



BY JARROD SHAPIRO, DPM

Let the Sun Shine In

But the Sunshine Act
is overbearing and must be modified.



Practice Perfect is a continuing every-issue column in which Dr. Shapiro offers his unique personal perspective on the ins and outs of running a podiatric practice.

Most of us are well informed about the Sunshine Act. However, as a quick review, let's go over some of the details of this act, all of which are easily available online. Recall that this is actually called the Physician Payments Sunshine Act, which is a provision in the 2010 Affordable Care Act (section 6002) requiring medical products manufacturers to report to the Centers for Medicare and Medicaid Services (CMS) payments to physicians or teaching hospitals.

Here's a list of what must be reported:

- General payments such as cash,

in-kind services, consulting and speaker fees, gifts, honoraria, travel and entertainment expenses, charitable contributions, and grants.

- Ownership or investment in the company by physicians or their families.
- Research payments for clinical investigations.

Here's a shorter list of what does *not* need to be reported:

- Any payment of less than \$10, unless the payments total more than \$100 over one year.
- Product samples, discounts and rebates, educational materials intended for patients, devices loaned for clinical trials, warranty services, and shares in publicly traded mutual funds.

The consequences for failure to report are significant. Manufacturers may be fined anywhere from \$1000-\$10,000 per unreported pay-

ment, with a maximum of \$150,000 per year. If it were deemed that the manufacturer deliberately failed to report, they might be fined up to one million dollars per year. It is easy for a physician to understand the need and importance of regulating medical products manufacturers, as well as protecting patients from both predatory physicians and corporations. However, there are a few personal issues we must consider.

Cost

Let's talk first about cost. Many of the surgical products we all use are incredibly expensive to develop. Surgical instruments require many stages in their development and utilization. Think about your favorite fixation device. That device has undergone years of development, testing, and revision before being used in your hands. Remember that,

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in addition to working well in the patient, these devices must also be relatively simple for us to use quickly in an operating room. That alone makes the surgical instrument development process much more complicated. Remember also that medical supplies must also be sterile and safe to use in patients. This is a very expensive undertaking. It requires a company to invest significant amounts of money, and this is not something individual physicians or, in many cases, academic institutions are able to afford. Can you imagine one of our podiatry schools spending millions of dollars to develop a surgical implant or drug?

Patient Care

This leads to the next issue, which is patient care. It seems brutally obvious that without these companies, the developing art and science of surgery and medicine would proceed at a much slower pace. For example, the AO/ASIF foundation created a surgical instrument company in order to further develop internal fixation. Similarly, the incredibly important drug insulin was also developed by a private company, as are all

drugs today. One can easily wonder where we would be if something like the Sunshine Act were around in the 1920s. The preference would be to try out new techniques and technologies on bone models and cadavers rather than on patients. How much more difficult would this be without a surgical company willing to spend the money on this type of thing? We do not like experimenting on our patients, and this relationship allows us the opportunity to improve our own skills while keeping our patients safe.

Physician Education

Consider physician education. These companies invest heavily in our educational process for students, residents, and physicians. How many journal clubs around the country are sponsored by these companies? What would our national conferences look like without the sponsorship of medical companies?

Now, not to be so naïve as to believe these companies just want to educate us, any fool would realize this is part of their marketing strategy. Can you blame them? In order for any business to continue to exist, they must make money. For them, making money means selling their products. This is the real world. These compa-

nies live or die based on the market. If their product is not good enough, then in a very Darwinian fashion, they will lose the competition against better products and the company then must either change or disappear.

Laws like the Sunshine Act have arisen as a result of the government's and perhaps the public's perception that individual physicians and companies have acted unethically. However, most of us do not function this way, and this law seems excessive and unnecessary. We do need to protect our patients, and we do need some regulation. But that regulation must be well-balanced. Currently, that is not the case and this balance needs to be re-established. We should continue to work with the representatives from the surgical supply companies with full knowledge of their importance to patient care and the medical profession. To those companies who continue to support us despite the difficulties of increasing regulation, thanks and we hope that you will continue to do so. **PM**

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