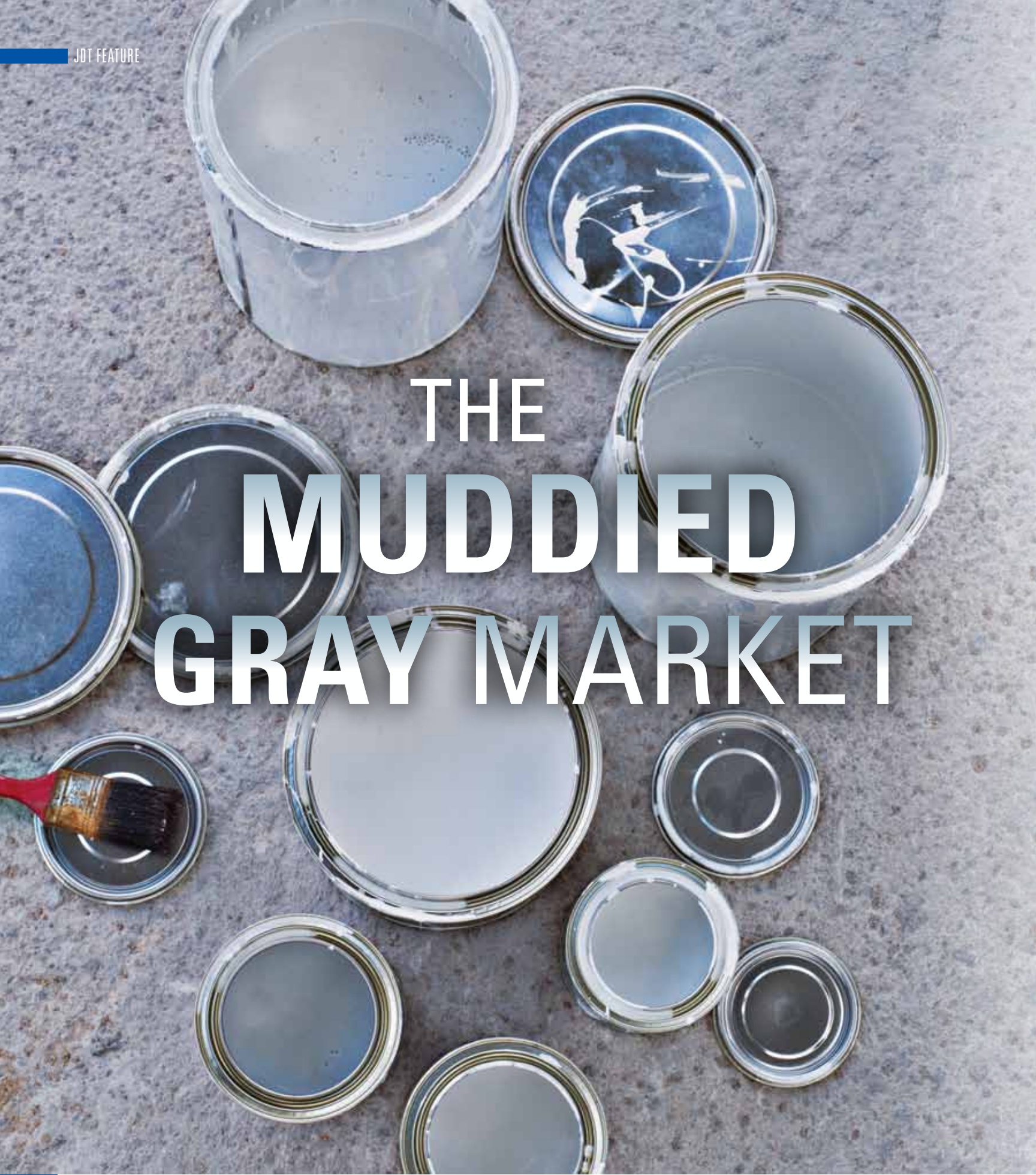


THE MUDDIED GRAY MARKET

The Gray market is labeled gray for a reason – its murky and unclear guidelines make it difficult to determine what may or may not be labeled as such. While black market products are those that are stolen or are flying under the radar in terms of regulatory compliance, gray goods are legitimate items being sold by the manufacturer but then are re-routed and distributed by unauthorized wholesalers at discounted prices. Eric Wenzel, Global Business Director, 3M Oral Care, further clarifies.

"When we talk about the gray market, we are talking about products sold through an unsecured supply chain," said Wenzel. "There are three main categories these products fall into.

1. **Products that are diverted from an authorized channel:** These products often don't comply with local laws and may have compromised quality due to improper handling or storage conditions.
2. **Repackaged or relabeled products.** This practice often happens with products nearing the end of their shelf life. Gray market dealers may change or remove the expiration date and repackage the product in order to sell it to unsuspecting buyers. In some cases, products may be sold years past their expiration date, which can lead to problems like improper curing or bonding.
3. **Counterfeit goods:** These are fake products designed (with varying levels of competence) to look like the real thing. This category is the least common but should be of the highest concern for the industry, as it poses the greatest risk to safety.

Boasting a price tag that often seems "too good to be true"; in fact it is. The products can lack quality control, be past expiration, contain defects or cheaper components and come with no warranty or traceability. Gray market distribution carries a much more expensive price tag when along with it comes the long-term negative impact on the industry.

Wayne Ledford is the president of IdentAlloy/IdentCeram Council, an organization that helps dentists find material manufacturers, suppliers and dental laboratories willing to verify and document the source and quality of materials being used (www.identalloy.org). He emphasizes to laboratories that they have a serious stake in this, because if products are not purchased from authorized distributors, then they might not be getting what they think they are.

Ledford said, "For instance, if the distributor is selling a product intended for a foreign market, it may not meet the requirements of U.S. regulators. The products also may not have been stored or shipped as recommended by the manufacturer. Furthermore, if there's ever a problem with the product in the lab or in the mouth, where does the lab turn to for support? Reputable manufacturers and dealers keep detailed records of batch numbers to reference if issues occur. In addition they have a staff of technical support representatives to help troubleshoot or solve customer issues. Finally, there's the issue of fraud. We have seen cases of customers who purchase a piece of equipment online from a seller who quotes prices much lower than the market, only to find out that the website is a shell and has no product to sell. By the time that's discovered, the site is down and the customer has lost their money, long-term or short term, the buyer and the patient are at risk."

If there are defects in the material, the lab is left with the ramifications in terms of lost chairtime for remakes, repairs and other liability. It is up to the lab to be knowledgeable of the vendors they are using, each product they are purchasing and FDA compliance.

"WE ARE TALKING ABOUT PRODUCTS SOLD THROUGH AN UNSECURED SUPPLY CHAIN."

—Eric Wenzel

Keith Goldstein is CEO of DESS USA, a U.S. distributor of implant components. While his organization has gone through vigorous processes of obtaining FDA clearance of products, he points out that there are some manufacturers that claim to be FDA approved but it may only be on one component, not necessarily all of them. It should also be noted there is not actually FDA approval. FDA provides pre-market processes for product review and if FDA confirms the testing of materials and equipment, then manufacturers are able to register and list their products for sale. He is also concerned that due to the lack of FDA testing of gray market products, this could lead to increased chance of failure in the patient's mouth.

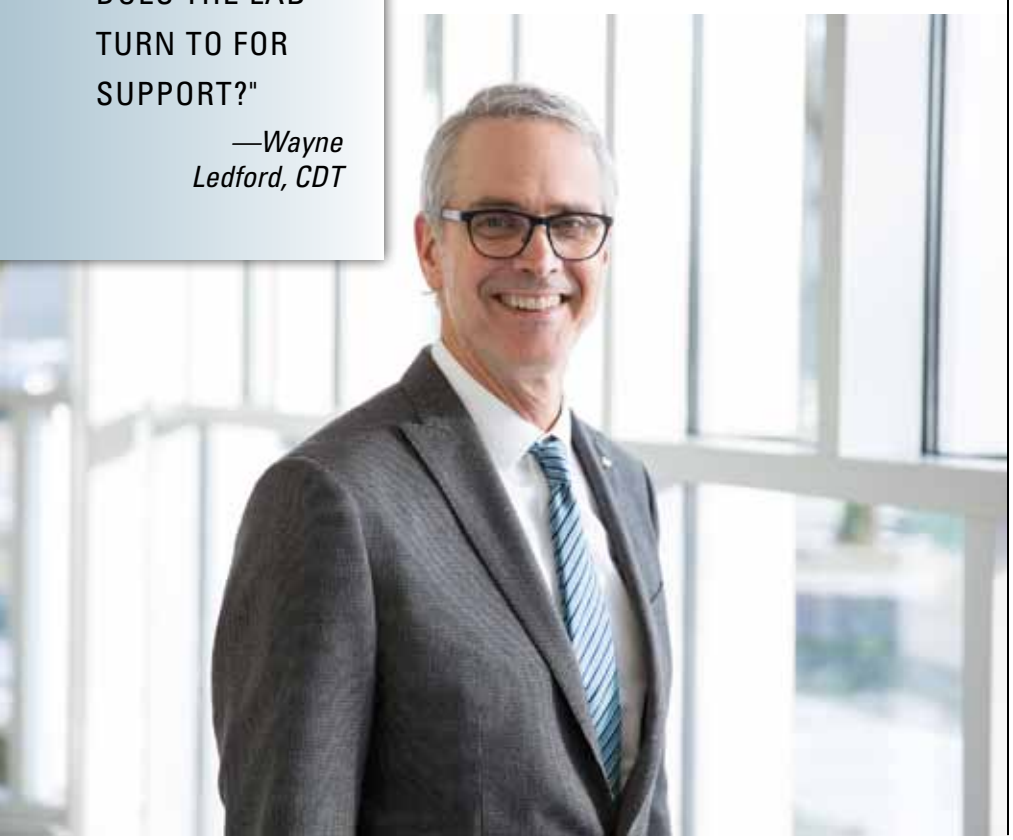
"With no testing being done there's no assurance of long-term success," said Goldstein. "If a product has been validated through a third party such as FDA or ISO, this provides that regulatory oversight necessary to audit the components. The industry needs to be better educated on what FDA clearance really means. The parts may look and feel great in your hand but these are made with such high precision that there are elements that the human eye can't judge whether it's a good or bad part. FDA submissions ensure that specific part has been approved with documentation and testing validation. I envision over time that as more and more people place implants and try to cut costs, there will be more failures and the industry will suffer overall when this occurs. The dentist trusts the lab and the patient trusts the dentist and no one is fully disclosing what they are using, which is really disheartening to the patient."

"THE INDUSTRY NEEDS TO BE BETTER EDUCATED ON WHAT FDA CLEARANCE REALLY MEANS."

—Keith Goldstein

"IF THERE'S EVER A PROBLEM WITH THE PRODUCT IN THE LAB OR IN THE MOUTH, WHERE DOES THE LAB TURN TO FOR SUPPORT?"

—Wayne Ledford, CDT



The NADL has launched it's What's In Your Mouth Campaign in order to address transparency in dentistry (http://dentallabs.org/). This campaign is geared toward educating the public on their right to know where their dental restorations are coming from, who is making them and what materials are being used in the process. It also aims to raise awareness regarding the important role and value of the dental laboratory and a trained and educated dental technician as part of the dental restorative team. Further steps need to be taken however to better inform not just the public, but those within the dental laboratory industry the importance of knowing their vendors.

Goldstein recommends that if a company states their products are FDA-registered, it is the users responsibility to complete due diligence and pull up the 510K documentation to check the exact products that are FDA registered. When asked about product serial numbers or FDA registration, illegitimate sellers

might claim that the information isn't available. FDA registration is public information and can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm.

This may be a tedious process but the reassurance is well worth the effort.

Ledford further points out that dentists also need to complete their due diligence. They should be willing to talk with their dental laboratory to discuss the source of the products the lab uses. If the material is an alloy or ceramic, they should ask the lab to provide IdentAlloy or IdentCeram certificates with the case. Laboratories should contact manufacturers and request MSDS sheets and verification of regulatory compliance. The CDL and DAMAS programs offer excellent frameworks for these verifications.

3M as an organization has a multi-faceted approach involving all major players to protect patient safety.

- They have policies, procedures and systems globally to instill and ensure ethical business conduct.
- They proactively monitor gray market sales, catch unauthorized products and stop them at the source. They seek legal and regulatory actions to deter illegitimate dealers and actively remove illegitimate listings of 3M products on the internet.
- They've been working with the industry and dental community and have launched a series of awareness campaigns including educational videos and resources on their website (www.3M.com/buydental).

As far as initiatives on the part of the dental laboratory, Wenzel recommends that labs should always do a background check on new dealers and that labs should be transparent with their purchasing procedures and providers. If a lab discovers it's been using gray market materials accidentally, they should inform the manufacturer to help them be aware of the source of the gray market dealer. Simple signs to be on the lookout for to help identify gray-market products are a blocked barcode, smeared or low-quality printing, out-of-date product name, text such as "for export only" and if the packaging isn't sending up red flags, consider the pricing structure. If the price is significantly below standard pricing, the product may be gray market or counterfeit.

Bennett Napier, CAE, NADL executive director, has assisted many laboratories with clarification on gray market materials and the ramifications of purchasing them. The biggest message he would like to emphasize is that labs are accountable for the decisions they make.

"It really comes down to trust but verify," said Napier. "Don't just take a vendor's word for it; ask for documentation because ultimately, ignorance is not a defense. If something goes wrong with a product the lab will be held accountable and therefore they have a responsibility to put themselves in a good position by having product verification. Whether it's private pay or especially when insurance reimbursement is involved, a patient needs to get the promised product." **JDT**