

# IMPORTING INJECTABLES

There are numerous ways to decrease the cost of toxins and fillers, including importing materials from another country and using less expensive materials, but the results achieved with such products may be less than optimal.

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As the commoditization of toxins and fillers accelerates and the recognition of the person driving the needle diminishes, cosmetic procedures are becoming increasingly subject to pricing pressures. In response to these pressures, several businesses have begun to offer less expensive alternatives to the toxins and fillers offered by authorized sources in the United States. Although not a new phenomenon, the recent resurgence warrants mention.

Solicitations via e-mail, fax and postal mail all attempt to build market share with a host of products that are, at best, illegally imported and, at worst, counterfeit. Un-

fortunately, patients frequently do not care or know to ask about the source of the product being inserted into their bodies, and are more interested in just knowing the cost. As a result, the incentive for decreasing the cost of material increases.

## ISSUES WITH PURCHASING PRODUCTS FROM UNAUTHORIZED VENDORS

One common way to decrease the cost of products is simply by purchasing them from vendors outside the traditional pathways. For physicians who are large consumers of products like Botox, Dysport, Restylane, Perlane, Radiesse and Sculptra, this can result in savings of tens of thousands of dollars. These savings not only allow practices to be more profitable; they also enable them to compete with the providers

who charge \$200 for injections. However, there is a lack of understanding on the part of patients about the health risks presented by these products and on the part of physicians about the various legal issues surrounding their use. Although programs involving “good purchasing” certification and patient education about unauthorized product purchases were contemplated by several corporations, none were ever implemented. As a result, patients have no way to know who is and is not purchasing authentic products, and injectors have little reason not to avoid expensive, legitimate channels.

## PATIENT SAFETY CONCERNS

For those who purchase product through secondary channels, there are two distinct avenues. The first involves buying the same product from another country where it is approved. It is beyond my knowledge to consider the legality of such transactions, but, from a patient care perspective, this provides products that are safe and approved for use in the United States, albeit from a channel that is not. Healthcare reform has created alternate channels for drug purchases for individuals, and pharmacies to the north and south of the border have been taking advantage of this pricing discrepancy.

The second avenue does not involve purchasing the same product and instead involves drugs and devices that are either counterfeit or otherwise tainted. Obviously, as reported recently in the *Wall Street Journal*, this practice has significant consequences for patients who rely on their doctors for drugs to treat various conditions, including cancer. However, there is also a potential risk for patients receiving cosmetic treatments. Whether it is a botulinum toxin



injection or a dermal implant, a material is being injected into the skin. Counterfeit toxin may be derived from a research-grade material or may be a product that is manufactured to look like the real thing. In the best-case scenario, this is inert material. However, in the worst case, this may contain harmful chemicals or other impurities. When impurities create fillers that are not sterile or that contain permanent filling material, the consequences can be devastating. Finally, as other countries gain the ability to make toxins, they have been able to produce products that have biologic effects, and substitution of these products may be harmful if they are stronger than the label indicates.

**PRODUCT QUALITY MATTERS**

A third method for decreasing the price of cosmetic products is to use a different product. With the advent of

multiple types of botulinum toxins and fillers, it is likely that injectors trying to cut costs will use less expensive products. These may not be inferior but are simply discounted based on volume or because of promotions. In general, newer products will have lower prices in order to gain market share.

While not harmful to the patient, the practice of substitution is disingenuous at best. In my practice, I had a patient complain about a decreased duration of efficacy from treatment with a filler; once we obtained the records for the procedure, it was discovered that the patient had been injected with a low-density, inexpensive filler but had been told it was something else.

The lack of branding of the person performing these types of procedures has led to a demand for treatments that are based solely on price. As pricing pressure increases, patients are seeking

less expensive treatments, which has forced some injectors to dilute products or substitute with cheaper materials.

In cases where products are diluted, patients get less than they bargained for. However, when counterfeit materials are used, they may get much more. The price paid can be quite high. The savings aren't always worth the consequences. ■

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*Disclosure: Dr. Beer is an owner of Theraplex LLC, and consults, speaks or performs clinical trials for Medicis, a division of Valeant, 3M, Sanofi Aventis, Bioform Medical, Allergan and Stiefel, a GSK company. He is also a Director of the Cosmetic Bootcamp meeting.*

**Trianex™ 0.05% (Triamcinolone Acetonide Ointment) Rx Only INDICATIONS AND USAGE**

Trianex™ 0.05% (Triamcinolone Acetonide Ointment) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

**CONTRAINDICATIONS**

Trianex™ 0.05% (Triamcinolone Acetonide Ointment) is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

**PRECAUTIONS**

**General**

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see PRECAUTIONS-Pediatric Use).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

**Information for the Patient**

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

**Laboratory Tests**

The following tests may be helpful in evaluating the HPA axis suppression:

Urinary free cortisol test  
ACTH stimulation test

**Carcinogenesis and Mutagenesis and Impairment of Fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

**Pregnancy Category C**

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

**Nursing Mothers**

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

**Pediatric Use**

**Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.**

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

**ADVERSE REACTIONS**

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning, Itching, Irritation, Dryness, Folliculitis, Hypertrichosis, Acneiform eruptions, Hypopigmentation, Perioral dermatitis, Allergic contact dermatitis, Maceration of the skin, Secondary infection, Skin atrophy, Striae, Milia.

**OVERDOSAGE**

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

**DOSAGE AND ADMINISTRATION**

Trianex™ 0.05% (Triamcinolone Acetonide Ointment, USP) is generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

**CAUTION:**

For external use only. Not for ophthalmic use.

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