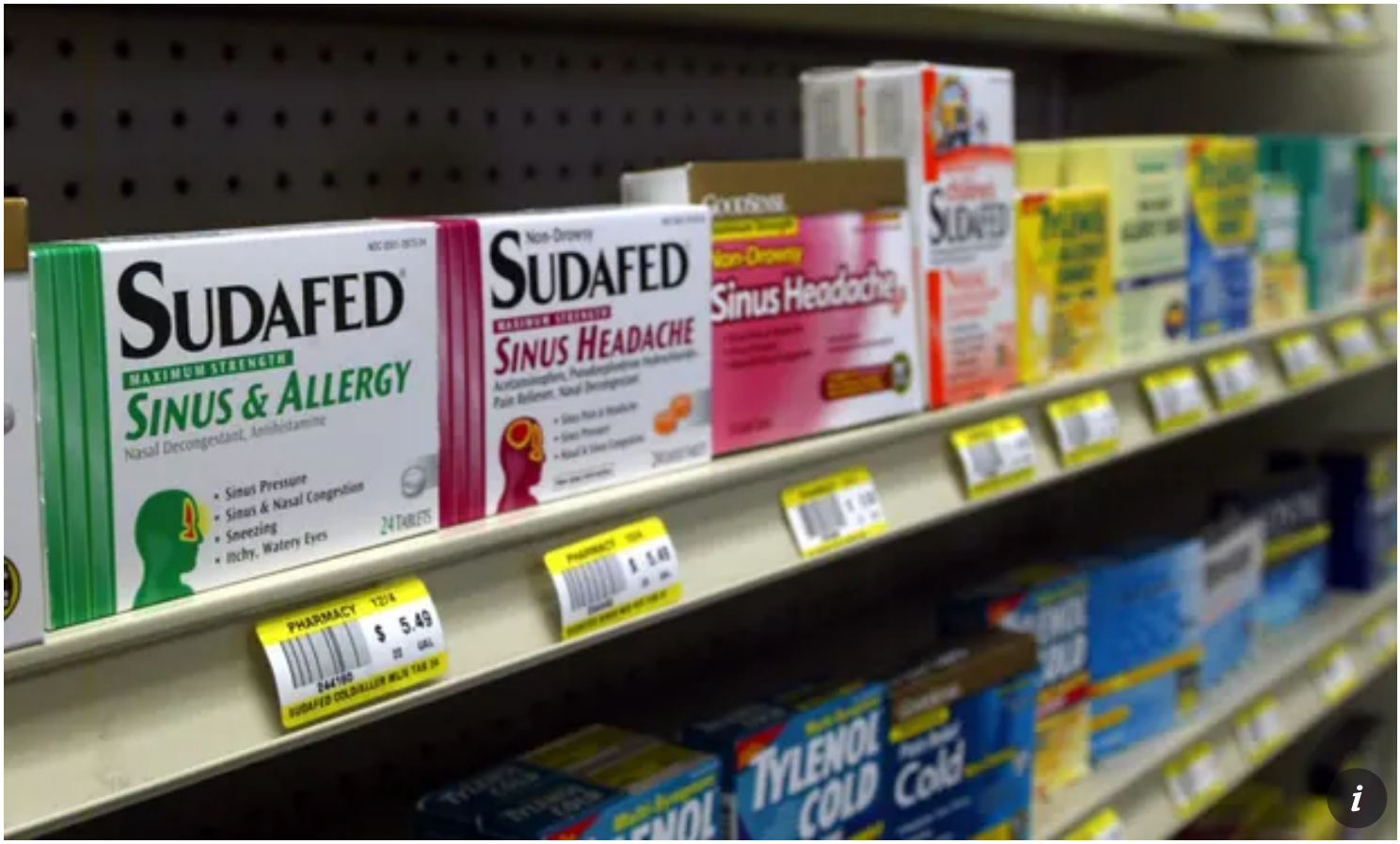

US news

Decongestant ingredient in popular products does not work, FDA concludes

Advisory panel reviewed studies of phenylephrine, an active ingredient in Benadryl, Mucinex, Sudafed PE and Tylenol

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Tue 12 Sep 2023 17.18 EDT

A common decongestant ingredient of numerous popular over-the-counter cold and flu remedies does not work, the Food and Drug Administration (FDA) concluded on Tuesday.

An advisory panel spent two days looking at studies of phenylephrine, an active ingredient in well-known medicines including Benadryl, Mucinex, Sudafed PE and Tylenol, and reported to the FDA that it is no more effective than a placebo.

The announcement raises the likelihood of the medicines disappearing from shelves this fall while manufacturers scramble to formulate alternative formulas without it, according to the New York Times, which first reported the development.

The FDA must now decide whether to set up a vote to ban the ingredient altogether.

“I think we clearly have better options in the over-the-counter space to help our patients, and the studies do not support that this is an effective drug,” said Maria Coyle, chair of the advisory panel and associate professor of pharmacy at Ohio State University.

The Guardian has contacted Reckitt, the parent company of Mucinex, and Johnson & Johnson, which manufactures Benadryl, Sudafed and Tylenol, for comment.

The FDA, the Times said, insists that phenylephrine, which is present in both adult and children’s versions of cold medicines, is safe to take. And it is still considered effective if taken as a nasal spray, if used in surgery, or to dilate the eyes.

But multiple studies assessed by the FDA’s non-prescription drugs advisory committee found that it is destroyed in the gut, making it useless when taken orally, whether in tablet, capsule or liquid form.

Concerns over its effectiveness surfaced publicly in 2007, when University of Florida pharmacists urged the FDA to take the drug off the market. “The bottom line is quality research has told the true story of phenylephrine,” Dr Leslie Hendeles, one of the original research group, and now professor emeritus at the university, told the Times on Tuesday.

In a statement released immediately before the FDA panel’s meeting, the Consumer Healthcare Products Association (CHPA), which represents drug manufacturers, argued that the ingredient was effective, citing a survey that claimed 83% of Americans found it helped symptoms, and insisting it played “a critical role in public health”.

“Oral phenylephrine has been relied upon as a beneficial nasal decongestant by American families for decades, and FDA has repeatedly concluded the ingredient is safe and effective,” the statement said.

“This determination, established by multiple double-blind, placebo-controlled trials and supported by two previous FDA advisory panels, has also been validated by a meta-analysis of relevant clinical studies.”

The CHPA also warned against “significantly negative unintended consequences” of removing products containing phenylephrine from the market.

Consumers, the group said, would be less likely to spend time seeking medical advice from doctors or pharmacists if they were unable to easily purchase an over-the-counter remedy.

And it notes that products containing the alternative decongestant medicine pseudoephedrine are less readily available because they are subject to purchase restrictions in many states, largely because it can be illegally processed into methamphetamine.

“This poses unequal burdens for consumers living in areas with limited access to traditional retail options based on geography, schedules, or socioeconomic factors,” it said.

“Simply put, the burdens created from decreased choice and availability of these products would be placed directly onto consumers and an already-strained US healthcare system.”

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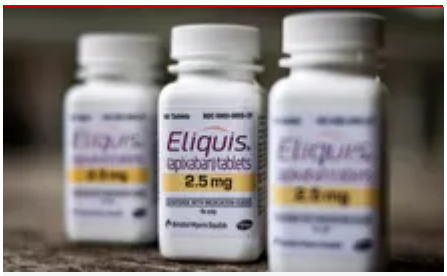

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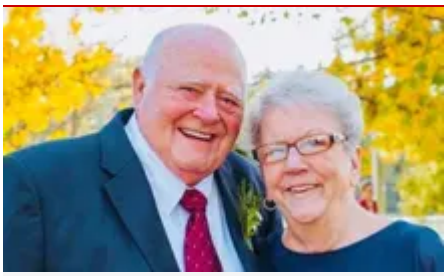

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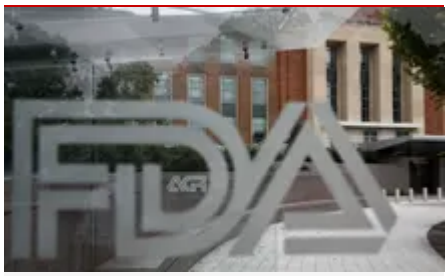

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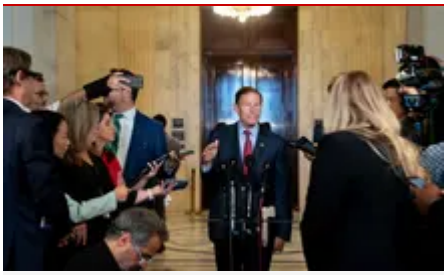

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