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Cases of Kidney Failure, Muscle Damage Should Prompt FDA to Ban Crestor

WASHINGTON, D.C. – Public Citizen today called on the U.S. Food and Drug Administration (FDA) to immediately remove the cholesterol-lowering drug rosuvastatin from the market. The drug, marketed by AstraZeneca as Crestor, has been linked to cases of life-threatening muscle damage and kidney failure or damage.

Since it was approved just over five months ago, three patients in the United States who were taking approved doses of rosuvastatin developed kidney failure or muscle damage. One of those patients, a 39-year-old woman, died of kidney failure and rhabdomyolysis, or muscle damage. Data obtained from the United States, the United Kingdom and Canada show seven cases of rhabdomyolysis and nine case of kidney damage or failure occurred after FDA approval.

In studies before its approval, seven people were struck by cases of rhabdomyolysis, an adverse reaction involving the destruction of muscle tissue that can lead to kidney failure. Baycol, another statin, was removed from the market in the fall of 2001 after at least 31 reports of fatal rhabdomyolysis. Even so, Baycol did not show life-threatening rhabdomyolysis in pre-approval clinical trials. Crestor is the only statin to have the reaction arise before its approval.

In July 2003, Public Citizen Health Research Group Director Sidney Wolfe, M.D. strongly urged the FDA not to approve rosuvastatin, because in addition to the risks of muscle and kidney damage, Crestor has not been shown to reduce the risk of heart attacks and strokes, in addition to lowering cholesterol levels. Three other statins – lovastatin, pravastatin and simvastatin – have shown such a benefit.

In today's petition, Wolfe wrote that the decision by two major U.S. health insurers and the Swedish government not to reimburse patients for the drug underscores the concerns already raised and strengthens the case for banning the drug. Nonetheless, AstraZeneca is currently launching a major direct-to-consumer advertising campaign to promote the drug.

"The FDA should never have approved this drug in the face of such serious and potentially lethal adverse effects," Wolfe said. "The only way the agency can show it has concern for patient safety, and not drug industry wishes, is to pull Crestor from market immediately."

Since 1996, Public Citizen has either warned consumers not to take or petitioned for the ban of six dangerous drugs that were later taken off the market, including Redux, Propulsid and Baycol.