Questions for the Record

From Science Lab to Medicine Cabinet: How China is Cornering the Market on our Medicines

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Representative Robert J. Wittman – District [VA-01]

Witness – [Dr. Marta E. Wosińska]

1. **The economics of the generic injectable manufacturing presents structural challenges for domestic production. This is made particularly acute with regard to U.S. dependence on Chinese-origin APIs and finished generic injectables. What steps should Congress consider taking to help create a more predictable market in the United States for domestically manufactured generic injectable drugs?**

Answer - Dr. Marta E. Wosińska

"Efforts to reduce U.S. dependence on China for medicines are not only about national security and health-care resilience—they also offer a chance to strengthen the domestic manufacturing base and support high-quality jobs.

However, if U.S. policymakers focus narrowly on bringing only active pharmaceutical ingredient (API) and finished dosage form (FDF) production onshore, they will leave in place key vulnerabilities that tie our generic injectable supply to China.

In my view, an effective approach to derisking U.S. medicine supply from China requires:

1. Identifying where along the full manufacturing chain our exposure to China resides.
2. Targeting onshoring for most important drugs, while working with allies to derisk others.
3. Aligning policy tools to support investment and reliable production at all key stages.

I elaborate on these three elements below.

Where exposure to China exists

U.S. dependence on China for medicines does not sit only, or even primarily, at the API and FDF stages that we traditionally call drug manufacturing. In fact, the primary exposure is upstream from API. Here is the exposure listed from least to most:

- China's current role is limited in finished dosage form production but is likely to grow over time absent a deliberate policy response.
- China supplies about a quarter of generic API volume, with particularly heavy and undeniable reliance in antibiotics; This footprint is growing across may other therapeutic classes.
- The greatest exposure to China is upstream from API, with API manufacturers obtaining inputs that either directly or indirectly from China. 40% of key starting materials (KSMs) are only available from China, but when one adds auxiliary chemicals that help transform those KSMs into API, and other critical formulation ingredients, the exposure only grows further.

Because the greatest threat to U.S. medicine supply chains resides upstream, a strategy that solely focuses on the pharmaceutical manufacturing API or FDF phases will not derisk our drug supply chains from China.

The need to prioritize

Before discussing tools, it is critical to acknowledge budget constraints. Whatever form intervention takes—direct appropriations to support infrastructure investments, Medicare add-on payments, or 'Made in America' requirements—the result ultimately shows up as higher

government spending and, potentially, higher patient out-of-pocket costs. There is no way to realign incentives on a scale without taxpayers and potentially patients paying more.

The size of the problem makes prioritization especially important. Just on the finished-dose side, U.S. patients consume hundreds of billions of doses annually, across thousands of products and a global network of hundreds of manufacturing sites. And that is before we factor in the upstream—key starting materials, intermediates, and other inputs that feed into APIs and finished dosage forms—where much of the China exposure resides.

Changing this footprint requires government intervention because the incentives of pharmacies, hospitals, wholesalers, manufacturers, and payers all point toward buying the cheapest option, without internalizing what fragile supply chains can do to patient access. Shifting those incentives, whether through positive rewards or regulatory constraints, will either require taxpayer funds, raise premiums (including what Medicare and Medicaid spend), or increase patient out-of-pocket spending. There is no free lunch here, which is why government action must be highly selective rather than spread thinly across the entire market.

A sensible prioritization framework should weigh at least three elements: clinical importance (how essential the drug is to preventing death or serious harm), patient reach (how many patients would be harmed if supply is disrupted), and supply-chain vulnerability (including exposure to China and a history of disruption). Using those criteria, policymakers can identify a subset of medicines and supply-chain links for which government-backed reinforcement is most important. In general, this group will include medicines essential to saving patients in acute — across finished products and upstream chemicals.

Using policy to address that exposure

Once we have identified which drugs and which parts of their supply chains are most critical to reinforce—most notably generic sterile injectables and oral-dose antibiotics—the question for Congress is how to create a more predictable, economically viable market for these products that is less dependent on China across the chain and that actually rewards reliable supply. In my view, the relevant tools fall into two broad categories—supply-side and demand-side—with the right mix depending on the drug, its ranking on the priority scale, and the current state of its supply chain.

Supply-side vs demand-side tools

Supply-side interventions are about making it financially viable to build and maintain the manufacturing infrastructure we want. They work on fixed costs and technology choices: for high-priority drugs, they can help justify investments in more modern, resilient capacity that would not be attractive based on expected net present value alone.

Demand-side tools operate on the purchasing side: they change which products are attractive to buy by rewarding reliability and resilient sourcing once that capacity exists. They work best when supply-side barriers have been addressed; without viable resilient capacity to respond, even strong purchasing incentives cannot make the economics work for manufacturers.

In practice, this can create a chicken-and-egg problem, which is why, for the highest-priority drugs, supply- and demand-side measures may need to be deployed in a coordinated way.

Policy tools for sterile injectables

For generic sterile injectables, much of the FDF production is still in the United States, so policymakers are not starting from scratch at the FDF level. This means that supply-side interventions can focus more on API and upstream. Also, many of these drugs are used primarily in the hospital setting, which means Medicare is uniquely positioned on the demand side to influence how they are paid for and purchased.

For generic sterile injectables, supply-side interventions should start with upstream inputs, where much of the China exposure resides, and where antibiotics play a particularly important role. A practical approach would:

- Support development of industrial parks or clusters for key starting materials and critical intermediates used across multiple injectables, so producers can share specialized infrastructure, utilities, and regulatory expertise rather than duplicating it project by project.
- Invest in modern API and FDF capacity for high-priority injectables so that we have reliable non-Chinese production for the finished drugs hospitals actually need.
- Where it is not realistic or cost-effective to build all upstream and API capacity in the United States, focus on anchoring capacity in trusted allies, while using U.S. policy tools to encourage those partners to diversify away from Chinese inputs and to make their non-Chinese production reliably available to the U.S. market.

For APIs and FDF for high-priority injectables, supply-side interventions should focus on making it financially viable to build and upgrade the facilities we actually need, and they will require meaningful funding. Over the last six years, federal investment in the pharmaceutical industrial base has been extremely modest—roughly comparable to the cost of only a few advanced fighter jets spread over that entire period—which is not commensurate with the scale of the challenge. To change that, Congress should:

- Use low-cost loans to reduce upfront capital costs for modern API and FDF facilities that are designed for high reliability and quality.
- Offer partially forgivable loans, with forgiveness tied to maintaining supply, meeting stringent quality benchmarks, and shifting sourcing of key inputs away from China.
- Create well-structured tax incentives (for example, refundable or transferable credits, or credits usable against payroll or other non-income taxes) so that low-margin generic manufacturers can actually benefit from them.
- Condition all financial support on credible plans and timelines to source key starting materials, critical intermediates, and other vulnerable inputs from the United States or

trusted partners, rather than simply adding API or FDF capacity that continues to depend on Chinese upstream materials.

Demand-side tools are essential to make sure that the resilient capacity we build is actually used, but not all federal purchasers have the same leverage. For generic sterile injectables, the most important demand signal comes from hospitals, which is why Medicare should be the primary focus of congressional action, with DOD and VA playing a supporting, more limited role. Against that backdrop, Congress should:

- Authorize and fund a Medicare hospital add-on payment for high-priority generic sterile injectables that are supplied under long-term, reliability-oriented contracts and meet clear sourcing criteria (for example, multiple sites and derisked upstream inputs). This builds on the Senate Finance concept and is the most important demand-side lever because Medicare sits at the center of the hospital market.
- Encourage the Department of Defense and the Department of Veterans Affairs to use long-term contracts for domestically produced sterile injectables in facilities they directly control, recognizing that their hospital footprint is relatively small because so much TRICARE care has shifted into the private sector. These contracts can help anchor some domestic capacity but cannot substitute for Medicare-based incentives in the broader hospital system.
- Ensure that new demand-side incentives are explicitly aligned with supply-side support: laws should prioritize domestic products where adequate capacity exists, then allied-sourced products with derisked upstream inputs when domestic capacity is not yet sufficient, so that the purchasing signal reinforces the investments needed to move supply chains away from China rather than pulling in the opposite direction.

Policy tools for antibiotics

Among oral dose products, antibiotics warrant distinct treatment because their upstream is different from most other small-molecule drugs: many rely on fermentation-based APIs, and for several key oral-dose antibiotics China is not just a supplier of upstream chemicals but the primary source of the API itself. They also overlap heavily with sterile injectables, since many injectable antibiotics draw on the same fermentation and upstream infrastructure as oral-dose products, so any strategy for sterile injectables will already touch part of this space.

Against that backdrop, Congress should:

- Impose sizable tariffs on Chinese antibiotics (currently at 10%), which will affect not only FDF antibiotics made in China but also any non-Chinese product with Chinese API. This will shift demand towards European antibiotics in the short term, while allowing US API capacity to be built.
- Integrate oral-dose antibiotics into fermentation and upstream investment plans described above, ensuring that new non-Chinese fermentation and key starting-material capacity—

whether in the United States or trusted allies—is sized and structured to serve both oral-dose and sterile injectable antibiotics.

- Eliminate or otherwise modify Medicaid inflation rebates for antibiotics to enable the critical passthrough needed for market incentives to work.

Policy tools for other oral-dose generics

For the widely used everyday medicines that treat hypertension, high cholesterol, and depression, the retail market is dominated by Medicare Part D, Medicaid, and commercial plans. Commercial plans are major payers but are hard for Congress to direct. Congress could change Part D incentives to reward more reliable products, but that would require major restructuring of a benefit now built around plan competition on premiums and minimizing net drug costs. The federal entities with more direct procurement leverage—DoD and VA—account for only a small share of prescription drug spending. Medicaid programs face intense budget pressure and political scrutiny over drug spending, which makes it challenging to justify paying more for reliability or layering on new incentives for resilient products.

That reality means that for oral-dose generics, trade policy and upstream investment with allies have to do more of the work than sophisticated payment reforms.

I recommend Congress consider the following:

- Use China-only tariffs, calibrated for shortage risk, on key starting materials, intermediates, and APIs imported directly from China, to encourage Indian and other allied manufacturers to move away from Chinese inputs, while avoiding broad tariffs on finished drugs from allies that would blunt this incentive and keeping tariff and payment signals aligned rather than at cross-purposes.
- Support allied investment in upstream capacity (for example, through development finance or joint industrial projects) so that India and Europe can build out non-Chinese KSM, intermediate, and fermentation capacity that also serves U.S. needs.
- Encourage the administration, through authorizing language and oversight, to pursue trade arrangements with key pharmaceutical allies that lock in open access for medicines and inputs produced on non-Chinese supply chains, in exchange for shared commitments to reduce reliance on Chinese KSMs and intermediates.

Conclusion

Derisking from China has to stay at the center of this agenda: it ultimately means moving whole supply chains, not just the downstream pharmaceutical production steps. But Congress has limited fiscal and political capital, so it must prioritize which medicines and supply chains to onshore fully, which to anchor partly in the United States, and where to rely on trusted allies to fill the remaining gaps. Within those priorities, supply-side and demand-side policies need to work in tandem, with the mix calibrated to the situation, so that we are both building more resilient capacity and creating a market that actually uses it.

Getting that balance right across sterile injectables, antibiotics, and other high-priority oral-dose generics is how the United States can meaningfully reduce China's leverage over our medicines without sacrificing access or affordability for patients."