that are an area of increasing focus by prosecutors. Device-consultant relationships can be complex and involve financial incentives to healthcare professionals, including consulting and development contracts—in exchange for their business. These four companies were entered into a lengthy Corporate Integrity Agreement (the fifth entered into a Non-Prosecution Agreement). As a result, the first four companies paid penalties totaling $311 million, and all five were required to hire Independent Compliance Monitors—who served for an 18-month period. Each company also was required to enter into a lengthy Corporate Integrity Agreement with the Department of Health and Human Services. Using the orthopaedic industry’s experience as an instructive example, here are five key lessons learned that may help your company avoid future problems:

For every consulting service required, articulate an objective basis for that need. A device manufacturer should have in place a transparent process that comprehensively assesses its consulting needs at the outset. Among other requirements for a given year are justified by legitimate business needs and are commercially reasonable. Such a process should begin by identifying key strategic business objectives and aligning them with its consultant service needs. For example, a company could also provide for an internal vetting mechanism by which requested services are reviewed at multiple levels outside of the sales teams and marketing. Moreover, a Senate bill proposes to require device and pharmaceutical companies to publicly report any physician compensation exceeding $50,000 annually. It is clear that many states already enacted disclosure laws. This month, Eli Lilly became the first major pharmaceutical company to publish an online registry of its consulting services. In the orthopaedic cases, DOJ required that all consulting relationships with healthcare professionals. Public disclosure of these relationships is increasingly common, and a movement to require disclosure is gaining momentum. In the orthopaedic cases, DOJ required that payments to physicians be disclosed prominently on each company website. Moreover, a Senate bill proposes to require device and pharmaceutical companies to report detailed compensation they pay to surgeons—including consulting and development contracts—in exchange for their business. A prototypical violation involves a device manufacturer from conferring a financial benefit upon a healthcare professional in order to induce the use of the manufacturer’s products. A prototypical violation involves a device manufacturer from conferring a financial benefit upon a healthcare professional in order to induce the use of the manufacturer’s products. 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