

Part 3 - Sales and Marketing Codes of Conduct

Life is hard. But it's harder when you're dumb.

Papa God and the Monkey was one of my kids' favorite stories when they were little. In it, a woman slips and drops a pot of honey she was carrying on her head. A monkey sitting in a mango tree nearby saw what happened and heard the woman say: "Oh Papa God, why did you give me so much misery?"

The monkey wondered what "misery" meant. So, after the woman left, he scampered down from the tree and saw a thick golden liquid running out of the cracked pot. He tasted it, liked it very much and polished it off. "Hmmm...." said the monkey to himself, "This must be misery. Misery is sweet and sticky."

The next day, the monkey wanted some more so he closed his eyes and prayed: "Papa God, dear Papa God, please, please send me some misery." When he opened his eyes, he found himself on a tiny desert island without a single tree in sight. In front of him lay a huge sack.

"Ah" said the monkey while opening the sack, "Papa God has sent me a lot of misery." Thank you, Papa God!"

Suddenly, out of the sack jumped seven big dogs who chased the monkey. The monkey ran for his life, but there was no place to hide.

"Oh Papa God, save me, save me, I don't want this misery!" cried the monkey as he ran. As soon as he said this, a tall coconut tree appeared which the monkey climbed to escape the dogs.

The moral of this story is that "Papa God knows that too much misery is not good for anyone."

I'm supposing that the thousands of healthcare firms and individuals caught in one or more of the Bear Traps would agree.¹ Also, like the monkey in the story, I think that much of the misery they've experienced has been caused by ignorance rather than malevolence. There are now and have been bad actors who deliberately violated the rules for personal gain or to boost sales. But, I'd wager that the majority of those caught in the Bear Traps simply did not even know they were there. The remedy for this ignorance is not praying to "Papa God" for help; it's well-written sales and marketing codes of conduct.

As those of us who have done this work know, drafting effective sales and marketing codes is challenging. First, they must address the laws and ethical standards associated with the numerous business activities that present government enforcement risks. For healthcare manufacturers and distributors, these include, but are not limited to:

¹ As mentioned in Part 1 of this series, the term "Bear Traps" as used herein refers to the Anti-kickback Statute ("AKS"), the False Claims Act ("FCA"), the Physician Self-Referral Law (a.k.a. the "Stark Law,"), the Civil Monetary Penalties Law ("CMP") or the Eliminating Kickbacks in Recovery Act ("EKRA"). Enforcement actions pursuant to these laws against thousands of individuals and companies in the healthcare sector have resulted in incarcerations and tens of \$billions in fines.

- Product promotion and response to medical and scientific inquiries
- Meals with HCPs, non-HCPs, and government officials
- Entertainment and recreational activities with HCPs and government officials
- Gifts to HCPs and government officials
- Demonstration and evaluation products
- Product samples
- Raffles, competitions, and games of chance
- Commercial discounts
- Professional services agreements with agents, HCPs, and Healthcare Institutions
- HCP investment interests
- Royalties
- Company conducted business meetings, product training and educational events
- Commercial activities at third-party educational events and trade shows
- Charitable contributions, educational grants, and independent research grants
- Sunshine reporting
- Product complaint and adverse event reporting
- Prescription data management
- Clinical trials, market studies and product research
- Channel management and third-party distributors
- Sales and marketing code training

To provide effective guidance, sales and marketing codes will necessarily reference, and ideally provide direct links to, numerous forms and processes that are part of the internal controls mentioned in Part 2 of this series that are required to enable compliance. These include a broad range of procedures and forms for:

- First-party and third-party due diligence and auditing of distributors and agents
- Distribution agreements
- Professional services and management contract needs assessment
- Professional services and management contracts
- HCP travel sponsorships
- Sunshine reporting
- Travel and expense reporting
- Grants and charitable contributions

Second, sales and marketing codes must be tailored to address the rules and ethical standards in each of the jurisdictions in which your firm operates. This is particularly challenging for multinational companies who sell products in dozens of countries.

At Bausch & Lomb, working from a general template we developed in-house, a colleague and I drafted over forty country-specific codes of conduct that were deployed in all the countries in which we had a direct sales presence. However, I'd recommend against this approach. Although it has the advantage of being highly tailored to each jurisdiction, maintaining so many codes proved to be very burdensome. Instead, I'd recommend no more than five regional codes each of which cover multiple countries. Significant differences between the laws or ethical standards in

countries within a single region, can be efficiently called out in tables within various sections of the code to the extent necessary. My team and I implemented this strategy with great success at Carestream Health.

As challenging as it may be to conduct the research necessary to master all of these subject areas, draft a user-friendly code, translate them into multiple languages and effect a global launch, this is the easiest part of the process. When drafting and deploying sales and marketing codes, it is vital to understand that the ultimate object of this exercise is to have a meaningful impact on your colleagues' behavior. No matter how eloquent your Code might be, words on paper by themselves do not get the job done. So, in addition to getting the rules right, you must set out to win hearts and minds of your company leadership and your colleagues on the front lines.

The best way to get your colleagues to support the codes and embrace essential internal controls is to invite them to participate in their development. Give them an early heads up about the code-drafting project and tell them that you want to partner with them to get it right. In so doing take the time to explain why this is important to both them personally and the business. Once an initial draft is completed, circulate it to your business leaders for review and comment. Take the time to listen to them and respond thoughtfully and respectfully to their comments and concerns. Be patient.

When performing this work at Bausch & Lomb, and later at Carestream Health, for all regions around the world, my team and I took over a year to conduct the legal research, draft the codes and complete the consultations with our colleagues before the codes were finalized. In addition, even after they were launched, we showed great flexibility in making alterations to the codes and our internal controls in response to comments received from the field about what was working and not working.

At both Bausch & Lomb and Carestream Health, once the codes were ready to launch, we enlisted the assistance of our senior and local management around the globe to distribute them. In so doing, we prepared letters and short presentations in multiple languages to help our leaders send the codes to employees in their regions and help them understand the importance of the codes to our business.

Although drafting and deploying sales and marketing codes is a significant undertaking, it is an essential step in helping your law department, compliance department and your business colleagues have clear line of sight to where the Bear Traps are and how to avoid them. In addition to being a vital resource for you and your colleagues, they can be leveraged to develop and implement an effective training program. This will be the subject of Part 4 of this series.