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Suicide Warnings for 2 Anti-Smoking Drugs

By [GARDINER HARRIS](#) and [DUFF WILSON](#)

WASHINGTON — Federal drug regulators warned Wednesday that patients taking two popular drugs to stop smoking should be watched closely for signs of serious mental illness, as reports mount of suicides among the drugs' users.

But officials emphasized that fear should not stop patients from taking the smoking-cessation medicines, Chantix, made by [Pfizer](#), and Zyban, made by [GlaxoSmithKline](#), which also sells it under the brand name Wellbutrin, for depression.

"Stopping smoking is a goal we should all be working towards," said Dr. Curtis J. Rosebraugh, director of a drug evaluation office at the [Food and Drug Administration](#). "We don't want to scare people off from trying a medication that could help them achieve this goal. You should just be careful."

Pfizer will add a so-called black box warning — the F.D.A.'s most serious caution — to the packaging information for Chantix.

The Pfizer drug, introduced in 2006, has about 90 percent of the market for prescription smoking-cessation drugs, according to [IMS Health](#), a health care information company. Even so, Chantix sales — \$846 million in 2008 — had been less than Pfizer had hoped because of previous warnings of its side effects.

Glaxo will expand its existing black box warning on Wellbutrin, citing suicidal thoughts by patients who use it for depression, to include Zyban, which has had only modest sales in the smoking cessation market.

Both companies will also be required to conduct clinical trials to assess the mental health risks associated with the drugs' uses. Pfizer is already enrolling schizophrenia patients in a trial.

Because smokers and people trying to quit are statistically more likely to be depressed and suicidal, officials for both companies said it was difficult to identify the specific impact of the drugs on those risks. "Nicotine withdrawal itself can be very difficult for people to endure," Dr. Steve Romano, a Pfizer vice president, said Wednesday.

Analysts said the F.D.A. action would have little effect on sales because of previous indications of the drugs' psychiatric risks.

"I think the market and physicians have already been sensitized to this," said Catherine J. Arnold, an analyst for [Credit Suisse](#).

"I'm not panicking," said Jami Rubin, an analyst for [Goldman Sachs](#), "Sales are already down a lot. It is and will remain a small niche product."

Chantix had already experienced a slight sales decline last year from the \$883 million achieved in 2007. And this year's first-quarter sales of \$177 million were 36 percent below the corresponding period last year.

Ms. Arnold predicted that sales would probably continue falling to around \$740 million for all of 2009, but that demand for smoking-cessation treatments would enable it to grow modestly after that — to perhaps half of the \$2 billion in annual sales Pfizer had originally hoped for the drug.

European officials first alerted the F.D.A. in 2007 to problems associated with Chantix. In September of that year, Jeffrey Carter Albrecht, a keyboard player from the pop-music group Edie Brickell and New Bohemians, was killed by a neighbor who had complained that Mr. Albrecht was banging on his door, ranting. Mr. Albrecht's girlfriend blamed Chantix, which she said had made him hostile.

The widely publicized event led to a cascade of similar reports and scrutiny by F.D.A. safety officials, who have now received 98 reports of suicides and 188 reports of suicide attempts among those taking Chantix.

As officials looked more closely, they found to their surprise that Zyban has similar associated risks. The agency received 14 reports of suicides and 17 reports of suicide attempts among those taking Zyban.

No one knows why the drugs are associated with mental problems. In some cases, patients could be experiencing nicotine withdrawal, but some of the reports involved patients who had yet to stop smoking. And many of the events happened just as patients began or stopped therapy, officials said.

"If this is nicotine withdrawal, it really doesn't matter," said Dr. Robert Temple, an F.D.A. official. "You need to pay attention to them."

The agency's action requires the drugs' makers to mention the risk of suicide in advertising, and it prevents the companies from using "reminder" ads, during which consumers are encouraged to talk to their doctors about a health issue but the product's name is not mentioned.

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