

## AstraZeneca e-mails show debate on Seroquel risks

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(AP) -- Marketing executives at British drugmaker AstraZeneca PLC for years blocked efforts by company scientists to raise concerns antipsychotic drug Seroquel caused weight gain and other problems, saying that would harm sales, plaintiff lawyers say.

They say their claim is backed by internal documents released Wednesday as part of ongoing lawsuits against the company brought by patients alleging they were harmed by the blockbuster drug for schizophrenia and bipolar disorder.

Some of the internal e-mails and other documents, released late Tuesday to The Associated Press, show efforts to keep public information about Seroquel positive amid a spirited debate between the company's scientists and its marketing executives.

Ed Blizzard, a Houston attorney whose firm is helping to represent about 6,000 Seroquel plaintiffs, said data showing Seroquel was "not very effective" and had serious side effects "was either spun or skewed or outright concealed."

AstraZeneca spokesman Tony Jewell said that since the drug was approved in late 1997, the label or detailed package insert has stated that diabetes, [high blood sugar](#) and [weight gain](#) have been observed in patients in clinical studies.

He noted that the U.S. [Food and Drug Administration](#) in the past several

years has approved Seroquel as safe for new uses - bipolar mania, then bipolar depression and then an extended-release version.

Other internal e-mails and planning documents suggest the company pondered uses for which Seroquel was not approved by the Food and Drug Administration, including in [dementia](#) patients, though none of the documents indicate the company actually marketed the drug for those uses.

Doctors are allowed to prescribe drugs for unapproved uses, but drugmakers can't promote them for those uses.

A strategic plan dated 2000 suggested a "key success factor" would be to "broaden Seroquel use on and off label," specifically targeting educational programs "to share off label data."

Jewell said in an e-mailed statement that the documents do not recommend "inappropriate promotion" of the drug and refer to intentions to seek approval for additional indications. The statement also points out physicians often prescribe atypical antipsychotics like Seroquel off-label.

Blizzard challenged that in a conference call. "The only way they can broaden its use off-label is by marketing it to physicians," he said.

Seroquel was AstraZeneca's No. 2 drug in sales last year, with revenue of \$4.5 billion.

Blizzard said U.S. District Judge Anne C. Conway in Orlando, Fla., who has been coordinating pretrial details of nearly 6,000 federal Seroquel lawsuits, recently ordered them returned to the federal courts where they were filed.

First, she is settling issues such as which of the many documents plaintiff lawyers obtained through pretrial discovery should be available for use in those trials and open to the public. AstraZeneca has claimed its documents are confidential but agreed to release hundreds in February and 400 more Wednesday.

In a chain of e-mails in one document, a scientific safety committee in June 2000 recommended removing "limited" before the words "weight gain" in the list of Seroquel side effects, because many patients gained significant weight.

Marketing staff suggested trying other explanations, such as whether patients took other drugs that could be blamed. One marketing executive, Medical Affairs Manager Richard Owen, then wrote that such a change "is potentially damaging to Seroquel."

The change in the drug's label was finally made in 2002. That was after Barry Arnold, the vice president for clinical drug safety, complained repeatedly to the physician in charge of Seroquel drug safety about "Commercial (executives) having such an influence."

Yet soon after the label change, AstraZeneca trademarked the term "weight-neutral" as a slogan for Seroquel, Blizzard noted. He said data showed about one-quarter of patients taking Seroquel increased their weight by more than 7 percent.

Later in 2002, Simon Hagger, global brand manager for Seroquel, e-mailed nearly 20 marketing staffers to say "we are under clear instruction from the highest level within AstraZeneca at this time not to discuss details surrounding trial 41," outside the company. That patient study, concluded that year, found elevated levels of blood sugar.

AstraZeneca has been trying to get Seroquel approved in the U.S. for

treating patients with depression and anxiety disorder, a group that includes more than 20 million people.

In April, a panel of FDA scientific advisers said Seroquel's side effects, including weight gain, high blood sugar and potential heart problems, were too troubling to make it a first choice against depression or anxiety. On a split vote, the panel said Seroquel could be used as an added therapy for patients taking other medicines but not getting relief from depression. The FDA has yet to issue a final ruling.

"Going back almost 20 years, AstraZeneca has conducted 118 studies on the safety and efficacy of Seroquel," company spokesman Jewell said.

AstraZeneca faces roughly 15,000 lawsuits over Seroquel, about 60 percent of them in state courts.

AstraZeneca's U.S.-traded shares rose 75 cents to \$41.05 Wednesday morning.

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