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The Honorable Mike Crapo
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United States Senate
Washington, DC 20510

Dear Chair McMorris Rodgers and Ranking Member Crapo:

On behalf of the American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians who treat mental health and substance use disorders, I write in response to your stakeholder Request for Information (RFI) regarding our nation's drug shortages.

Amid a national crisis in mental health, it is encouraging to see Congress prioritize improving and increasing access to evidence-based treatment, including ensuring a sufficient supply of medication. The COVID-19 pandemic exposed gaps in our country's mental health care system and highlighted the immediate need to strengthen our broader health care infrastructure.

The APA offers the following feedback on the state of the nation's medication supply and recommended actions to address this dire situation. With your leadership, Congress can ensure that federal agencies have the resources and authorities necessary to get medications to patients in need and improve the health of all Americans.

Scope and Impact of Drug Shortages in Behavioral Health

Drug shortages are detrimental to patient care. In a recent poll of 465 members of the APA, 99% reported their patients were struggling to access medically necessary prescriptions. The top three shortages identified by our psychiatrists were stimulants (96.6%), benzodiazepines (12.0%) and antipsychotics (9.2%).

Notably, 13 psychiatrists also described issues in patient access to the vital medication for opioid use disorder (MOUD) buprenorphine with potentially deadly consequences. Given Congress' work to address the opioid epidemic, this cannot go unmentioned. Efforts to increase access include the recent elimination of the X-waiver, but if underlying policy or economic factors limit the availability or amount of buprenorphine in the system care will remain unattainable.

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For physicians, the drug shortage comes in the form of untenable administrative burden and exacerbated burnout. In our poll, several psychiatrists even reported considering leaving practice – a result we simply cannot afford in the current environment of healthcare workforce shortages.

For patients, the shortage looks like two-hour drives to multiple pharmacies that might have their medication or concerns of relapse. More than patients with other diagnoses, those filling mental health prescriptions face added stigma from their communities and even their pharmacists. The most vulnerable patients are among the most impacted by the shortages, as children and underserved populations in rural or economically disadvantaged areas often have limited resources, time and options to advocate for themselves.

Patients that have already struggled through significant adversity to access care suddenly find themselves without their medications. The difficulty attaining prescribed medications can greatly increase mental health patients' anxieties, which in turn makes them vulnerable to relapse into substance use for buprenorphine patients and to behavioral/productivity issues or costly emergency hospitalizations for patients prescribed stimulants or benzodiazepines.

Generics and Public Health Plans

Shortages of certain medications create a domino effect. Faced with a generic shortage, patients are encouraged to seek brand name drugs. These are often more expensive, not covered by insurance or delayed due to prior authorization requests. Patients then have multiple copays as they coordinate with their physician, further increasing costs.

Shortages of these medications are leading to an increased equity issue for children, especially those on public insurance who cannot afford brand name drugs when the generic is not available. For some youth with neurodevelopmental disorders, not getting their stimulant medications can result in intense behavioral disruptions and violence.

For adult patients, skipping medication can lead to missed school, missed work or even judicial penalties for actions that could have been curtailed through appropriate medication. Congress should ensure that generics are reimbursed at a rate that encourages production to meet the demands for those on public insurance.

Market and Policy Conditions Adverse to Whole Health

Compounding manufacturing shortages are systemic health industry issues, such as prior authorization delays, workforce shortages and changes in pharmacy dispensing policies without clarity or coordination.

Prior authorization presents a barrier to care by increasing costs and impeding timely access to appropriate services. Insurers promote it as a mechanism for savings, but the impact of drug shortages is

dramatically exacerbated by insurer denials and requirements that patients “fail first” on one medication before approving the preferred medication. This process often results in psychiatrists completing extensive paperwork and multiple phone calls to advocate for their patients that would otherwise be spent on clinical time. There is no evidence that this process improves the quality of patient care or is cost effective.

According to a 2022 survey by the American Medical Association, four in five physicians reported that prior authorization can lead patients to abandon their recommended course of treatment. For individuals with psychiatric disorders, gaps in treatment can lead to relapse, along with increased health care costs and devastating effects for individuals and their families.

Prior authorization delays are also often intensified by a lack of timely transparency from pharmacies with stock of lifesaving medications, which results in dangerous and costly “pharmacy shopping.” Psychiatrists report it is not uncommon for a parent of a child with ADHD to call up to 20 pharmacies without success. This puts physicians in the uncomfortable position with patients needing multiple schedule II prescriptions sent to multiple pharmacies, despite the prescription drug monitoring programs, just in attempt to help them stay in classes and keep their jobs.

Pharmacy benefit programs and FDA rules compound the shortage problem because rules do not accept rational changes in medications. For example, adapting to shortages by prescribing two 10 mg tablets instead of one 20 mg tablet requires a new prescription.

The APA supports improving prior authorization processes and transparency:

- Reduce the maximum time to approve prior authorization requests.
- Require payers to provide specific reasons for denials.
- Require payers to report metrics on how many prescriptions they authorize and deny.
- Require denials and denial reviews be conducted by physicians with expertise in the treatment under review.
- Extend reforms to both established drugs and newer formulations.

Additionally, broader lack of access to care drives an incomplete understanding of the treatment and prescription needs of Americans impacted by mental health conditions. The economically significant healthcare workforce shortages directly affect drug shortages.

With many Americans still struggling to find accessible and available care, the supply and demand around prescriptions is constantly in flux. Providing consistent and cost-effective treatment to patients will alleviate the ups and downs of drug production, and for that the country needs a sustained and well-trained healthcare labor force.

The APA urges support of legislative proposals that will help to reduce physician workforce shortages:

- The REDI (Resident Education Deferred Interest) Act (H.R. 1202/S. 704).
- The Mental Health Professionals Workforce Shortage Loan Repayment Act of 2023 (S.462).
- The Resident Physician Shortage Reduction Act of 2023 (H.R. 2389/S.1302).
- Conrad State 30 and Physician Access Reauthorization Act (S. 665).
- The COMPLETE Care Act (S. 1378) – to increase uptake of the evidence-based Collaborative Care Model integrating primary and behavioral healthcare, a unique workforce multiplier.

CMS and Cross-Agency Collaboration

The APA encourages the federal agencies to deploy a coordinated response to the drug shortages. Many factors can affect drug shortages, including supply chain disruptions and fluctuations in demand, agencies often have difficulty sharing or acting on timely information. Data sharing can help organize a response to prevent inequities to communities who have a greater need for certain drugs or who have traditionally had greater challenges in accessing care.

As of June 7, 2023, the FDA listed 138 drugs on the shortage list. In the FDA’s report to congress on drug shortages CY 2022, the agency acknowledged the value of early notification processes from manufacturers when a shortage is expected and the variety of preventative measures the FDA can utilize. However, even with this process in place, there are still too many drugs on the shortage list and many more that are causing hardship to patients and their families when trying to get a prescription filled. Other tools can be coordinated with the FDA’s information to prevent and course correct drug shortages.

Throughout the COVID-19 pandemic, medical supplies were affected by the supply chain and fluctuations in need. The administrations responded by setting up task forces to address the issue. The government coordinated resources, manufactures, end users and others to ensure that the needs of Americans were met. There was also coordination to distribute to particularly impacted communities, preventing increased inequities that have traditionally plagued low-income areas and communities of color. The continued drug shortages highlight the need for a similarly coordinated response among all agencies to address the issues and coordinate information to prevent additional shortfalls from impacting care.

The APA supports increased coordination and transparency between drug manufacturers, distributors, dispensers and regulators:

- Create a coordinating body to take the information from each agency and act prior to a declared shortage.
- Enable CMS to communicate beneficiary usage data in real time to understand fluctuations in need.
- Authorize FDA access to “proprietary” prescribing data from distributors and pharmacies to improve tracking and response they currently are required to purchase in incomplete forms.
- Authorize federal access to data on manufacturer quota increase requests and actual production levels per license to understand raw material demand.

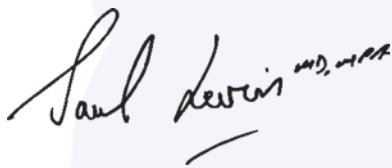
- Require DEA to provide information on controlled substances to ensure medically necessary and lifesaving drugs are accessible when a legitimate prescription is written.
- Engage with ASPR to ensure that adequate reserves of medications exist for our patients in the national stockpile to be distributed to impacted areas if shortage exists.

Beyond the Drug Shortage List

Psychiatrists and their patients are facing challenges with getting prescriptions filled for many controlled substances that are not currently on the drug shortage list. Real time reporting on shortage determinations and reasoning must be reviewed by the federal agencies to ensure that manufacturers can produce more when there is a need. Any delay in care due to arbitrary limits in supply or allowable distribution should never be tolerated.

We appreciate your timely focus on identifying legislative steps Congress can take to address ongoing drug shortages. The APA is eager to aid your efforts. If you have any questions, please contact Dana Doran at ddoran@psych.org or (202) 459-9708.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin" followed by "MD, MPA" in smaller letters. There is a horizontal line under the name "Saul".

Saul Levin, MD, MPA, FRCP-E, FRCPsych
CEO and Medical Director

The Impact of Stimulant Shortages on Patients: Cases from Members of the APA

Responses have been edited for length and clarity.

Medications for Opioid Use Disorder

- A patient had to drive around to multiple pharmacies while in opioid withdrawal to get a short supply of buprenorphine. The same patient had to go through withdrawal a second time for 3 days from buprenorphine while unable to refill his prescription, putting him a high risk for relapse to heroin/opioids due to pharmacy shortages.
- A patient had been using the same fentanyl pills as recent peer who overdosed and died. Insurance delayed her ability to start Suboxone through a prior authorization back-and-forth for nearly a week, during which time she was in danger of dying.

Children's Mental Health

- I have a 4-year-old patient with ADHD who was running into traffic impulsively and running away from her parents at parks before starting stimulants. The cascading shortages of stimulants have made it harder for her parents to get her medicine, which is a life-or-death issue for this girl.
- I care for children attending a special needs school. One 10-year-old boy with autism, ADHD and disruptive mood dysregulation disorder had finally stabilized after multiple school placements, aggression towards school staff and his peers, and several stays at day programs. His stimulant medication became unavailable, resulting in a resurgence of this aggression. He subsequently bit a peer when he was not on his medication, which will impact his relationships with his peers, when he desperately wants to make friends. We still have not been able to get the stimulant he had been stable on and are in the process of trial and error with similar medications.

Prior Authorization

- I recently received a request for prior authorization. Less than one hour later, before I responded, we received a denial. It's pretty clear the company had no intention of approving the medication.
- Many patients with schizophrenia are denied or delayed in getting the antipsychotics they need. This leads to discontinuation of medication and as a result these patients have more inpatient admissions with worsening psychosis, increased numbers of suicidal attempts, increased episode of violence, break ups with their family and children, self-medicating with drugs and alcohol.

Mental Health Stigma

- Pharmacist responses to my patients' requests for stimulants or benzodiazepines are often sarcastic, critical and demeaning. Patients are frequently treated as if they are addicted or seeking street drugs inappropriately and end up feeling that they are being treated like criminals... I don't believe this would happen with other specialties as there is a strong bias against mental health disorders that I see daily.
- A pharmacy withheld my patients' medications for several days due to their own lack of medical knowledge and never reached out to me, the prescribing physician. If the pharmacy was concerned, they should have called my office rather than bullied my patient. This patient has severe anxiety and is on the autism spectrum, so these interactions caused significant stress and a delay in obtaining their medications.

Generics/Ineffective Insurance Coverage

- My patient is a 35-year-old married mother of two toddlers. She was diagnosed with ADHD in college and treated with psychostimulants with beneficial results. To maintain her current medication the patient now pays around \$600.00/month for a diverse necessary second daily dose that the insurance pharmacy manager has refused to approve, stating it exceeds the total number of capsules allowed per month.
- I had an appeal rejected for a two-dose prescription needed daily, but the insurer will only allow 30 capsules per month. This is a racial and gender patient who cannot afford to pay the extra \$200 per month for the second half of their medication (another 30 capsules).

Suicidality/Emergency Hospitalizations

- I have a patient who responds to only one antipsychotic, thioridazine. Twice the drug has not been available, both times have resulted in hospitalization.
- I had a patient who was stable on her stimulant regimen through college and graduate school. She lost access to her medications due to medication shortages and prior auth delays as we tried to switch to a bioequivalent dose of another stimulant. She was let go of her first job out of school, became depressed and was psychiatrically hospitalized with severe suicidal ideation. She has not gotten back on track.

Limiting Care

- We may need to start taking on fewer patients to have more time to deal with the shortage problems. Some providers have stopped taking on patients with ADHD because they don't have time to deal with the complications caused by the shortages. Others are charging patients more for the time spent dealing with the shortage complications, increasing the cost of care.
- I limit the number of patients with ADHD that I will treat in my practice due to the hassles of prescribing a controlled substance that can't get filled in a timely fashion due to prior authorization requirements or stimulant shortages causing rewriting of scripts and recalculation of exact counts until next visit. Prescribing stimulants is now such a hassle that fewer providers generally are willing to prescribe them, forcing some stable patients who were getting their medications from primary care to try to find a psychiatrist, further limiting access for more acute psychiatric problems.

Workforce/Physician Burnout

- At this point I am looking at non-clinical jobs in psychiatry, and even a career change altogether. I am fed up with the government bureaucracy, the lack of transparency, the false assurances that the shortage is over, the daily impact on my staff having to call dozens of pharmacies and repeatedly sending in the same prescriptions day after day.
- My administrative time has increased threefold in the last 6 months. I'm considering quitting my academic hospital-based job to go full time in private practice. This shortage is changing how physicians practice.
- I personally (as the MD) spend up to 10 hours per week of unpaid administrative time due to the shortage, which has limited my ability to take on new patients during a severe mental health clinician shortage.