Op-Ed: Bureaucrats need to listen to patients

By David Williams

August 23, 2022

By now, millions of Americans have heard the good news that hearing aids will soon be available over the counter and will likely hit the shelves by the end of 2022. The newly finalized rule by the Food and Drug Administration (FDA) gives patients the option of bypassing costly exams at the doctor's office.

While the rise of over-the-counter hearing aids should be celebrated by consumer and patient advocates, this rule change is just the beginning of the fight for patient-centered care. Federal agencies are determined to force patients to spend hours in the waiting room to access crucial technologies that could save or improve their lives. It's time for lawmakers and bureaucrats to put consumers first and lower health-care barriers.

Hearing aids are not the only game-changing health-care product stymied by federal gatekeeping rules. According to a 2020 report by the Cato Institute, "the FDA requires consumers to obtain prescriptions before purchasing naloxone, a safe, effective drug that reverses opioid overdoses. The drug reverses depressed respiratory rate and blood pressure by knocking opioids off the recipient's opioid receptors and binding itself to those receptors." Even though the medication has been on the market for decades and poses negligible risks to individuals not suffering an opioid overdose, the agency still sees it necessary to require a doctor's signoff.

States have designed workarounds and "standing orders" to ease non-prescription access, but even these fixes come with costly reporting requirements for pharmacies. In addition, community organizations often find themselves in a legal gray area when it comes to quickly dispensing the life-saving medication to patients suffering overdose. Similar to hearing aids, it is easy for liberalization opponents to point to worst-case scenarios in which patients don't properly use these products or get confused. But, requiring doctor's visits for everything under the sun is not the answer. Patients can wait a month or longer just to see a family medicine doctor and may need to shell out hundreds of dollars if their insurance is skimpy/nonexistent.

The FDA is beginning to acknowledge this new reality in the realm of at-home testing. Thanks to a slew of medical innovations, patients can take tests for everything from COVID to allergies to cholesterol ... without seeing their doctor first. New types of blood tests can extend this progress to cancer detection for malignancies that often go undetected and typically require invasive exams. Patients cannot get their hands on multi-cancer early detection blood tests without first getting a

sign-off from their doctor. And, even if they were able to, these tests may soon become more expensive and less available thanks to the actions of the Federal Trade Commission (FTC).

The agency has made clear that it will fight test sequencing companies' attempts to acquire test developers, even if integrating the two services would lead to significant efficiencies for consumers down the road. This fight has already spilled over into federal court, costing innovators time and money that could've been spent screening patients and designing even better tests. While the FTC is concerned about industry concentration, the most practical barriers to patient access come from the gatekeeping imposed by other agencies such as the FDA.

Instead of burying developers in legal fees and onerous rules, federal officials should work together to expedite access to patients. This would mean allowing investment dollars to flow into the health-care sector while keeping prescription requirements at a minimum. Allowing over-the-counter sales of hearing aids is just the first step in a revolution that will empower patients and change lives.