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Botox Linked to 16 Deaths

Botox and Myobloc have been associated with 16 deaths, four of them in children, and with 180 adverse effects that occurred after the drug spread to vital organs, according to Public Citizen, a health advocacy group.

The drug, a neurotoxin that is used to relax muscles, should come with a far stronger warning label and patients should be given a letter detailing its risks, the group said in a petition filed Thursday with the Food and Drug Administration.

The drugs' manufacturers and others have reported to the F.D.A. 658 cases of problems associated with Botox and Myobloc, Public Citizen said. The serious adverse effects include muscle weakness, dysphagia (difficulty swallowing), and aspiration pneumonia, the latter sometimes resulting in death.

Executives at Allergan, the maker of Botox, issued a statement saying that adverse reactions were rare and because many patients who get the drug are seriously ill, it is not proved that Botox caused the reactions. My understanding is Public Citizen is requesting a stronger warning label, not a recall. So, I find it interesting that Allergan is taking such a defensive stance on this issue. I would think if there's the potential to improve public safety for one of your products, as a good corporate citizen, you'd jump on it.

What about Botox that is administered at a spa? The most commonly known use of Botox is as a cosmetic procedure to reduce wrinkles usually between the eyebrows or around the eyes. Often, your injection is given by a nurse and there isn't even a doctor on the premises. Do these consumers know of the possible side effects? There has been at least one death associated with cosmetic usage. The dosage for wrinkle treatment is much lower than the dosage used for treating cervical dystonia, a painful knotting of neck muscles to relieve debilitating pain. So, theoretically, the risk to cosmetic users is relatively low. However, as an educated consumer, wouldn't you like to know what the possible side effects are before your treatment?

The deaths might have been prevented had patients been adequately warned of the possible dangers, said Dr. Sidney M. Wolfe, director of Public Citizen's health research group. The labels for Botox and Myobloc mention the issue but not prominently enough, Dr. Wolfe said.

"Nobody should die from the medical use of Botox," Dr. Wolfe said. "The fact that they are shows that patients don't have a clue about these problems."

I don't think it's too much to ask that as a consumer, I know what risks are associated with using Botox.