Foreign Drugs Get Little Scrutiny by FDA

By ANDREW BRIDGES – 2 hours ago

WASHINGTON (AP) — The Food and Drug Administration isn't paying enough attention to inspecting the growing amount of drugs produced by foreign manufacturers, say lawmakers who want the agency to update its approach.

The head of the FDA is being called before a congressional committee Thursday to explain his agency's lopsided approach to inspecting drugs, both domestically and overseas.

Members of the House Energy and Commerce subcommittee on oversight and investigations say the FDA's overwhelming emphasis on domestic inspections places the public at risk, as more and more drugs come from overseas.

While nearly all U.S. drug makers are inspected at least once every two years, foreign manufacturers can go eight or more years between inspections, according to congressional investigators. While the domestic inspections are mandated by a law drawn up long before imports seized a sizable chunk of the drug market, there is no such requirement that the FDA conduct foreign inspections with any regularity.

Prescription drugs and drug ingredients pour into the United States from an estimated 3,000 foreign companies, though the real number is unknown and could be as high as 6,700, congressional inspectors said in a memo to members of the subcommittee ahead of Thursday's hearing. Among those invited to testify: FDA commissioner Dr. Andrew von Eschenbach. The agency declined an interview request ahead of the hearing.

The FDA plans to inspect just 300 foreign drug firms this year, announcing in advance its intent to do so each time. Of those inspections, most are of plants that make drugs awaiting FDA approval. Just 15 are of the type of periodic assessment meant to ensure a company's products remain safe in the years following FDA approval, though some pre-approval inspections also include some post-approval surveillance.

In contrast, the FDA comes close to inspecting the roughly 3,300 domestic drug manufacturers once every two years as required.

An estimated 80 percent of the active pharmaceutical ingredients used to make drugs sold in the U.S. are imported. Among finished drugs, an estimated 40 percent are made

abroad.