

By Marilyn Marchione Associated Press , April 19, 2005

"ANAHEIM, Calif. — With prescription drugs Vioxx and Bextra already pulled from the market, a study has raised disturbing questions about the heart safety of long-term use of over-the-counter pain relievers such as Advil, Motrin and Aleve."

"Smokers in Norway who took such drugs for at least six months had twice the risk of dying of a heart attack, stroke or other heart-related problem."

"The study was relatively small — 908 people — and involved people prone to heart problems and cancer because they smoked. But specialists said it supports the Food and Drug Administration's recent decision to warn about long-term use of all such painkillers except aspirin."

"The findings add to the suspicion that the heart risk extends beyond the so-called cox-2 drugs — Bextra, Vioxx and Celebrex — to the larger family of medications known as non-steroidal anti-inflammatory drugs, or NSAIDs, which include naproxen, ibuprofen and virtually all other over-the-counter pain relievers except acetaminophen or Tylenol."

"In recent months, many doctors have switched patients to these over-the-counter medications, believing them to be safer alternatives."

"To the best of our knowledge, these are the first data to support putting a box warning on NSAIDs, not just cox-2s," said Dr. Andrew Dannenberg, a Cornell University scientist who helped do the Norway study.

"Some results from the Norway study were presented in February hearings at the FDA, but consisted of only one summary slide and "nobody really picked up on it," said Dr. Raymond DuBois, a Vanderbilt University cancer expert who had no role in the work."

"The fresh information presented on Monday should persuade others to study these over-the-counter drugs in more depth, DuBois said."

"Oral cancer is a deadly and disfiguring disease that is an especially big problem in Asia. Worldwide, about 275,000 cases and 127,000 deaths occur each year. In the United States, about 29,370 new cases and 7,320 deaths are expected this year."

"Dr. Jon Sudbo of the Norwegian Radium Hospital in Oslo, who led the research, and others wanted to see if NSAIDs could prevent oral cancer, since studies showed they could help ward off other types of cancer. They chose more than 3,000 people at high risk for oral cancer because of their smoking habits from the Norwegian Cancer Registry, a database of more than 123,000 people."

"A deeper look revealed that the NSAID users were dying at twice the rate of the others from heart-related problems. There were 42 cardiovascular deaths among the 263 painkiller users and 41 deaths among the much larger group of 562 people who had never taken such drugs."

"Risk was highest among ibuprofen users, who were nearly three times more likely to die of cardiovascular disease than non-NSAID users. Aspirin was the only NSAID that did not seem to raise the risk, but the numbers of aspirin users in the study were small."

"Doctors said the NSAID dose made no difference in risk, but others said this should be studied in future experiments."

"There are important uncertainties. One of them is the doses and one is what the effect would be in the larger population," said Dr. Michael Thun, chief of epidemiology for the American Cancer Society, who had no role in the study."

"Thun said he would propose a larger study on over-the-counter NSAIDs using the cancer society's huge database, which contains information on more than 1.2 million Americans."