could be considered to partially mitigate the inability of manufacturers to raise prices in the context of manufacturing cost increases:
 - a. One-time re-establishment of the inflation penalty baseline for eligible generic products contingent on investments in manufacturing upgrades. Legislation could allow a one-time re-establishment of the baseline period for the measurement of inflation penalties for selected generic products in exchange for manufacturers' investment in upgrading production lines to meet a pre-determined threshold of resilience and maturity. Eligible products would be selected as discussed under section 1b.
 - b. Re-establishment of the baseline period for calculation of the inflation penalty for generic drugs marketed before April 1, 2013 to the fifth full calendar quarter after marketing. As explained above, the baseline period for the calculation of the inflation penalty for generic products marketed before April 1, 2013 was arbitrarily set to Q3 2014. Drugs marketed before April 1, 2013 may have had prices close to marginal costs by Q3 2014, and thus any increase in production costs would generate a penalty. The re-establishment of the baseline period to the fifth full calendar quarter after marketing would mitigate the differentiation with drugs marketed after April 1, 2013 introduced by the Bipartisan Budget Act of 2015.
 - c. Re-design of the inflation penalty for eligible generic products to a trigger-based model. As explained above, inflation penalties limit manufacturers' ability to raise prices when manufacturing costs increase, especially for drugs with large share of Medicaid and 340B sales. To mitigate this problem while preventing price hikes, the inflation penalty could be redesigned to only penalize large increases in prices, for instance, above 3 times the rate of general inflation in a year. Eligible products would be selected using parameters discussed under section 1b.

Comment

Drug shortages are not a problem of the masses, but a problem of the exceptions. Many drugs have no substitutes. The shortage of a single product can trigger a major public health disruption³¹ and have devastating consequences on population health.¹ Policy intervention should aim to prevent drug shortages across the entire therapeutic arsenal of drugs approved by the FDA. Policymaking should refrain from solutions that only incentivize supply chain resilience for high utilization products or for drugs within certain therapeutic classes.

Drug shortages are a terribly complex problem. My policy recommendations address economic drivers of drug shortages that can be influenced through reform of federal health insurance programs. There are however many factors contributing to shortages that are outside of the influence of federal health program policy levers, the subject of this hearing.

I acknowledge that the solutions proposed will likely result in increased government spending. I am unaware of any budget-neutral policy solutions that would effectively address the economic drivers of drug shortages. This spending is a necessary investment in our country's health and

national security. Just as we invest in the construction and maintenance of roads and bridges for economic prosperity, we must invest in generic manufacturing infrastructure to further our health and well-being and protect national security.

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