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**COMMITTEES:** COMMITTEE ON FINANCE COMMITTEE ON THE BUDGET COMMITTEE ON ENERGY AND NATURAL RESOURCES SELECT COMMITTEE ON INTELLIGENCE JOINT COMMITTEE ON TAXATION

August 3, 2023

Dear Alvogen,

Oregonians and the community pharmacies they count on for local, dependable service regularly tell me of their difficulty securing access to much-needed medications for attention deficit hyperactivity disorder (ADHD), particularly the generic versions of these medications. I've engaged with federal agencies on how they are working with manufacturers to address this troubling shortage.

The Drug Enforcement Agency (DEA) informed me that it told all manufacturers in a May 18 letter about their concerns regarding the supply of amphetamine and amphetamine products. In that letter, the DEA notes that in 2022, manufacturers sold about 70 percent of their allotted quota for ADHD products for the year, with 1 billion dosage units that were authorized but not shipped or sold. A few months into the 2023 calendar year, manufacturers also had allotted quota they had not fully used. The agency added in the letter that it stood ready to "expeditiously review and adjudicate individual applications under the current authorized quota levels for amphetamine, in accordance with DEA regulations." However, shortages persist.

On August 1, the U.S. Food and Drug Administration (FDA) and the DEA released a joint statement at my request providing an update on the shortage of prescription stimulants hurting Oregonians and all Americans needing these crucial medications. The statement mentioned the 2022 shortfall and, concerningly, added that this year showed a similar trend - that manufacturers are not using their entire quotas. Both agencies called on manufacturers to either increase their manufacturing of these medications or relinquish their remaining allotment for the DEA to redistribute to manufacturers that wished to produce more than their allotted quota.

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The following actions are urgently needed: companies with spare quota allotments should relinquish them to the DEA so the DEA can approve applications from companies that have requested an increase; companies with excess production capacity that have met their quota allotment should apply for an increase; and manufacturers should sufficiently report voluntary and required information on their

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WASHINGTON, DC 20510-3703

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Those diagnosed with ADHD and their families, health care professionals, and policymakers are counting on industry and regulators to work closely together to both address the immediate crisis and consider long-term solutions to prevent and mitigate future shortages. Pharmacy shopping or half-filled prescriptions are not helpful, but more and more they are becoming the norm as people seek treatment for recognized medical conditions.

I respectfully request your answers to the following questions about your manufacturing plans by Thursday, August 10th, 2023:

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I urge you to take appropriate action outlined by the DEA and promptly respond to this letter. Your actions and response will provide the answers Americans and their health providers need to keep ADHD medications available to patients when they are lawfully prescribed.

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Ron Wyden

United States Senator

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August 3, 2023

Dear Amneal Pharmaceuticals, Inc.

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**COMMITTEES:** 

August 3, 2023

Dear Aurobindo Pharma USA, Inc.,

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Dear Aytu BioPharma, Inc.,

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Dear Camber Pharmaceuticals, Inc.,

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August 3, 2023

Dear Epic Pharma, LLC,

Oregonians and the community pharmacies they count on for local, dependable service regularly tell me of their difficulty securing access to much-needed medications for attention deficit hyperactivity disorder (ADHD), particularly the generic versions of these medications. I've engaged with federal agencies on how they are working with manufacturers to address this troubling shortage.

The Drug Enforcement Agency (DEA) informed me that it told all manufacturers in a May 18 letter about their concerns regarding the supply of amphetamine and amphetamine products. In that letter, the DEA notes that in 2022, manufacturers sold about 70 percent of their allotted quota for ADHD products for the year, with 1 billion dosage units that were authorized but not shipped or sold. A few months into the 2023 calendar year, manufacturers also had allotted quota they had not fully used. The agency added in the letter that it stood ready to "expeditiously review and adjudicate individual applications under the current authorized quota levels for amphetamine, in accordance with DEA regulations." However, shortages persist.

On August 1, the U.S. Food and Drug Administration (FDA) and the DEA released a joint statement at my request providing an update on the shortage of prescription stimulants hurting Oregonians and all Americans needing these crucial medications. The statement mentioned the 2022 shortfall and, concerningly, added that this year showed a similar trend - that manufacturers are not using their entire quotas. Both agencies called on manufacturers to either increase their manufacturing of these medications or relinquish their remaining allotment for the DEA to redistribute to manufacturers that wished to produce more than their allotted quota.

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This state of affairs is unacceptable and can be reversed.

The following actions are urgently needed: companies with spare quota allotments should relinquish them to the DEA so the DEA can approve applications from companies that have requested an increase; companies with excess production capacity that have met their quota allotment should apply for an increase; and manufacturers should sufficiently report voluntary and required information on their

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WASHINGTON, DC 20510-3703

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Those diagnosed with ADHD and their families, health care professionals, and policymakers are counting on industry and regulators to work closely together to both address the immediate crisis and consider long-term solutions to prevent and mitigate future shortages. Pharmacy shopping or half-filled prescriptions are not helpful, but more and more they are becoming the norm as people seek treatment for recognized medical conditions.

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I urge you to take appropriate action outlined by the DEA and promptly respond to this letter. Your actions and response will provide the answers Americans and their health providers need to keep ADHD medications available to patients when they are lawfully prescribed.

Sincerely,

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Ron Wyden

United States Senator

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August 3, 2023

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Sincerely,

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Ron Wyden

United States Senator

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August 3, 2023

Dear Lannett Company, Inc.,

Oregonians and the community pharmacies they count on for local, dependable service regularly tell me of their difficulty securing access to much-needed medications for attention deficit hyperactivity disorder (ADHD), particularly the generic versions of these medications. I've engaged with federal agencies on how they are working with manufacturers to address this troubling shortage.

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I urge you to take appropriate action outlined by the DEA and promptly respond to this letter. Your actions and response will provide the answers Americans and their health providers need to keep ADHD medications available to patients when they are lawfully prescribed.

Sincerely,

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Ron Wyden

United States Senator

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**COMMITTEES:** COMMITTEE ON FINANCE COMMITTEE ON THE BUDGET COMMITTEE ON ENERGY AND NATURAL RESOURCES SELECT COMMITTEE ON INTELLIGENCE JOINT COMMITTEE ON TAXATION

August 3, 2023

Dear Prasco,

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Ron Wyden

United States Senator

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August 3, 2023

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United States Senator

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August 3, 2023

Dear Sandoz Pharmaceuticals,

Oregonians and the community pharmacies they count on for local, dependable service regularly tell me of their difficulty securing access to much-needed medications for attention deficit hyperactivity disorder (ADHD), particularly the generic versions of these medications. I've engaged with federal agencies on how they are working with manufacturers to address this troubling shortage.

The Drug Enforcement Agency (DEA) informed me that it told all manufacturers in a May 18 letter about their concerns regarding the supply of amphetamine and amphetamine products. In that letter, the DEA notes that in 2022, manufacturers sold about 70 percent of their allotted quota for ADHD products for the year, with 1 billion dosage units that were authorized but not shipped or sold. A few months into the 2023 calendar year, manufacturers also had allotted quota they had not fully used. The agency added in the letter that it stood ready to "expeditiously review and adjudicate individual applications under the current authorized quota levels for amphetamine, in accordance with DEA regulations." However, shortages persist.

On August 1, the U.S. Food and Drug Administration (FDA) and the DEA released a joint statement at my request providing an update on the shortage of prescription stimulants hurting Oregonians and all Americans needing these crucial medications. The statement mentioned the 2022 shortfall and, concerningly, added that this year showed a similar trend - that manufacturers are not using their entire quotas. Both agencies called on manufacturers to either increase their manufacturing of these medications or relinquish their remaining allotment for the DEA to redistribute to manufacturers that wished to produce more than their allotted quota.

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This state of affairs is unacceptable and can be reversed.

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WASHINGTON, DC 20510-3703

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Those diagnosed with ADHD and their families, health care professionals, and policymakers are counting on industry and regulators to work closely together to both address the immediate crisis and consider long-term solutions to prevent and mitigate future shortages. Pharmacy shopping or half-filled prescriptions are not helpful, but more and more they are becoming the norm as people seek treatment for recognized medical conditions.

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I urge you to take appropriate action outlined by the DEA and promptly respond to this letter. Your actions and response will provide the answers Americans and their health providers need to keep ADHD medications available to patients when they are lawfully prescribed.

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Ron Wyden

United States Senator

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August 3, 2023

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Ron Wyden

United States Senator

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August 3, 2023

Dear Solco Healthcare US, LLC,

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August 3, 2023

Dear SpecGX LLC,

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August 3, 2023

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Ron Wyden

United States Senator

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August 3, 2023

Dear Sunrise Pharmaceutical, Inc.

Oregonians and the community pharmacies they count on for local, dependable service regularly tell me of their difficulty securing access to much-needed medications for attention deficit hyperactivity disorder (ADHD), particularly the generic versions of these medications. I've engaged with federal agencies on how they are working with manufacturers to address this troubling shortage.

The Drug Enforcement Agency (DEA) informed me that it told all manufacturers in a May 18 letter about their concerns regarding the supply of amphetamine and amphetamine products. In that letter, the DEA notes that in 2022, manufacturers sold about 70 percent of their allotted quota for ADHD products for the year, with 1 billion dosage units that were authorized but not shipped or sold. A few months into the 2023 calendar year, manufacturers also had allotted quota they had not fully used. The agency added in the letter that it stood ready to "expeditiously review and adjudicate individual applications under the current authorized quota levels for amphetamine, in accordance with DEA regulations." However, shortages persist.

On August 1, the U.S. Food and Drug Administration (FDA) and the DEA released a joint statement at my request providing an update on the shortage of prescription stimulants hurting Oregonians and all Americans needing these crucial medications. The statement mentioned the 2022 shortfall and, concerningly, added that this year showed a similar trend - that manufacturers are not using their entire quotas. Both agencies called on manufacturers to either increase their manufacturing of these medications or relinquish their remaining allotment for the DEA to redistribute to manufacturers that wished to produce more than their allotted quota.

DEA tells me the May 18 letter intended to spur manufacturers with excess production capacity to increase their production. Yet as of August 1, according to the agencies' analysis that has not happened and manufacturers are yet again on track to fall ONE BILLION doses below quota, even as patients struggle to obtain medication that their professional health care providers have legally prescribed.

This state of affairs is unacceptable and can be reversed.

The following actions are urgently needed: companies with spare quota allotments should relinquish them to the DEA so the DEA can approve applications from companies that have requested an increase; companies with excess production capacity that have met their quota allotment should apply for an increase; and manufacturers should sufficiently report voluntary and required information on their

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WASHINGTON, DC 20510-3703

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I respectfully request your answers to the following questions about your manufacturing plans by Thursday, August 10th, 2023:

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I urge you to take appropriate action outlined by the DEA and promptly respond to this letter. Your actions and response will provide the answers Americans and their health providers need to keep ADHD medications available to patients when they are lawfully prescribed.

Sincerely,

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August 3, 2023

Dear Tris Pharma, Inc.,

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