Are Strict Compliance Rules Hurting Education?

Four ophthalmologists weigh in.

BY PRISCILLA P. ARNOLD, MD; DAVID F. CHANG, MD; STEPHEN S. LANE, MD; AND SHERI ROWEN, MD

PRISCILLA P. ARNOLD, MD

Compliance regulations for medical education have become much more tightly defined, especially in the past 5 years. This has affected physicians as teachers and as learners. On the positive side, relationships between industry and physicians making presentations must be disclosed. Members of the audience have a right to know this information and should have an interest in knowing it. Although these relationships do not lessen the importance of a presentation, they do confer a perspective that may merit consideration by the audience.

Many physicians may not realize the intricate nature of the mandate not only to disclose but also to resolve a conflict of interest. Current regulations place extensive responsibility on organizations awarding continuing medical education (CME) credits. I will use an abbreviated example of how the American Society of Cataract and Refractive Surgery (ASCRS) has met this challenge to comply with the guidelines of the Accreditation Council for Continuing Medical Education. The fourfold approach of the ASCRS includes full disclosure of any ophthalmology-related financial interests, a mandatory annual faculty education module/test for program participants, an extensive system of checks to develop balanced content, and monitoring and evaluation to confirm compliance. Obviously, this process requires significant additional administrative work and money for a large meeting.

Industry's support of research and teaching has been a critical driver of innovation benefitting physicians and patients. Strict regulations now limit the way a medical industry can sponsor events presenting commercial products. "Off-hours" meetings at large symposia sponsored by medical companies have increased significantly. At them, no off-label use of drugs or technology can be discussed, however, which can frustrate those wanting to learn about those indications. A positive is that these events appear to be popular and well attended, but they are not allowed to offer American Medical Association Physician Recognition Award Category I CME credits, which is a disadvantage for the audience.

One of the regulations causing greatest concern is the mandated public reporting of even modest financial support or "industry gifts." This so-called Sunshine Legislation seems to assume that a financial relationship of any type is improper professionally, and it certainly discourages the type of cooperative efforts that have helped drive innovation. Most doctors would disagree with these very narrow regulations and public reporting.

Despite some positive aspects to current compliance regulations, one would wish for a more limited, balanced approach. The open flow of ideas and information advances patients' care, and physicians must continue to demand that opportunity.

DAVID F. CHANG, MD

The pharmaceutical and medical device industries have a long tradition of supporting physicians' education. Despite their obvious financial motives, that companies want us clinicians to learn to most effectively and safely utilize their products is a legitimate and important educational service. Excessively punitive government fines for "off-label promotion" during the past several years have rocked the pharmaceutical and device industries. As a result, many large companies have adopted reactionary policies of avoiding anything that overzealous regulators could even remotely construe to be off-label promotion of the manufacturers' products.

The compliance pendulum has now swung toward a ridiculous extreme. Providing topical antibiotic samples for off-label presurgical prophylaxis is too risky. Speakers at industry-sponsored educational programs are instructed not to answer audience members' questions that

mention an off-label use. Speakers are not even allowed to cite published peer-reviewed studies that support off-label uses, and their slide decks are edited by the company's internal regulatory compliance staff. The unintended consequence is that this punitive and paranoid environment hinders and constrains physicians' education. Ultimately, it is patients' care that suffers when our education is overly restricted and regulated.

The leadership of the ASCRS has discussed these problematic trends at length. For example, according to a recent ASCRS poll, most US residents gain little to no experience implanting multifocal IOLs during their training. A company-sponsored lecture or program, however, will not be able to address topics such as a postoperative PRK/LASIK enhancement, refractive lens exchange, or the treatment of 1.25 D of astigmatism with concurrent astigmatic keratotomy. These everyday clinical practices are all off label.

For that reason, ASCRS is developing CME programs targeting specific educational objectives that are no longer being addressed through industry-sponsored programs. Although CME programs have their own strict set of regulatory guidelines, speakers are allowed to discuss the off-label use of products as long as doing so is acknowledged.

To become physicians, we were trained first in college and then in medical school to be evidence-based scientists. We understand that peer-reviewed published studies are more credible than anecdotal opinions. We understand that device and pharmaceutical companies have a profit motive. We understand the potential for bias when speakers have a financial conflict of interest; we ask for disclosure so that we can decide whether a particular opinion may be biased. I would rather allow faculty the freedom to educate me as best they can and then decide for myself if some or all of their advice is biased or conflicted. The FDA's role has never been to create and regulate preferred practice guidelines. To artificially regulate physicians' education based on whether the FDA has approved the recommendations therefore makes no sense; rather, it makes a mockery of my training and education as a scientist.

STEPHEN S. LANE, MD

Increased federal scrutiny and subjective, sporadic efforts at compliance, ethics, and economics have caused stakeholders in health care to collide, despite their commitment to a common goal.

Medical Education and Free Speech

Despite years of wrangling over free speech and the regulation of off-label discussion, the issue is far from resolved. Pharmaceutical and device manufacturers, along with the companies that develop educational and promotional communications, are unclear on what may and may not be said under different circumstances, and all feel bound by their own internal legal review processes. These internal legal "opinions" are oftentimes more onerous than likely needed for fear of punishment—for good reason. Punishment can range from warning letters, injunctions, and criminal investigations to large fines for damages under the False Claims Act. Recent fines charged to companies accused of promoting unapproved uses of their products have reached well into the hundreds of millions of dollars. An unfortunate result is a "vanilla" approach to teaching where internal regulators' excessive scrutiny of materials leads to the replacement of novel, interesting discussions by gifted and talented teachers with a regurgitation of the product label. The idea of making learning fun is almost absent today due to the sterilization of teaching materials by regulators and corporate lawyers.

Several years ago, some folks in government and consumer do-gooders suddenly "discovered" that doctors were consulting for companies that made medicines and things like lens implants and lasers. They also realized to their collective horror that these same companies not only paid these consulting doctors, but that they also sometimes provided gifts to doctors and their staff members—terrible things like lunch for the office or a bunch of embossed coffee mugs or sticky notes around the nursing stations. Even more recently, the startling discovery was made that these same pharmaceutical and medical device companies have been supporting postgraduate medical education. As a result, pharmaceutical and device manufacturers have become the subject of increasing governmental scrutiny.

I do not think any of us doctors is going to quit what we are doing because we have to buy our own pens, and I doubt that any of us will take down our shingle just because we have to make our own sandwiches. My concern is that participation in major medical meetings will decrease if legislating away industry's support makes attendance more expensive. Of the $2.4 billion spent yearly on CME, about 60% is provided by pharmaceutical and device manufacturers.[1] CME fulfills an essential public purpose, yet political pressure is causing many to recommend eliminating industry's support. That would remove more than half the funding, and it is unrealistic to think that health care professionals or medical publishers will pay the additional costs. The unintended consequence will be that physicians' education will suffer and, ultimately, that the quality of patients' care will decline.

What Is the Future?

It is easy for physicians to become so focused on the gloom and doom of regulatory compliance that they lose sight of the goal of CME and other types of medical education. The objective is to help physicians and other health care professionals maintain their competence and to facilitate continued intellectual growth for the sole purpose of improving patients' care. Regulations such as the declaration of conflicts of interest (disclosure) exist to maintain programs' integrity in pursuit of this goal, and medical education companies that continue to act ethically and remain focused on patients will avoid conflict. Ensuring that the motive for the educational initiative is to improve patients' care can minimize the risk of noncompliance.

Amid the constant change that defines today's regulatory environment, it is impossible for anyone to know with certainty what lies around the corner. Developing and delivering medical education programs that truly improve patients' care and comply with regulations will ultimately boil down to the ethics of the individuals and companies involved. Adopting formal programs and implementing systems for ensuring the impartiality and scientific rigor of medical education content are valid and reasonable steps. One can only hope that, by adopting these steps, the ultimate goal of improving patients' outcomes will be met. I am afraid that the "cost" of this, however, will be the disappearance of educational creativity and of discussions of off-label uses (even where sound, scientific, peer-reviewed clinical data exist) by innovators and educators—yet another unintended consequence. The pendulum has swung too far and appears to be stuck. I hope it will swing back!

SHERI ROWEN, MD

After traveling and giving talks across the country during the past several years, it has become increasingly clear to me how new compliance constraints are limiting the educational opportunities we can share with our fellow physicians. In the past, a free exchange of information allowed us to discuss all aspects of patients' care honestly, no matter the program's sponsor. We could speak of off-label indications, differing treatment regimens, extended uses, and so on.

Because the FDA's approval of a drug entails astronomical testing costs, a single indication is usually studied to make bringing a product to market feasible. We physicians are then allowed to use pharmaceuticals (and devices) as we see fit. Generally, we find that products work well and safely for many disease states not listed on the label. For that reason, we have traditionally asked speakers at national and regional educational meetings to share such information from their clinical practices. Now, hours of speaker training sessions are devoted just to compliance and regulatory issues, and presenters are severely limited in what they may discuss out of companies' fear of exorbitant punitive fines.

I once had a patient whose painful, visually debilitating epidemic keratoconjunctivitis infiltrates were unresponsive to treatment. I remembered a colleague's describing the off-label use of ganciclovir ophthalmic gel under similar circumstances. I tried it, and within days, my patient was symptom free. Had I not heard about other possible uses of this agent, my patient could have sustained long-term visual impairment. When asked about nonsteroidal antiinflammatory drugs in cataract surgery, most ophthalmologists will say that they use these agents to prevent cystoid macular edema, yet we are not permitted to make such comments at an industry-sponsored program. As a speaker at such events, I am terribly frustrated not to be able to share useful information that I think would benefit my colleagues. Clinicians' sharing of experiences benefits patients, and physicians need a public forum in which to hold such discussions. ■

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1. Lindstrom RL. Thoughts on the ophthalmologist's role in education and innovation. Charles D. Kelman Innovator's Lecture presented at: ASCRS Symposium & Congress; March 28, 2011; San Diego, CA.