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

Whether the term stirrs 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 be used 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. Health-care needs industries products. Globalization is an attempt to agree on one system for assessing medical device safety and performance. This is no simple task and there are serious concerns, especially with regard to how dental products are being affected.

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 reverse 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 co-sponsored 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

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