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For Immediate Release:

July 19, 2011

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Proposed Diabetes Drug Should Not Be Approved, Public Citizen Tells FDA
Experimental Drug May Have Caused Bladder and Breast Cancer, Other Serious Ailments in Diabetes Patients

WASHINGTON, D.C. – A drug proposed to treat patients with diabetes should not be approved because it has serious risks and no evidence of clinical benefit, Public Citizen said today in testimony before the Food and Drug Administration’s (FDA) Endocrine and Metabolic Drugs Advisory Committee.

The drug, dapagliflozin, is the first proposed drug in a new class of chemical agents for treatment of type-2 diabetes. The drug, developed by Bristol-Myers Squibb and AstraZeneca, works by blocking reabsorption of glucose by the kidneys, causing large amounts of glucose to be removed from the body via urine.

“The FDA in its review of this drug identified several serious safety concerns,” said Dr. Sidney Wolfe, director of Public Citizen’s Health Research Group. “Additionally, although the manufacturers of this drug have requested approval based solely on its ability to lower blood sugar levels, they presented no evidence of improvement in important clinical outcomes, such as decreased complications of diabetes affecting the kidney, eye and heart, or decreased mortality.”

In the studies testing this experimental drug, diabetes patients receiving dapagliflozin experienced increased rates of bladder and breast cancer, serious liver toxicity, vaginal yeast infections, bacterial urinary tract infections and dehydration.

“The increased rate of bladder and breast cancer in patients who received dapagliflozin raises concern that this new chemical agent may promote the development of these tumors in diabetes patients,” Wolfe said. “Also, one subject who received this drug developed evidence of serious drug-induced liver injury. These serious risks, in the absence of well-documented clinical benefits, should preclude approval of this drug.”

To read the testimony, visit: <http://www.citizen.org/testimony-on-dapagliflozin-071911>.

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Public Citizen is a national, nonprofit consumer advocacy organization based in Washington, D.C.

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