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Black Market Procedures Compromise Patient Safety and Integrity of Medical Aesthetic Industry

By Kevin A. Wilson, Contributing Editor

In business a profitable venture will unavoidably result in attempts to duplicate that success. In a free market economy the word used to describe this reality is 'competition', a challenge that ultimately leads to improvements in quality and service, as well as overall industry growth. Unfortunately, it's also inevitable that if someone's making money legitimately, somebody else may use this success as a springboard to a quick profit, without regard to safety, quality, fairness or intellectual property rights.



Black Market Procedures Compromise Patient Safety and Integrity of Medical Aesthetic Industry

A recent *Letter from the Editor*, published in the Autumn 2011 edition of *THE Asian Aesthetic Guide*, by Michael Moretti¹, highlighted this issue. "While wearing a counterfeit scarf, carrying a knock-off purse or watching a bootlegged DVD violates the original manufacturer's intellectual property – this is not potentially life threatening," said Mr. Moretti. "Conversely, injecting an illegally manufactured neurotoxin or dermal filler can have very serious consequences." Additionally, the feature editorial *Researcher Examines the World of Fake Injectable Products*, by Andy Pickett, Ph.D., B.Sc., founder and director of Toxin Science Limited (Wrexham, U.K.), published in the same issue², delved into the world of counterfeit facial injectables.



Michael Moretti
Publisher
THE Aesthetic Guide
Aliso Viejo, CA

Jeffrey Dover, M.D., F.R.C.P.C., past president of the *American Society of Dermatologic Surgery* (ASDS), described how one company fought product counterfeiting. "A fake product was being manufactured abroad and the packaging looked almost exactly the same," he began. "In response, the legitimate company began including a hologram on the individual product label to help users establish authenticity. It's a shame that they had to go to such lengths but they were protecting a valuable asset, not simply their intellectual property but their reputation as a distributor of safe, effective, quality products. While the most common outcome of poorer-quality aesthetic medicine is probably patient dissatisfaction, the overriding issue is patient safety and patient care."



Jeffrey Dover, M.D., F.R.C.P.C.
Medical Director
SkinCare Physicians
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Past President
American Society of Dermatologic Surgery



Joseph Niamtu, III, D.M.D.
Cosmetic Facial Surgeon
Richmond, VA

While top physicians agree that patient safety is what separates this problem from that of counterfeit cellular telephones, there's more going on than the production of fake or low-quality products, according to cosmetic facial surgeon Joseph Niamtu, III, D.M.D. (Richmond, Va.). "Just as in any other competitive market there are people operating under the table and contrary to the ethics of the medical industry," he said. "This has been pervasive in foreign countries and is a growing problem in the U.S. I have seen this to be more prevalent in close knit ethnic communities or circles of friends trying to get a good deal by 'beating the system.'"

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Furthermore, "the problem isn't confined to small communities or cities, even if those may be concentrations of such activity for a variety of reasons," Dr. Niamtu explained. "This encompasses all groups of people because there is always a market for illegal goods



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and services. People are constantly looking for a cheaper product and don't care if what they're buying might have been stolen or imported, for example. In the medical industry the consequences to patients can be devastating, disfiguring or fatal. Take Priscilla Presley for example."



Angelo Cuzalina, M.D., D.D.S.
Cosmetic Surgeon
Tulsa Surgical Arts
Tulsa, OK
2011 President
American Academy of Cosmetic Surgery

Angelo Cuzalina, M.D., D.D.S., a cosmetic surgeon at Tulsa Surgical Arts (Tulsa, Okla.) and 2011 president of the *American Academy of Cosmetic Surgery* (AACS), emphasized; "most physicians and surgeons care and adhere to the oath they took to do right by their patients, and rock bottom pricing should be a red flag that may suggest that the patient should look elsewhere," he said.

"Even more dangerous are unlicensed practitioners, some who may not have much or any real medical training, inside or outside the U.S.," Dr. Cuzalina added. "These people may not know what they're doing and may not follow procedural guidelines." He also called attention to instances of parties in people's homes for group injections of dermal fillers or neurotoxin, "Anyone taking part in something like that is just asking for trouble."



Tom D. Wang, M.D.
President
American Academy of Facial Plastic & Reconstructive Surgery
Portland, OR

According to Tom D. Wang, M.D., current president of the *American Academy of Facial Plastic & Reconstructive Surgery* (AAFPRS), the promotion of patient safety in aesthetic medicine is the primary objective of the Physicians Aesthetic Coalition (PAC), an organization formed in early 2011 made

up of AAFPRS, ASDS, the *American Society for Aesthetic Plastic Surgery* (ASAPS) and the *American Society of Ophthalmic Plastic and Reconstructive Surgery* (ASOPRS). "These core organizations banded together to ensure that patients receive the highest level of care and safety possible. Black market aesthetic medicine is the antithesis of this."

"People have always wanted cut-rate pricing and uncertain economic conditions have created an environment more conducive to the black market," Dr. Wang continued. "They try to lure unsuspecting patients with the prospect of low cost treatment, usually sacrificing quality and safety, under the guise of equivalence to treatment otherwise available from accredited practitioners at a higher cost."

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"Patients may be unaware of the true dangers of pursuing black market or off-label treatment," Dr. Wang noted. "Some are willing to leave the country to obtain these procedures at what appears to be substantially reduced rates, but often with significantly higher risk involved. Facilities here, or internationally, offering low-cost aesthetic medicine may not be able to properly intervene in the case of complications, for example. So it's up to us to advocate for the patient and to educate them, and this is one area where we can have an impact."



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Dr. Wang made clear that he is not the official spokesperson for PAC, and added that while there is no specific plan within PAC to combat black market aesthetic medicine as of yet, the coalition's general initiatives to promote safety through patient and physician education are an essential part of the remedy. "We can only do so much work individually, or as individual organizations," he began. "Together, through PAC, we can accomplish much more. Traditionally there have been turf issues between these kinds of organizations, which tend to get in the way of progress, and this is an attempt to set those things aside."

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However, Dr. Niamtu takes issue with PAC's basic principles. "Ultimately PAC is a self-serving group positioning themselves at the forefront for publicity, putting themselves on a pulpit. They may have sincere intentions but they are not inclusive," he said. Contemporary cosmetic surgery is performed well by numerous specialties. "I am a maxillofacial surgeon originally, but I am licensed to practice cosmetic surgery. We have a prominent, respected practice and we do it well."

"Many specialty practices tout themselves as being 'core' or otherwise holding the keys to the dermal filler universe; but in reality nurses or trained personnel perform the treatments," Dr. Niamtu pointed out. "The fact that this coalition is limited to only a small number of specialties is ludicrous. There are 'core' physicians that have terrible results and 'non-core' physicians that are masterful. The bottom line is that being part of any given specialty does not guarantee competence; there are many other factors that come into play."

Along these lines Dr. Cuzalina personally sent PAC a letter supporting their work, but also expressing his disappointment at AACS being excluded from this coalition. "They should have representatives from all disciplines, but we weren't asked to join. I think it's a good idea that may help patients and the industry if they actually form a task force to address practice and product quality control issues. Otherwise it looks like a publicity stunt."

Beyond patient safety there is the danger posed by negative shifts in public opinion, Dr. Cuzalina added. "There has historically been a stigma associated with cosmetic procedures. Although this seems to be changing, there is still the potential for a continued or unabated flow of illicit products and procedures to bring down the industry as the public is influenced by big stories. People tend to make generalizations about things based on negative press." He mentioned that in his region – Oklahoma, as opposed to Los Angeles or New York City – there are few issues with shoddy work or counterfeit products because patients are naturally more wary. "This population isn't as inundated with aesthetic medicine. They're generally leery and more concerned about the potential risks."

On the other hand, Dr. Niamtu feels the problem may be somewhat overblown. "There are high-profile news stories and bad press that tarnish aesthetic medicine, but for the most part, physicians are pretty ethical. The need for regulation and strong ethics is there, but in many ways so much of this is beyond



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our control. I don't think the impact on the industry is quite so big. I'm not against anything to promote patient safety, but bad press and bad practitioners are inevitable as long as people are willing to set aside common sense and gamble with their health. There are no guarantees so you must be careful."

"Of course patients need to exercise care and take responsibility for themselves, but they count on us and our expertise. We need to be worthy of that trust, which inherently makes us a more attractive option to the very patients we're trying to help."

While patient resources are available to help discern who is a reputable practitioner and who may not be, nothing's perfect. "State agencies track patient complaints, for example, and there are difficult-to-achieve accreditations available that demonstrate safety and proficiency," said Dr. Cuzalina. "The term 'board certified' can be misleading as the 'board' and the association are not necessarily the same thing. In the end, less reputable physicians tend to not spend the time and money to get their facility accredited or stay as current with continuing education, which is another red flag."

Overall quality of a facility can also be measured somewhat by its size, reputation and the number of procedures they perform. "When one specialty says that only a

board certified member of their specialty is safe or competent, that's self-serving. Just because they've passed some test doesn't mean they're any good at what they do," said Dr. Niamtu, "which is not to say certifications are worthless, but that there are many factors one can look at. I advise patients that if it sounds too good to be true, it probably is."

"It is sad that the desire to look better can override common sense on occasion," added Dr. Cuzalina. "One would think most people are smart enough to avoid liposuction or injectable treatments where there is obviously something grossly amiss. Fortunately, the vast majority of us want happy, healthy patients and treat them in a very safe and ethical manner."

Dr. Dover, who is also medical director of SkinCare Physicians in Chestnut, Hill, Mass., believes the onus is on physicians to learn their trade, constantly improve and to procure FDA cleared products and devices from only reputable sources. "There's no such thing as cut-rate procedures, devices and products," he said. "As physicians we are the initial market for unscrupulous profiteers and that's where we slam the door shut. Of course patients need to exercise care and take responsibility for themselves, but they count on us and our expertise. We need to be worthy of that trust, which inherently makes us a more attractive option to the very patients we're trying to help." ■

References:

1. Moretti M. *Black market products threaten future of burgeoning medical aesthetic industry. THE Asian Aesthetic Guide.* Autumn 2011, pp. 17.
2. Pickett A. *Researcher examines the world of fake injectable products. THE Asian Aesthetic Guide.* Autumn 2011, pp. 34-40.