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PSORIATIC ARTHRITIS MEDICAL NEWS

FDA CALLED DEFENSELESS AGAINST BAD DRUGS
November 18, 2004 WASHINGTON (AP)

The American public is "virtually defenseless" if another medication such as Vioxx proves to be unsafe after it is approved for sale, a government drug safety reviewer told a congressional committee Thursday.

"I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx," said David Graham, who warned that the arthritis drug had been linked to an increased risk of heart attack and stroke.

He told the Senate Finance Committee that there were at least five other drugs on the market today that should be looked at seriously to see whether they should remain there. He cited the acne drug Accutane, the weight loss drug Meridia, the anti-cholesterol drug Crestor, the pain reliever Bextra, and the asthma drug Serevent.

AstraZeneca Pharmaceuticals, maker of Crestor, said it was confident that the drug was safe. "To date, the FDA has not given us any indication of a major concern regarding Crestor," said spokeswoman Emily Denney.

Tim Lindberg, a spokesman for Abbott Laboratories, said, "science continues to support the safe use of Meridia to treat obesity, the leading health epidemic in the U.S."

Carolyn Glynn, spokeswoman for Roche Pharmaceuticals, maker of Accutane, said that "it's important to point out that this drug is reserved for a very serious indication, that it does carry risks and that it's very important for physicians, patients, pharmacists to monitor, to conform to all of the risk programs because this drug is extremely beneficial as long as it's used safely and appropriately."

GlaxoSmithKline, maker of Serevent, issued a statement saying that it "stands firmly behind" the product, "which is safe and effective when used appropriately and in accordance with labeling and treatment guidelines."

Representatives of Pfizer, the manufacturer of Bextra, were not immediately available for comment.

Another FDA official, Dr. Sandra Kweder, said that she did not agree with Graham's assessment with the risk posed by the five drugs singled out by Graham.

She said, "there is no magic formula" to determine the drugs that pose the most pressing safety concerns. She said there are thousands of drugs on the market, each one carrying risks and benefits. "That is clearly Dr. Graham's

opinion" regarding the five drugs, she said, denying that the FDA intimidates scientists whose opinions differ with superiors.

She was asked whether her office, the Office of New Drugs, is an impediment to enforcing concerns about drug safety. "You know, sir, that is not the FDA I know.

Vioxx's maker, Merck & Co. pulled the drug from the market on Sept. 30 after a study indicated the popular painkiller doubled the risk of heart attacks and stroke when taken for longer than 18 months.

Raymond V. Gilmartin, the company president, said in prepared testimony that Merck acted within four days of learning about the risk.

"Given the availability of alternative therapies and the questions raised by the data withdrawing Vioxx was consistent with an ethic that has driven Merck actions and decisions for more than 100 years," he said.

Gilmartin also said the company was surprised by the cardiovascular risk because it differed from past clinical trials. "My wife was a user of Vioxx until the day we withdrew it from the marketplace," he said.

The Food and Drug Administration has defended its actions regarding Vioxx. In a statement issued late Wednesday, the agency cited its "well-documented and long-standing commitment to openness and transparency in its review of marketed drugs."

However, Sen. Charles Grassley, R-Iowa, who chaired the hearing, suggested that an independent board of drug safety might be needed to ensure the safety of medications after they're approved for the market.

"Consumers should not have to second-guess the safety of what's in their medicine cabinet," he said.

Graham told the committee that research indicated that Vioxx caused up to 160,000 heart attacks and strokes.

"If we were talking about Florida or Pennsylvania, 1 percent of the entire state population would have been affected," he said. "I'm sorry to say Sen. Grassley, but 67 percent of the citizens of Des Moines would be affected and, what's worse -- the entire population of every other city in the state of Iowa."

Graham said his research helped to coax the FDA to withdraw a number of drugs including Fen-phen, a weight loss drug, Lotronex, Baycol and Rezulin. "During my career I have recommended the market withdrawal of 12 drugs," he said. "Only two of these remain on the market today."

At the same time, though, he questioned the agency's commitment to removing unsafe drugs from the market, since it would call into question their earlier approval.

Sen. Jeff Bingaman, D-New Mexico, said the problem was within the FDA's own culture.

"The culture within the FDA, being one where the pharmaceutical industry, which the FDA is supposed to regulate, is seen by the FDA as its client instead," he said.

He called on President Bush to appoint a new head for the agency. Lester Crawford has been acting commissioner of the agency.

In the FDA statement, Crawford said the FDA initiated and paid for reviews of Vioxx and antidepressants after those drugs had hit the market. "That is evidence the system is working," Crawford said.

Critics contend the agency ignored risks in both instances, then intimidated its own reviewers when they pointed to safety concerns.

In October, the FDA ordered that all antidepressants carry warnings that they "increase the risk of suicidal thinking and behavior" in children who take them.

The FDA's statement disturbed lawyer Andy Birchfield, who is evaluating thousands of potential cases against Merck on behalf of injured patients.

"How can they see that type of problem and look back and say 'We did everything right'?" Birchfield said. "When they're not willing to recognize mistakes, we have no hope for them voluntarily taking measures to correct the situation."

Crawford's statement did not mention Graham by name, but suggested that the reviewer was a maverick who did not follow agency protocol.

Graham was lead author on a research project that studied the records of almost 1.4 million Kaiser Permanente patients, including 40,405 treated with Pfizer's Celebrex and 26,748 treated with Vioxx. The study found that high doses of Vioxx tripled risks of heart attacks and sudden cardiac death.

Vioxx was responsible for an additional 27,785 deaths from heart ailments from 1999 to 2003, Graham concluded.

He has told congressional investigators that superiors pressured him to soften his conclusions.

Crawford said in his statement that the reviewer "voluntarily chose to revise his conclusions, and he did so, in his own words, "without compromising my deeply held convictions.'" Copyright 2004 The Associated Press. All rights reserved.

Editors Note: The following day, AP issued another version of the story with additional facts.

EXPERT WARNS AGAINST 5 FDA-APPROVED DRUGS
November 19, 2004 - WASHINGTON (AP)

At least five medications now sold to consumers pose such risks that their sale should be limited or stopped, said a government drug reviewer who raised safety questions earlier about the arthritis drug Vioxx.

In testimony before the Senate Finance Committee, Food and Drug Administration reviewer David Graham cited Meridia, Crestor, Accutane, Bextra and Serevent. Drug makers defended the use and safety of their products.

Graham contended the country is "virtually defenseless" against a repeat of the Vioxx debacle. Dr. Steven Galson of the FDA rejected that comment as having "no basis in fact."

Merck & Co. pulled Vioxx from the market on Sept. 30 after a study indicated the popular painkiller doubled the risk of heart attacks and stroke when taken for longer than 18 months.

The committee chairman, Sen. Charles Grassley, suggested an independent board of drug safety may be needed to ensure the safety of medications after FDA approval. An "awful lot of red flags" were raised before Vioxx was withdrawn, said Grassley, R-Iowa., and the agency disdained, rather than listened to, its own reviewers.

Graham contended that FDA has an inherent conflict of interest that triggers "denial, rejection and heat" when safety questions emerge about products it has approved.

In his view, the five most worrisome drugs that demand speedy action:

Meridia, a weight-loss drug. He said the agency should consider whether its benefits outweigh the risks of higher blood pressure and stroke among people taking it. "I don't think Meridia passes that test," Graham said.

Crestor, an anti-cholesterol drug. He said the government should evaluate the occurrence of renal failure and other serious side effects among people taking Crestor. Two of three other statin competitors prevent heart attack and stroke and do not cause renal failure, he said.

Accutane, an acne drug linked to birth defects. Graham said the drug represents a 20-year "regulatory failure" by the FDA and sales should be restricted immediately.

Bextra, a painkiller. Graham said the drug poses the same heart attack and stroke risk as Vioxx. He recommended designing studies to look at the drug's cardiovascular risks.

Serevent, an asthma treatment. He said the drug was shown, with 90 percent certainty in a long-term trial in England, to cause deaths due to asthma. GlaxoSmithKline, told by the FDA to do a large, clinical trial, begged off. "We've got case reports of people dying, clutching their Serevent inhaler," Graham said. "But Serevent is still on the market."

Galson, acting director of the FDA's Center for Drug Evaluation and Research, said the agency already has taken steps to alert consumers to those drugs' safety concerns. That includes heightened warnings for Serevent; tougher

risk-management plans to ensure pregnant women don't use Accutane; and an upcoming advisory committee hearing regarding Bextra.

"Each of these do have special safety issues, but they're under evaluation and we're watching them carefully," Galson said.

Tim Lindberg, a spokesman for Abbott Laboratories, said, "science continues to support the safe use of Meridia to treat obesity."

AstraZeneca PLC, maker of Crestor, has confidence in the drug, spokeswoman Emily Denney said. "To date, the FDA has not given us any indication of a major concern regarding Crestor," she said.

Carolyn Glynn, spokeswoman for Roche Holdings AG, a maker of Accutane, acknowledged that the drug carries risk and said it is reserved for serious cases. "This drug is extremely beneficial as long as it's used safely and appropriately," she said.

Susan Bro, a Pfizer spokeswoman, said Bextra did not increase the risk of serious cardiovascular events in a recent analysis of nearly 8,000 arthritis patients who took the drug from six weeks to 52 weeks. She said Bextra has been found to be safe and effective when used as indicated.

GlaxoSmithKline, maker of Serevent, issued a similar statement about its product.

In his testimony, Graham said the FDA's Office of New Drugs unrealistically maintains a drug is safe unless reviewers establish with 95 percent certainty that it is not.

That rule does not protect consumers, Graham told the Senate committee. "What it does is it protects the drug," he said.

Grassley accused the FDA of attempting to intimidate Graham. Sen. Jeff Bingaman, D-N.M., urged President Bush to name a new leader at the FDA, where Lester Crawford is the acting commissioner.

Graham said he fears continued intimidation.

"I was frightened before," he told reporters after the hearing. "Senior management at the FDA did everything in their power to intimidate me prior to my testimony," he said. Copyright 2004 The Associated Press. All rights reserved

UNSAFE DRUGS - WHO IS RESPONSIBLE?

Barbara K. Hecht, Ph.D., Frederick Hecht, M.D., Medical Editors,
MedicineNet.com

The drug Vioxx (rofecoxib) was approved in 1999 by the FDA. This year, after being on the market for more than 5 years, the maker of Vioxx, Merck, voluntarily withdrew it because the drug appeared to be associated with an increased risk of strokes and heart attacks. How could the whole process of drug

approval in the US have gone so awry? Who is responsible? Major finger pointing has started and a US Senate investigation is underway. Heads are surely going to roll over the Vioxx issue but the question is whose?

Traditionally, most research and development in medicine were done with federal funds under the auspices of academic institutions that prided themselves on being independent and objective. Truth and honor was the aspired code. Then, as funding sources changed, academic institutions and individual researchers developed increasing financial ties to commercial companies. This raises concerns as to who can now serve as an objective overseer and critic of the pharmaceutical industry.

The journal Lancet has just published the results from a cumulative meta-analysis, which show that the unacceptable cardiovascular risks of Vioxx were evident as early as 2000 -- a full 4 years before the drug was finally withdrawn from the market by its manufacturer Merck. The Lancet editorial goes on to say that, "...this points to astonishing failures in Merck's internal systems of post-marketing surveillance, as well as to lethal weaknesses to the US Food and Drug Administration's regulatory oversight."

Her Comment: It seems that the FDA views the pharmaceutical industry as its client -- one that need to be encouraged and nourished. This makes it virtually impossible for the FDA to also regulate and discipline the drug companies. The bottom line is -- to whom does the FDA ultimately owe its allegiance? The drug industry or to the drug consumer? I don't see how the FDA can continue to have it both ways.

His Comment: The FDA is on the hot seat and, in my opinion, that is right where it deserves to be. Americans have a reasonable right to expect the FDA to protect them from undue harm from drugs from the pharmaceutical industry.

In the past, the FDA has had similar problems. For example, in the 1960s the drug thalidomide was on the market in many countries but not yet in the US. The FDA narrowly averted approving thalidomide. Only the efforts of Dr. Helen Taussig, a pioneering pediatric cardiologist at Hopkins, saved the day. She had personally seen children with severe limb malformations from thalidomide in Europe.

FDA, DRUG INDUSTRY UNDER FIRE ON SAFETY
By Amanda Gardner - HealthDay Reporter

THURSDAY, Nov. 18 (HealthDayNews) -- U.S. Food and Drug Administration officials defended their record on drug safety Thursday in the face of attacks from both inside and outside the agency.

Drug giants also found themselves with their feet held to the fire during a Senate Finance Committee hearing.

Dr. David Graham, an FDA reviewer who initially recommended the arthritis drug Vioxx be taken off the market, told committee members that the blockbuster medication may have caused up to 160,000 heart attacks and strokes, or 1 percent of the entire state of Florida.

"I would argue that the FDA, as currently configured, is incapable of

protecting America against another Vioxx," the Associated Press quoted Graham as saying. "We are virtually defenseless."

The drug's maker, Merck & Co., voluntarily withdrew Vioxx in late September after its own studies found an unacceptable cardiovascular risk. The FDA did not force the recall.

Sen. Jeff Bingaman (D-N.M.) pointed to the FDA's own inner workings as the culprit. "The culture within the FDA, being one where the pharmaceutical industry -- which the FDA is supposed to regulate -- is seen by the FDA as its client instead," he said.

Dr. Sandra Kweder, director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, spoke up for her agency. The "FDA worked actively and vigorously with Merck to inform public health professionals of what was known regarding cardiovascular risk with Vioxx, and to pursue further definitive investigations to better define and quantify this risk," she said. "Indeed, the recent study findings disclosed by Merck, leading to its decision to voluntarily withdraw Vioxx from the marketplace, resulted from FDA's vigilance in requiring these long-term outcome trials to address our concerns."

The drug has had a somewhat checkered history. The FDA approved Vioxx in May 1999. In 2002, labeling changes were required to highlight an increased risk in cardiovascular events, especially at the higher, 50-milligram dose.

Raymond Gilmartin, Merck's chairman and CEO, said the company "puts patients first," according to prepared testimony. He told the panel that Merck had conducted many studies on Vioxx both before and after its approval, and the research had found the results at best safe and at worst contradictory. He said he was surprised by the results of the study that led to its withdrawal. "Merck believed wholeheartedly in Vioxx," he said. "In fact, my wife was a user of Vioxx until the day we withdrew it."

Graham was the lead author on one study, which involved almost 1.4 million Kaiser Permanente patients. According to the AP, the study found high doses of Vioxx tripled the risk of heart attacks and sudden cardiac death.

Graham also testified that at least five other drugs are on the market today should be looked at seriously to see whether they should remain there, the AP reported. He cited the acne drug Accutane, made by Hoffmann-La Roche Inc. (Roche); the weight-loss drug Meridia, made by Abbott Labs; the anti-cholesterol drug Crestor, made by AstraZeneca; the pain reliever Bextra, made by Pfizer Pharmaceuticals; and the asthma drug Serevent, made by GlaxoSmithKline.

According to the AP, Graham has testified that his bosses pressured him to downplay his Vioxx conclusions. A statement issued Wednesday by Dr. Lester Crawford, acting commissioner of the FDA, said, "the project officer voluntarily chose to revise his conclusions, and he did so, in his own words, 'without compromising my deeply held convictions.'"

According to Crawford, that "project manager," assumed to be Graham, did not submit a draft report requested by his superiors until after Vioxx had been voluntarily withdrawn from pharmacy shelves. "Senior drug experts in [the] FDA did not have this report or the underlying data prior to that time,"

Crawford said. Crawford also alleged that Graham had submitted his findings to The Lancet without going through the "long-established peer-review and clearance process established for scientific papers submitted by FDA scientists."

Both Crawford and Kweder emphasized that additional steps are being undertaken by the FDA to strengthen its mission to protect the public's health. This included a "five-step plan to strengthen its drug safety program," Kweder pointed out, and three guidance documents designed to "assist pharmaceutical firms in identifying and assessing potential safety risks not only before a drug reaches the market but also after a drug is already on the market."

SOURCES: Nov. 18, 2004, Senate Finance Committee testimony of Sandra Kweder, M.D., deputy director, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; statement from Lester Crawford, D.V.M., Ph.D., acting commissioner, U.S. Food and Drug Administration; Senate Finance Committee statement, Raymond Gilmartin, chairman and CEO, Merck & Co., Inc.; Associated Press

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REPORT: BEXTRA HEART RISKS SIMILAR TO VIOXX

Study shows arthritis drug has high incidence of attacks, stroke
Reuters - Nov. 10, 2004

NEW YORK - The arthritis drug Bextra, made by Pfizer Inc., has shown a high incidence of heart attacks and strokes among patients, according to an American Heart Association study, the New York Times reported on Wednesday.

Bextra is similar to Merck & Co.'s drug Vioxx. Merck voluntarily recalled Vioxx from shelves in late September when a study showed it increased the risk of a cardiac event.

The AHA's preliminary study of Bextra was unveiled on Monday at a meeting in New Orleans, which pooled data from 5,930 patients taking part in 12 trials. It found 2.19 times the number of heart attacks or strokes among patients given Bextra, compared with those given placebos, the Times reported.

"The magnitude of the signal with Bextra is even higher than what we saw in Vioxx. This is a time bomb waiting to go off," Dr. Garret A. FitzGerald, a cardiologist and pharmacologist at the University of Pennsylvania who presented the study, told the Times in an interview.

The newspaper said that the new study of Bextra was not considered to be as persuasive as the trial that led to Vioxx's withdrawal because it was backward-looking and reorganized data that had been presented in other settings.

A spokeswoman for Pfizer told the Times that heart problems with Bextra appeared only in studies involving patients at very high risk of heart disease who were undergoing cardiac surgery -- a detail Pfizer disclosed on Oct. 15.

Other studies of Bextra, involving 8,000 patients with arthritis who were followed for 6 to 52 weeks, found no heart problems, she told the newspaper.

A representative for Pfizer was not immediately available to comment to Reuters early on Wednesday.
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EXPERTS TO DISCUSS ARTHRITIS DRUG RISKS November 12, 2004 - WASHINGTON (AP)

Government experts asked to discuss the safety of arthritis drugs in the same class as Vioxx will get an avalanche of paper, including confidential unpublished trials and their first glimpse at long-term safety studies.

The Food and Drug Administration is asking its arthritis advisory committee members to block out Feb. 16-17 for the session.

Still there's no guarantee that the volume of information will be enough for the panel to answer the most important question: Do the same heart safety concerns that pushed Vioxx off the market apply to related painkillers?

"I don't know whether there is enough data available to say there is a class effect that would be appropriate to generalize to all cox-2 inhibitors about coronary artery disease. But that is what we are all concerned about," said Dr. Gary Stuart Hoffman, a member of the FDA arthritis advisory panel.

"It's possible that the committee will decide there isn't adequate data and additional studies or ongoing studies need to be continued," said Hoffman, chairman of rheumatic and immunologic diseases at the Cleveland Clinic Foundation.

The crucial issue, say leading cox-2 inhibitor researchers, is whether the new painkillers cause blood clots, which trigger heart attacks and strokes. Or do the drugs simply fail to prevent blood clots in people otherwise at risk for heart woes?

"I tell people often that in building a better ... nonsteroidal anti-inflammatory drug, we lost something in the mix. What we lost was the ability to thin the blood, which is what aspirin and like drugs used to do," said Dr. John Cush, another arthritis advisory committee member and chief of rheumatology and clinical immunology at Presbyterian Hospital in Dallas.

The panel also is expected to discuss whether it's ethical to give dummy pills to patients in pain. Placebo-controlled trials are the gold standard. An advisory panel in June dismissed placebos as unethical, even for a few weeks.

According to a presentation this week by the FDA's Office of New Drugs deputy director, government arthritis experts will review all available data about cox-2 inhibitors, including Vioxx, Bextra and Celebrex.

The data includes a placebo-controlled trial involving 3,600 patients that ponders whether Celebrex prevents colon polyps and another that tests the popular painkiller as a possible Alzheimer's treatment, according to Dr. Sandra Kweder's presentation.

Independent safety and monitoring boards for those two Celebrex studies are closely watching for any spike in heart attacks or strokes in the monthly data updates. So far, there has been no repeat of the doubling of risk of such cardiovascular woes that led Merck & Co. to withdraw Vioxx from the market.

In light of a preliminary study that showed Bextra doubled risk of heart attack and stroke in patients with heart disease, the federal advisers will also look at additional studies of that painkiller.

In a press release, Pfizer dismissed the study, presented at the American Heart Association annual meeting, as "unsubstantiated conclusions" that had not been subjected to independent scientific review.

Dr. Curt Furberg, the Wake Forest University School of Medicine professor of public health sciences who did the Bextra analysis, says it points to safety concerns with other painkillers. The FDA has asked Furberg to attend the February meeting.

"With the information on Bextra, you really have to ask does this apply to all of them?" he said.

Patients are asking themselves the same question.

Dr. M. Peter Lance is the principal investigator of a three- to five-year study looking at whether Celebrex -- alone or used with selenium -- can prevent recurrence of colon cancer. Since the Vioxx controversy, Lance has held town hall style meetings to allay concerns among healthy patients enrolled in the trial.

"There have been a lot of questions. We have done everything in our power to be open," said Lance, a professor of medicine at the Arizona Cancer Center, part of the University of Arizona. "So far, we have not seen a significant drop off."

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NEW WORRIES TARNISH ARTHRITIS DRUGS

From Vioxx to Bextra, pain medications are linked to heart risks

The Associated Press - Nov. 11, 2004

WASHINGTON - One by one, arthritis drugs that promised to ease pain without causing ulcers are losing their luster.

In September, Merck & Co. yanked Vioxx from the market when a trial showed that long-term use of the painkiller nearly doubled the risk of heart attack and stroke.

This week, researchers said a preliminary study indicated that Bextra -- another painkiller in the same class -- also more than doubled the risk of heart attacks and strokes among patients with heart disease.

Pfizer, which manufactures Bextra, said researchers made "unsubstantiated conclusions" during their presentation at the annual meeting of the American Heart Association in New Orleans. The company also said the research was "based on information that has not been published in a medical journal or subject to independent scientific review."

The news sent a ripple through the meeting and caused the company's stock to tumble.

Pfizer already has told regulators it will add to its packaging a black box warning, the most strident alert, to warn consumers of a potentially fatal skin reaction linked to Bextra.

Scientists renewed a call for more studies of the painkillers in patients with heart disease, the group likely to suffer the most harm from this class of drugs known as cox-2 inhibitors. For clinicians at Kaiser Permanente, which serves 8.3 million patients, the Bextra study already has prompted discussion of safer alternatives. And some pressured the Food and Drug Administration to halt advertising directed at consumers.

"Arthritis drugs are not saving people's lives. Ironically, they're inducing heart attacks and may be losing people's lives," said Dr. Eric J. Topol, a Cleveland Clinic cardiologist who was among the first to warn about heart woes associated with the new painkillers.

The FDA controls drug marketing directed at consumers, Topol said. "The reality is they could shut that down at any time."

Kathleen Quinn, an FDA spokeswoman, could not say which actions the agency would take.

The FDA doesn't discuss negotiations or talks with companies, she said. "We will be taking a look at the whole class of drugs."

Quinn said the FDA has not accelerated the timing of an upcoming meeting on cox-2 inhibitors, currently planned for mid-February.

What's a bone-weary consumer to do?
Experts give contrasting advice.

The cox-2 drugs were praised for blocking the enzyme that causes the pain and swelling of arthritis inflammation. The drugs, however, were selective in their targets, bypassing the cox-1 enzyme that helps the stomach maintain a protective lining.

John Talley, the chemist who invented the Celebrex and Bextra molecules, said the cox-2 drugs helped people who couldn't tolerate the older generation of painkillers. "I do think these drugs have been a tremendous benefit to folks. And they've been extensively studied," Talley said.

Consumers and doctors agreed, to the tune of 40 million cox-2 inhibitor prescriptions written in the first nine months of 2004, according to IMS Health, a company that tracks drug industry trends.

Whether there is a class wide problem with cox-2 inhibitors, to many, remains debatable.

"I would hate for people to go off these medications on what may turn out to be unfounded rumors," said Dr. Elizabeth A. Tindall, incoming president of the American College of Rheumatology. "Each drug has to be carefully scrutinized. I don't think they've quite done that with Bextra to the extent they did with Vioxx."

Clinicians who are the decision-makers at Kaiser Permanente, however, are alarmed by the Bextra findings and agree that there are safer alternatives.

"These drugs are no better for control of pain than Motrin," said David Campen, Kaiser's medical director of pharmacy operations. "And most people don't enjoy the expensive drug's slight benefit because they're not at risk for stomach ulcers, Campen said."

Topol, of the Cleveland Clinic, said naproxen should be the first anti-inflammatory of choice for people with arthritis who have heart problems.

"If there's even a potential risk for heart disease, that's where you don't want to err in the wrong drug class," Topol said.

To examine heart risk associated with Bextra, a Wake Forest University School of Medicine researcher looked at studies involving some of the most vulnerable patients, those with heart disease undergoing coronary artery bypass graft surgery.

Taking Bextra more than doubled the risk of heart attacks and stroke, compared with dummy pills.

Dr. Curt Furberg, a public health sciences professor at Wake Forest, questioned the timing of Pfizer's release of the data. The company mentioned the study in a statement in October.

"I think it's healthy to get the information out and have a debate. I think it will probably pressure Pfizer to be more open," said Furberg, among the academicians invited to attend the FDA's February session on cox-2 inhibitors.
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I chose not to take Bextra as my alternative to Vioxx. I am discussing alternatives to all cox-2 inhibitors (have been off since 10-1-04) with my Rheumatologist on Wednesday. If you are taking any of these medications, I would suggest that you please talk with your Doctor.

Good Health to All,

Jack Nicholas
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