

Compliance Today – November 2019 Conflicts of interest: Preventing a compliance crisis

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Recently, I was fortunate to give a presentation on another area of great concern within the research and healthcare arena (research misconduct) in which I remarked on how simple the topic must appear to those not deeply involved. It is truly a black-and-white issue, I proffered, almost with sarcasm, and certainly in a rhetorical fashion. Simply don't falsify, fabricate, or plagiarize, and misconduct is of no concern. And yet, I could spend likely triple the time allotted elaborating on why misconduct is never this direct and often appears in multiple shades of gray.

Similarly, conflicts of interest (COI) in healthcare compliance have long held negative connotations and, as of late, continue to strike at the inherent integrity we expect from our health and research institutions, although in different ways. Most people think of these conflicts from an anti-kickback standpoint or spin tales of pharmaceutical representatives bribing doctors with courtside seats to the NBA Finals to prescribe their latest blockbuster drug. And while those days may be mostly behind us, with staunch and rigid regulations on what information healthcare and research professionals must disclose regarding all their activities and interests, I can still name two significant and public COI cases in the last nine months that you've likely followed carefully.

Although my livelihood may be tied to compliance, law, and regulations, I can hardly advocate that introducing even more regulations on this topic would have prevented these recent cases or strike at the heart of the problem. Further, I would even argue that the current strife somewhat hinges on certain restrictions, creating such a negative public view of any conflicts whatsoever that unrealistic expectations have been placed on providers and organizations. The reality is that experts in one particular area of clinical practice will also likely be many of the same experts in that same area of clinical research and even education. As such, those individuals will be sought out by various organizations for a myriad of purposes throughout their careers, some for profit and some not, to share their knowledge and represent their subject matter expertise. We can't, as a society, hold idealistic expectations that because someone is a physician, they don't also seek appropriate compensation for their time and effort. Or, that because someone is performing noble research sponsored by a nonprofit entity, they shouldn't also be allowed to profit from their efforts in separate endeavors—if managed appropriately. In fact, in certain arenas, such as clinical research in academia, competitive interests are actually accepted in practice and viewed as an inherent “perk” to not working for Big Pharma, as long as the conflicts are disclosed and managed.

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