"Accepted once, accepted everywhere." This simple phrase describes the holy grail of globalization.

Whether the term stirs thoughts of riots in Barcelona or exclusive secretive meetings between the corporate elite, what most people may not realize is that globalization of the dental industry reflects a desire to have "one regulatory approach accepted by all countries." In a recent presentation to the industry and FDA, I introduced this topic as “The Good, The Bad and the Ugly.” Though radical tensions can develop from pursuing a one-size-fits-all approach to regulating dental products, the objective is worth pursuing.

When regulations differ from one country to another, the seller and buyer run into an invisible barrier to trade. Within the dental industry, barriers to trade also prevent doctors from treating their patients. There is a direct cost to our quality of life when we cannot get treatment for what is ailing us.

It is ironic that barrier regulations originate from a government’s attempt to protect public health. However, too often a country’s ministry of health will begin enforcing a new regulation that prevents doctors from having continued access to dental products they have been using for years.

Whereas most citizens can appreciate the removal of unsafe dental products, many products that are safe and effective are often denied legal access for reasons that have nothing to do with safety. Common sense tells us that if a product is legally used in well-developed countries in Europe, the United States or Japan, it should be good enough to for use everywhere. In fact, of the 192 countries in the world, there are 40 different regulations.

If you make a dental product accepted in one country, chances are it won’t be accepted everywhere without a lot more work. It is important to note that many countries do take a common-sense approach. Without any treaties, or free-trade agreements, many countries will simply ask for evidence a product is approved by the country in which it was made. In fact, the U.S. dental industry reported selling dental products into 170 countries last year.

More harm than good?

A phrase sometimes heard spoken between ministries of health is, "Public health trumps trade." However, "trumping" dental trade harms public health.

Our devices prevent and treat diseases more common than any other. The surgeon general’s report on oral health in America indicates population-based studies have demonstrated an association between periodontal diseases and diabetes, cardiovascular disease, stroke, and adverse pregnancy outcomes. The World Health Organization has found that the most prevalent childhood disease is dental caries, which is five to seven times more prevalent than asthma.

When a country’s ministry of health attempts to strictly regulate medical devices, they too often threaten the well-being of the very people they have taken an oath to protect. Ministries of health are aware of this fact and are working harder to create regulations that are like other countries'. The goal is to find that one approach everyone worldwide can agree on. Many ministries of health have been working together to find one approach that all countries will accept. In fact, in 1992 a special task force was created to do just that.

Regulating devices

In 1992, the World Health and World Trade Organizations cosponsored the Global Harmonization Task Force (GHTF), tasked to create guidance on how all medical devices everywhere should be regulated. Representatives from industry and governments of the United States, European Union, Canada, Australia and Japan have since worked to develop 50 guidance documents that any country in the world can borrow to develop their own medical device regulations.

The GHTF’s “guidance documents” cover a broad range of topics including; how medical device are

www.dental-tribune.com

See Page 24
are shaping their regulations around high-risk devices. In fact, all industry representatives in one of the most critical study groups made high-risk pacemakers, cardia-
stents, neonatal respirators and ar-
tificial kidneys. Businesses that “represent industry” are all from very large corporations with annual sales revenues reported at $500 mil-
ion to $5 billion.

This consensus building with large corporations making high-risk medical devices has “harmonized” the GHTF recommendations, with-
out giving adequate attention to its impact on the dental industry of oral health care worldwide. To compi-
clicate matters further, many of the ministries of health that helped cre-
ate the recommended approaches to regulating medical devices world-
wide have deviated from the recom-
mendations in substantial ways by adding national requirements on top of the GHTF recommendations, which have seriously hurt industry and oral health care within their country.

Canada’s trial

In January 2005, Health Canada adopted a new medical device regu-
lation based on many different GHTF guidance documents, which
they had helped create. Along with adopting a variation from the GHTF risk classification recommenda-
tions, Health Canada also adopted unique Canadian requirements on how manufactures should have fac-
tories inspected.

Though their requirements for designing and manufacturing dental products was based on the interna-
tional standard ISO 13485, many dental companies around the world, who already had certified to ISO 13485, found that Health Canada would not accept their existing ISO 13485 certificates. Health Canada sent notices to dental manufacturers threatening to revoke their licenses if they did not have inspections per-
fected to their version of the in-
spection, called the Canadian Med-
ical Device Conformity Assessment System.

As a result, many dental products ceased to become legally available in Canada. For two years, many niche products became impossible to legally obtain, even though many of them had been licensed and legally available for many years pre-
vious to Canada’s new “harmonized
regulation.”

At one point, Canadian dentists pressed the Canadian Dental Associ-
ation to look into why they were no longer able to buy dental products they had been using. Dentists con-
tinued to buy whatever they could, regardless of whether the products were properly licensed in Canada or not. However, many members of the dental industry refused to continue selling their product to Canadian dentists for risk of being caught by Health Canada. Health Canada’s New Medical Device Regulation put the entire health-care system in jeopardy.

Though the Canadian inspection is remarkably similar to the interna-
tional inspection, few inspectors were available for performing it when the regulation went into af-
fact, especially in Europe and Asia. As a result, entire medical device categories suddenly ceased to legal-
ly exist in Canada. Several years into the enforcement of the new “global-
like” regulation, Health Canada still struggles to get industry to cooper-
ate with their new regulation, while dentists still look for any way they can to maintain a steady stream of dental products.

The future

It is important to note that the lack of availability of dental prod-
ucts in Canada has not prevented Canada from being the No. 1 im-
porter of U.S.-made dental products. Twenty percent of the U.S. export market is to Canada, which is the largest of any country the United States exports to.

“Accepted once, accepted every-
where” seems to be an elusive pipe
dream, but the more similar regula-
tions are to each other, the more trade will improve. Globalization can be a good thing and will contin-
ue to be pursued by industry and regulators. It is our responsibility to actively represent the dental indus-
tries’ concerns and help preserve oral health care worldwide.