

# It's Time for Evidence

Christopher D. Ingersoll

**A**thletic trainers use numerous devices and products in their practices. These range from braces, splints, and other protective devices to creams, gels, and therapeutic modalities. Some of these products are certified (eg, some helmets) or regulated (eg, therapeutic ultrasound machines by the Food and Drug Administration). However, many products, such as shin guards, patellar straps, and chemical cold packs, are not certified, regulated, or held to any standard whatsoever. These product manufacturers have no accountability or responsibility to demonstrate that their products meet any minimal standard. Even those devices that are regulated may be evaluated based on their energy output or some other physical factor but not on their ability to provide a therapeutic or protective effect. As a result, certification or regulation may or may not serve its intended purpose.

Some manufacturers have no responsibility to provide us or patients with evidence that their product does what it is supposed to do; they need only manufacture the product and market it to us. Anyone can construct an ankle brace, for example, and sell it based only on the belief that the design makes sense and should prevent ankle injuries. The maker need not provide any evidence that the brace will protect the joint from injury or even a disclaimer describing what the brace can and can't do. Additionally, relying on past studies evaluating other ankle braces to assess a new device could be a flawed approach, particularly if the design, materials, or other elements are different in the new brace. No drug could be marketed based on the fact that it uses some of the same compounds as other drugs and that logically it should work. Why should the products or devices we use not meet the same or a similar standard?

Perhaps it is not the manufacturers' responsibility to make sure that sufficient evidence exists to support the purported effects of their products. However, this would be contrary to the established system in our country with other therapeutic agents (eg, pharmaceuticals). Whether manufacturers voluntarily agree to consider the results of randomized clinical trials of their products before putting them on the market, some regulatory agency forces them to do so, or we as professionals insist that manufacturers do so before we buy their products needs to be worked out. The point is that it has to happen somehow. We can no longer provide patients with products, treatments, or devices for which no evidence of therapeutic or prophylactic effect exists. We cannot tell patients with confidence that they will receive the desired therapeutic or prophylactic

effect if we cannot provide them with at least a minimal level of evidence. If we do so in the absence of evidence, we are violating the confidence that patients have in us as learned health care professionals.

When we employ a device, apply an agent, or otherwise use a product, we need to know its therapeutic or prophylactic effects. This evidence cannot be anecdotal (eg, testimonials from famous practitioners) or in-house, unpublished research done by the manufacturer. The evidence needs to be generated using the method established for therapeutic agents such as pharmaceuticals: the scientific method. In many cases, randomized controlled trials are necessary. As highly educated professionals, we athletic trainers have a responsibility to put the best available evidence to use when selecting products or devices for our patients. Knowing that the evidence for the therapeutic effects of a device or product is inadequate and applying it anyway presents a problematic level of accountability that athletic trainers must consider.

I don't personally believe that any of the manufacturers we work with intend to put faulty or ineffective products on the market. Nor do I believe that they are disinterested in the actual therapeutic effects of their products. I simply believe that they have developed and marketed their products in the way products are typically developed in sports medicine and athletic training. Times are changing and accountability expectations are high for practitioners and manufacturers alike. Perhaps it is time to consider a new model?

Working together, device and product manufacturers and athletic trainers must evaluate products before they are generally available on the market to establish safety and determine therapeutic or prophylactic effects. We need to continue to work together to determine efficacy in larger, longer-term studies after the product is marketed. This relationship works quite well in other medical areas. For example, orthopaedic surgeons work with implant manufacturers to determine the effectiveness of the implants. Endocrinologists work with pharmaceutical companies to evaluate drugs for diabetes. The relationships developed between practitioners and manufacturers have been positive and have resulted in improved products. Now seems as good a time as any to start developing these relationships between manufacturers and athletic trainers. Some of these relationships already exist, but there is still work to be done. And by the way, the *Journal of Athletic Training* would be a great place to publish these trials!