

# FDA APPROVES SALE OF PRESCRIPTION PLACEBO

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WASHINGTON, DC—After more than four decades of testing in tandem with other drugs, placebo gained approval for prescription use from the Food and Drug Administration Monday.

"For years, scientists have been aware of the effectiveness of placebo in treating a surprisingly wide range of conditions," said Dr. Jonathan Bergen of the FDA's Center for Drug Evaluation and Research. "It was time to provide doctors with this often highly effective option."

In its most common form, placebo is a white, crystalline substance of a sandy consistency, obtained from the evaporated juice of the *Saccharum officinarum* plant. The FDA has approved placebo in doses ranging from 1 to 40,000 milligrams.

The long-awaited approval will allow pharmaceutical companies to market placebo in pill and liquid form. Eleven major drug companies have developed placebo tablets, the first of which, AstraZeneca's Sucrosa, hits shelves Sept. 24.

"We couldn't be more thrilled to finally get this wonder drug out of the labs and into consumers' medicine cabinets," said Tami Erickson, a spokeswoman for AstraZeneca. "Studies show placebo to be effective in the treatment of many ailments and disorders, ranging from lower-back pain to erectile dysfunction to nausea."

Pain-sufferers like Margerite Kohler, who participated in a Sucrosa study in March, welcomed the FDA's approval.

"For years, I battled with strange headaches that surfaced during times of stress," Kohler said. "Doctors repeatedly turned me away empty-handed, or suggested that I try an over-the-counter pain reliever—as if that would be strong enough. Finally, I heard about Sucrosa. They said, 'This will work,' and it worked. The headaches are gone."

Researchers diagnosed Kohler with Random Occasional Nonspecific Pain and Discomfort Disorder (RONPDD), a minor but surprisingly pervasive medical condition that strikes otherwise healthy adults. RONPDD is only one of many disorders for which placebo has proven effective, Bergen said.

"Placebo has been successful in the treatment of everything from lower-back pain to erectile dysfunction to nausea," Bergen said. "That's the beauty, and the mystery, of placebo. It's all-purpose. Think of it like aspirin, but without any of the analgesic properties."

The FDA is expected to approve the drug for a wide range of mood disorders later this year. According

to Bergen, initial research has shown placebo to be effective in the treatment of bipolar disorder, depression, dysthymia, panic disorder, post traumatic stress disorder, seasonal affective disorder, and stress.

As industry analysts predict the drug's sales will top \$25 billion in the first year, the approval of placebo is expected to unleash one of the pharmaceutical industry's biggest marketing battles to date.

GlaxoSmithKline expects to have two versions of placebo on the shelves in late December. One, a 40-milligram pill called Appeasor, will be marketed to patients 55 and over, while the other, Inertra, designed for middle-aged women, is a liquid that comes in a 355-milliliter can, and is cola-flavored. Eli Lilly plans a \$3 million marketing campaign for its 400-milligram tablet, Pacifex.

"All placebos are not the same," Eli Lilly spokesman Giles French said. "Pacifex is the only placebo that's green and shaped like a triangle. Pacifex: A doctor gave it to you."

Despite such ringing endorsements, some members of the medical community have spoken out against placebo's approval, saying that the drug's wide range of side effects is a cause for concern.

"Yes, placebo has benefits, but studies link it to a hundred different side effects, from lower-back pain to erectile dysfunction to nausea," drug researcher Patrick Wheeler said. "Placebo wreaked havoc all over the body, with no rhyme or reason. Basically, whichever side effects were included on the questionnaire, we found in research subjects."

Added Wheeler: "We must not introduce placebo to the public until we pinpoint exactly how and why it works. The drug never should have advanced beyond the stage of animal testing, which, for some reason, was totally ineffective in determining its effectiveness."

In spite of the confusing data, drug makers say placebo is safe. "The only side effect consistent in all test subjects was a negligible one—an almost imperceptible elevation in blood-glucose levels," French said. "It's unfair to the American people to withhold a drug so many of them desperately think they need."

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