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*The National Society of Dental Practitioners and the Dentist's Advantage Insurance Program for Dentists*

## **RISK MANAGEMENT ALERT**

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### **USE OF NON FDA APPROVED MATERIALS**

There have been several recent inquiries to the Dentist's Advantage Hotline concerning the use of FDA non-approved dental materials and devices. Many dental offices are using such materials and devices to contain costs.

There are FDA rules and regulations concerning the import of, use of and sales of these materials and devices. Many factors go into the ways the FDA approves medical and dental materials and devices. They are entrusted with protecting the health and welfare of our citizens in many ways including the safety of medical and dental materials and devices used in this country. Violations of FDA rules and regulations can be serious and expensive.

Additionally, If there are any suits or complaints concerning or as a result of using non approved materials/devices, the defense of those claims would be very difficult, if not impossible to defend. The defendant in such cases would have to prove that the practice was within the standard of care!

It is highly suggested the before using or continuing to use non-FDA approved materials/devices that you closely review FDA regulations at [FDA.org](http://FDA.org). They also list, on a continual basis, a complete list of approved items. Many state dental regulations require the use of only FDA approved materials/devices.

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