Most people find it difficult to pass up a bargain, and dentists and dental staff members who select and order products are no exceptions. It is relatively common to see some dental products offered in dental magazines and journals at discounts of 10 to 50 percent. Are you using products that you have purchased at significant discounts? Do you, the dentist, even know if you are using such products, as the ordering of supplies in most dental offices is handled by members of the staff?

A key question to ask is how some dental retailers can sell dental supplies at deeply discounted prices while others continue to sell at the recognized market level. The discounted products may not be legitimate ones produced by the manufacturer from which you think you or your staff purchased them. You may be using “gray-market” or even counterfeit products, and you may not know it. Gray-market products include branded goods intended by the brand owner for one national market that instead are diverted and resold by unauthorized distributors to another market.

Counterfeit products, on the other hand, never originate from the brand owner. Counterfeiters simply pass off fake materials under the guise of a well-known product. There is a surprising lack of published information on this subject. However, a few related articles are interesting.¹⁻⁴

Large dental companies, such as 3M ESPE (St. Paul, Minn.), Dentsply (York, Pa.), and Kerr (Orange, Calif.), deal with gray-market or counterfeit products regularly, and some find that it is difficult to estimate what percentage they represent of products sold. Kirsten Edwards, director of clinical affairs for Kerr, estimated that about 5 to 8 percent of apparent Kerr products are gray market or counterfeit (oral communication, Feb. 23, 2010). These products are sold under the pretense of being brand-name items.

It is possible to save money by purchasing discounted products, but is it worth the potential hazards of buying and using such products? As an example, say that you are grossing about $600,000 per year with about a 60 percent overhead before taxes, and your supply expenses are equivalent to about 5 percent of your gross income, or about $30,000 for the year. Assuming you save 10 percent off your supply cost, you have saved about $3,000 in a year, or about $250 per month. However, what if these discounted products are expired, altered or even counterfeit, and you have a material...
failure—such as postoperative tooth sensitivity—in a group of patients? Additionally, the legal liability associated with using a dental material that is not approved for sale in the United States or cannot be tracked back to its origin of sale is a significant threat. Even if you determine the cause of the problem, have you really saved anything? Is it worth the $250 per month? To whom do you go when the product does not meet its expressed purpose, or if you have problems with patients' complaints?

In this column, I discuss the prevalence of gray-market and counterfeit products, manufacturers' concerns about them, the need for communication between the dentist and the staff member ordering the products, how to identify such products and, most importantly, what to do to avoid the problem.

**DENTAL INDUSTRY’S CONCERNS REGARDING GRAY-MARKET AND COUNTERFEIT PRODUCTS**

The dental industry is regulated by the U.S. Food and Drug Administration (FDA) to ensure that the dental products you use and place in patients' mouths—considered to be medical devices by the FDA—meet accepted standards. The FDA also approves the claims that the manufacturers make about their products and inspects manufacturing facilities for ongoing compliance. Manufacturers' concerns about gray-market or counterfeit products are about more than financial loss. They also center on potential health risks for patients and negative brand perception among clinicians who might use a gray-market or counterfeit product and not get the expected clinical result.

A representative of 3M ESPE states that the company sees the presence of unauthorized intermediaries selling products that are not authorized for sale in the United States (Kathy Gaertner, global director of channel sales for 3M ESPE, written communication, Feb. 23, 2010). These items often are products intended for sale in developing countries that have been repackaged and sent back to the United States for sale to American dentists. When products that are not cleared for sale in the United States are repackaged, you cannot be guaranteed that you are buying the product you think you are buying. Warning and traceability information may be missing, and the products may no longer comply with regulatory requirements. Often, these repackaged products are outdated or expired with a fraudulent expiration date that has been extended. The gray-market product may have been compromised by improper shipping, or by storage in non–temperature-controlled facilities, thereby resulting in compromised product efficacy.

“The only way to know you’re getting the 3M ESPE product quality you trust is to purchase [products] through certified 3M ESPE distributors,” states Kathy Gaertner of 3M ESPE (written communication, Feb. 23, 2010).

Dentsply Chief Clinical Officer Dr. Linda Niessen described the company’s concerns about gray-market or counterfeit products’ not providing the clinical outcomes that dentists have come to expect from Dentsply brands (L. Niessen, written communication, Feb. 23, 2010). Company personnel routinely see examples of discounted noncompliant, expired or repackaged Dentsply products. They have seen cases in which early generations of products, no longer registered in the United States with the FDA, are being acquired in developing markets. These products are imported into the United States illegally and then resold to U.S. dentists as the newest product under different brand names. The primary packages are labeled clearly as the early-generation product, while the directions for use and the invoice falsely claim the product to be the newest-generation product. Gray-market activity not only creates a clinical risk exposure for dentists, but also deprives their dealer partners of the opportunity to supply a quality product behind which the manufacturer will stand. Dentsply has 22 authorized dealer partners; Dr. Niessen says that if a Dentsply product comes from anyone else, it is likely to be counterfeit or altered.

Kirsten Edwards of Kerr states that counterfeit OptiBond Solo Plus, Herculite and other popular Kerr brands have been sold through unauthorized dealers (oral communication, Feb. 23, 2010). To the naked eye, the packaging appears to be identical to the official company packaging. This includes lot codes that match legitimate codes for lots sold to authorized dealers. The company cautions dentists that if the price of a Kerr product is significantly below standard U.S. or Canadian pricing, the product is likely to be gray market or counterfeit and could violate civil and criminal laws. Kerr also has filed a citizen petition with the FDA seeking action against several unauthorized dealers that have been found distributing gray-market or counterfeit Kerr products. As of the publication of this article, no action has been taken by the FDA to stop this activity.
It is obvious that unscrupulous, profit-motivated distributors can find many ways to simulate major products and to sell them to you and me at discounted prices. The Internet has made this easier.

**HOW DO GRAY-MARKET OR COUNTERFEIT PRODUCTS GET INTO YOUR OFFICE?**

Why do we not identify these products before they get into our offices? How do they get into our practices without our recognizing that they are gray-market or counterfeit products? I have the answer: to reduce or eliminate the problem, most dentists must change their behaviors. Who orders and purchases the dental supplies for your office? If you are a typical dentist, dental supplies are ordered, purchased, shelved and placed in your operations by a competent, knowledgeable dental assistant or, in some offices, by the office manager. These loyal staff members are eager to please you by making supply purchases as inexpensively as possible. Bargain rates of 10 percent or more off standard prices are as attractive to them as they would be to you if you were doing the ordering. How many relatively unknown companies vie for your supply business? You know that many advertisements come through your office on a daily basis. Your staff member collects these ads and attempts to make choices about the company from which to order. Do you routinely meet with your staff member in charge of ordering to review and confirm the brands and prices of the products? Does your staff member know the necessity of confirming that the distributor is an authorized dealer? It is doubtful that in an organized office, in which the dentist has delegated responsibility to staff members, that the dentist and the staff member who orders supplies meet to discuss product ordering. In my opinion, such a meeting would reduce or eliminate the problem of gray-market and counterfeit product proliferation. It is time for every dentist to hold these meetings.

I suggest that on a scheduled basis, the dentist and the staff member ordering supplies meet to determine desired brands and needed quantities of these brands of products. Before the meeting, the staff member can collect information about the various companies from which specific categories of products are available and have the information ready for the dentist’s review at the meeting. This preparation will reduce the time needed for the meeting, which can be brief.

Manufacturers sell their products either directly to you or through their authorized distributors and dealer partners. Ordering only from known, authorized retailers will ensure that the products are legitimate and from respected manufacturers.

All major manufacturers have lists of authorized distributors available. If you have a question about the legitimacy of a discounting distributor, you can verify that the distributor is an authorized retailer by contacting the product’s manufacturer.

Purchasing from the major U.S. distributors such as Benco Dental, Burkhart Dental Supply, Darby Dental Supply, Goetze Dental, Henry Schein and Patterson Dental helps ensure that the supplies are legitimate, covered by warranties and manufacturer support. There are other reasons I prefer to purchase from these major distributors. By doing so, I know that in spite of often paying somewhat more for some items, I have their repair support. Additionally, I can ask their local sales representatives about the properties of specific products and the acceptance or rejection that products are receiving in my community.

**HOW DO YOU IDENTIFY GRAY-MARKET OR COUNTERFEIT PRODUCTS?**

There are several ways to identify potentially gray-market or counterfeit dental supplies.

**Low price.** The product is selling for significantly below the known market price. You may determine the market prices by looking in the online or printed catalogs of the major dental retailers noted earlier.

**Unknown distributor name.** You know the major retailers, and you know the major private-label independent companies that do not sell via the major retailers. If the company selling the product does not have a recognizable name, you have reason to be suspicious. Do some homework to learn about the supplier, particularly if you are purchasing online, before you decide to make a purchase.

**Suspicious packaging.** If you attend a dental meeting and see a significantly discounted apparently identifiable product, you should consider the following relatively easily observable characteristics. Examine the printing on the package. Is it smeared, irregular, uneven or not of the quality you have previously observed on packaging of products with the same brand name? Is the product name current, or a previous name you remember for an earlier version of the product? Is the bar code or...
any aspect of the product description blocked out? Is the product marked “for export only” or “Not registered for sale in the European Union or United States”? Be sure the label on the product matches the product name on the directions for use. Is the language on the package something other than English?

**Check the expiration date.** Is the product expired? Does it appear that the expiration date has been changed?

If you are suspicious of a product, and you are attending a convention, go to a known authorized distributor of the brand in question, examine its packaging and ascertain the price of the product. You may see an immediately apparent difference.

**ACTIONS TO TAKE RELATIVE TO GRAY-MARKET AND COUNTERFEIT SUPPLIES**

I suggest the following preventive actions to avoid the problems potentially related to purchasing gray-market or counterfeit products.

**Use authorized distributors.** If you have any question about the legitimacy of a distributor, call the manufacturer and request a verification of the distributor’s authenticity.

**Expect to pay a fair market price for products.** Authorized distributors offer occasional price reductions as specials. However, brand-name products have an expected fair price that does not vary significantly among distributors.

**Avoid deeply discounted prices.** If the price is too good to be true, you probably are looking at a suspect product.

**Investigate.** If you have questions about any product, have your staff investigate the retailing company by visiting the manufacturer company’s Web site and comparing the image and description of the product in question with the manufacturer’s information. Most manufacturing companies feature images of their products on their Web sites.

In addition, dental manufacturers themselves are taking steps to prevent gray-market or counterfeit products. They are using new types of labeling to facilitate the identification of gray-market and counterfeit products. When these products are identified, the manufacturers are taking action against the vendors to remove them from the market.

**SUMMARY**

As verified by dental manufacturers, there is no question that gray-market and counterfeit products are being distributed and sold on the U.S. dental market. “Buyer-beware” policies should prevail in dental offices. Dentists should meet with and assist office staff members in selecting products and identifying authorized product distributors. Questionable products and unknown, unauthorized distributors should be avoided. Although discounted dental products are available, the cost of overcoming the potential problems for patients caused by inferior products can be far greater than the amount saved.

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