

Know Your Vendor

The Pitfalls of Gray-market Products

by Doug Stegman and Bennett Napier, CAE



Second opinions are common in health care; whether a doctor is sorting out a difficult case or a patient is not sure what to do next. In the context of our magazine, the first opinion will always belong to the reader. This feature will allow fellow dental professionals to share their opinions on various topics, providing you with a "Second Opinion." Perhaps some of these observations will change your mind; while others will solidify your position. In the end, our goal is to create discussion and debate to enrich our profession. — Thomas Giacobbi, DDS, FAGD, Editorial Director, *Dentaltown Magazine*

In a down economy, many businesses look at ways to save money for the bottom line. When price pressures increase, new players enter the fray to offer a cheaper but not always better product option. This is certainly true in dentistry, both on the clinical and laboratory side. Dentistry is a wide open market for "gray-market" products due to the number of distributors globally.

It's important for dentists and dental laboratories to take the time to know who you are working with in terms of a vendor relationship and also have a keen understanding of the pitfalls of buying materials or equipment at a price that is "too good to be true."

There is a distinction between black-market and gray-market products. Black-market products are those that are stolen or are flying under the radar in terms of regulatory compliance such as FDA registration.

Gray goods are genuine goods that the manufacturer sells abroad but are then imported into the U.S. without the manufacturer's permission. The goods often are sold on the Internet or by unauthorized wholesalers, sometimes at prices below the manufacturer's U.S. prices.

There is a correlation between black- and gray-market products; in either case it might not meet FDA registration requirements or other compliance standards for use in the domestic market.

A good example of this is, in January of this year, U.S. Marshals, acting under a court order sought by the U.S. Food and Drug Administration (FDA), seized all dental devices from Rite-Dent Manufacturing Corporation, located in Hialeah, Florida. The seizure of dentistry products valued at \$208,910 followed an FDA inspection that found significant deficiencies in the company's manufacturing processes that might have affected the safety and effectiveness of the products.

The seized products included alginate impression material, ultra impression material, enamel bonding system, pit and fissure chemical curing sealant, tooth-shade resin material, cavity varnish, polycarboxylate (PCA) cement and zinc phosphate cement, all used in the practice of dentistry.

FDA inspections of the Rite-Dent facility, most recently in November 2010, revealed continuing significant deviations from the current good manufacturing practice requirements for the products. FDA's recent inspection also confirmed that the company had not obtained FDA marketing approval or clearance for a device called the Ultra Impression System. (*Editor's note: For more on this seizure, please visit: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm237894.htm>*)

Gray-market distributors are able to purchase products abroad normally well below the wholesale cost of their U.S. counterparts. Manufacturers might sell like-products cheaper overseas because the gray products (a) might not come with the standard U.S. warranty; (b) might contain cheaper components; and (c) might not meet U.S. safety and/or environmental standards.

Because gray products might materially differ from domestic goods, including quality control, product characteristics, labeling and other key elements, a dentist or dental laboratory might be disappointed by the quality of the gray products. If there is a material or mechanical defect, you could be left holding the bag in terms of lost chairtime for remakes, repairs and or other liability.

The accounting firm KPMG (www.kpmg.com) estimates that the gray-market costs the information technology industry more than \$40 billion in annual sales alone. To date, there are no definitive statistics on how much gray market affects dentistry.

In the *Journal of the American Dental Association* article "Are You Using Gray Market Counterfeit Dental Products," Dr. Gordon J. Christensen shared programs by key manufacturers such as 3M ESPE, Dentsply and Kerr to combat the increasing gray market presence in dentistry. You can find gray-market products in almost every product category from materials (i.e. CAD/CAM blocks, porcelain, alloys, hand pieces) to equipment.

Dental manufacturers can use trademark and patent law to defeat the gray market. In fact, the argument for stopping gray-market medical devices is much stronger than the argument for stopping gray-market consumer products such as food and cosmetics.

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The Lanham Act is a federal regulation that exists to help combat gray-market products. Unlike black-market products, gray products may be lawfully sold in the United States if they are identical to their U.S. equivalent. Gray goods that are materially different, however, might violate § 32, 42, or 43 of the Lanham Act, and, thus, cannot be sold in the United States.

To hide the fact that they are selling gray products at well below retail prices, gray marketers often do not list prices but request prospect customers to telephone or e-mail for the price. When asked about product serial numbers or FDA registration information, gray sellers often claim that such information is not available.

Courts have found the following differences in gray goods material: (a) altered or obliterated serial numbers; (b) non-English language instructions, manuals or labels; (c) a significantly reduced price from that of the U.S. exclusive distributor and/or sold without the standard, comprehensive U.S. warranty; and (d) physical differences, including packaging and/or product composition. All of these areas are currently regulated for dental materials and equipment through the Code of Federal Regulations (CFR 801 and 820) and enforced by the Food and Drug Administration.

The National Association of Dental Laboratories through its general counsel, Reed Smith law firm headquartered in Washington, D.C., has published a guide, *Legal Relationships of Dental Laboratories*. It is worth noting a chapter of that guide relative to the Uniform Commercial Code (UCC).

UCC Section 2-301 defines the basic obligations of the sales relationship as follows: the seller, or dental laboratory, must transfer and deliver, and the buyer, or dentist, must accept and pay, "all in accordance with the contract." Section 2-601 purportedly gives the buyer the right to reject the goods delivered in that they fail to conform "in any respect" to the agreement. This includes compliance with implied warranties of fitness and merchantability.

Implied warranties with respect to observable defects are waived when the dentist has examined the goods as fully as desired or has refused to examine the goods at all. Likewise, the parties have the power to modify or eliminate implied warranties.

Helpful Tips on Identifying a Gray Market Vendor and Due Diligence:

1. Is the price "too good to be true"?
2. Is the marketing from the distributor mainly through e-mail?
3. Is customer service for the vendor hard to reach?
4. Is FDA registration information readily available of both the vendor and the material?
5. Is the vendor able to provide you with reputable referrals?
6. Is the vendor an authorized distributor of the manufacturer?

Second, and more importantly, when a nonconforming product is rejected, the seller has a limited right to cure the defect. Furthermore when a reasonable time for rejection has elapsed, acceptance of goods is presumed and risk of loss for discoverable defects shifts to the dentist.

The code provides a full range of remedies for breach of contract to both the dentist and the laboratory. A dentist confronted with the laboratory's breach is entitled to return the defective goods, enter another contract to purchase a substitute and then to recover damages for the substitution. This right is subject to a laboratory's right to cure, however. Alternatively, a dentist faced with a breach of warranty may keep the defective appliance and recover the difference between the value of the item accepted and the value if it had been as warranted.

Case in point as it relates to gray-market products, is who is liable in the supply chain if something goes wrong? Is it the dentist who writes the prescription and seeks a material that might not meet U.S. requirements; is it the dental laboratory who tries out a "new vendor" in order to deliver a desired price point to keep their dentist account happy? Depending on the scenario, it could be either or both. In either situation, if the manufacturer can prove that gray-market products were used, they are likely under no obligation to remedy the situation. ■

Author Bios

Doug Stegman is the owner of Stegman Laboratories in Phoenix, Arizona. Stegman Laboratories is one of less than 100 dental laboratories in North America to achieve third-party certification through the DAMAS quality assurance process. Mr. Stegman is a past president of both the Arizona Dental Laboratory Association and the National Association of Dental Laboratories. To contact Doug Stegman, please e-mail: doug@stegmanlabs.com, visit: www.stegmanlabs.com, or call 602-266-2001 or 877-783-4626.



Bennett Napier, CAE has served as Co-Executive Director for the National Association of Dental Laboratories and its affiliate, the National Board for Certification in Dental Laboratory Technology since 2001. Napier has Bachelor's degrees from the University of North Carolina in Political Science and Sociology, and attended the Graduate School of Public Policy at the Georgia Institute of Technology. He also holds a Master's of Science Degree in Applied Politics and Policy from Florida State University. He can be reached at bennett@nadl.org, or 800-950-1150 or 850-205-5626.

