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US panel sees risk in long-used osteoporosis drug

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A panel of U.S. government health experts says a long-established bone strengthening drug should no longer be used by women because there is little evidence it works and it may actually increase the risk of cancer.

The Food and Drug Administration panel voted 12-9 that the risks of the inhalable osteoporosis drug outweigh its benefits when used to treat brittle bones.

The drug, known chemically as calcitonin salmon, has been prescribed for osteoporosis in postmenopausal women since the 1980s. Currently, Novartis and Upsher-Smith market the drug in nasal spray form as Miacalcin and Fortical, respectively.

But health authorities around the world have been reviewing the drug's safety after two recent studies showed a slightly higher rate of cancer among patients taking calcitonin pills. The drug is also available as an injection to treat other conditions, including excess calcium in the blood.

The European Medicines Agency concluded last July that calcitonin should no longer be used to treat osteoporosis, due to the drug's cancer risk.

An internal FDA memo released ahead of Tuesday's meeting said it's difficult to draw a direct link between the drug and cancer. However, "the potential for a cancer risk with calcitonin salmon therapy cannot be ignored. The majority of all calcitonin salmon trials showed an increased

risk estimate."

A narrow majority of panelists voted against continued use of the drug, pointing out that the drug has not been shown very effective at preventing bone fractures.

"I think the cancer risk seems to be low, but it tips the balance for this drug, which has very little evidence of efficacy," said Amy Whitaker, a professor at the University of Chicago.

But other panelists said the drugs are an important option for patients who have bad reactions to newer drugs, including bisphosphonate drugs like Fosamax.

"We have a whole lot of patients who can't take the other drugs, and I think our patients would be in worse shape without this," said Bart Clark, professor at the Mayo Clinic College of Medicine.

Calcitonin salmon is a manmade version of a hormone found in the salmon fish.

Prescriptions for calcitonin have plummeted in recent years amid safety concerns about the drugs. Between 2006 and 2011 the number of U.S. patients receiving the drug fell 51 percent to 205,000.

The FDA approved the drugs from Novartis and Upsher-Smith based on studies showing that they increased bone mineral density. However, no studies have definitely shown that higher density actually reduces bone fractures. The largest study of calcitonin, which followed 1,200 women for about five years, was plagued by logistical problems, including a high level of patients who dropped out.

The FDA often approves drugs based on so-called surrogate endpoints,

or initial measures that suggest the drug will make real improvements in patient health. In cancer drugs, for example, tumor shrinkage is considered a predictor of longer survival.

Drugmakers favor the approach because it helps them get products to market sooner. But it has proven problematic for the FDA when drugs do not live up to their initial promise.

The FDA panel was nearly unanimous that any future calcitonin drugs should be required to show real effectiveness in preventing bone fractures. The group voted 20-1 in favor of such a requirement.

The FDA does not have to follow the advice of its panels, though it often does.

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