

Robin Gail Oshman, M.D., Ph.D., F.A.A.D.

101 Long Lots Road

Westport. CT 06880

203-454-0743

Proposed House Bill No. 5654

An act allowing dentists to perform certain facial therapies as part of their dental practice.

I am opposed to this bill.

Injecting neurotoxins and dermal fillers into the face may sound simple enough until one studies the possible side effects and risks of these injections. There are nerves which can be damaged with injections, blindness and necrosis of the skin have been documented with fillers. These are just a few of the risks associated with these procedures. When paralyzing muscles with neurotoxins such as Botox one can prevent swallowing, create drooping eyelids and cause a dissymmetry to the face. Unless you are a well trained physician who is qualified in reversing or avoiding these dangers you should not be injecting the face.

Prior to injecting neurotoxins a good history must be taken to determine whether the patient has any neurologic problems, any muscle problems or any allergies. One needs to take a medication history to decide if any of the patient's medications interact adversely with the neurotoxin. Physicians are trained to take and properly interpret this information.

The skin is the largest organ of the body. The face is a small part of that organ with all of the complications and intricacies of the entire body. Unless one truly understands the way skin functions and reacts to different substances one should not be injecting any substances into the face.

Below are the side effects extracted from the package inserts of the neurotoxin Botox and the filler Juvederm. After reading these complications I am sure that you will agree that only physicians and those trained in the field of Medicine should be permitted to inject these substances.

BOTOX®:

- **Problems swallowing, speaking, or breathing**, due to weakening of associated muscles, can be severe and result in loss of life. You are at highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat chronic migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Do not receive BOTOX® if you: are allergic to any of its ingredients (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site.

The dose of BOTOX® is not the same as, or comparable to, another botulinum toxin product.

Serious and/or immediate allergic reactions have been reported, including itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX®.

Tell your doctor about all your medical conditions, including if you: have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX® passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® with certain medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you received BOTOX® in the past.**

Tell your doctor if you received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*®, *Dysport*®, or *Xeomin*® in the past (tell your doctor exactly which product you received); have recently received an antibiotic injection; take muscle relaxants; take allergy or cold medicines; take sleep medicine; take aspirin-like products or blood thinners.

Other side effects of BOTOX® include: dry mouth, discomfort or pain at injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of eyelids, dry eyes; and drooping eyebrows.

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive any JUVÉDERM® injectable gel formulation?

Do not use these products if you have a history of multiple severe allergies or severe allergic reactions (anaphylaxis), or if you are allergic to lidocaine or the Gram-positive bacterial proteins used in these products.

What precautions should **my doctor** advise me about?

- Tell your doctor if you are pregnant or breastfeeding. The safety of these products for use during pregnancy or while breastfeeding has not been studied
- The safety of JUVÉDERM VOLUMA® XC in patients under 35 years or over 65 years, the safety of JUVÉDERM® XC and JUVÉDERM® Ultra XC injectable gels in patients under 18 years, and the safety of JUVÉDERM VOLLURE™ XC and JUVÉDERM VOLBELLA® XC in patients under 22 years has not been studied
- The safety and effectiveness of JUVÉDERM VOLUMA® XC in areas other than the cheek area, JUVÉDERM® XC and JUVÉDERM VOLLURE™ XC for areas other than facial wrinkles and folds, and JUVÉDERM® Ultra XC and JUVÉDERM VOLBELLA® XC in areas other than the lips and perioral area have not been established in clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formations) or pigmentation disorders, as use of these products may result in additional scars or changes in pigmentation
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Patients who experience skin injury near the site of injection with this product may be at a higher risk for side effects
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of these products may result in an increased risk of infection
- Tell your doctor if you are using medications that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners, as this may result in increased bruising or bleeding at the injection site
- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages within the first 24 hours following treatment

What are possible side effects?

The most commonly reported side effects with JUVÉDERM® injectable gels included injection-site **redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching**. For JUVÉDERM VOLBELLA® XC, dryness was also reported. For JUVÉDERM VOLUMA® XC, most side effects were moderate and lasted 2 to 4 weeks. For JUVÉDERM® XC, JUVÉDERM VOLLURE™ XC, and JUVÉDERM® Ultra XC injectable gels, most side effects were mild or moderate and lasted 14 days or less. For JUVÉDERM VOLBELLA® XC, most side effects were mild or moderate and lasted 30 days or less.

One of the risks with using these products is unintentional injection into a blood vessel, and while rare, the complications can be serious and may be permanent. These complications, which have been reported for facial injections, can include **vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring**.

As with all skin injection procedures, there is a risk of infection.

After reading these package inserts it becomes clear that only physicians have the training and expertise to administer these agents.

Robin Gail Oshman, MD, PhD, FAAD
Immediate Past President
Fairfield County Medical Association

