

## **MEDIA INTERVIEW QUESTIONS – updated November 2011**

### **FOR NATIONAL ASSOCIATION OF DENTAL LABORATORIES LEADERSHIP**

**Answers provided by Bennett Napier, CAE**

#### **1. What is the NATIONAL ASSOCIATION OF DENTAL LABORATORIES?**

The NATIONAL ASSOCIATION OF DENTAL LABORATORIES is a trade association comprised of over 1,600 members, the majority of which are commercial dental laboratories. Other members in the association include state and regional lab associations, dental technology schools, individual dental technicians and dental laboratory suppliers.

##### **1a) What is the purpose of your organization?**

The NATIONAL ASSOCIATION OF DENTAL LABORATORIES is advocate for the dental laboratory industry supporting dentistry and serving the public interest by promoting high standards. NATIONAL ASSOCIATION OF DENTAL LABORATORIES accomplishes this by providing programs, services and networking opportunities responsive to the evolving technical, educational, professional and business needs of dental laboratories.

#### **2. How does the dental lab industry work?**

When a person goes to the dentist and the dentist suggests a treatment plan that includes prosthesis, for example a dental crown or a bridge, the dentist will then prepare the patient's mouth and take an impression of the mouth. The impression, along with a prescription written by the dentist will then be sent to a dental laboratory.

The majority of dental laboratories in the U.S. are small, family owned businesses with less than 5 employees. Of course there are some laboratories that have more than 100 employees. Dental laboratories are typically in a separate location from the dentist's office and serve multiple dentist clients.

Upon receipt, the laboratory will review the prescription and disinfect the impression. The impression is then utilized to make a few plaster models that will be used to assist the technician in determining the appropriate form, fit and function of the finished prosthesis. The technician then begins the functions associated with manufacturing the restoration. This is a multi-step process that requires the technician to possess knowledge and experience in material science, anatomy, physiology, among other things.

Once the restoration is complete, the laboratory returns it, along with a study model, to the dentist's office.

#### **3. Talk about National Association of Dental Laboratories 2007 letter to the FOOD AND DRUG ADMINISTRATION (Interagency Working Group on Import**

**Safety). What is the NATIONAL ASSOCIATION OF DENTAL LABORATORIES asking the FOOD AND DRUG ADMINISTRATION to do, and how are they responding? What are the current regulations for dental imports, and what does the NATIONAL ASSOCIATION OF DENTAL LABORATORIES believe should be the proper regulation?**

The NATIONAL ASSOCIATION OF DENTAL LABORATORIES does not oppose offshore manufacturing. However, we feel strongly that every patient in the United States has a reasonable expectation that the dental work that goes into their mouth is safe, and free from harmful materials, whether that work is made in a domestic dental laboratory or a foreign dental laboratory.

We are a largely unregulated domestic industry and rely on our own voluntary standards. Since those standards are voluntary, foreign laboratories are not required to follow them except for registration with the Food and Drug Administration.

For a foreign dental laboratory to bring work into the United States requires them to register with the U.S. FOOD AND DRUG ADMINISTRATION and appoint a U.S. agent for official communication purposes. Once their registration is approved, and their shipments come into U.S. ports of call, the cases must contain disclosure information of what types of restorations are in the boxes using FOOD AND DRUG ADMINISTRATION product codes. If approved by Customs and FOOD AND DRUG ADMINISTRATION field agents, the cases are released for distribution into the U.S. to the purchaser, either a dental laboratory or a dentist.

The FOOD AND DRUG ADMINISTRATION has the authority to stop a shipment of dental restorations at port indefinitely but has little manpower to make determinations if something is safe or unsafe. The FOOD AND DRUG ADMINISTRATION does have the authority to inspect foreign dental laboratories or contract with a third party in another country to conduct such inspections, but Food and Drug Administration records reflect that does not happen very often.

The NATIONAL ASSOCIATION OF DENTAL LABORATORIES submitted seven recommendations to the FOOD AND DRUG ADMINISTRATION in September for consideration (***see footnote under question 11, items a-f, for a full description***)

The Food and Drug Administration has responded to our association that it will be working on a guidance document this year that addresses existing regulations on both domestic and foreign dental laboratories. However, some of our association's recommendations may require further Congressional action as the Food and Drug Administration does not have current regulatory authority to implement certain recommendations that we have submitted.

**4. What is the newfound trend of outsourcing work to foreign dental labs doing to your industry?**

Outsourcing to foreign dental laboratories in the U.S. started in the mid 1980's. However, it has significantly increased during the last five years. Like much of offshore trade in the U.S. manufacturing industry there is the usual downside – concern over the inability to compete with much less expensive foreign labor, less foreign regulation and overhead, resulting in significantly cheaper pricing.

Here in the U.S. we have to concern ourselves with paying competitive wages to our employees and ensuring the livelihood of our profession. However, again, like other manufacturing industries, some in our industry have embraced utilizing outsourcing to offshore dental laboratories as a way to stay competitive.

The demand for dental services in the U.S. is increasing and there is a need to help meet that demand with additional production capacity. Further, dental insurance has some affect on the necessity to utilize foreign dental laboratory services, as the reimbursement rates for dental work set by dental insurance plans, are hard to achieve at U.S. labor, overhead and equipment rates.

### **How has it changed what you do?**

I don't think it has changed the core work of what we do as a dental laboratory but how we do it. It requires more due diligence by dental laboratories that seek to work with a foreign dental laboratory to ensure they are working with a quality outsource partner.

### **5. What are the concerns of outsourcing dental work, as far as the safety of metals and alloys, and the threat of lead contamination?**

Obviously, in light of the concern over unsafe import products our association had to evaluate the potential for unsafe products within the dental industry. As you stated previously, our industry is unregulated and therefore the standards, although very good, are all voluntary and therefore not enforced. We know, from the other recalls that we have all read about, that the FOOD AND DRUG ADMINISTRATION doesn't have the manpower to inspect all products being imported into the United States. Dental restorations are no different.

Yes, all materials provided and utilized are supposed to be approved by the FOOD AND DRUG ADMINISTRATION, but that was also the U.S. consumer's assumption with toys. At this point I think that the American public now acknowledges that ultimately, the U.S. import manufacturer and the U.S. consumer is dependent entirely upon the foreign manufacturer following those safety guidelines.

If the foreign manufacturer fails to do so, we are at considerable risk. However, unlike toys, there isn't anyone in the U.S. routinely market testing the safety of dental restorations, therefore in our industry, due diligence is very important.

Again, we feel strongly that all dental patients have a reasonable expectation of having a safe dental restoration placed in their mouth. We want to play our part in ensuring their safety.

### **Also, what about the lack of identification or disclosure?**

The National Association of Dental Laboratories strongly supports a patient's right to know the source of their dental restorations and the materials included in their restorations. Even before the recent issues with import safety concerns, the NATIONAL ASSOCIATION OF DENTAL LABORATORIES had supported stronger measures to make sure patients are safe and better informed, and that is what our organization has been pushing for at the state and national level for more than three decades. So far, there has been little action at those levels responding to our recommendations, and we hope that will change as more people are educated on the current environment.

### **6. Are there labs outsourcing all over the US?**

Domestic outsourcing, meaning outsourcing some work to other laboratories in the U.S. is pretty common. Currently, based on FDA data, approximately 38% of dental restorations in the U.S. are manufactured in full or part by foreign dental laboratories.

It should be noted that dentists also are directly outsourcing to labs in other countries without going through a laboratory in the U.S. and may do this without being registered with the FOOD AND DRUG ADMINISTRATION, as the current exemption that the NATIONAL ASSOCIATION OF DENTAL LABORATORIES opposes allows.

### **Why do labs or dentists choose to outsource to a foreign dental laboratory?**

There is tremendous pressure on U.S. laboratories to stay competitive and to offer lower prices and to also offer the latest technology, which is expensive. The reality is that there is only so much that a U.S. laboratory can do to lower their overhead and U.S. dentists can work directly with foreign dental laboratories who boast significantly lower prices.

Some laboratories in the U.S. feel that they can incorporate offshore outsourcing into their current business model in order to continue to employ their current workforce. Other laboratories have turned completely to outsourcing all of their work to a foreign dental laboratory. However, regardless of whether a laboratory has chosen to utilize offshore outsourcing or not, nearly all laboratories in the U.S. are feeling the pressure and are struggling to compete.

Some dental schools and large group dental practices choose to outsource to foreign dental laboratories to reduce direct costs for the laboratory portion of their operating expenses. An average dental crown produced in the U.S. is \$150.00 where a foreign produced dental crown averages \$35-50.00.

## **7. What should consumers, patients know? Do they have a right to know where their dental work is made?**

Consumers in the United States should ask their dentist where their dental restoration was manufactured and they should ask that the specific materials utilized in their finished restoration be documented in their records. Every patient has a right to know that what is in their bodies is safe. I'd want to know.

As I said, even before the issues surrounding the safety of imported products came about early last year, the NATIONAL ASSOCIATION OF DENTAL LABORATORIES had advocated for mandatory disclosure of the manufacturing laboratory as well as the materials contained within the finished dental device. We have done this directly in meetings with the American Dental Association and the Food and Drug Administration since 2004 and continue to do so. We feel a strong commitment to the U.S. dental patient and we will continue to work to seek recognition of the standards that our industry has developed to ensure patient safety.

## **8. What has the outsourcing done to the chain of trust in the dental community? Specifically, how has it changed the relationship between the dentist and the lab, and moreover, the relationship between the dentist and the patient?**

Although foreign outsourcing has been going on for more than 20 years, the marketplace that we are in now is different. The new "global marketplace" allows just about any consumer in the U.S. to obtain just about any product manufactured anywhere in the world and has changed our society.

We know that most patients have no idea that their dentist doesn't make their restorations, so likely the potential of having an unsafe product doesn't occur to them. And, likely most general dentists don't think that they are receiving any offshore restorations. Therefore, on a daily basis, likely the relationship that most dentists and laboratories enjoy and most dentists and their patients have remains unchanged.

The issue of foreign outsourcing and potential unsafe products within the dental industry may not be filtering down from a national level on the dentist side, although our association is actively trying to change this so that the dentist knows what questions to ask of their dental laboratory. The NATIONAL ASSOCIATION OF DENTAL LABORATORIES has actively worked toward educating dentistry on the rapid changes facing our industry.

## **9. Whose responsibility is it to inform the patient they may be wearing a foreign device? The dentist, the lab? Where does the accountability lie?**

The U.S. Food and Drug Administration requires a foreign dental laboratory to register with them as an offshore manufacturer. They also require any U.S. dental laboratory

that is importing foreign goods to register as an initial importer and if they provide it to their dentists under their own label then also to register as a repackager/relabeler. Therefore the information regarding where a restoration is made, is supposed to be disclosed to the dentist. However, currently there is no requirement for the dentist to disclose this information to the patient.

This is one of the primary objectives identified in the National Association of Dental Laboratories letter to the Interagency Task Force. Again, remember, many dentists are working directly with foreign dental laboratories and are not required to register and therefore are also not required to document the source.

**10. Does or can outsourcing of dental work pose a danger for the general public? What about leaching of these materials in someone's mouth, particularly lead?**

In a recent American Dental Association news article a Food and Drug Administration official was quoted as saying and I am paraphrasing, that "with the volume of work coming in, it is difficult to track and ensure the safety of every dental restoration". With that said, there are certain materials that are unsafe for use in a dental restoration.

Depending on the type of device prescribed for the patient and any modifications the dentist may perform Chairside placing the product in the patient's mouth, certain materials could be absorbed through saliva, or if they are permanent restorations placed in the mouth and contain an unsafe material, such materials could be absorbed through the tissue or bloodstream. Chemicals of concern include but are not limited to lead, chromium and cadmium.

**11. What is your best hope for your industry now? In a perfect world, what should be done to protect the public? What is the solution?**

As our association outlined in the seven key points to the Interagency Task Force we feel that it is imperative that the FOOD AND DRUG ADMINISTRATION" consider the following recommendations.

a) The FOOD AND DRUG ADMINISTRATION should expand its regulatory interpretation of "qualified to place a product on the market" to include a reference to the Certified Dental Technician designation when speaking about the manufacture of dental devices, whether the product is foreign or domestic. In this sense, a best practice would be to have one CDT in each laboratory. This is in line with National Association of Dental Laboratories Model bill for state legislation.

b) The FOOD AND DRUG ADMINISTRATION should remove the exemption of U.S. dentists from having to comply with QS/GMP regulations, which includes labeling and disclosure. There are U.S. dentists and dental schools that are directly purchasing their dental laboratory work from foreign dental laboratories and there is no current requirement for them to comply with the same requirements that a U.S. dental

laboratory has to do in the same scenario. This scenario leaves a void in transparency and traceability for product recalls.

c) The FOOD AND DRUG ADMINISTRATION should grant approval of the dental Appliance Manufacturers Audit System (DAMAS) to be an approved third party verification/inspection mechanism as it relates to FOOD AND DRUG ADMINISTRATION inspection. This would allow DAMAS accredited dental laboratories to be exempt from FOOD AND DRUG ADMINISTRATION inspection.

d) The FOOD AND DRUG ADMINISTRATION should review the voluntary material content disclosure program for dental devices, Identalloy and IdentCeram for compliance for labeling elements for CFR 820, web link: [www.Identalloy.org](http://www.Identalloy.org)) The FOOD AND DRUG ADMINISTRATION should consider requiring all dental laboratories, both foreign and domestic to register either with the FOOD AND DRUG ADMINISTRATION, or encourage such requirement of registration through appropriate agencies at the individual state level in State Dental Practice Acts, which generally would be with a state Department of Health.

f) The FOOD AND DRUG ADMINISTRATION should conclude that the end user for dental devices is the patient, not the prescribing dentist, and as such, the point of origin of manufacture of where a dental restoration was created should be accessible to the individual patient. It is a consumer's right to know where their dental device was manufactured and what materials are in their mouth.

g) Dentists should be required to include the registration number of their contracting dental laboratory on the prescription that is kept in the patient's record. Such registration information could be the FOOD AND DRUG ADMINISTRATION registration number or state specific registration number (in those states where required) for the dental laboratory.

### **KEY POINTS TO ENSURE ARE COVERED**

- 1) The National Association of Dental Laboratories believes that dental patients have a reasonable expectation that the products they have in their mouths are safe.
- 2) The National Association of Dental Laboratories supports measures that provide more information to dental patients about dental materials and where a product was manufactured.
- 3) The National Association of Dental Laboratories advocates enforcement of existing regulations and advocates for strengthened regulations in certain areas by the Food and Drug Administration.