

FDA panel: Not enough data to OK "abusedeterrent" opioid

July 26 2017, by Linda A. Johnson

A panel of Food and Drug Administration advisers voted against approving a new opioid painkiller with a unique feature for deterring abuse: It releases a deep-blue dye if someone tries to get high by crushing, chewing or snorting pills.

Panelists voted overwhelmingly against approving Intellipharmaceutics International's generic version of extended-release Oxycontin, a key <u>drug</u> in the U.S. <u>opioid</u> addiction epidemic. The FDA usually follows its advisers' advice.

Doctors and scientists raised many concerns about the dye's safety for intended patients, and its effectiveness in deterring opioid abusers. Most said the company hadn't done enough studies of the drug.

Some suggested blue stains around the mouth or nose from trying to abuse the drug could become popular among addicts. Others said the dye's "Scarlet Letter" shaming approach was insensitive.

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