

Keeping Pace: Updating Your Code of Ethics for the 21st Century Economy

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It's been said that the average person breaks the law -- unwittingly, of course! -- at least once a day. Civil liberties lawyer Harvey Silverglate [claims it's more like three -- and federal laws, at that](#). Whether it's a minor traffic infraction or crossing the street outside the crosswalk, or, believe it or not, connecting to the wrong open WiFi network, it is part of living in an increasingly regulated world that it has become hardly possible to engage in any pursuit without implicating some obscure -- or obvious -- local, state, federal law or regulation.

Individuals going about their lives can and often do so without having to concern themselves too much with such legal technicalities. In business, though, it's quite another proposition to operate unaware of the laws that govern your service, product, or industry. This is especially so in the health care industry, where a complex legal and regulatory infrastructure protects patient safety, privacy, and independent medical decision making. History shows that businesses and entire industries that haughtily push the limits of legality or make a mockery of the ethical mores of the societies in which they operate often find themselves dragged into the hot lights of an investigative hearing to answer tough questions.

The medical technology (medtech) industry has a longstanding commitment to patient safety: Our member companies are literally in the business of improving and saving lives! From the syringes that inject epidurals to the pacemakers that extend people's lives by decades, from the hip replacements that restore one's ability to walk to the intraocular lenses that restore vision, the medtech industry is of inherent, intrinsic value to society. To put it another way, no one ever asks us, "What good have you done lately?"

For decades, our industry has sought to ensure that its role in the health care system is beyond reproach -- that the public knows we are driven by science and not profit, by the needs of the patients and not the financial interests of the health care providers who purchase our products. Even while the laws and regulations applicable to medtech innovation, manufacturing, and commercialization--as well as laws applicable to the industry's interactions with other health industry stakeholders---are extensive, dense, subject to regulatory guidance from multiple authorities, actively enforced and difficult to navigate, there are instances where **additional** industry self-regulation is beneficial.

At [the Advanced Medical Technology Association \(AdvaMed\)](#), the Washington, D.C.-based trade association that represents the medtech industry where I serve as the Chief Legal Officer and COO, we [recently updated our voluntary Code of Ethics](#), establishing additional self-regulation in an already intensely regulated industry, through a process we hope serves as a model for businesses and industries seeking to assure customers, investors, employees, regulators, and legislators that they're committed to responsible business behavior and the highest ethical and legal standards.

The robust and transparent process we executed to renew our Code, I believe, was key to achieving its unanimous approval by the near 60-member AdvaMed Board (populated by medtech CEOs elected by more than 400 medtech company members). ***When industry CEOs express this level of commitment to voluntary self regulation, it is meaningful!***

Background

Reaching back several decades, the laws (some criminal) governing the health care industry were broad in scope and intended for the industry as a whole. medtech wasn't the primary focus, and indeed at that time was a more nascent industry. This naturally led to grey areas, questions, concerns, and difficulties applying those laws to our industry.

For example, [the federal Medicare/Medicaid Anti-Kickback Statute](#) establishes criminal prohibitions on any solicitation or payment of remuneration (in cash or in kind) through the "one purpose" test (i.e., you are deemed to have criminal intent even if only one of many other legitimate purposes is to influence referrals or business). That law is subject to regulatory "safe harbors" and decades of judicial interpretation and agency guidance and overwhelmingly address relationships among other industry stakeholders (e.g., hospital/physician relationships). In fact the breadth of the law, its criminal enforcement and the complexity of the interpretive guidance can chill appropriate and beneficial arrangements.

When a medtech company hires a physician as a consultant to better understand the practical implications of its innovations and how to improve them, payment to that physician is clearly for bona fide scientific consultation that fosters precisely the kind of collaboration society needs in order to make technological advances in medicine. Put another way, it's hard to see how **any** medtech company could possibly create or improve a product without the help of a medical practitioner. But, such arrangements can be seen as implicating the statute.

To provide clarity and guidance on the application of this broad-based legal authority, we created a Code of Ethics to lay out what constitutes an appropriate relationship (i.e., expressing indicia such as written agreement, legitimate need documented in advance, consultant expertise aligned with actual need, fair-market-value compensation, among other factors). Our objectives were not to "get around" any existing laws but to ensure companies' compliance and ability to engage in beneficial science-based, commercial and educational interactions in a murky legal environment shaped by Board prohibitions.

Our earliest Code, developed the late 1970s, stemmed in part from public scrutiny of pharmaceutical companies' marketing practices which became the subject of congressional hearings. Our industry took note of those developments and recognized the value in creating a Code to help steer companies to the highest ethical road. But rather than adopt another industry's standards, we developed our own. We recognized that our role in the health care delivery system was unique, that development and safe, effective use of medical technologies required hands-on education and close interactions among industry and health-care providers (who also may be customers). While such close interaction, viewed from a distance, or in the eyes of a skeptic may appear improper, our Code helps define the ethical basis for these interactions.

Our industry is committed to ensuring that every medical device's place in the doctor's office or operating room is driven by the latest science and with patient safety and best medical interests as the No. 1 priority.

In other words, the innovation-, training-, and education-based or other bona fide relationship between a medical device maker and the health care provider should have nothing to do with the procurement decision-making process. Our Code of Ethics seeks to ensure that patients can walk into a doctor's office confident that the products prescribed

for them are in their best interest, and not based on a slick marketing campaign or improper incentives paid by companies to skew their doctor's decision-making.

Certainly in your own business or industry there are comparable relationships requiring public confidence or otherwise worth ensuring are on the up and up.

Why Would a Code of Ethics Require Updating?

We've updated our Code over the decades as the laws, enforcement practices, science, and business models themselves have changed. This is a dynamic industry--the pace of medtech innovation is very rapid, making change the one constant.

For example, in this industry in the 1980's we experienced scrutiny of relationships between orthopedic companies and surgeons, particularly with respect to the payment of royalties for consulting. In response, we re-evaluated our Code, identified some gaps, and added further voluntary self-regulatory guidance to prevent abuses while preserving the ability of innovators to engage in royalty-based arrangements.

In our most recent revision this past year, while there was no direct scrutiny, science and the industry are advancing at such a fast pace that we thought it prudent to keep up.

Also, and just as importantly, we realized that our Code was a document written largely by lawyers even though most of its readers were not. They were medical device salespeople, business executives, and physicians. We needed a Code, simply put, that was more accessible, searchable, and updated for the digital age.

The Process Makes for Progress

In setting about to write a more digestible yet thorough and robust Code, we made it a point to first determine who our audience was and to speak directly to them. We interviewed:

- Sales reps
- Physicians
- medtech executives, employees, and lawyers

We sought input from every corner of the industry on both sides of the medtech-provider equation. We needed to better understand the perspectives of all the organized groups that interact with our industry--including industry critics. So, for example:

- We informally interviewed former prosecutors and former officials for their perspectives on the Code, seeking input on any gaps or areas for concern, areas of confusion they might have seen
- We were sure to speak with other health care stakeholders -- for example, hospital groups of all types, from not-for-profit community hospitals to urban academic hospitals
- We met with physician societies and specialty groups to get input from advanced practitioners who are on the cutting edge of the science seeking to perfect new technologies and find new cures

In short, wherever we could see some of the greatest and most extensive interactions with our industry, we made sure to seek their input.

One of our key audiences was the government itself. We wanted to be sure that regulators and legislators at all levels knew we were serious about self-regulation. We interviewed those with deep backgrounds in our industry to ensure our Code reflected our commitment to patient safety.

Of course, our primary audience was the industry itself. We looked up and down the corporate chain of command, meeting with sales reps, those who had been trained on the Code by their compliance lawyers, to understand what, if anything, they found confusing or helpful about Code. Increasingly our industry depends less on the traditional sales rep

model and more on senior medtech executives selling to senior hospital and health care system executives as companies become partners and solution providers as opposed to mere vendors, so we were sure to meet with CEOs and other high-level executives.

We reflected on their collective input of these various stakeholders ... and then the hard work began!

Under our governance rules, unanimity wasn't required to adopt an industry wide Code. All we needed was majority approval by our Board of Directors comprised of 60 CEOs from across our industry. But I believe we were able to achieve unanimity for several important and, I hope, replicable reasons.

One of the primary drivers was industry confidence in our team and the process.

We made it clear at the beginning of the year-long endeavor that we welcomed input and guidance from every company, large or small, U.S.-based or not. We created conditions in which everyone had a voice, everyone was heard, everyone could share their perspectives openly -- and all perspectives were valued. Companies large and small had equal voices.

We held biweekly, open-ended meetings, listening sessions and conference calls with member company counsels. We provided detailed, clear agendas in advance so that member companies had time to thoughtfully prepare for each discussion. We then provided the minutes afterward so that there was clarity about what was both discussed and decided. Drafts of the Code were shared frequently for review and revision. One staff lead held the digital pen, to ensure we all focused on the same document and text. We updated our Board at regular intervals, and a standing subcommittee of the Board, our ethics committee, reviewed our progress on a quarterly basis.

The transparency of the process built trust among those gathered around the table. It is tough to overstate the difficulty of gathering highly competitive companies in the same room, given the potential fracture lines that could easily have occurred over so many technical legal issues.

THE CODE

As an association with members based both in- and outside the U.S. that innovate and sell products all over the world, legal minds naturally will ask, "Which choice of law governs?" Our guiding principle where there are state level or other jurisdictional differences in standards was to adopt the higher standard. In an industry as committed to patient safety as ours is, not to mention an industry regulated by the U.S. Food and Drug Administration (FDA) -- universally considered the international gold standard for medical device regulation -- it wasn't difficult to obtain agreement from our member companies.

Voluntary vs. Mandatory?

Ours is a voluntary Code of Ethics. Before you dismiss that as a weakness, especially as you consider your own industry's Code of Ethics, there are some crucial questions to think through.

1. **Antitrust, Anti-competition:** Our process included antitrust counsel in every meeting and on every call. To a skeptic, a Code may appear to be an agreement among competitors. Here, our intention was to foster innovation and guide legal compliance and business ethics. Antitrust issues may arise to the extent a Code is "enforced" to the detriment of competition, and our counsel shared lessons from association Code antitrust enforcement cases.
2. **Who Will Be the "Enforcer"?** Another reason we advanced a voluntary Code was based on the complexity and risk of administering any form of industry self-enforcement. Aside from the anti-competition risk, we thoughtfully reflected upon the potential legal liability of establishing the association as the Code enforcer, and the

cost (not only the objective cost, but also the diminution of resources otherwise available to other member priorities to promote ethics and compliance, such as training, developing tools, etc.). Questions we considered included: Who will serve as the arbiter of the disputes? Who is going to make the decisions? What's their liability? Is there a risk that compiling of data in a complaint or dispute resolution process might later lead to a subpoena and then require you to serve as a witness in an investigation? These are tough questions that need to be thought through.

We felt confident that a voluntary Code, supported by enablers to incentivize ethics was a better approach than a punitive one. We consulted with outside counsel, as well as with our companies and our Board, and believe the Code is supported well enough by internal mechanisms to ensure it has value and is meaningful.

For example, as a voluntary association, we are governed by a Board of CEOs, and for a CEO to stand for election to our Board, one criterion of eligibility is whether the company has signed on to the Code. Ethical leadership starts at the top. We also seek company executives and compliance officers to sign a Code of Ethics certification, attesting that the company has taken certain enumerated steps to adopt, train and effectuate policies consistent with the Code. It is clear that there's a strong incentive for medtech companies to adopt and strictly abide by the voluntary Code.

All of our member companies voted to approve the new Code of Ethics, and as part of their approval they have one year to realign their internal policies and procedures and re-train staff and to ultimately certify that they are in compliance. We then will make that publicly available.

Lessons Learned

As stated above, one of the first lessons is to staff the initiative with the best. Matt Wetzel as deputy counsel at the time took the lead, and we channelled all communications and drafts through him. Speaking with one voice is essential to retain clarity and confidence in the process.

Before leaving our company recently, he wrote [an exceptional piece on LinkedIn](#) laying out six lessons learned beyond those expressed above. It is hard to improve upon his analysis, so I will quote extensively from it.

“Lesson 1: A Well-represented Constituency Goes a Long Way”

As I mentioned above, our industry is incredibly diverse, which made writing a Code of Ethics for 400-plus entities that range from multi-billion-dollar behemoths to far smaller companies with only a few dozen employees -- every one of which came to our conference calls and meetings over the course of year with equally diverse interests, business models, and niches in the medtech space -- an nearly impossible task. Ensuring that everyone had a voice -- an *equal* voice, making it a point to avoid favoritism -- was key to arriving at the consensus we achieved.

“Lesson 2: Consensus is Built on Process, Not Policy”

As Mr. Wetzel concisely summed it up: “The more solid the process, the less assailable the final product.” We knew that if everyone felt they had the opportunity to weigh in substantively, there would be enough good will and good faith to garner the support we needed for the final product.

“Lesson 3: Finding a Compass and an Anchor in medtech Values”

From the outset, our objective was to write a Code based on the already-accepted “six medtech Cornerstone Values” that drive every company in our industry: innovation, education, integrity, respect, responsibility, and transparency. Our discussions about the Code of Ethics always came back to this moral compass. A heated discussion with dozens of GCs, CLOs, CEOs, and other executives was often cooled by a return to which of our

six values we were trying to promote. Determining your own company's or industry's North Star will help you immensely to write your Code *to* those values.

“Lesson 4: An Industry Code Serves Many Purposes”

As Matt points out, “the Code is really one part mission statement, one part ethical Code, one part Code of conduct, and one part defensive document.”

He further explains:

“As a mission statement, the AdvaMed Code's provisions, restrictions, and values all speak to protecting patients, their rights, and their safety; providing patients with high-quality care; supporting Health Care [Professionals in] their delivery of high-quality, safe, effective care; and shielding collaborative and important relationships between industry and HCPs that result in cutting edge products that save and transform lives.

“As a Code of Ethics, the AdvaMed Code offers high level guidance and principles for companies.

“As a Code of conduct ... some aspects of the AdvaMed Code intentionally provide more detail and process points for companies to follow.

“Finally, as an umbrella for the entire industry, the AdvaMed Code highlights those practices and behaviors that we believe are appropriate (under the circumstances and subject to the restrictions described in the Code) and should be protected. One recent example is the provision of meals and refreshments to physicians and other HCPs. ... While it is critical to have strong guardrails and parameters for meals in place (spending limits, appropriate settings, appropriate topics, etc.), discussing business over meals is a longstanding and appropriate practice, and the Code addresses meals from this perspective.”

“Lesson 5: The Substance May Remain the Same, but the Context May Change”

While our 2018 rewrite of the Code last updated in 2008 did not require wholesale changes, the health care world in general and our medical device industry in particular are changing at a breath-taking pace. If your industry moves fast, your Code of Ethics likely needs to as well.

“Lesson 6: Planning, Planning, Planning”

As Mr. Wetzel points out, we were lucky that our decision to update the Code was not driven by external events (i.e., a particular scandal or legal/regulatory trouble on the horizon). This allowed us to lay out a thoughtful, robust process to (1) learn as much as we could from all stakeholders about life in the medtech world, (2) apply what we learned from this input to our discussions about the Code and where and how it needed to be updated, and (3) to give companies plenty of time to “adjust [their] policies, procedures, training, monitoring, and auditing plans” to the new Code.

So, how do you decide if your company or industry needs a Code of Ethics? A good rule of thumb might be: Where the use of a product or service has the potential to affect the safety, health, or well-being of your customers or the public, and where there's potential for decision making along the chain of command that might be anything less than in the customer's or public's best interest, you need a Code of Ethics.

An industry's or company's reputation can be difficult to build and to retain but can be destroyed instantaneously by ethical lapses broadcast across a newspaper headline, cable news story, or lawsuit.

A strong Code of Ethics instills confidence in the industry -- confidence from customers, investors, employees, and regulators ... in short, everyone that matters to its success.

And if doing the right thing and being socially responsible isn't reason enough, take it from someone who has spent his legal career in Washington, D.C., working close to and closely

with legislative committees and enforcement agencies in the US and globally -- you don't want to wonder if a Code of Ethics might have been a good idea as you respond to a subpoena or investigative request!

Chris White is Chief executive responsible for all corporate operations (IT, facilities, membership, governance HR/talent development, corporate structure, legal). Also serve as chief legal officer of the association and secretary to the Board of Directors. Provide counsel, executive judgment, strategic perspective, creative solutions and guidance across all functional areas. Devised and executed corporate acquisition & integration of Conference entity. Restructured Board governance to expand Board and increase Board effectiveness. Lead Association's global legal and compliance policy work, including comprehensive industry Code of Ethics and program.

AdvaMed is a global not for profit representing medical technology manufacturers and innovators. More here: <https://www.advamed.org/>