



SENATE SPECIAL COMMITTEE ON AGING
FULL COMMITTEE

Made in America: Restoring Trust in Our Medicines

November 19, 2025 – 3:45 PM

OVERVIEW

On Wednesday, November 19, the Senate Special Committee on Aging held a hearing titled, “Made in America: Restoring Trust in Our Medicines.” Senators and witnesses discussed: drug product contamination, precursor chemicals, key starting materials (KSM), and active pharmaceutical ingredients (API), API sourcing, labeling, economic incentives for domestic production, manufacturing and product quality, government procurement, Food and Drug Administration (FDA) inspections and inspection violations, reliance on India and China, methods to limit drug shortages, antibiotics supply, the sales price of generic drugs, cybersecurity, the Administration for Strategic Preparedness and Response (ASPR), government funding mechanisms, Section 232 tariffs, and quality testing on imported products.

OPENING STATEMENTS

- Chairman Rick Scott (R-FL)*
- Ranking Member Kirsten Gillibrand (D-NY)*
**Opening statement not yet available.*

WITNESS PANEL

- Mr. Tom Neely – Chairman of the Board, Oxford Pharmaceuticals*
- Mr. Allan Coukell – Chief Government Affairs & Public Policy Officer, CivicaRx*
- Mr. Patrick Cashman – President, USAntibiotics, LLC*
- Dr. Eric Edwards, MD, PhD – CEO, PHLOW-USA*
**Opening statement not yet available.*

QUESTION AND ANSWER SUMMARY

Sen. Ron Johnson (R-WI) – Drug supply chain issues are “not new.” China purposefully contaminated heparin in 2008.

Mr. Coukell – In 2007 or 2008, someone in China figured out a way to “spoo” the standard test for heparin’s active ingredient, did so for economic reasons, and sold defective drugs into the U.S. This revealed how dependent the U.S. is on foreign supply chains. The Food and Drug Administration (FDA) was given new authorities, but structurally we are “still headed in the wrong direction.” The active pharmaceutical ingredient (API) in heparin is produced in the U.S., but American heparin is more expensive than Chinese heparin.

Sen. Johnson – Are precursor chemicals and key starting materials (KSM) the same thing?

Dr. Edwards – Precursor chemicals are the chemical starting materials which feed into intermediate materials and API.

Sen. Johnson – How many precursor chemicals and KSM are there?

Dr. Edwards – Thousands, and the majority are made in China.

Sen. Johnson – Is this a refining process? There are thousands of precursor chemicals, but are there “general categories” of precursor chemicals?

Dr. Edwards – There are thousands of drugs in the supply chain. It is critical for the U.S. to prioritize; we must secure the industrial base by focusing on critical medicines, considering vulnerability, criticality, and reach. There may be a smaller subset of medicines, linked to a subset of API, necessary to sustain the health of the population.

Sen. Johnson – Oil is a precursor chemical. Some precursor chemicals are derived from plants, and others from bacteria. Could you describe “the chain” all the way up to API and the final drugs?

Dr. Edwards – Some KSM are derived from petrochemicals or rare earth minerals. Some KSM can be synthesized to create solvents or reagents needed to manufacture API. Other times, API can be created using synthetic biological processes. Phlow partnered with another company to leverage a synthetic process to create an API for which we could not source the KSM domestically. There are a variety of chemical sources and processes involved; it is critical to map and understand where KSM are coming from, so that we can prioritize where to begin.

Sen. Johnson – Where does Oxford source its API?

Mr. Neely – Of the thirteen product families Oxford produces, the API for two come from China. All other sources are in Europe. Vertical integration of API manufacturing can create costs savings, which is necessary to compete with China.

Sen. Johnson – Complete, accurate labeling on the sources of pharmaceutical product components like API will “radically change” supply chain issues. People will be willing to pay a higher price, especially for generic drugs which are already relatively inexpensive.

Mr. Neely – I agree. If I purchase an API from Europe, but that company gets the precursor materials from China, “this defeats the purpose.”

Ranking Member Kirsten Gillibrand (D-NY) – What economic incentive is most impactful in your determination of how you operate and invest in the U.S.? What is the largest limiting factor preventing your company from operating in the U.S.? How do procurement rules create a “race to the bottom?” How would purchasing and procurement “signals” impact your company’s domestic manufacturing capabilities?

Mr. Neely – Volume is a critical factor for Oxford Pharmaceuticals, so we operate 24/7 to maximize the capability of our plant. Today, we can produce 1.8 billion doses annually. However, we currently only produce about 1 billion doses annually “because the distributors are focused on price.” I think a market carveout for domestic producers, similar to the sugar market, would allow us to meet our total capacity and would be most impactful.

Mr. Coukell – CivicaRx has “a couple dozen” generics drugs in development for our facility. Some of those products are currently sold in the U.S. by other producers at extremely low prices, so while we are developing those products, we do not expect to be able to sell them unless there is a shortage. Some generics can be sold in the U.S. at competitive prices, but for other very low-cost drugs, some of which are critical medicines, we must create a consistent demand for the U.S.-created product to incentivize U.S. production.

Mr. Cashman – All recent federal government contracts for amoxicillin are structured as set-asides for small businesses. These set-asides, when applied to critical medicines with vulnerable supply chains, create negative consequences. USAntibiotics exists today because of the financial support of Jackson Healthcare. They viewed the acquisition of USAntibiotics as a national security prerogative, but because of Jackson Healthcare’s ownership, USAntibiotics is “effectively barred” from selling to the federal government due to the size of the company.

Dr. Edwards – The U.S.-China Economic and Security Review Commission released a report today calling for product disclosure of country of origin of KSM and API, as recommended earlier by Sen. Johnson. This is an important policy objective. There are misaligned incentives in the pharmaceutical supply chain; the market will not shift back to the U.S. if the buyers of essential medicines are rewarded for choosing the lowest cost. Information about quality sourcing and supply chain fragility are important, but this data will not be impactful if purchasers are not financially supported, or contractually required, to act on it. Federal entities should establish procurement policies that value supply chain reliability and quality.

Sen. Tommy Tuberville (R-AL) – Does Oxford sell to the Department of Veterans Affairs (VA) or the Department of Defense (DoD)?

Mr. Neely – Yes, but the process is “slow.” We would like to see more growth in this area. Changes to government procurement could be supported by Section 232 tariffs, followed by policy changes by the VA, DoD, and Medicare. This could allow domestic companies to better source those programs while maximizing their own capabilities.

Sen. Tuberville – Is there a bid process?

Mr. Neely – There are two parts to the system: the Federal Supply Schedule (FSS) and bidding. We have unsuccessfully bid on several opportunities, and we have been passed over in favor of firms that are Chinese-American and partnered with other firms that are Indian-American. Bidding policies could be clearer and create a more level playing field.

Sen. Tuberville – Mr. Neely, in your opening statement you said Oxford could quadruple its production. What would the company need to do this?

Mr. Neely – All we would need is \$18 million for capital expenditure and equipment. Oxford has already invested \$130 million in the plant, but would need \$18 million more. Our choice currently comes down to a business decision about return on investment. We are currently under-producing because distributors only care about cost.

Sen. Tuberville – CivicaRx has a “No China” policy, correct?

Mr. Coukell – Yes, unless the product in question cannot be sourced from anywhere else.

Sen. Tuberville – What needs to change to make U.S. generic drug production viable?

Mr. Coukell – Some injectable drugs are financially viable for U.S. producers, but other drugs sell at 30 to 40 cents per dose, which is not viable in the U.S. We need a system where purchasers select for quality and domestic production, and something needs to make those producers whole for the increased cost of those products.

Chairman Rick Scott (R-FL) – Does the FDA warn Oxford Pharmaceuticals of inspections? What would happen if FDA found a violation during an inspection?

Mr. Neely – FDA does not provide warning. A very severe violation, like a Form 483 violation, could close the company and lead to criminal charges against myself and other company leaders.

Chairman Scott – FDA warns foreign facilities of inspections, giving manufacturers time to prepare. Even then, major violations – including wildlife inside the facility – have been observed, as documented recently during an inspection of an Indian facility. If FDA found those violations in your facility, what would happen?

Mr. Neely – We would be closed. Indian manufacturers can game the system by swapping what drugs are produced in which factories once violations are observed, and they can “threaten” the U.S. by stating closure of a plant will create a shortage, due to U.S. reliance on Indian generics.

Chairman Scott – Has the FDA ever waived a violation for a foreign manufacturer? Would the FDA waive a violation for Oxford, if the consequences of the violation would cause a shortage?

Mr. Neely – The FDA would not waive a violation against Oxford to avert a shortage. Anecdotally, I have heard the FDA has waived violations for foreign manufacturers.

Chairman Scott – How does CivicaRx’s model help limit shortages?

Mr. Coukell – We employ several methods to limit shortages, including pursuing long-term fixed-volume commitments with purchasers and suppliers, creating stability; producing a six-month buffer for drugs we produce to protect against shortages caused by another supplier dropping out of the market; and conducting rigorous quality oversight of suppliers on an ongoing basis.

Chairman Scott – What would happen to the U.S. supply of antibiotics if USAntibiotics’ plant closed?

Mr. Cashman – The U.S. would be “completely dependent” on China and India. Without our plant, there would be no domestic production of antibiotics.

Chairman Scott – How many months of supply of amoxicillin does the U.S. currently possess?

Mr. Cashman – I do not know. USAntibiotics keeps a year’s worth of API and about a year’s worth of finished products in our plant.

Chairman Scott – If the FDA found animals in your facility, what would happen? Would the FDA care if closing the plant would cause a shortage?

Mr. Cashman – We would be shut down. I do not believe the FDA would take a shortage into consideration.

Chairman Scott – Why is it important to produce API domestically?

Dr. Edwards – API is the most critical component of a drug. Without the industrial base for API, the U.S. relies often on a single source to produce the medicines we need. This is a matter of public health security and national security, including for warfighters. Soldiers may need to utilize a drug with ingredients from a foreign adversary. This is “unacceptable.”

Chairman Scott – Is it “too much to ask” for pharmaceutical plants to not have birds and lizards?

Mr. Neely – It is not too much to ask. Quality is not cheap; for every dollar Oxford spends, 38 cents goes to quality. Foreign competitors cut costs by ignoring quality, so they can get to the lowest price possible and win contracts.

Ranking Member Gillibrand – Drug manufacturers are often the target of cyberattacks, which can disrupt the supply chain. Which link of the supply chain is most susceptible to cyberattacks, and what measures does your company take to promote cybersecurity? How much do these measures cost? Mr. Coukell, how can drug manufacturers work with federal entities to ensure robust cybersecurity measures are taken?

Mr. Coukell – A pharmaceutical plant can be shut down by a cyberattack. Many Indian companies have been targeted by cyber-ransom. While U.S. companies are also potentially at risk of these attacks, it follows that a company cutting corners on manufacturing quality is also likely not investing in cybersecurity. Several U.S. programs support domestic manufacturers, but we do need to ensure domestic producers and international partners maintain a high level of cybersecurity.

Dr. Edwards – This is a “critical aspect” of the pharmaceutical supply chain. Every element of the chain is at risk, none more than the others. In partnership with the Administration for Strategic Preparedness and Response (ASPR), Phlow’s government program incorporated cybersecurity from the start. We have worked with the Department of Homeland Security (DHS), the Federal Bureau of Investigation (FBI), and the Cybersecurity and Infrastructure Security Agency (CISA) to ensure our systems are robust. In 2017, Merck experienced a ransomware attack that created over \$1 billion in potential damages. Cybersecurity threats are not just a theoretical issue. Cybersecurity should be integrated from day one.

Mr. Neely – New Drug Supply Chain Security Act (DSCSA) regulations and serialization rules have improved this issue. We are able to track medications to the consumer level.

Ranking Member Gillibrand – Phlow has a partnership with ASPR, and CivicaRx is funded by ASPR through the Biomedical Advanced Research and Development Authority (BARDA). Please describe your experiences. For all the witnesses, what kinds of support do your companies need? Transparency requirements are “common ground” and Chairman Scott and I want to work on this immediately.

Dr. Edwards – Phlow has worked with ASPR for five years, spanning multiple administrations and the COVID-19 pandemic. The Government Accountability Office (GAO) has recommended the Department of Health and Human Services (HHS) implement a department-wide mechanism to coordinate drug shortage activities to allow agencies and partners to work together and break down silos. ASPR, and others working on shortages, require long-term sustained funding, to enable partnerships like the agency has with Phlow. Phlow cannot solve the lack of U.S. pharmaceutical industrial base alone; there must be many companies working to bring the industrial base back.

Mr. Coukell – Nearly one third of the costs needed to start CivicaRx’s facility came from ASPR. This investment came during the pandemic, when the funding needed to make these investments was available. In the years since the pandemic, the Office of Industrial Base Management and Supply Chain (IBMSC) has had a low and flat budget, hindering its ability to make further investment.

Mr. Neely – This committee “should want” a new facility, like Oxford Pharmaceuticals’, to be operating at full capacity. We would need a grant of \$18 million.

Mr. Cashman – Congress should pursue development of a strategic U.S. antibiotic manufacturing fund with targeted grants and low-interest loans; tax incentives for domestic API production; supply chain visibility; and recognition of essential medicines as national security assets, allowing manufacturers to access industrial base support.

Chairman Scott – Mr. Coukell suggested hospitals be compensated for quality. Under Medicare Advantage (MA), hospitals are compensated for quality, but not regarding medicines, correct?

Mr. Coukell – Price currently drives generic drug purchasing. When reviewing suppliers, Civica considers which supplier is least likely to fail in the future, taking into account quality systems. Generic drug purchasers should adopt a similar mindset.

Chairman Scott – The Centers for Medicare and Medicaid Services (CMS) probably has enough data on quality to consider whether hospitals and health plans take drug quality into account when they determine medicine suppliers. “I will find out.” For each of you, what would happen if DoD and VA purchased 100 percent of their volume from your companies for products you currently produce?

Mr. Neely – Oxford Pharmaceuticals “would make money for the first time in ten years.”

Mr. Coukell – Every company would welcome this business, but DoD and VA account for one to two percent of the total market, each. Changing how they procure drugs would be meaningful for the company awarded the contract, but this would not shift the market.

Mr. Cashman – This would be “transformational” for USAntibiotics, as it would give us the solid base of volume needed to grow our commercial business.

Mr. Edwards – This would allow us to base load our facilities, support active-duty soldiers, secure a supply chain of 25 to 50 drugs soldiers rely on, and send a market signal that could attract additional private investment to sustain our business.

Chairman Scott – How would the DoD and VA purchasing entirely domestically from companies like yours change the quality of care for servicemembers and VA patients?

Mr. Edwards – Patients and physicians are generally unaware of where their medicines are from. This change could restore trust in the quality and origin of medicines, and ultimately lead to positive changes in patient health and well-being, including fewer adverse events, as well as national resiliency

Mr. Neely – My family takes 23 generic drugs, all covered by Medicare. 20 of those drugs are produced in India, 2 are produced in China, and 1 is produced in Canada.

Chairman Scott – And, knowing the country of origin does not mean you know where the ingredients of those drugs are from.

Mr. Neely – My involvement in the industry is the only reason I was able to find out where the drugs are produced. For example, for a cholesterol medication, the “owner” of the medication is based in the U.S., but production and packaging occur in India.

Mr. Coukell – There is a difference between a product defect and a company with inadequate quality systems. We want to shift the market to favor companies less likely to cause a drug shortage due to failure to supply, but this does not necessarily mean defective product does not still occur.

Chairman Scott – Some research has indicated generic drugs from India and China can greatly increase a patient’s risk of hospitalization. How should the Department of Commerce use the Section 232 investigation authority to support domestic manufacturers?

Mr. Neely – Section 232 actions could “jump start” the changes needed in the industry. Industry and market reform will take a long time, but it has to get started somewhere. Section 232 can help.

Chairman Scott – Why does USAntibiotics not have contracts with DoD or VA?

Mr. Cashman – USAntibiotics is not considered a small business, and all amoxicillin contracts in recent years have been small business set asides. Jackson Healthcare’s investment in our business has made it so we cannot compete for amoxicillin contracts.

Chairman Scott – Are medicines imported from China or India subject to independent quality testing?

Mr. Cashman – The DoD has a quality testing program. All imported medications should be tested before they are sold to the U.S. market.

Dr. Edwards – I am familiar with a small number of pilot programs to this effect.

Chairman Scott – Does it not surprise you that every imported drug is not tested?

Dr. Edwards – “We operate on an honor system” for medications, but not for groceries, or clothing, or other products.

Mr. Neely – At Oxford, we test every raw material that comes into our plant and continue quality testing through production to packaging.

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