HACKS

THE PERILS OF PARALLEL IMPORTATION

This "cost-saving" practice exists in a legal grey area, and the purported benefits don't support the risks.

BY ALEX R. THIERSCH, JD

As every medical aesthetic practice owner or operator can tell you, keeping costs as low as possible is vitally important for the survival of these businesses. Unfortunately, practices located in the United States typically have to purchase pharmaceuticals at cost from manufacturers, and that can have a major impact on their bottom lines, since drug costs in the United States are not strictly regulated. Some medical aesthetic practices attempt to combat this by engaging in a practice known as parallel importation, which allows them to save significantly on legitimate, name-brand drugs. However, this practice is highly controversial, and partaking of it might end up costing you a lot more than if you'd simply paid list price in the first place.

UNDER CONTROL

In countries such as the United Kingdom, Germany, France, Sweden, and Canada, government regulates the cost of pharmaceuticals. Broadly, these measures are designed to prevent drug manufacturers from charging too much for what those governments consider essential medicine, but they also apply to pharmaceuticals used for elective procedures, such as those offered by medical aesthetic practices and medical spas, including botulinum toxin and fillers.

However, in the United States, the government does not play a significant role in determining the cost of pharmaceuticals—drug manufacturers essentially can charge whatever they feel the market will bear for their products. Remember when Martin Shkreli's firm raised the price of Daraprim 56-times higher than it had been? In the United States, that's perfectly legal. As a result, drug prices in the United States are significantly higher than in practically every other country in the world.

In response, some US-based practices have begun to purchase drugs from licensed dealers in countries where price controls are enforced. This costs them significantly less—up to 50 percent less, in some cases—than they would have to pay if they were buying the drugs directly from the manufacturer. This is known as parallel importation.

This transaction benefits both parties. The buyers get legitimate products for much less than they would have to pay if they were buying from the manufacturers, and the dealers—no longer bound by price controls, since they are selling to the United States—can make a decent profit simply by marking the product up slightly. These are not cheap, counterfeit pharmaceuticals like the ones that are typically manufactured in China and have notoriously flooded the medical aesthetics market in recent years; these are the same drugs that are approved by the FDA and sold in the United States.

A TEXTBOOK CASE

If you're unfamiliar with parallel importation, you're probably thinking to yourself that this can't be legal, but a quick

look at some of the elements of the transaction might suggest otherwise. After all, the sale of the drug to the foreign distributor is legal, and the distributors are selling FDA-approved products that are the same as those that are sold in the US. So one question remains: Is the sale from the distributor to the practice legal?

The answer is not as clear-cut as it seems. In 2013, the US Supreme Court ruled on the case *Kirtsaeng vs. John Wiley & Sons, Inc.* that involved Supap Kirtsaeng, a man from Thailand who opened a business selling the international editions of university textbooks, which are much less expensive than the domestic versions, albeit identical. He procured these textbooks from relatives abroad and then sold them to US college students using eBay. The business was hugely successful for Kirtsaeng (after all, if there's anything that's as ridiculously overpriced in the US as prescription drugs, it's college textbooks), but when John Wiley & Sons found out that he was doing this, textbook publisher sued him. The US Supreme Court ruled in favor of Kirtsaeng by a 6-3 majority, which has led to the interpretation that parallel importation is broadly legal. (Wiley's reaction to this was not to lower the prices of their domestic editions, but rather to raise the prices of their international editions, because … of course it was.)

However, the legality of parallel importation in regard to drugs has yet to be ruled upon by a US court. While Kirtsaeng suggests parallel importation is legal, drugs are regulated by the government, which makes the issue significantly more complicated. Drug packaging is one of the issues that should give prospective parallel importers pause. Prescription drugs are typically sold with inserts that specifically demonstrate the product's compliance with the standards set forth by that country's government. Therefore, if a pharmaceutical intended for sale in, say, Canada is sold to a customer in the United States, the packaging the US-based customer receives will reflect the drug's legal status in Canada, not in the US. It almost certainly is precisely the same product that a practice would buy from the manufacturer or an authorized distributor in the US (most drugs are designed with worldwide standards in mind so that they can be produced as efficiently as possible), but because the packaging was designed for sale in Canada, it doesn't include information related to the product's use in the US. This might seem like a very minor distinction if the product is exactly the same, but it can make an enormous difference from a legal standpoint.

Distributors in countries with cost controls aren't fazed by this legal grey area, however—they aggressively market themselves to US-based medical aesthetic practices. You don't have to look very hard to find them—they email incessantly, and their websites live out in the open on the Internet rather than hiding on the "dark web" like many other shady businesses. The representatives of these dealers generally tell prospective customers that they can produce all the paperwork they need regarding the products' legality, and they often suggest that the markings on the packaging proving that the manufacturer produced the drug are enough verification to prevent any legal entanglements. This is not necessarily true.

WHY OR WHY NOT?

The issue isn't whether or not the product is legitimate—products from parallel importers almost certainly are. The issue is that importing drugs specified for sale in other territories simply is not legal in the United States. I've spoken with many attorneys about this issue, and the consensus opinion is that if the distributor is not approved by the FDA to do business in the United States (and the parallel importers are not), it is illegal for US customers to buy pharmaceuticals from them.

What's more, drug manufacturers abhor parallel importation (for reasons that should be obvious), and although it might seem somewhat counterintuitive, they wield tremendous power within enforcement agencies. These companies are very aggressive in investigating and attempting to prosecute the distributors who sell these products to US-based medical aesthetic practices. In some cases, they even seek prosecution against the buyers, which makes this an extremely risky proposition; not only are you risking significant fines and perhaps other penalties by crossing the FDA, you're also potentially making an enemy of a company that sells a product or products that your patients expect you to offer.

However, a lot of parallel importation is occurring, and since the FDA doesn't have the authority to prosecute the distributors in the countries where these transactions are occurring, it is more likely to go after the buyers—the "low-hanging fruit." Still, there's so much of this going on that an individual practice's chances of being discovered using these products are relatively low, so some feel it is worth the risk. If an adverse outcome occurs while using a product acquired via parallel importation, however, a medical aesthetic practice exposes itself to significant legal issues by having used a drug that is intended for sale and use in a foreign country. Offenders may incur major fines, and the medical professionals involved in the administration of these drugs could face the suspension of their medical licenses.

"When I counsel my clients who are medical spas or cosmetic practices, [I tell them] you have to recognize the risk that comes with any effort to import products," says Michael S. Byrd, JD, partner for ByrdAdatto, a national business and healthcare law firm specializing in medical aesthetics. "If ultimately they don't have any action or negative result against them, there's still a huge destruction in costs if they get raided and have their stuff confiscated and

go under investigation. And so, my counsel would be that if you do anything other than buying an American, FDA-vetted product, you have to recognize that risk is there."

TOO GOOD TO BE TRUE

Despite the relatively minor risk of being caught, ByrdAdatto and AmSpa steadfastly believe that medical aesthetic practices should not participate in parallel importation. The potential consequences clearly outweigh the cost savings. If your practice's profitability depends on getting 30 percent off Botox, you need to re-evaluate the way you do business and allocate your money. It's a good idea to remain compliant with the FDA and other regulatory agencies, regardless of whether you think a drug is overpriced. In the medical aesthetic industry, deals that seem too good to be true often are. Consult with your healthcare attorney if you need more information. ■

Author's note: The American Med Spa Association (AmSpa) works with ByrdAdatto and, as a member, along with a number of other great benefits, you receive a discount off of your initial consultation. To learn more, log on to americanmedspa.org.

ALEX R. THIERSCH, JD

- Alex R. Thiersch, JD, is a Chicago healthcare attorney who represents medical spas, plastic surgeons, and aesthetic medical professionals.
- Founder and director of the American Med Spa Association (AmSpa), which was created for the express purpose of providing comprehensive, relevant and timely legal and business resources for medical spas and medical aesthetic physicians throughout the United States.
- Partner at ByrdAdatto Law Firm.
- For more information about becoming a member or to learn about AmSpa's upcoming events, log on to www.americanmedspa.org.
- alex@americanmedspa.org.