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Letter to the Editor

Physician Alert: Beware of Counterfeit Medical Devices

It is well known that copycat versions of designer clothing, watches, and other consumer goods are readily available through street vendors and/or the Internet. A more serious counterfeiting problem has recently arisen in the realm of aesthetic medical devices. As opposed to legitimate, legal devices, the counterfeit versions infringe on patent rights, falsely claim to have clearance by the US Food and Drug Administration (FDA), and infringe on branding of well-recognized, FDA cleared products [1]. In many cases, clinical photographs of outcomes produced with an FDA cleared product are used to promote knockoff devices. The counterfeit devices enter the US and are cleared through customs under false pretenses, only to be sold to potentially unsuspecting (or unscrupulous) buyers. While most all FDA approved technologies in the aesthetic device space are illegally copied, perhaps the most alarming numbers of devices target legitimate devices manufactured by Zeltiq, Inc. (Pleasanton, CA) and Ulthera (Mesa, AZ).

The legitimate Zeltiq device uses a patented process referred to via the trademarked term "cryolipolysis" to produce selective injury to adipocytes via an external, noninvasive process. Zeltiq currently holds at least 5 US and 48 foreign patents with another 19 US and 80 foreign patents pending. Zeltiq's device is FDA cleared in the US, holds a CE mark, and other medical approvals worldwide [2]. Zeltiq's technology utilizes controlled cooling with built in thermal-feedback safety measures designed to prevent overcooling of tissue. Ulthera's device uses focused ultrasound delivered at various depths beneath the skin to produce focal thermal lesions that, when delivered appropriately, produce noninvasive lifting of skin, injury to sweat glands, and other clinical effects. This technology, too, is heavily protected by both US and foreign patents and has built in safety measures. Like the Zeltiq device, the Ulthera platform produces safe, reliable, reproducible tissue effects. In contrast, the counterfeit devices offer no assurance of safety, reliability, or reproducibility. In fact, numerous patient injuries are documented to have been produced by these copycat systems (Figs. 1 and 2). Unfortunately, details of the treatments that led to the injuries demonstrated in these clinical photographs are not available. Based on the clinical photographs, these appear to be freeze injuries which may have occurred due to lack of a temperature monitoring and feedback mechanism or failure to protect the skin via other means. Such injuries have not been reported in over 1 million treatment cycles performed with Zeltiq's technology.

Physicians can be misled and tempted to purchase counterfeit devices in several ways. Marketing, graphics, and other materials offered in support of counterfeit devices can appear very similar to those produced by manufacturers of the legitimate product. In some cases, clinical photographs of patients treated with FDA approved, legitimate devices are used without permission from by foreign companies selling copycat devices. This is true of at least one counterfeit Ulthera device manufactured in South Korea [3]. At first glance there appears to be a significant economic incentive for purchasing counterfeit devices as they may be acquired for only a small fraction of the cost of the legitimate technologies they imitate. However, upon more careful analysis, any apparent economic advantages are grossly outweighed by the real risks and liabilities associated with using technology that is not FDA approved and has not been proven to be safe and effective. Potential adverse consequences associated with using counterfeit technology include lack of clinical efficacy, failure of devices to perform as expected with resultant patient injury or unanticipated adverse events, medicolegal liability, loss of medical licensure, civil prosecution, and even criminal prosecution. It is worth noting that many medical malpractice insurance carriers may not provide coverage for litigation arising from the use of devices that are not approved for use by the FDA. Another noteworthy fact is that the FDA has a little-known division known as the Office of Criminal Investigations that has the same type of arrest authority as other federal law enforcement agents and which focuses its efforts on threats to the public health "particularly in the area of counterfeit and unapproved medical products" [4]. Violation of statutes governed by the FDA can also result in mandatory exclusion from participation in federal healthcare programs [5].

The prevalence of counterfeit devices is lower in the US than internationally, but numerous knock-off devices have been identified domestically. These devices have been purchased by both core and non-core physicians as well as by med spas. It is not clear whether a physician was involved in instances where med spas purchased devices [6].

This problem of counterfeit medical devices is more prevalent than most physicians (and consumers) might imagine. Currently, there are approximately 29 knock-offs

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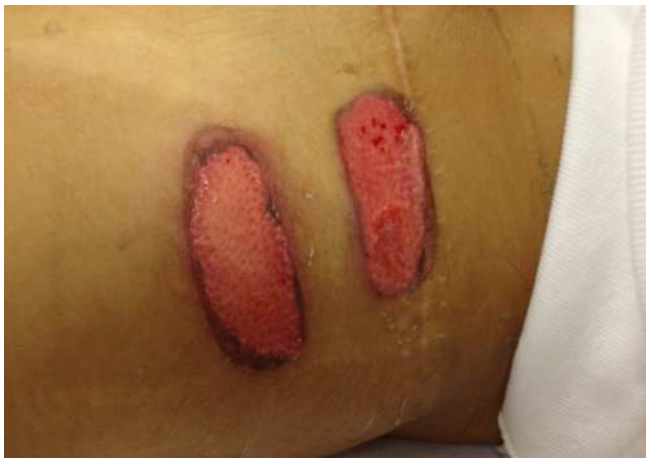

Fig. 1. Burns produced by counterfeit Zeltiq device.

of the Zeltiq device. The term cryolipolysis is protected by a registered trademark to refer only to cold-induced changes in fat produced by the Zeltiq device. However, this term is being widely used in association with counterfeit technologies that do not have the same built in safety measures as the original technology. This generates confusion in the marketplace. The majority of the counterfeit Zeltiq devices are produced in China although some originate from other Asian sources and Europe. Similarly, there are at least five counterfeit versions of the Ulthera device, all of which originate in South Korea. Many counterfeit devices appear to be legitimate as they have their own webpage and supporting marketing materials and use familiar-sounding messaging. A small number have approval by foreign government regulatory agencies but are in violation of existing patents held by the US manufacturers who originally developed (and patented) the technology. All of the counterfeit devices are unregulated by the FDA and thus illegal to sell in the United States as medical devices. Despite their unregulated and unapproved status, many of

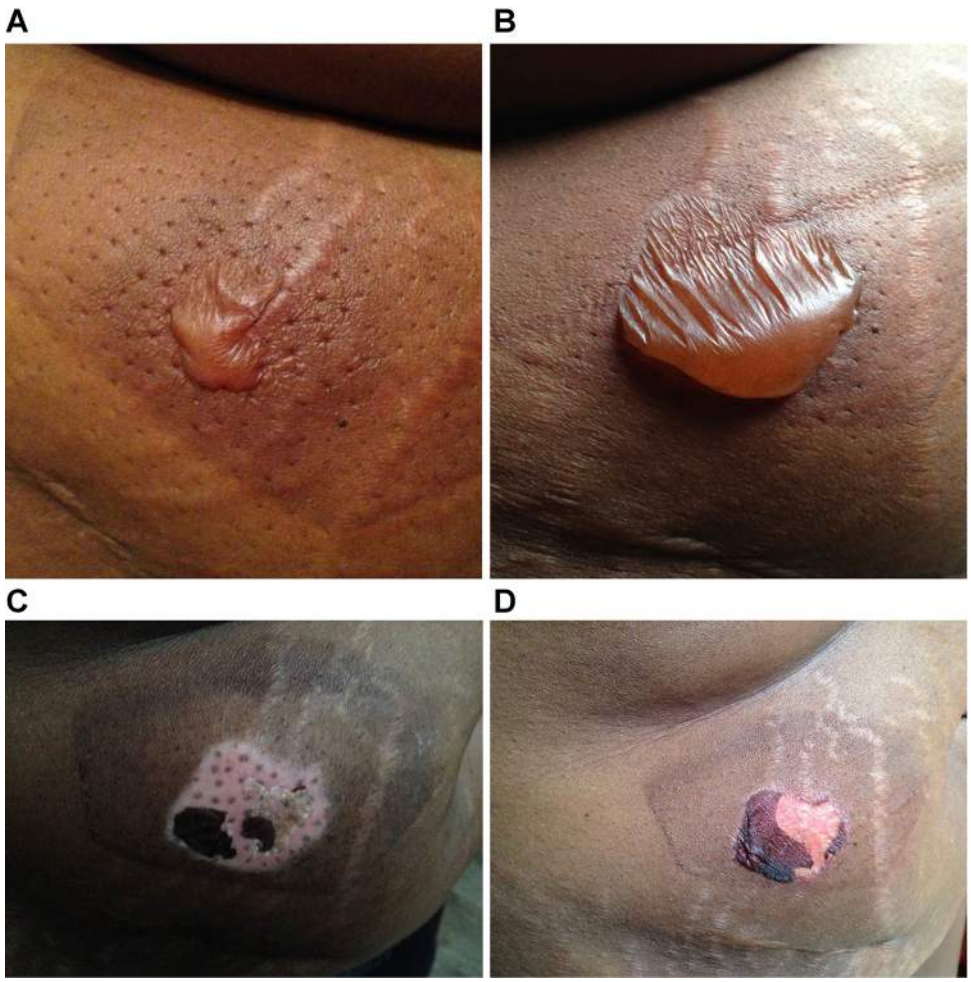

Fig. 2. **A**: Injury caused by treatment with counterfeit Zeltiq device, Day 1 after treatment. **B**: Injury caused by treatment with counterfeit Zeltiq device, Day 2 after treatment. **C**: Injury caused by treatment with counterfeit Zeltiq device, Day 7 after treatment. **D**: Injury caused by treatment with counterfeit Zeltiq device, Day 13 after treatment.

these devices can be purchased in the US via the internet or through distributors, and some are even are displayed at legitimate trade shows such as the recent American Academy of Dermatology meeting.

Physicians should be aware of the existence and prevalence of counterfeit medical devices and need to understand that use of these devices in the United States can lead to severe economic, civil, and criminal penalties. We are living in a "buyers beware" environment when it comes to the purchase of medical technology. If considering purchasing medical technology ensure that the equipment is acquired directly from the manufacturer or an authorized representative, that the technology is authentic, and that it is approved by the FDA for its intended use.

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