Responses to Questions for the Record for Dr. Wosińska

Following the 10/8/25 Full Committee Hearing
of the U.S. Senate Special Committee on Aging
regarding:
Bad Medicine: Closing Loopholes that Kill American Patients

November 10, 2025

Thank you for the opportunity to testify at the October 8, 2025, hearing on closing loopholes in pharmaceutical drug policy and to contribute further by answering these questions for the record.

Question 1 (Ranking Member Gillibrand):

You have written about how federal transparency initiatives will fall short of their goals if purchasers, such as hospitals, have no economic or institutional motivation to act on such information.

How can hospitals be incentivized to consider quality and reliability over the cost of drugs?

What are some of the potential downsides of transparency initiatives should they not be executed alongside other initiatives, such as reforming economic incentives?

Answer: Transparency initiatives in drug manufacturing often fail to achieve their intended goals—not because the information is wrong, but because they lack the right incentive structures to motivate action. Simply making information available is not enough; those who receive it must be both motivated and equipped to act on it in ways that align with broader economic incentives or institutional structures. Without this alignment, transparency efforts become costly nice-to-haves, and may even produce unintended consequences that worsen the very problems they were designed to solve.

To understand which transparency approaches are most likely to succeed, it is useful to first examine the main types of transparency initiatives and how they interact with underlying economic incentives—which often diverge from what serves patients best. There are three main types of transparency initiatives:

1. Government-facing initiatives
2. Patient-facing initiatives
3. Institutional buyer initiatives

Existing **government-facing initiatives** primarily focus on mapping supply chains to identify geopolitical exposure and with it identify which drugs require alternative sources in which production stages of supply chains. Incentives to act on this information will be driven, to a large extent, by Congress (by setting out the tools and directives as well as appropriating funds to follow through) and the administration (by identifying which existing tools they can deploy).

Patient-facing initiatives include adding to the pharmacy label either the Country of Origin or a rating of product quality. The goal of these efforts is to shift markets through patients as they begin to shop for versions that presumably are less likely to have product defects. There are two intertwined reasons, however, why such initiatives could go astray. First, without reforms for how pharmacies are reimbursed, patients have limited options in how they respond to sourcing information, other than deciding not to fill the prescription. Second, neither measure is strongly correlated with actual product quality, making potential misinterpretation by patients particularly concerning.

When it comes to **institutional buyers**, efforts have focused largely on creating transparency in the hospital and clinic sector, not the retail pharmacy sector (where the consumer-facing measures seem to have gotten more attention). In the hospital space, there are two main types of transparency initiatives:

- Supply chain reliability assessments and;
- Early warning systems.

The data needed to support these transparency initiatives varies depending on the goal. Supply chain reliability assessments focus on evaluating the long-term dependability of a manufacturer's supply chain over the duration of a multi-year contract, using indicators such as plant redundancy, inventory controls, raw material sourcing, risk management practices, and historical shortage records. In contrast, early warning systems aim to detect abrupt risks or disruptions in the near term—drawing on real-time signals like new shortage posts on the ASHP website, reports of product discontinuations, sudden order limits from any wholesaler, newly announced adverse FDA inspection findings, recalls, or reports of supply interruptions in global logistics.

The economic incentives for these two transparency approaches diverge sharply.

Early warning systems enable hospitals to continue prioritizing low-cost procurement without regard for long-term supply reliability, only shifting tactics and rapidly increasing orders at the first hint of trouble. This dynamic offers clear advantages to well-resourced institutions equipped to act quickly, which in turn has driven commercial vendors to develop various rapid alert tools. Yet this competitive hoarding erodes the advance notice intended for regulators, limits FDA's ability to intervene, and accelerates the very shortages these transparency initiatives are supposed to help prevent.

In turn, purchasing in times of relative stability—whether through spot buys or contracts—is dominated by the strong incentive to choose the lowest-cost option. There is little to push hospitals or group purchasing organizations toward factoring in supply chain reliability or resilience, as most do not directly bear the costs when a disruption occurs. While there are tools and frameworks available to inform more resilience-focused procurement, hospitals have options but typically lack a meaningful reason to use them, absent clear financial rewards or contractual requirements.

Policymakers would be wise not to fuel early warning systems for hospitals but to support supply chain reliability efforts in two ways: by supporting the related transparency efforts and by creating economic incentives.

Policymakers can promote supply chain reliability in drug procurement by ensuring purchasers have access to meaningful, actionable information. Changes to current reporting requirements—such as requiring suppliers to specify not only who a drug is "manufactured for" but also who it is "manufactured by"—would make it far easier to track products to facilities that do not have a good compliance record. Supporting FDA's Quality Management Maturity (QMM) initiative is another foundational step, as public disclosure of QMM ratings would highlight manufacturers that invest in robust quality and operational practices, allowing buyers to consider reliability and performance in addition to price during contract negotiations.

Policymakers should complement transparency efforts by pursuing payment and contracting policies that create meaningful economic incentives for hospitals and manufacturers to prioritize supply chain reliability. Current proposals—such as those from the Senate Finance Committee and HHS—would authorize financial rewards or penalties based on a buyer's or supplier's record of ensuring supply continuity, product quality, or timely response during shortages. By tying payment rates directly to reliable performance—or imposing disincentives for repeated supply failures—these initiatives aim to move the market beyond cost alone, encouraging long-term investments in resilience throughout the supply chain.

Question 2 (Ranking Member Gillibrand):

In your research you recommend a broad strategy when it comes to deciding which drug supply chain resiliency efforts to prioritize and support. More specifically, you recommend that the Administration for Strategic Preparedness and Response shift from a fixed list of essential drugs toward a longer list that stratifies drugs by how critical they are, their reach, and how vulnerable they are to disruption.

Could you say more about how this longer, stratified list would better enable the federal government to support resilience efforts?

Answer: When it comes to supporting drug supply chain resilience efforts, setting priorities is important because of the scale and complexity of the drug supply chain. There are well over 2,000 approved prescription drugs, spanning a large array of ingredients, manufacturing technologies, and production sites that collectively produced 187 billion tablets and capsules for American patients in 2024, not counting other dosage forms. The lack of economic incentives in the market coupled with the magnitude of what it would take to secure all drug supply chains requires that the government prioritizes where to engage.

Prioritization is not only needed but possible because not all drugs are equally important. For example, some drugs are lifesaving in emergencies, such as epinephrine auto-injectors for severe allergic reactions or insulin for patients with type 1 diabetes. Others, like certain chemotherapy agents or antibiotics, are critical for treating serious infections and cancers. Drugs for chronic conditions, such as antihypertensives and statins, affect large patient populations but interruptions are not generally life threatening, especially in the short term.

U.S. government prioritization began with the FDA's list, created under a 2020 Executive Order, which identified over 220 drugs and medical countermeasures most needed for immediate and life-saving medical use in hospitals. The Administration for Strategic Preparedness and Response (ASPR) subsequently narrowed this to 86 drugs, focusing more tightly on those deemed essential

for acute care. Most recently, at the direction of the administration, ASPR further narrowed the target to about 26 drugs, selecting those for strategic stockpiling initiatives.

Budget and time constraints have made this narrowing process unavoidable. With limited new funds appropriated by Congress for comprehensive supply chain resilience, the administration's current efforts are focused on building and maintaining a six-month supply of active pharmaceutical ingredients (APIs) for this small subset of drugs. If policymakers pursue costlier or more complex resilience strategies such as supporting new domestic manufacturing of API and all its inputs, not even all 26 may be covered, and prioritization within this short list would become necessary under a limited budget.

A broader, stratified list would give policymakers flexibility to adjust investments as resources change. If Congress allocates additional funds, efforts could expand without reworking the prioritization framework. Such a list would guide readiness planning, clarify what additional money could achieve, and allow for a quick response as budget realities evolve.

In practice, criticality and reach remain fairly stable for most products unless major therapeutic advances occur; vulnerability can change quickly. Initial reviews should focus on identifying drugs with the greatest health impact and reach. Detailed, regularly updated vulnerability assessments can then be reserved for a larger list of higher-priority drugs, concentrating resources where they matter most and avoiding exhaustive analysis of less critical products.

To build a practical, ranked drug framework, it is also essential to factor in resilience-building cost and capacity constraints. The main cost drivers are often tied not to the price of the drug itself, but to the logistics of production—such as the potency of the active pharmaceutical ingredient (affecting how much can be handled in existing facilities if capacity is limited) and the specialization required of manufacturing processes. These realities can force tradeoffs, requiring policymakers to choose between covering more drugs that fit within common, flexible plant capacity, or prioritizing medicines that do not demand highly specialized production setups and supply chains.

Question 3 (Ranking Member Gillibrand):

Your work highlights why drug manufacturers outsource chemical synthesis for drug manufacturing to China. Chemical synthesis can create toxic materials and could be quite harmful to the environment. You recommend that the U.S. fund chemical industrial parks as part of onshoring efforts.

Could you say more about how funding domestic industrial parks could help to reduce American reliance on chemicals synthesized in China?

Answer: Efforts to derisk pharmaceutical supply chains from China require developing alternative sources for critical chemical inputs. Diversification does not necessarily mean full onshoring; establishing production capacity in allied, cost-competitive countries can often achieve greater efficiency while mitigating geopolitical risk. However, for strategically sensitive or high-risk materials, selective onshoring can enhance national resilience.

An important part of derisking supply chains from China is at the earliest, unregulated steps: key starting materials, intermediates, and auxiliary chemicals like reagents and solvents used in synthesis. This is where U.S. drug supply chain exposure is the greatest.

The reliance is driven by Chinese firms' strong cost advantage through significant economies of scale coupled with lower labor, energy, and transportation costs. Historically, a lax regulatory framework allowed Chinese producers to operate with higher environmental and workplace risks than Western and Indian competitors, enabling their cost advantage. Following the Beijing Olympics, China began to reckon with environmental pollution and began raising standards and investing in greener manufacturing methods.

The question is then, how should the U.S. respond if it chooses to onshore chemical manufacturing. Environmental deregulation alone will not succeed in shifting production to America because China will continue to hold an insurmountable cost advantage driven by lower energy, lower labor, and deep economies of scale. In fact, a race to the bottom on environmental standards would require the U.S. to set regulations lower than even India and China are willing to accept—countries that have already rejected the dirtiest manufacturing practices as economically and socially unsustainable.

The future of chemical manufacturing lies in advanced green chemistry technologies that represent the next generation of global competitive advantage. These approaches are more efficient, create higher value-added products, and generate more skilled, higher-paying jobs than legacy chemical processes.

Chemical industrial parks offer a more sustainable and scalable alternative to traditional one-company-at-a-time funding. By co-locating multiple manufacturers within shared infrastructure—centralized wastewater treatment, utilities, analytical testing facilities, and logistics—these parks significantly lower the per-unit overhead for each producer. This model is widely used in Europe, India, and certain U.S. states.

Parks also create resilience: if one tenant exits, another can step in using the same infrastructure, protecting the government's investment and maintaining supply continuity. For policymakers working within budget constraints, industrial parks provide a mechanism to support multiple products and processes simultaneously, rather than betting on individual companies or isolated facilities.

Centralized environmental controls—shared wastewater treatment plants equipped to handle toxic intermediates, air quality monitoring, and hazardous waste management—enable cost-efficient pollution control far more effective than individual facilities can achieve. This allows domestic chemical production to meet U.S. environmental standards without imposing prohibitive costs on each manufacturer, reversing the historical trend of exporting pollution alongside production.

Question 4 (Senator Warnock):

Rural health providers in Georgia rely on access to affordable drugs to treat patients, including older Americans. Due to financial vulnerability, rural providers have limited capacity to build a stockpile of drugs in preparation for supply shortages.

How can Congress work to ensure rural hospitals and clinics can provide affordable and safe drugs to seniors in times of a drug shortage crisis?

What kind of policy changes would incentivize domestic drug suppliers to develop generic drugs and improve aging rural populations' access to prescription drugs?

Answer: It is indeed the case that rural providers, especially those not part of a large health system, have severely limited ability to withstand supply disruptions. This stems partly from scale: they often lack staff dedicated to supply chain management, operate on thin financial margins that leave little room for inventory investment, and cannot leverage the purchasing power of larger systems. Independent rural facilities face a particularly acute challenge: unlike small hospitals within integrated systems that can at least access their parent organization's negotiating leverage and shared contracts, truly independent rural providers must navigate procurement entirely on their own.

A 2023 STAT article illustrated this dynamic during the national shortage of carboplatin and cisplatin. Large health systems weathered the disruption easily, using their purchasing power and strong supplier relationships to stockpile supplies. Small, often rural, independent oncology clinics could not—they lacked these advantages and were sidelined by allocation systems favoring historical bulk orders. Many small clinics had to ration care, send patients to distant centers, or delay lifesaving treatment altogether, intensifying distress and risking poorer outcomes for vulnerable populations. The shortage exposed systemic flaws in drug procurement practices and underscored the urgent need for reforms to ensure more equitable access to essential drugs.

Analytics and data systems play a major role in the disparities seen during chemotherapy drug shortages because large hospital systems typically have sophisticated analytics tools that allow them to monitor drug inventory, predict shortages, and swiftly respond by stockpiling or reallocating supplies across their networks. These systems provide actionable data on usage rates, inventory levels, and shortage signals, enabling proactive strategies like early purchasing or redistribution before official shortage notifications are issued. In contrast, small independent clinics often lack access to such analytics and automation, making it difficult for them to anticipate shortages or compete for limited supply—further widening the gap in access during crises like the carboplatin and cisplatin shortage.

Expanding the use of advanced analytics with small providers has the potential to help these providers better anticipate drug shortages, optimize inventory, and negotiate more effectively with suppliers, reducing vulnerability during supply chain disruptions. However, the cost, technical complexity, and need for specialized staff pose significant obstacles. Many small clinics operate with tight budgets and limited personnel, making it difficult to adopt and maintain sophisticated data systems even if the technology itself is available. They will always be behind the curve and therefore last in line.

For most small and rural clinics, greater resilience may come from direct preparedness strategies, such as regional stockpiling programs, collaborative purchasing efforts, and supportive policy reforms that redistribute essential drugs during crises.

One such recent effort was CMS establishing a separate payment system for small independent facilities, many of them rural, to help them create and maintain a buffer inventory of essential

medicines. This authority is based on the same legal mechanism used for N95 mask stockpiling during the pandemic. The program allows qualifying hospitals to receive targeted Medicare payments specifically for the costs of purchasing and storing a reserve supply of designated drugs, with eligibility focused on hospitals most likely to face financial and logistical barriers to stockpiling.

However, this authority is limited by statutory language that restricts reimbursement to only "reasonable costs." The "reasonable costs" constraint ties reimbursement only to Medicare's share of a hospital's business, meaning that hospitals must maintain buffer inventory sufficient to serve their entire patient population—including Medicaid, uninsured, and commercially insured patients—but can only be reimbursed for the Medicare portion of those inventory costs. Additionally, the costs of tracking, monitoring, and reporting on buffer stock inventory are not reimbursed under the program. These limitations mean that the payments offered may not fully cover the financial and operational burdens of creating and maintaining a substantial buffer stock, limiting participation.

To address these limitations, Congress should strengthen the existing CMS framework by amending the statutory authority that currently restricts reimbursement to "reasonable costs" tied only to Medicare's share of hospital business. Specifically, Congress should authorize CMS to provide full reimbursement for buffer stock costs regardless of payer mix, recognizing that hospitals must maintain inventory for all patients, not just Medicare beneficiaries.

Additionally, the statute should be amended to support a fixed payment model rather than the current submit-a-bill approach, which would reduce administrative burden and make participation more attractive to resource-constrained rural hospitals. The fixed payment should also cover the costs of tracking, monitoring, and reporting on buffer stock inventory—costs currently excluded from reimbursement.

Congress and CMS can also influence how wholesalers allocate scarce products during shortages. Wholesalers typically allocate based on historical purchasing patterns over a short lookback period (often 3-6 months), which systematically disadvantages small rural providers with variable ordering patterns. A rural hospital that orders 100 units of a critical drug every 12 months may receive zero allocation if the lookback period captures only the months between orders. Meanwhile, large integrated health systems have a significant advantage: they can bypass wholesalers entirely and purchase directly from manufacturers during shortages, securing supply outside the allocation system altogether—an option unavailable to small independent hospitals.

To level the playing field, CMS could mandate that wholesalers use longer, smoothed lookback periods as a condition of participation in Medicare or Medicaid programs—for example, calculating allocations based on 12-24 month rolling averages rather than recent 3-6 month snapshots. Additionally, Congress could direct FDA or CMS to establish minimum fairness standards for allocation methodologies during shortages, similar to how other federal agencies regulate allocation of scarce resources. Finally, allocation formulas should be reformed to use objective metrics tied to patient population served, licensed bed capacity, or facility size, rather than pure historical purchasing volume.healthpolicy.duke+2

Beyond influencing allocation during shortages, Congress can also make the entire pharmaceutical supply chain more reliable by reducing the risk and frequency of supply disruptions themselves. Legislative actions may include requiring redundancy and diversification among manufacturers, strengthening federal oversight for manufacturing quality

and inspections, incentivizing domestic production, and supporting proactive stockpiling at the national level. These measures would help prevent supply shocks from occurring and limit their scale, ensuring that small rural hospitals are not perpetually vulnerable to access disparities even when major disruptions occur.

Question 5 (Senator Warnock):

Hurricane Helene shut down Baxter International's North Carolina facility and caused a nationwide intravenous (IV) fluid shortage. Hospitals across the country were forced to ration their IV fluids until the company restored its manufacturing capability. I sent a letter to the Food and Drug Administration and the Department of Health and Human Services leadership pushing them to provide relief during this crisis.

How could Congress leverage technology like predictive analytics to strengthen the resilience of domestic drug supply chains in times of natural disasters?

Answer: Predictive analytics can be an invaluable tool for monitoring supply chains and anticipating shortages, but their use during a crisis—such as the IV fluid shortage following Hurricane Helene—can compound existing vulnerabilities. When predictive analytics signal an emerging scarcity, large health systems often respond by accelerating stockpiling or bulk purchasing, which can deplete inventory faster and outcompete smaller hospitals for limited resources. This dynamic can leave rural and independent providers even more exposed, intensifying the very shortages that technology is aiming to mitigate.

Better, real-time tracking of saline usage at both inventory and patient levels would significantly improve a hospital system's ability to allocate scarce resources during a shortage. Saline and other IV fluids are FDA-approved drugs, yet many hospitals treat them as supplies rather than medications. This classification outside the pharmacy system means administrations and usage are often not barcode-scanned or tracked like medications, making it difficult for health systems to know where the product is being used or how much.

To address this tracking problem, CMS could require health systems to reclassify and track IV fluids as FDA-approved drugs rather than allowing them to be handled outside pharmacies as untracked supplies. Enhanced analytics could identify which units or patients have the greatest clinical need, optimize distribution, and reduce waste or unnecessary stockpiling throughout the network.

While real-time tracking and robust analytics enable smarter, more equitable allocation of supplies during a shortage, hospitals also need practical and systemic strategies to prepare for major disruptions. For high-volume products like saline, maintaining a buffer inventory is particularly challenging given the heavy usage, physical volume, and cost of storage. Hospitals must adopt additional safeguards and diversify their approaches beyond stockpiling to prepare for potential shortages.

For hospitals, avoiding sole-source contracts is a key step. Reliance on a single supplier for saline or other essential fluids can dramatically widen the impact of any supply disruption, whereas maintaining relationships with multiple vendors lessens vulnerability—enabling continued provision of urgent services even during supply chain shocks**.** Recent shortages have

exposed disparities based on with which manufacturer a hospital contracts. During the 2024 saline shortage following Hurricane Helene, hospitals contracting with Baxter received only 40-60% of normal allocations, while those using B. Braun experienced minimal disruption as B. Braun's facilities were unaffected.

Manufacturers can help by investing in more flexible or 'fungible' production systems that allow rapid pivots to different bag sizes or formulations as market demand and regulatory priorities shift. Facilities able to quickly change production lines or scale outputs for alternative product sizes improve overall supply chain resilience, reducing the risk and magnitude of shortages from specific disruptions. Encouraging manufacturers to adopt these adaptive capabilities can increase redundancy and responsiveness, ultimately protecting the entire healthcare system during crises.

Congress and the administration can play vital roles in supporting alternative hospital preparedness strategies for saline shortages—using both regulatory "sticks" and financial "carrots." On the regulatory side, policymakers could strengthen antitrust enforcement and oversight to discourage anticompetitive practices, such as exclusive or sole-source contracts that undermine supply resilience and limit access during disruptions. On the incentive side, Congress could expand payment models or grant programs to encourage hospitals to diversify suppliers and invest in logistics for alternative sourcing.