FDA weighs over-the-counter switch for key drugs

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Some of the most widely used prescription drugs, including those to treat cholesterol and high blood pressure, could be available over the counter under a new proposal being weighed by government regulators.

Food and Drug Administration officials said Wednesday they are considering waiving prescription requirements for certain drugs used to treat ailments like diabetes, asthma and migraine. Driving the move is a wave of computer technology, including touch-screen kiosks found in pharmacies, designed to help patients self-diagnose common diseases.

FDA regulators told reporters that easing access to obtain certain medications could help address undertreated epidemics like diabetes. Of the more than 25 million Americans with diabetes, an estimated 7 million are not diagnosed and therefore do not receive treatment. Diabetes is a leading cause of heart disease and stroke.

"These are discussions that need to start happening as we think about people's health needs and how to improve access," said FDA Commissioner Dr. Margaret Hamburg.

The over-the-counter switch is one of several FDA proposals aimed at increasing access to established drugs or speeding up approval of experimental medications.

After years of high-profile drug-safety cases in which the FDA restricted access to certain medications, the agency is increasingly

highlighting its efforts help drugmakers get new innovative drugs on the market. The shift comes as drug companies and their allies in Congress have pressured the agency to speed up approvals, complaining that U.S. requirements are more burdensome than those in Europe and elsewhere.

Some Republican-backed proposals in Congress would even change FDA's mission statement, requiring the agency to encourage medical innovation and job creation. Since its creation, the FDA has traditionally evaluated medical products solely on their safety and effectiveness.

"The world is changing and we have to change to with it," Hamburg said. "We're not talking about abandoning standards for safety and efficacy, we're talking about leveraging opportunities in science so we can do a more effective job as regulators and also improve the drug development process."

Over the years, the FDA has approved the switch of several high-profile prescription drugs to over-the-counter use. In 2003, the FDA cleared Prilosec, an over-the-counter version of the blockbuster AstraZeneca heartburn drug Nexium. The FDA only approves such changes if studies show that patients can safely take the drug after reading the package labeling. Under the industry-backed proposal, drugmakers could use electronic questionnaires, diagnostic devices like blood pressure monitors and other computer-assisted technology to guide patients.

In some cases, patients would still need to see a doctor to obtain an initial prescription before getting over-the-counter refills. In other cases, patients would need to speak with a pharmacist but would not need a prescription to receive medication.

The agency also predicts a number of benefits from decreasing doctor visits.

"Eliminating or reducing the number of routine visits could free up prescribers to spend time with more seriously ill patients, reduce the burdens on the already overburdened health care system and reduce health care costs," the agency states in recent federal notice about the proposal.

Drugmakers would have to request a switch for each drug individually, and the FDA would judge the safety of each proposal on a case-by-case basis.

FDA officials stress that the idea is still in the early stages and a public meeting is scheduled for later this month to gather comments.

"We're not talking about very specific drugs right now, we're talking about the concept," said Dr. Janet Woodcock, director of FDA's drug center.