



Implementing a Royalty Review Program: Safe Practices for Medical Device Manufacturers and Design Surgeons

by: *Shawn D. Sentilles*

In recent years, medical device manufacturers have paid millions of dollars in fines for allegedly inducing physicians to use their products. One frequently cited form of inducement is overpayment of royalties. Lack of statutory and administrative guidance has led to uncertainty about the use of royalties to fund product development projects. Despite this uncertainty, medical device manufacturers continue to pay royalties to design surgeons. Royalties persist due to economic realities: (1) royalties incentivize surgeons to invest time away from lucrative medical practices; (2) royalties lower upfront hourly payments, due to the prospect of a future royalty stream; (3) royalties allocate risk between the parties, since an unsuccessful design will result in lower royalties; and (4) royalties incentivize top quality design work, since a successful design will result in higher royalties.

Factor (4) is most important: medical devices are implanted in patients, so it is essential to incentivize surgeons to design the best products possible. For a safe, effective product, royalties are well worth the cost. By adopting a royalty review program, medical device manufacturers can minimize the risks associated with royalty payments. In recent

years, deferred prosecution agreements administered by the Department of Justice have helped establish standards for royalty review programs. A royalty review program should be in writing.

Royalties should be paid only for contributions of intellectual property. An impartial decision maker – such as a royalty review committee – should review design projects to objectively assess whether proposed team members are qualified to be on the design team, the size of the design team is reasonable, and royalty rates and terms are fair market value. Recommendations as to which surgeons to include on design teams should be made by research and development, not by marketing or sales. Written product development royalty agreements should be in place before design work begins. Prior to paying royalties, a company should verify that team members earned their royalties by participating in meetings and contributing to the design of the product.

Following precautions such as these, through the administration of a royalty review program, will help ensure the safe and effective use of royalty payments to fund product development projects.

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QUARTERLY

Volume 19, Number 1

Spring 2016

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