

## Charting health's 'oops' factor

As interest in new studies quickly propels medical claims into the mainstream, reversals and confusion ensue.

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Karen Wilcox polices her health, zealously following a diet for diabetics and taking her prescribed cholesterol and blood pressure drugs.

But that doesn't keep her from wondering whether she and her doctor s are making the right choices.

"They're all supposed to be safe medications," she said. "I hope they are."

Wilcox heard about Vioxx, a popular new arthritis drug, being taken off the market this fall because it increases the risk of heart attack and stroke.

Vioxx isn't the only recent reversal. Last month, top federal scientists admitted a stunning error. They overestimated the number of deaths caused by obesity in a report released with great fanfare this spring.

The list goes on: warnings on antidepressants about suicide risks. The war over whether Americans are getting the right advice on fat, calories and carbs. The shocker that hormone therapy increases some health risks instead of easing them.

It's enough to make a patient wonder if doctors can get it right.

"Sometimes I personally feel the doctors aren't aware of a lot of things," said Wilcox, 53, who lives in Tarpon Springs.

It's not just patients who wonder. The National Institutes of Health will sponsor a forum on medical studies next month, featuring prominent scientists from around the country. The punch line of the title: "Why Do We Sometimes Get It Wrong?"

There are myriad reasons for changing course, health experts say. The media trumpets medical news louder and faster these days, sometimes before the complete picture is known. Drug companies have gotten too much power to bring medicines to market with too little study, say a growing number of doctors. And certain types of flaws pop up again and again in medical studies to skew the results. Despite all the genuine advances in treatment and technology, such mistakes can leave medical consumers feeling confused or angry. They don't know whose advice to follow about their own health.

"It's bad news when medicine or public health jumps the gun," said Arthur Levin, director of the

Center for Medical Consumers, an advocacy group in New York. "Obesity is still a tremendous problem in the U.S., but it doesn't help advance the cause of dealing with it when you misrepresent the evidence and overstate the case.

"Now people will say, 'Maybe I can just continue eating these massive portions. Maybe being 50 pounds overweight isn't so bad.' Every time you shake people's faith, it may be bad for people's health."

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Medical reversals are not exactly a new problem.

"Forever, we have said one thing one day and then, 'Oops. We changed our mind,'" said Donna J. Petersen, dean of the University of South Florida College of Public Health.

TV ads even used to feature doctors promoting one cigarette brand over another, she said.

Science has corrected itself as knowledge evolves, said Dr. Paul Wallach, associate dean for curriculum and medical education at USF's College of Medicine. After all, everyone once thought the Earth was flat.

"The difference is the speed at which it happens," Wallach said.

It used to be that few people outside medicine were interested in the latest study. And when a new one came out, Wallach said, the doctors reading it knew not to take too much stock in the result.

But now a study with a provocative result can make headlines around the country.

And public attention goes not just to studies that are published in medical journals, where they have been reviewed by other scientists. The media also is reporting on studies at medical meetings, even though those results are often preliminary.

"Meetings get a lot of coverage now," said Dr. Lisa Schwartz, associate professor at Dartmouth Medical School. "Some of the meetings are more focused on generating press coverage than on peer review."

But the early results often turn out to be wrong.

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Tim Jackson was relieved when the news about Vioxx came out. He had taken the drug, but stopped on his own before it came off the market.

"I was sort of thankful," said Jackson, a New York resident who often visits Tampa Bay on

business. "Very thankful, as a matter of fact."

But Jackson, 61, wonders why he gets the prescriptions he does. Do his drugs benefit him or his doctor and the drug companies?

"I've become suspicious in my old age," he said. "I think it's all about money - money for the drug companies."

The Vioxx recall tapped into a well of distrust from patients. But it also prompted stinging criticisms of the FDA from scientists, who say the federal agency has become too close to the drug companies it's supposed to regulate.

At a Senate hearing last month, a veteran FDA official accused the agency of not doing enough to police safety, and that five other well-known drugs need to be withdrawn or restricted because of dangerous side effects.

Others say patients need to ask themselves whether they want too much. Many patients wound up taking Vioxx for everyday aches and pains, not just for arthritis, said Dr. Stephen Klasko, USF's vice president of health sciences and medical school dean. Drugs such as Viagra and Botox, which make lives more fun rather than saving them, are booming.

"I have women coming in wanting Viagra prescriptions for their husbands as Christmas presents," said Klasko, who says no to such requests. "One of the things I worry about is that people are looking to drugs at an unprecedented rate to solve all their problems. Really healthy people are looking to medicine to make them perfect."

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Next month's NIH conference is designed to look at how scientists make errors in research studies. Dr. Elias Zerhouni, NIH director, wanted to bring together scientists from different fields to talk about avoiding such errors, said Dr. Barnett Kramer, associate director for disease prevention at the NIH.

"We make assumptions that aren't supported strongly enough by the data, and then we sometimes get it wrong," Kramer said.

He can reel off examples. Doctors performed too many radical mastectomies, gave drugs that didn't help patients' heart conditions, believed a certain vitamin would lower the risk of lung cancer - all until controlled trials proved them wrong.

Such reversals may involve different diseases, but they often have the same underlying problems.

Scientists assume things are true that actually haven't been proved. They decide that since two things occur together, one causes the other. Scientists watched thousands of women receiving hormone therapy and saw they had a lower risk of developing heart disease. They believed the

hormones must provide protection.

But when the Women's Health Initiative set up a controlled trial, and randomly assigned women to take hormones or not, the trial found the opposite: hormones actually increased the risk. Many doctors now believe that the women in the earlier studies, who chose to take hormones rather than being assigned to do so, tended to be healthier to start with.

In some ways, Kramer said, it's easier to make such mistakes now. Supercomputers can spot patterns in data, tempting scientists to jump to conclusions about why. Advancing knowledge of biology can prompt scientists to assume they know more than what controlled studies have proved.

"Human nature hasn't changed," Kramer said. "The tendency to make assumptions and go with them hasn't changed."

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In the end, patients like Wilcox try to watch out for their own health. She quizzes her doctor about possible side effects of new medicines and what she should avoid when she starts a new drug.

She's tried Atkins and she's careful about eating right for her diabetes. When she went shopping last week, she searched the mall food court for a healthy option - grilled chicken and steamed veggies.

But the drumbeat of conflicting health advice can still make such choices hard.

"It is confusing," Wilcox said. "I work at it to understand."