THREADING THE SURGICAL NEEDLE, NAVIGATING THE CHALLENGES OF PHYSICIAN-INDUSTRY COLLABORATION IN LIFE SCIENCES

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Physicians hold a unique position as innovators in the healthcare industry. Research suggests that more than half of new therapeutic uses for molecular entity drugs are discovered by practicing physicians independent of the pharmaceutical industry and academic research.[1] The extent of physicians' contributions to the medical device industry is even greater: from the invention of the stethoscope in 1816 by French physician René-Théophile-Hyacinthe Laennec to Dr. Julio Palmaz's invention of the first balloon-expandable coronary stents in the 1980s, physicians have contributed to the creation of most medical devices in use today.[2] In 2018 alone, 2,342 individual physicians received approximately $466 million in royalty and license payments from the life sciences industry for their intellectual property ("IP") contributions to the development of new products and/or for the ongoing improvement of existing products.[3]

Financial arrangements arising from the collaboration between physicians and the life sciences industry take many forms, including: royalty payments for the use of IP, consulting fees for product performance assessment and/or design, funding of research, and medical education activities. While these arrangements are not improper, they have the potential to pique the interest of regulators and whistleblowers, which stand to reap millions of dollars in potential settlements. The stakes are high: just in the last five years, violators paid $11.03 billion in settlements and judgments in connection with 2,340 *qui tam* lawsuits, $1.9 billion of which were awarded to whistleblowers.[4] Given the magnitude of the potential costs and penalties associated with litigation, it is of paramount importance for industry participants to ensure compliance with key laws in their financial relationships.

The Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") are key tools used by federal prosecutors to pursue alleged kickback arrangements involving healthcare providers. The AKS is a criminal statute that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by Federal healthcare programs (e.g., drugs, supplies, or healthcare services for Medicare or Medicaid patients).[5] The FCA imposes civil liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the Federal Government.[6] The Affordable Care Act ("ACA") strengthened these statutes by codifying

[1] *The major role of clinicians in the discovery of off-label drug therapies. Pharmacotherapy. 2006 Mar; 26(3):323-32., Demonaco HJ1, Ali A, Hippel Ev.*

[2] *Research suggests that physicians accounted for about 20 percent of the patents issued for medical devices between 1990 and 1996. Physician-Industry Cooperation in The Medical Device Industry, Aaron K. Chatterji, Kira R. Fabrizio, Will Mitchell, and Kevin A. Schulman, Health Affairs 2008 27:6, 1532-1543*

[3] *As calculated by HAI from Open Payment Data reporting system: https://openpaymentsdata.cms.gov*

[4] *US Department of Justice, Fraud Statistics Overview accessed 9/20/2019 from: https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery*

[5] *Department of Health and Human Services, Office of Inspector General. A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse accessed 9/20/2019 from: https://oig.hhs.gov/compliance/physician-education/01laws.asp*

[6] *Centers for Medicare and Medicaid Services. MLN Booklet: Medicare Fraud and Abuse: Prevent, Detect, Report accessed 9/20/2019 from: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244.pdf*

the Physician Payments Sunshine Act ("PPSA"). The PPSA made violations of the AKS false claims under the FCA and modified the AKS to explicitly state that specific intent is not required for a defendant to violate the AKS.[7] In addition, the ACA tightened scrutiny of payments to physicians by drug and medical device manufacturers by mandating annual reporting of all payments and other transfers of value, and any ownership or investment interest physicians, or their immediate family members, have in their company.[8] Knowingly failing to submit payment information carries civil money penalties of not less than $10,000, but not more than $100,000, for each payment.[9]

A recent case involving device maker Life Spine, Inc.,[10] a spinal implant company, is emblematic of cases alleging violations under both AKS and FCA. The case was brought by the Manhattan U.S. Attorney against the spinal implant company, its CEO, and another executive, for illegally paying millions of dollars in kickbacks to surgeons in exchange for using its products. The lawsuit claims the company aggressively recruited surgeons, who had the potential to use a high volume of Life Spine products, to enter into agreements to serve as paid consultants. Additionally, Life Spine offered surgeons the ability to transfer their patents/patent applications to Life Spine in exchange for payments and promised support to bring the surgeons' new products to market. The lawsuit claims Life Spine tied these agreements and the associated payments – as well as the company's continued commitment to devote resources to the surgeons' product development projects – to the surgeons' usage of Life Spine's products.

To stave off the specter of costly litigation and avoid the potential erosion of trust between physicians and patients, drug and medical device manufacturers must establish the commercial reasonableness of their financial arrangements and ensure all payments to physicians are consistent with fair market value. To this end, obtaining an independent valuation can be beneficial in preserving public trust and ensuring that financial arrangements between physicians and the life sciences industry comply with federal regulation.

The Income, Cost and Market valuation approaches, which are applicable to the valuation of business enterprises or assets, are also applicable to the valuation of IP and consulting agreements. Regardless of the appropriate valuation methodology selected for a specific assignment, a prudent professional must take into consideration facts and circumstances related to the specific IP being valued. When assessing the value of IP, for example, an independent valuator brings specific industry and market knowledge, an understanding of the competitive landscape, and the level of specialization within the industry segment where the IP is being deployed. The ultimate determination of FMV must consider the availability of specialists with similar know-how, product development time and expected life cycle, technical characteristics of the IP, relative contributions of physicians to overall development, the manner and timing of proposed payments, and comparable market transactions.

KEY TAKE-AWAY

Physicians hold a unique position as innovators and educators in the healthcare industry, particularly with medical device and drug manufacturers. However, such standing carries the potential for abuse through improper financial relationships with life sciences firms. With increased scrutiny of physician-industry relationships, it becomes important for manufacturers to ensure compliance with the AKS, FCA, and PPSA. Industry should take care to document the commercial reasonableness of financial arrangements and structure financial relationships in ways that do not provide undue benefits to physicians that are in a position to generate referrals. An independent, third party opinion of the terms of any proposed financial arrangement can be beneficial in ensuring compliance with federal regulation. HealthCare Appraisers' professionals have provided fair market value opinions to some of the world's premier life science companies as well as to individual physicians and physician-led organizations interested in commercializing their innovations.

[7] *42 U.S.C. § 1320a-7b(h)*

[8] *https://www.cms.gov/OpenPayments/index.html*

[9] *42 CFR § 403.912*

[10] *Department of Justice, Southern District of New York, press release published 7/23/2019 and accessed 9/20/2019 from: https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-files-lawsuit-against-spinal-implant-company-its-ceo-and-another*