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Physician-Consultants:

Five Lessons Learned From the Orthopaedic Monitorships

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In today's healthcare arena, relationships between medical device manufacturers and healthcare professionals are complex and multi-faceted. Healthcare professionals may be customers, of course—but they may also teach at industry-sponsored training events, educate practitioners in the use of the manufacturer's products, assist in the development of new devices, conduct clinical trials, and perform a variety of other consulting services. These relationships are, by their nature, vulnerable to abuse, and they are an area of increasing focus by prosecutors. Device manufacturers should have a strong grasp of the applicable laws and a clear plan for following them. Federal law prohibits 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 giving a lucrative consulting contract in order to secure the consultant's brand loyalty to the manufacturer.

The consequences of inadequate attention to this legal minefield can be tremendously expensive and have the potential to impact an entire industry. In 2007, for example, after a lengthy investigation into the five major orthopaedic-device manufacturers, the U.S. Department of Justice ("DOJ") filed criminal charges against four of the companies, alleging that they gave various financial incentives to surgeons—including consulting and development contracts—in exchange for their business. These four companies ultimately entered into Deferred Prosecution Agreements (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 reported to DOJ—to oversee their operations 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.

Taking 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. This ensures that the company's consulting requirements for a given year are justified by legitimate business needs and are commercially reasonable. Such a process should begin by identifying the company's strategic business objectives and aligning them with its consultant service needs. For purposes of objectivity, the process should also provide for an internal vetting mechanism by which requested services are reviewed at multiple levels outside of the sales teams and business lines. Upon management approval of this prospective needs assessment, consulting services are limited to those enumerated therein, unless an exception is sought via a pre-established process.

Have an objective basis for why a particular consultant is necessary and qualified to provide a given service. In conjunction with the needs-assessment process described above, a device manufacturer should regularly evaluate the field of available consultants. The company should aim to create a talent pool of recognized experts who, by training, experience, and past performance—not sales

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dictates—are right for the job. The goal should be to create a list of pre-approved consultants who are legitimately qualified to perform specific consulting services. This can mitigate concerns that the company chose a particular provider to serve as a consultant for improper purposes.

Regularly evaluate the fair market value of consulting services. A device manufacturer should ensure that the rates it pays to healthcare professionals for consulting services are consistent with fair market value. Because such an analysis can be quite complex, it may be appropriate for a company to retain a fair-market-value expert to periodically evaluate its payment rates.

Create a comprehensive process for reviewing royalty-earning contracts and payments. For a device manufacturer that relies on product-development collaboration with healthcare professionals, the process by which royalty-bearing consulting agreements are entered and paid requires close attention. This is an area of particular concern due to the difficulties in objectively quantifying a consultant's intellectual contribution, coupled with the high dollar value of many such agreements. Thus, in addition to the standard process by which a consultant is selected, a company should establish a clear and well-documented protocol for determining whether each royalty-bearing consultant has made a contribution sufficient to justify the payment of royalties.

Consider whether to disclose financial 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 publicly report any physician compensation exceeding $500 annually. Several states have already enacted disclosure laws. This month, Eli Lilly became the first major pharmaceutical company to publish an online registry of its physician compensation. While voluntary disclosure may not be appropriate for every business model, some manufacturers may want to consider staying ahead of the curve on this trend.

Manufacturer-consultant relationships can be good for business and for healthcare generally. But in light of the recognized potential for abuse inherent in these relationships, they should be undertaken and managed pursuant to clear, well-structured processes to ensure compliance with the law.

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