FDA warns of botulism with unapproved use of Botox

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(AP) -- Health officials warned doctors and patients Thursday about potentially deadly risks of using the anti-wrinkle drug Botox and similar drugs for unapproved uses to treat certain types of muscle spasms.

The Food and Drug Administration said Botox and two other injections carry risks of rare botulism symptoms, particularly when given to children to help relax uncontrollable muscle movements.

While Botox is best known for clearing wrinkles by paralyzing facial muscles, the botulin-based drug also is widely used for muscle-spasm conditions. In rare cases, the toxin can spread beyond the injection site to other parts of the body, paralyzing or weakening the muscles used for breathing and swallowing, a potentially fatal side effect. Signs of botulism can appear just hours after injection and include difficulty swallowing or breathing, slurred speech and muscle weakness.

Manufacturers Allergan, Solstice Neurosciences and Medicis will have to bolster warnings on their products and collect additional safety data. The companies will also be legally required to distribute medication pamphlets about the risks to patients.

The agency began investigating the problems last year at the behest of Public Citizen, a consumer advocacy group.

Public Citizen's Dr. Sidney Wolfe said the agency's response was appropriate, but he complained it came more than a year after his group

brought the problems to light.

"The response is mainly adequate but it is way too late for a lot of people who have been injured or even died while taking these drugs," Wolfe said. "There's no reason they had to wait this long."

In a response posted online Thursday to the group's petition, FDA said it uncovered 225 cases of botulism related to the drugs during its analysis and 17 deaths for which its analysis seemed to suggest botulism as a cause. However, the agency said it was impossible to definitively say the drug caused the deaths.

FDA said most of the reports of hospitalization and death were in children with cerebral palsy taking the drugs for spasticity in their legs. That use is not approved in the U.S., though regulators said it is still legitimate.

"These are patients who have a significant disability because of spasticity and these products provide a very effective means to relieve that significant problem," said Acting Deputy Director Dr. Ellis Unger. "We don't want to discourage that use, but people need to understand the risks involved."

Unger said the agency's review looked at reports stretching back to 1989, when Botox was first approved. He said it's likely off-label use of the drug has increased since then, though the agency does not track prescribing patterns.

The majority of drug-related problems seen in adults came after treatment for muscle spasms and cervical dystonia, a type of neck contraction for which the drugs are approved. Some of those patients had to be hospitalized and put on mechanical ventilation in order to breath. While the agency said it has received reports of botulism

symptoms in patients taking the drug for anti-wrinkle uses, none of those cases have been confirmed.

Unger noted that patients getting injections for cosmetic use receive much smaller doses than those treated for spasms.

"You're basically trying to relax the muscle, and the amount you need depends on the size of the muscle," Unger said, adding, "So a muscle in the leg can be quite large and requires a fair amount of the product."

Botox and competitors Myobloc, from Solstice Neurosciences, and Dysport, from Medicis, will carry a boxed warning, the most serious type the agency enforces.

The new labeling urges physicians to tell patients about the risks of botulin-based drugs and to seek medical care if they develop any symptoms.

Irvine, Calif.-based Allergan said it would cooperate with the agency and stressed that the problems reported by FDA are rare.

"Botox has been marketed in the United States for nearly 20 years, its safety and efficacy profile are well understood, and reports of suspected distant spread have been rare," the company said in a statement.

FDA's action came the same day it approved Dysport, the third botulin-based drug now on the U.S. market. It joins Botox in the market for treating wrinkle lines on the forehead. Medicis' drug is not approved for cosmetic uses.

Regulators stressed that physicians cannot interchange the products.

"By switching patients from one drug to the other there's a risk of

underdosing, and more importantly, overdosing," said Unger.

Shares of Allergan fell 96 cents, or 2 percent, to $46.31 in midday trading while Medicis Pharmaceutical Corp. rose $1.95, or 14 percent, to $15.52.