results of supply discontinuations and reduced market competition would probably be higher costs for public payers and increased risk of drug shortages. For example, generic drug shortages were found to be associated with higher prices for alternative therapies[4]; and a national shortage of norepinephrine was associated with increased mortality.[5]

In addition, broad tariffs on generic drugs are unlikely to achieve the policy intent of safeguarding national security from geopolitical threats to the U.S. medicine supply. Capital investments in domestic manufacturing require multiple years of lead time and presumably prioritize high-margin products, rather than low-cost generic medicines. Most U.S. generic drug imports are from Indian and European manufacturers (for example, more than 60% of generic oral drug volume comes from India).[2] Both these jurisdictions have been independently engaged in recent policymaking to reduce reliance on active pharmaceutical ingredients from China, for instance. However, U.S. tariffs on generic drug imports from India and Europe would reduce, not increase, those manufacturers' capacity to invest in alternative suppliers of pharmaceutical ingredients. Reciprocal tariff actions by trade partners could also undermine the international competitiveness of U.S. generic drug manufacturers.

We believe that several changes to the administration's proposed policy on pharmaceutical tariffs are urgently needed to protect access to generic medicines. First, if it were not politically feasible to exclude all generic drugs, which would be the best solution, the administration could avoid shocks to the U.S. medicine supply by gradually phasing in targeted tariffs on generic drugs from specific countries that are deemed to pose geopolitical risks. Harmonization of such a policy with those of key trading partners, including Europe and India, could support parallel efforts to diversify suppliers of key active pharmaceutical ingredients.

Second, instead of tariffs, the Section 232 authority would be better used to pursue more direct policy mechanisms to stimulate generic drug markets, including grants and tax incentives for building generic drug manufacturing capacity as well as national stockpiles for essential medicines and the active pharmaceutical ingredients necessary for their production. Finally, any pharmaceutical tariffs should be time-delimited and require close monitoring of key outcomes, including effects on market competition, prices, and drug availability, to ensure that future trade policy is grounded in empirical evidence.

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Goals for Opioid Use Disorder Medications — Protection, Remission, and Recovery

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Medications such as methadone, naltrexone, and buprenorphine are the first-line treatment for opioid use disorder (OUD),[1] yet most addiction treatment programs don't offer these medications and most physicians don't prescribe them. The result is that only 20 to 25% of the patients who are at risk for overdose or other OUD-related harms receive medication for opioid use disorder (MOUD) — and even those patients are usually prescribed medication only for short-term detoxification. Along with stigma and lack of regulatory clarity, important barriers to broader prescrib-

ing include confusion and controversy about the appropriate clinical goals for MOUD. A key question has been when, if ever, to taper and discontinue medication.

Protecting people with OUD from withdrawal, overdose, and infectious diseases (e.g., HIV and hepatitis C) is the primary goal for many MOUD prescribers. These prescribers may accept some patients' continued misuse of illicit opioids but see protection from increasingly potent and dangerous synthetic opioids as a humane and immediately achievable goal. Other prescribers offer MOUD with the aim of facilitating a significant reduction in use of nonprescribed opioids — what the American Society of Addiction Medicine considers "remission of OUD."[1] Some of these clinicians see a lack of progress toward remission as a reason to terminate MOUD. Meanwhile, the majority of licensed addiction treatment programs choose not to provide MOUD. These programs use exclusively behavioral therapies and social supports to try to bring about "abstinence-based recovery" (one of us is on the board of directors of a company that offers MOUD prescriptions and was on the board of directors of a company that produces MOUD until February 2024).

Prescribing MOUD with a goal of protecting people who actively use drugs from overdose and infectious diseases is clearly effective. But are prescribers who take this approach settling for a suboptimal outcome? Conversely, does pursuing abstinence-based recovery unnecessarily jeopardize patient and public safety? In the absence of a consensus on realistic, achievable clinical goals for MOUD at the patient level, this controversy will persist, MOUD-penetration rates will remain low, and the public health response to the addiction crisis will remain suboptimal.

At the systems level, the OUD cascade of care model[2,3] is emerging as a standard tool for administrators of state and private health care organizations to monitor the management of OUD in their patient populations by tracking the movement of patients from identification and diagnosis to prescription of MOUD, sustained reduction in symptoms with MOUD, and ultimately referral to recovery-oriented services.[3]

An important feature of the cascade of care model is that it doesn't pit one therapeutic goal against another; instead, it builds on the immediate patient protections afforded by MOUD to facilitate longer-term personal and public health benefits of recovery in a sequenced — though nonlinear — progression. We believe operationalizing the stages of this model for use in the care of individual patients could offer practical guidance for prescribers and treatment programs, reduce ideological controversies hampering progress in the field of addiction medicine, and increase practitioners' willingness to treat OUD.

We argue that recovery is the most appropriate, achievable, and worthwhile goal of treatment for most patients with OUD and that recovery is possible while a patient is receiving MOUD — what we call "medication-based recovery." Abstinence has often been considered to be synonymous with recovery from substance use disorders. But evidence indicates that abstinence is neither necessary nor sufficient for recovery. According to most published definitions, recovery begins with a reduction in substance misuse to below problematic levels and involves meaningful improvements in personal health and social functioning.[4] For many years and for many types of substance use disorders, abstinence had been the only method by which people could achieve remission from substance misuse. In the case of OUD, however, medications can also support remission from use of opioids and other substances[1] and facilitate efforts to improve health and social functioning.

What would translating the cascade of care model to individual patient care entail? In keeping with the original systems framework, we suggest an approach to caring for individual patients with OUD that includes important, measurable stages: protection, remission, and recovery (see diagram).

Stage	Clinical Goal	Effective Tools for Achieving Goal	Time Frame
Protection	Prevention of overdose and infectious diseases	Medication for OUD (MOUD)	Immediate and continuing
Remission from OUD	Significant, sustained reduction in OUD symptoms	MOUD Behavioral therapy AA or NA attendance	1–6 mo: Early remission 7–12 mo: Sustained remission >12 mo: Stable remission
Recovery from All Substance Use Disorders (SUDs)	Significant, sustained reduction in all SUD symptoms and improvement in health and social functioning	MOUD Behavioral therapy Additional medical and social services, as needed	1–6 mo: Early recovery 7–12 mo: Sustained recovery >12 mo: Stable recovery

Proposed Model for the Care of Patients with Opioid Use Disorder (OUD).
AA denotes Alcoholics Anonymous and NA Narcotics Anonymous.

Protection — the first therapeutic goal of the cascade of care — involves standard screening and OUD diagnosis, followed by initiation of MOUD to reduce opioid misuse and related harms.

Remission from opioid misuse — which can be assessed with urine drug screening — is a desirable and attainable goal for most patients who have access to proper MOUD dosing, behavioral therapy, and social supports. Individual office-based prescribers may not have the resources necessary to help patients achieve remission, but they can refer patients to specialty programs that offer these services.

Recovery is an appropriate aim once patients have had a stable, positive response to MOUD and have significantly reduced their misuse of opioids. To this end, individual prescribers and programs should use all available evidence-based tools and services to help patients reduce their misuse of other substances (e.g., cocaine, alcohol, and benzodiazepines) to below problematic levels and improve their health and social functioning. For the three domains of recovery (significant, sustained reduction in substance misuse, improvement in health, and improvement in social functioning), there are well-validated measures that could be used during regular clinical monitoring and counseling sessions to promote sustained progress.

Some patients taking MOUD may initially not want to stop using nonprescribed substances, and others may have complex coexisting conditions that require protracted access to clinical and social services before recovery is feasible. Some prescribers and treatment programs threaten to stop prescribing MOUD to patients who aren't making adequate progress toward recovery. But because MOUD saves lives, discharging patients because of inadequate progress toward recovery is countertherapeutic and dangerous. In these circumstances, practitioners should continue to prescribe MOUD and make all reasonable clinical efforts to guide patients in making progress toward remission and recovery.

For decades, there has been disagreement in the field of addiction medicine about whether to prescribe MOUD for the sole purpose of protecting patients from overdose and related harms or to use behavioral methods to promote abstinence-based recovery. The OUD cascade of care model has helped resolve this conflict at the systems level by integrating goals for MOUD treatment into a framework involving measurable, progressive stages, from medication initiation and stabilization to referral to recovery services.[3] Applying this integrated approach at the level of individual patients is also reasonable. Remission and recovery are desirable goals for most patients taking MOUD and can be safely achieved without discontinuing medication. Although remission and recovery may require significant time and extensive clinical support, prescribers should continue their efforts to help patients achieve these goals.

Adopting this approach would have several implications. Many patients who are prescribed MOUD ask how long they will need to take medication. Rather than offer a time-based estimate, we suggest practitioners tell patients that abstinence-based recovery can be a realistic goal that is most safely achieved after first achieving medication-based recovery.

Operationalizing the cascade of care model will require regular clinical monitoring to assess patients' progress — a standard aspect of care for other chronic diseases.[5] Yet most insurers don't provide reimbursement for routine clinical monitoring during treatment with MOUD, and many practitioners incorrectly view monitoring as punitive.

Our proposal also calls into question the long-standing practice by most states of offering separate licenses and having separate reimbursement policies for OUD treatment programs that offer medications and those that don't offer medications, an approach that wouldn't be considered for most other diseases. All licensed programs should make all evidence-based clinical tools available.

Finally, for patients and their families, we hope that achievement of recovery — with or without medication — can be celebrated with pride, as people now celebrate "medication-based recovery" from other chronic diseases.

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