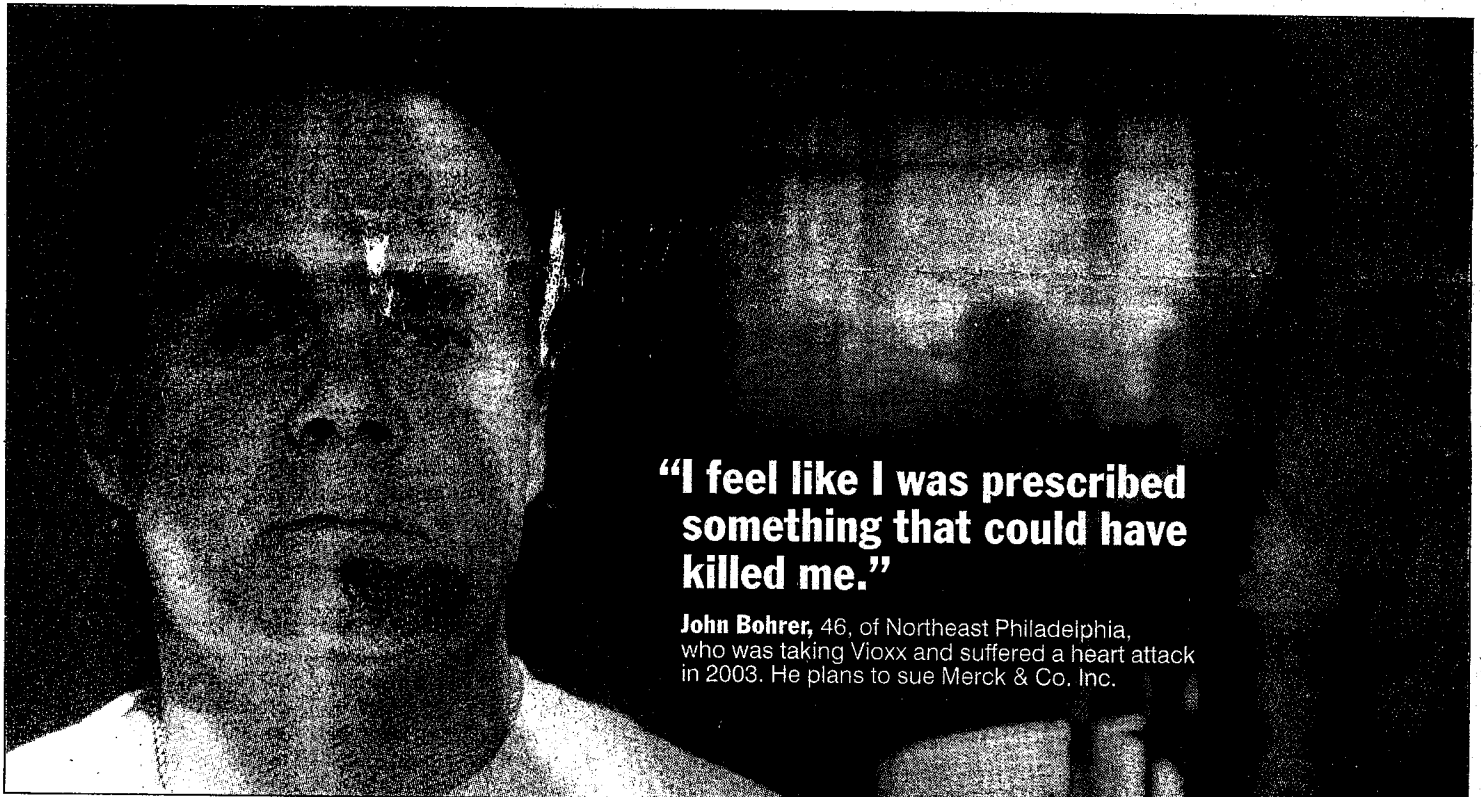


FDA hearings on drugs such as Vioxx, Celebrex and Bextra start tomorrow, but many doctors and patients have already halted use.

Painkillers' ill health



"I feel like I was prescribed something that could have killed me."

John Bohrer, 46, of Northeast Philadelphia, who was taking Vioxx and suffered a heart attack in 2003. He plans to sue Merck & Co. Inc.

REBECCA BARGER / Inquirer Staff Photographer

By Fawn Vrazo, Susan FitzGerald and Thomas Ginsberg
INQUIRER STAFF WRITERS

The federal government will begin hearings tomorrow to determine the fate of some of the most popular painkillers of all time, but many doctors and patients are already turning away from the drugs.

Amid mounting reports questioning the safety of arthritis painkillers known as Cox-2 inhibitors, new figures show that doctors have moved sharply away from prescribing Celebrex and Bextra, the two remaining Cox-2s after the withdrawal of Vioxx in September.

New prescriptions written by primary-care doctors for both drugs have plummeted, even though their maker, Pfizer Inc., defends their safety and efficacy.

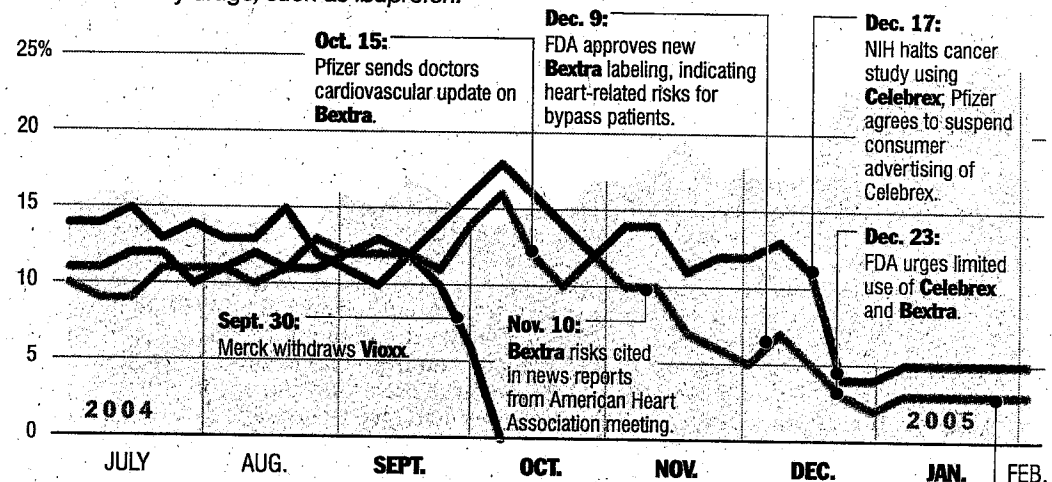
Celebrex accounted for just 5 percent of all new prescriptions in its category of painkillers last week — down from 18 percent in early October, according to ImpactRx Inc., a Mount Laurel firm that tracks the daily prescribing practice. See **PAINKILLERS** on A10

New Prescriptions Plummet

Prescriptions written by U.S. primary-care doctors* for Cox-2 drugs fell in the last four months amid a barrage of critical studies. Doctors are turning to older drugs such as ibuprofen.

— Vioxx — Celebrex — Bextra — Ibuprofen

Data are shown as a percentage of all new prescriptions for Cox-2 and related non steroidal anti-inflammatory drugs, such as ibuprofen.



*Based on daily tracking of 2,000 high-volume doctors nationwide.

SOURCE: ImpactRx Inc.

MIKE PLACENTRA / Inquirer Staff Artist

Jan. 28: Kaiser Permanente says it will stop prescribing Bextra.

"I can't go on living life this," said Paul Dolhancryk, 55, a plumber from Delaware County, who will undergo surgery in April to replace both arthritic knees. He had hoped to put off the surgery with use of Celebrex, but stopped taking the drug after hearing of safety concerns.



BOB WILLIAMS / Inquirer Suburban Staff

Many have halted use of disputed painkillers

PAINKILLERS from A1 tices of doctors. Bextra prescriptions dropped from 16 percent to 3 percent as doctors moved toward older drugs, such as ibuprofen.

"This is a huge decline," said Nancy Lurker, ImpactRx's chief executive officer. New prescriptions are a predictor of a drug's future use, she said.

The troubles facing Cox-2 drugs show what can happen when drugs are approved by the Food and Drug Administration and become blockbusters before their health downsides are fully understood. Already, millions of people were taking the Cox-2 drugs for nonlethal pain when research began showing that they could cause deadly heart attacks and strokes.

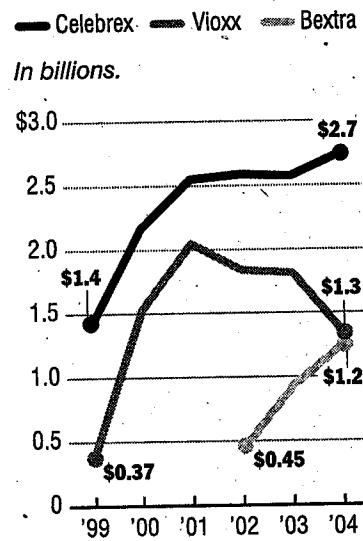
Garret FitzGerald, a University of Pennsylvania researcher, called it a "tragedy of blockbuster overreach." Painkillers that could help some patients became overused, he said.

The Cox-2 controversy has left doctors, patients and the public in "an acute confusional state," wrote Eric Topol, a researcher at the Cleveland Clinic Foundation. Some are abandoning the pills, others fear they have been harmed and are lining up to sue, while still others continue to take their pills warily.

Elaine Stern, 48, a nurse from Narberth, has replaced Bextra with ibuprofen, though it does not work as well for the arthri-

Cox-2 Sales

U.S. sales of Cox-2 painkillers grew to \$5.3 billion in 2004, with the approval of Celebrex in late 1998, Vioxx in 1999 and Bextra in late 2001.



SOURCE: IMS Health

MIKE PLACENTRA / Inquirer Staff Artist

longer tolerate their arthritic knees. Still, Lonner has stopped prescribing the drugs until more is known.

Advisory panels' options

At the three-day hearing starting tomorrow, two combined FDA advisory panels made up of 20 arthritis and drug-risk experts will review the evidence on Cox-2 and older drugs such

Pushed by marketing that touted a painfree, happy lifestyle, Cox-2 sales more than tripled in five years.

Drug companies have never said the drugs work any better at reducing pain than traditional and cheaper drugs, such as ibuprofen. And only two, Vioxx and Prexige, the latter sold only overseas, reduce bleeding, said Topol, a Cox-2 expert.

Cox-2 drugs are "a triumph of marketing ... testament to the fact that you can persuade people to spend more money for almost anything if you market it right," said Marcia Angell, former editor of the New England Journal of Medicine.

Some researchers believe Cox-2 drugs increase the risk of heart disease because they reduce prostacyclin, a heart-protecting fat. With less prostacyclin to protect arteries, people may become more prone to high blood pressure, heart attack and stroke, said Penn's FitzGerald, who in 1998 raised concerns about the drugs' downsides.

FitzGerald believes there is still a place for the drugs in a smaller pool of patients.

"I think the challenge here is to conserve the benefit, manage the risk," he said. "I think it would be a real mistake to withdraw the class."

It was the withdrawal of blockbuster Vioxx that put the spotlight on the FDA, accused by critics of reacting timidly to heart-disease concerns.

