

FDA weighs removing bolded warning from Chantix

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(AP)—The Food and Drug Administration will ask a panel of experts later this week whether a bold-letter warning on the anti-smoking drug Chantix should be removed based on company-supported evidence that the drug does not cause suicidal behavior.

Pfizer's twice-a-day tablet has carried the FDA strongest warning label, known as a black box, since 2009 because of reports of suicidality, hostility and depression. But the New York drugmaker points to recent studies and analyses suggesting there is no difference in <u>psychiatric problems</u> between people taking Chantix and other smoking-cessation aids.

Still, the FDA notes in briefing documents posted online that there is little precedent for removing a boxed warning. And the agency will ask its panel of outside efforts whether more data is needed before consider removing the warning language.

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