

The Integrity of Dental Materials... Is It Being Compromised?

Have you ever thought about our nation's Food & Drug Administration and the role they play when you purchase foods and



medicines or when you obtain medical treatments? The confidence we as consumers place in the safety and efficacy of these products, in large part, is based on the ingrained notion that the people of the USA have formed a watchdog group whose sole purpose is to make sure that these products live up to their claims and that they are safe. This group is employed by you and me and is referred to as the FDA.

In the absence of this type of regulation, we have witnessed greed trump the good of the consumer and the consumer has paid dearly, often in disfigurement or loss of life due to the sale of tainted products.

When you as a dental professional purchase a dental product for use in treating the dental conditions of your patients, both you and your patient enter into this therapy with the assurance that the products you intend to use have followed the guidelines and withstood the scrutiny of the FDA to assure their safety and efficacy. This allows our society to trade goods and services freely and with little fear. This is a great system to be a part of! On the other hand; within this system loopholes can be found. And greed is still powerful. Let me explain ...

A dental product, like a composite restorative material or a crown & bridge cement, is manufactured to perform in a certain way to achieve optimum results. Large amounts of money are spent on research and development to assure that these products meet key objectives. The intent is that once these products are delivered to the dental professional, and ultimately used on patients, they will perform up to the marketed purpose and expectations. The FDA's job is to insure this happens. In order for these chemistries to work as sold, they often have to be handled properly in transit and storage. They are packaged in sealed packaging to prevent malicious tampering. They are sold through a chain of authorized distributors who, under contract, guarantee that they will store and ship the products in a secure, safe and compliant method. These distributors also have on staff, professionals who receive ongoing training for troubleshooting and advising on proper storage, technique and usage of the products. This system assures that the patient being treated receives the best in dental care and can trust the end result to be safe and effective.

In today's dental market there exists a back door for products to slip into the system outside of the FDA regulated controls and into the hands of dental professionals and ultimately into a dental patient's final restoration. This back door is called the Gray Market. The dental materials Gray Market can be defined as the flow of dental materials into our country via untraceable means and outside of FDA regulated controls for safety and efficacy. You may wonder how and why this happens.

Companies like 3M, Kerr, Caulk, Discus, Pentron, Heraeus, GC etc. manufacture and sell their products worldwide. In many countries, the prices paid for these items is much lower than that of the US in order to provide optimum healthcare to poorer 3rd world countries and to insure their citizens have access to excellent treatment alternatives. During the process of distributing these products to these countries, unethical dealers will purchase large quantities of product and sell a portion of it to a third party that will then put the materials on a boat and bring it illegally back into the US. In many instances, these products are not in their original packaging. They often are shipped and stored in extreme heat and cold. They have no assurance that they have not been maliciously tampered with. And they have none of the protections afforded by products that follow the FDA regulated channels of safety. Counterfeit products that look almost identical in their packaging but are not even close to the real thing, find their way into the US via the same channels.

Once these products reenter the US, they can be sold at significantly lower prices than those products that have followed the FDA protections. The distributors that wholesale them are also able to sell them for more than they would have been able to in the 3rd world countries and are making larger profits. In addition, some authorized dealers will purchase certain quantities of these materials and infuse them with their regular inventories. This increases their profitability due to lowering the overall costs of the products while selling at lower than market prices. While this is unethical and violates their contractual agreements as authorized distributors, the power of greed trumps what's right and ultimately jeopardizes the profession.

It's not unlikely that products of unknown origins and questionable contents could make it into your hands via a fax-blast promotion that seems too good to be true.

It's only going to take one patient tragedy from a gray market product for the litigation sharks to attack our industry and your profession and put a black mark on it that will take years to recover from.

Nashville Dental is proud to be an authorized distributor for almost every major manufacturer of dental products in the US. We strictly adhere to the regulated guidelines of the manufacturers in order to assure that our customers and ultimately your patients receive products that meet the safety standards afforded by the FDA. It's these standards which give all of us the confidence to freely receive treatment in a culture that prides itself on the highest level of dental care in the world. We would not jeopardize that for greater profits. We hope that our customers and our competitors will take the same position on this back door to our integrity.

When it comes to buying your dental materials, just remember the following adaptation to an old saying, "If it seems too good to be true, it's probably GRAY MARKET." Don't gamble your career or your patient's care on a \$100 savings. It's never worth the risk.

