United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

May 14, 2026

Mr. Jason Hollar
Chief Executive Officer
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

Dear Mr. Hollar:

Thank you for your response to our recent inquiry regarding existing vulnerabilities that threaten the integrity and security of the U.S. pharmaceutical supply chain. We commend your efforts at Cardinal Health to mitigate critical drug shortages and facilitate safe and timely access of drug products to healthcare systems and patients. As chairman and ranking member of the U.S. Senate Special Committee on Aging, we are dedicated to ensuring that every American has access to safe, high-quality, and reliable medications. Our January 29, 2026, hearing entitled "*Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From*" underscored how little visibility purchasers, providers, and patients have into the true origin of generic drugs and the sources of their active pharmaceutical ingredients (APIs). These same opacity concerns apply directly to drugs exempted from FDA import bans entering distribution channels that lack clear, timely, or complete manufacturer-provided information. We appreciate the insight Cardinal Health has provided on maintaining supply to avert drug shortages, identification of import ban exemptions in current inventories, and proactive monitoring of FDA 483 Notices. Additionally, your response confirms that exempted products are actively being purchased and distributed, often for market share reasons or due to existing client agreements. We appreciate your diligence to transparency.

The Committee remains concerned that there is a lack of disclosure amongst clients of distributed products that originate from facilities under import alerts or operating under exemption status. It is also unclear whether prompt quality control measures are in place for Cardinal Health to review timely postings of FDA Form 483 observations and obtain and assess complete information from affected manufacturers. These gaps create conditions in which unsafe or non-compliant manufacturing practices can go undetected until products have already entered the U.S. market. For example, in 2021, a widely used blood pressure medication was found to be contaminated with nitrosamines, a probable human carcinogen. The contamination was traced to an API manufacturer in China that had previously been placed under an import alert but continued distributing product under an exemption. Delays in sharing critical inspection findings contributed to the circulation of contaminated

medication, ultimately leading to a large-scale recall and exposing patients to unnecessary risk. Such breakdowns are unacceptable; American patients should never be placed at risk of cancer, other adverse health outcomes, or substandard therapies. Strengthening transparency and oversight is essential to ensuring patient safety and upholding national security.

To better assess the adequacy of Cardinal Health's internal quality controls and communication processes, we request the following information by June 15, 2026:

1. Does Cardinal Health inform buyers that a product is under an import ban or import ban exemption? Is Cardinal Health required to do so or is that simply best practice? How are recalls handled?

2. How would country-of-origin-labeling improve Cardinal Health's ability to purchase domestically manufactured medications?

3. Does the FDA inform Cardinal Health when a drug they distribute receives a Form 483? Is the manufacturer legally required to inform Cardinal Health?

    a. What about for an exemption from an import ban?

4. Is Cardinal Health able to access unredacted Form 483s? Can they access the facility, outcome inspection, and specific drug(s) in violation or under import ban exemption?

5. In the event that Cardinal Health opts to dual award or switch the award for a drug exempted by the FDA, how often is there no other option? If there is another option, could you provide examples of what the market share is for the alternative products?

6. If Cardinal Health is distributing a generic drug under exemption from an FDA import ban where there is an alternative, what is the market share for the alternative products?

7. If a client is not part of the GPO, how would Cardinal Health inform them that their supplier's product is under exemption or received a Form 483 from the FDA?

8. Does Cardinal Health have any drugs exempted from FDA import bans on their formulary? If so, what alternatives exist and what are their market shares?

As chairman and ranking member of the U.S. Senate Special Committee on Aging, seniors' access to safe and high-quality medications is our top priority. Thank you for Cardinal Health's work to ensure access to affordable medications for older Americans. By ensuring transparency and accountability along the pharmaceutical supply chain, we can ensure that healthcare systems have the necessary tools to provide the best care to the American patient.

Thank you for your continued dialogue with the Committee and for your work to ensure the safety and reliability of the pharmaceutical supply chain.

Sincerely,

Rick Scott
Chairman
U.S. Senate Special Committee on Aging

Kirsten Gillibrand
Ranking Member
U.S. Senate Special Committee on Aging

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

May 14, 2026

Robert Mauch PharmD, PhD
President and Chief Executive Officer
Cencora
1 West First Avenue
Conshohocken, PA 19428

Dear Dr. Mauch:

Thank you for your response to our recent inquiry regarding existing vulnerabilities that threaten the integrity and security of the U.S. pharmaceutical supply chain. We commend your efforts at Cencora to mitigate critical drug shortages and facilitate safe and timely access of drug products to healthcare systems and patients. As chairman and ranking member of the U.S. Senate Special Committee on Aging, we are dedicated to ensuring that every American has access to safe, high-quality, and reliable medications. Our January 29, 2026, hearing entitled "*Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From*" underscored how little visibility purchasers, providers, and patients have into the true origin of generic drugs and the sources of their active pharmaceutical ingredients (APIs). These same opacity concerns apply directly to drugs exempted from FDA import bans entering distribution channels that lack clear, timely, or complete manufacturer-provided information. We appreciate the insight Cencora has provided on maintaining supply to avert drug shortages, identification of import ban exemptions in current inventories, and proactive monitoring of FDA 483 Notices. Additionally, your response confirms that exempted products are actively being purchased and distributed, often for market share reasons or due to existing client agreements. We appreciate your diligence to transparency.

The Committee remains concerned that there is a lack of disclosure amongst clients of distributed products that originate from facilities under import alerts or operating under exemption status. It is also unclear whether prompt quality control measures are in place for Cencora to review timely postings of FDA Form 483 observations and obtain and assess complete information from affected manufacturers. These gaps create conditions in which unsafe or non-compliant manufacturing practices can go undetected until products have already entered the U.S. market. For example, in 2021, a widely used blood pressure medication was found to be contaminated with nitrosamines, a probable human carcinogen. The contamination was traced to an API manufacturer in China that had previously been placed under an import alert but continued distributing product under an exemption. Delays in sharing critical inspection findings contributed to the circulation of contaminated

medication, ultimately leading to a large-scale recall and exposing patients to unnecessary risk. Such breakdowns are unacceptable; American patients should never be placed at risk of cancer, other adverse health outcomes, or substandard therapies. Strengthening transparency and oversight is essential to ensuring patient safety and upholding national security.

To better assess the adequacy of Cencora's internal quality controls and communication processes, we request the following information by June 15, 2026:

1. Does Cencora inform buyers that a product is under an import ban or import ban exemption? Is Cencora required to do so or is that simply best practice? How are recalls handled?

2. How would country-of-origin-labeling improve Cencora's ability to purchase domestically manufactured medications?

3. Does the FDA inform Cencora when a drug they distribute receives a Form 483? Is the manufacturer legally required to inform Cencora?

    a. What about for an exemption from an import ban?

4. Is Cencora able to access unredacted Form 483s? Can they access the facility, outcome inspection, and specific drug(s) in violation or under import ban exemption?

5. In the event that Cencora opts to dual award or switch the award for a drug exempted by the FDA, how often is there no other option? If there is another option, could you provide examples of what the market share is for the alternative products?

6. If Cencora is distributing a generic drug under exemption from an FDA import ban where there is an alternative, what is the market share for the alternative products?

7. If a client is not part of the GPO, how would Cencora inform them that their supplier's product is under exemption or received a Form 483 from the FDA?

8. Does Cencora have any drugs exempted from FDA import bans on their formulary? If so, what alternatives exist and what are their market shares?

As chairman and ranking member of the U.S. Senate Special Committee on Aging, seniors' access to safe and high-quality medications is our top priority. Thank

you for Cencora's work to ensure access to affordable medications for older Americans. By ensuring transparency and accountability along the pharmaceutical supply chain, we can ensure that healthcare systems have the necessary tools to provide the best care to the American patient.

Thank you for your continued dialogue with the Committee and for your work to ensure the safety and reliability of the pharmaceutical supply chain.

Sincerely,

Rick Scott
Chairman
U.S. Senate Special Committee on Aging

Kirsten Gillibrand
Ranking Member
U.S. Senate Special Committee on Aging

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

May 14, 2026

Mr. Brian Tyler
Chief Executive Officer
McKesson
6555 State Highway 161
Irving, TX 75039

Dear Mr. Tyler:

Thank you for your response to our recent inquiry regarding existing vulnerabilities that threaten the integrity and security of the U.S. pharmaceutical supply chain. We commend your efforts at McKesson to mitigate critical drug shortages and facilitate safe and timely access of drug products to healthcare systems and patients. As chairman and ranking member of the U.S. Senate Special Committee on Aging, we are dedicated to ensuring that every American has access to safe, high-quality, and reliable medications. Our January 29, 2026, hearing entitled "*Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From*" underscored how little visibility purchasers, providers, and patients have into the true origin of generic drugs and the sources of their active pharmaceutical ingredients (APIs). These same opacity concerns apply directly to drugs exempted from FDA import bans entering distribution channels that lack clear, timely, or complete manufacturer-provided information. We appreciate the insight McKesson has provided on maintaining supply to avert drug shortages, identification of import ban exemptions in current inventories, and proactive monitoring of FDA 483 Notices. Additionally, your response confirms that exempted products are actively being purchased and distributed, often for market share reasons or due to existing client agreements. We appreciate your diligence to transparency.

The Committee remains concerned that there is a lack of disclosure amongst clients of distributed products that originate from facilities under import alerts or operating under exemption status. It is also unclear whether prompt quality control measures are in place for McKesson to review timely postings of FDA Form 483 observations and obtain and assess complete information from affected manufacturers. These gaps create conditions in which unsafe or non-compliant manufacturing practices can go undetected until products have already entered the U.S. market. For example, in 2021, a widely used blood pressure medication was found to be contaminated with nitrosamines, a probable human carcinogen. The contamination was traced to an API manufacturer in China that had previously been placed under an import alert but continued distributing product under an exemption. Delays in sharing critical inspection findings contributed to the circulation of contaminated

medication, ultimately leading to a large-scale recall and exposing patients to unnecessary risk. Such breakdowns are unacceptable; American patients should never be placed at risk of cancer, other adverse health outcomes, or substandard therapies. Strengthening transparency and oversight is essential to ensuring patient safety and upholding national security.

To better assess the adequacy of McKesson's internal quality controls and communication processes, we request the following information by June 15, 2026:

1. Does McKesson inform buyers that a product is under an import ban or import ban exemption? Is McKesson required to do so or is that simply best practice? How are recalls handled?

2. How would country-of-origin-labeling improve McKesson's ability to purchase domestically manufactured medications?

3. Does the FDA inform McKesson when a drug they distribute receives a Form 483? Is the manufacturer legally required to inform McKesson?

    a. What about for an exemption from an import ban?

4. Is McKesson able to access unredacted Form 483s? Can they access the facility, outcome inspection, and specific drug(s) in violation or under import ban exemption?

5. In the event that McKesson opts to dual award or switch the award for a drug exempted by the FDA, how often is there no other option? If there is another option, could you provide examples of what the market share is for the alternative products?

6. If McKesson is distributing a generic drug under exemption from an FDA import ban where there is an alternative, what is the market share for the alternative products?

7. If a client is not part of the GPO, how would McKesson inform them that their supplier's product is under exemption or received a Form 483 from the FDA?

8. Does McKesson have any drugs exempted from FDA import bans on their formulary? If so, what alternatives exist and what are their market shares?

As chairman and ranking member of the U.S. Senate Special Committee on Aging, seniors' access to safe and high-quality medications is our top priority. Thank

you for McKesson's work to ensure access to affordable medications for older Americans. By ensuring transparency and accountability along the pharmaceutical supply chain, we can ensure that healthcare systems have the necessary tools to provide the best care to the American patient.

Thank you for your continued dialogue with the Committee and for your work to ensure the safety and reliability of the pharmaceutical supply chain.

Sincerely,

Rick Scott
Chairman
U.S. Senate Special Committee on Aging

Kirsten Gillibrand
Ranking Member
U.S. Senate Special Committee on Aging