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Public Citizen wants withdrawal of diabetes drug

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(AP) -- A consumer advocacy group is calling on government regulators to withdraw a diabetes drug from Novo Nordisk, saying the injectable medication raises the risk of thyroid cancer, pancreatitis and kidney failure.

Public Citizen sent a petition to the Food and Drug Administration saying the risks of Victoza far outweigh its benefits as a diabetes drug, a crowded field that includes nearly a dozen similar medications.

Citing internal agency documents, the group notes that FDA approved the drug in 2010 against the recommendation of three staff scientists.

"The need for new therapies for Type 2 diabetes is not so urgent that one must tolerate a significant degree of uncertainty regarding serious risk concerns," wrote reviewer Dr. Karen Mahoney, in an agency memo obtained by Public Citizen.

Mahoney and two other reviewers noted that Victoza caused thyroid tumors in both male and female rats and mice. The warning label for Victoza currently states it is "unknown whether Victoza will cause" thyroid cancer in humans because rodent studies cannot provide conclusive evidence of human outcomes. The label recommends patients with a family history of the disease not use the drug.

The FDA reviews drugs using teams of doctors, pharmacists and scientists. It is not unusual for some team members to disagree on the

safety of a drug.

Public Citizen also cites Victoza's association with pancreatitis, reports of which were 3.7-fold higher among patients tested with the drug than those taking other diabetes drugs. In its first 17 months on the market, the FDA received 200 reports of patients diagnosed with pancreatitis, according to a search of FDA databases. Public Citizen estimates only 10 percent of cases are reported to the agency, suggesting there may be as many as 2,000 cases of among patients taking Victoza.

About 150,000 prescriptions for the drug are filled each month in the U.S.

Any citizen or group can petition the FDA to remove a product from the market based on safety, economic or environmental reasons. The FDA often takes months or even years to render a decision on such requests.