FDA Says Prostate Drugs Can Cause Cancer

By Bibeka Shrestha

Law360, New York (June 10, 2011) -- The U.S. Food and Drug Administration on Thursday warned that several prescription drugs used to treat enlarged prostate glands and baldness could increase the risk of contracting an aggressive type of prostate cancer.

The FDA said it would add a new warning to the labels on Merck & Co. Inc.’s Proscar and Propecia and GlaxoSmithKline PLC’s Avodart and Jalyn to alert doctors that the drugs elevate the risk of high-grade prostate cancer, which spreads faster than other forms of prostate cancer.

Avodart, Jalyn and Proscar are used to treat benign prostatic hyperplasia, a common condition in men older than 40. BPH causes frequent urination and difficulty emptying the bladder, along with an enlarged prostate gland. Propecia is marketed for treating male pattern hair loss.

"The risk appears to be low, but health care professionals should be aware of this safety information, and weigh the known benefits against the potential risks," the FDA said.

The warning impacts the 5-alpha-reductase inhibitor class of drugs, primarily used to treat the symptoms of BPH.

Drugs in the class include finasteride, marketed as Proscar and Propecia, and dutasteride, marketed as Avodart. Jalyn is included in the drug class because it contains dutasteride.

After conducting two multiyear trials, the FDA found that the drugs helped reduce the risk of low-grade prostate cancer, but simultaneously increased the chance of contracting a more serious form of prostate cancer.

While Propecia was not included in either of the studies, the drug's warning label will be modified because it contains 1 milligram of finasteride.

"The applicability of the Avodart and Proscar studies to Propecia is currently unknown," the FDA said. "The outcomes of both studies have been added to the Propecia labeling out of caution."

The FDA added that while it believed the benefits of the drugs still outweigh the risks, patients and doctors should consider the new information before beginning treatment.

On Wednesday, the regulator announced that use of the highest-approved dose of cholesterol-lowering drug Zocor carried an elevated risk of muscle injury, recommending that no new patients take the Merck drug in that amount.
Only those patients who have taken Zocor or its generic form, simvastatin, for a year or more and have not experienced muscle toxicity should continue taking 80-milligram doses, the agency said in a statement.

Use of the drug at the dosage can lead to myopathy, a muscular disease associated with cramps, stiffness and spasm, according to the FDA.

The agency said it would change the safety labels on the drug to reflect this newly learned risk.

--Additional reporting by Greg Ryan. Editing by John Williams.