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Identifying and Mitigating Liabilities in Medical Device M&A

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Medical device mergers and acquisition (M&A) transactions are accelerating as greater regulatory clarity develops and review times shorten in the **U.S. Food and Drug Administration** (FDA) regulatory process and the capital markets react positively to consolidation and new public offerings. Additionally, private equity funds are participating in an increasing number of transactions involving firms with later stage or “mature” medical products. While the medical device industry offers great opportunities, understanding and mitigating potential liabilities presented by device transactions is essential to manage investment losses.

Unique Liabilities Presented by Medical Device Companies

Adverse Events and Recall Liabilities

Medical device companies are highly regulated by the FDA and other similar global regulators. Manufacturers, distributors and health care facilities are required to report adverse events, which are collected and posted publicly. Medical device companies also may undertake voluntary or involuntary recalls or field corrections. Investigating and responding to adverse event reports, other product performance issues and addressing recalls and field corrections can impact profit margins and corporate reputation. Given the long life of some medical devices, adverse event response, product performance and recall issues can be triggered by legacy products from which a buyer is no longer profiting but came as part of an acquisition.

Products Liability

Particularly in the U.S. market, medical device companies are faced with a potentially large number of lawsuits—and, as a result, potential liabilities—related to patient injuries and death from past sales of a device. State product liability laws vary widely, but most states have statutes of limitations that run for two to three years from the time of the injury or discovery of the injury, creating potential liability for years following an acquisition. Product liability due diligence should focus on adverse event reporting and product quality databases, as well as a robust insurance coverage assessment.

Intellectual Property Liabilities

Intellectual property (IP) is clearly a valuable asset for device companies, but it also presents potential liabilities due to risk of infringement. Strong freedom-to-operate diligence is critical to identifying potential IP infringement liabilities. Although IP infringement actions generally carry a relatively short three-year statute of limitations, the clock starts running from the date of discovery of the infringement. As a result, IP infringement liabilities can have lengthy tails and may not present within any certain time frame after the closing of an acquisition.

U.S. Federal Health Care Program Liabilities

Selling medical products in the United States is governed by a complex range of statutes and regulations. There are potential compliance issues under "fraud and abuse" laws, including the Anti-Kickback Statute and False Claims Act. For medical device manufacturers, the fraud and abuse laws focus in large part on the marketing and promotion of products, with a particular emphasis on financial relationships with referral sources and off-label promotion. The potential liability extends for a significant period after the closing of an acquisition, since most federal health program fraud and abuse laws carry a lengthy seven-year statute of limitations. In addition, the "Sunshine" provisions of the Affordable Care Act apply to medical device companies; this new fraud and abuse requirement mandates the disclosure of most financial relationships with physicians and teaching hospitals. There are stiff penalties associated with failing to comply with these requirements.

FDA and Global Regulatory Requirements

The FDA and other global regulators enforce compliance requirements associated with geographic-specific regulatory schemes, such as Current Good Manufacturing Practice requirements. Historical warning letters, regulatory inspections and audit observations can have an impact on future operations and products in the marketplace if not corrected. In addition to the cost of correcting open regulatory issues, investors need to consider the implications of a history or pattern of regulatory issues and the impact on the quality and value of the management team and business.

Anti-Corruption

The U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act and other global anti-corruption laws apply in a unique way to manufacturers and distributors of medical products. In many countries, physicians and hospital administrators are employees of government health care programs, leading to their treatment as a "foreign official" under the FCPA. As such, the FCPA's restrictions on bribery apply to nearly all purchasers of a medical device manufacturer's products, whether directly from the manufacturer or through a distributor. The FCPA statute of limitations is five years. The global focus on life sciences companies, including medical device firms, casts a wide net of potential liability. Device manufacturers and distributors should have or establish strong anti-corruption controls. Potential buyers of a medical device firm should conduct thorough diligence on the scope of any non-U.S. business and the corresponding relationships with international health officials.

Structures to Mitigate and Limit Liabilities of Buyers in M&A

Deal Structure

While corporate structures and tax issues typically dictate the M&A deal structure, in the medical device industry, the deal structure may be used to isolate or mitigate historical liabilities. Careful consideration should be given in initial stages of the deal's negotiation as to how its structure can be used to isolate and mitigate historical medical device and potential regulatory liabilities. In device

deals, the corporate and other tax objectives must be understood in the context of and evaluated against the universe of potential medical device liabilities.

In contrast to health services transactions, in which Medicare and Medicaid liabilities transfer to a buyer when it assumes the historical billing numbers (regardless of whether the deal is structured as an asset purchase, merger or stock purchase), medical device manufacturers may have more flexibility with deal structures. For example, most medical device manufacturers do not bill Medicare or Medicaid, and a buyer may not need to assume a target company's historical billing numbers. As a result, a buyer may mitigate some historical exposure to the Anti-Kickback Statute and False Claims Act by purchasing assets into a new entity instead of acquiring the business by a merger or stock purchase. Asset acquisition deal structures can also help to isolate historical products liability, global corruption issues and other historical operational liabilities.

Indemnification Package

With limited exceptions, indemnification packages for medical device deals do not materially differ from other health industry indemnification structures. Under a typical indemnification scheme in a purchase agreement, the seller would be liable for damages only if the buyer can prove that the liability resulted from a breach of a representation or covenant set forth in the purchase agreement. However, buyers in medical device deals negotiate "line item" or "specific" indemnities for the specific liabilities or risk areas that are identified during due diligence. A line item or specific indemnity requires a seller to compensate the buyer for a liability without having to prove that the liability resulted from a breached representation or covenant.

For example, a specific indemnity might be considered if, during due diligence, an abnormal level of FDA adverse event reports are identified with respect to one of the target's medical devices that has since been discontinued. To mitigate this potential liability, the buyer would request that the seller provide a specific indemnity for this liability. It is important for the buyer to request coverage for not only recall and regulatory liabilities related to the product, but also product liability issues. Additionally, if a specific indemnity covers the costs of a recall, it is important that the buyer have coverage for not only recalls that are required by the FDA or other regulatory authority, but also for voluntary recalls (which are far more common in the medical device industry). Similarly, given the lag time between the development of a situation and action taken by a regulatory body, an indemnity of unlimited or longer duration for any regulatory actions arising from pre-closing activities should be considered.

IP Indemnification

One area where indemnification packages in medical device transactions deviate from other industries is the treatment of IP. According to the *2012 SRS Life Sciences M&A Study* (its most recent available data), in life science M&A, the survival period for IP indemnification in 45 percent of all deals is longer than the general survival period. The survival period is typically longer than the general survival period by 6–18 months. Sometimes a survival period can extend through the actual or projected commercialization of a defined product line. These extended indemnification periods reflect the fact that a medical device company may have made pre-closing risk decisions and choices in the course of its business with respect to its IP, including new products or products under development, that a buyer should receive protection for post-closing.

Escrow Funds

According to the *2012 SRS Life Sciences M&A Study*, escrow sizes in life sciences deals tend to be slightly smaller than other industries at closing. However, 45 percent of all deals provide for the escrow fund to be replenished or increased when a milestone or other contingent payment is made, resulting in greater escrow protection for the buyer. Furthermore, according to the *SRS* survey, nearly 70 percent of all life sciences deals have an escrow fund period of 18 months or more. Longer escrow periods can provide buyers with greater comfort with respect to unidentified or unknown liabilities.

Representations and Warranty Insurance

A robust market is developing for representation and warranty insurance for medical device deals, with numerous insurers entering the market in recent years. These insurance products are particularly attractive in markets that pose high levels of liabilities that may be difficult to fully understand and identify through due diligence. An example is medical device companies that distribute globally through extensive distributor networks that are difficult to fully diligence. When using representation and warranty insurance to mitigate certain deal liabilities, it is important to engage in early discussions with brokers to develop an insurance package that can cover unknown regulatory and product liability issues. Of course, representation and warranty insurance require careful coordination with lawyers and brokers to ensure that the representations are thoughtfully drafted to cover the unknown issues that the insurance package is intended to cover and adequate timing is given for insurer review to issue the policy.

Conclusion

Medical device M&A transactions present a range of liabilities specific to medical devices. Many liabilities relating to medical devices can be identified and evaluated through due diligence, while others remain latent and subject to years of ongoing potential liability. Certain deal structures and indemnity provisions, though, can help a buyer of a medical device company navigate that complex network of potential liabilities.

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