BURR ALERT

Areas of Unique Legal Concerns and Solutions in Device M&A

By Chester "Chet" J. Hosch November 2015

With medical device related acquisitions at all-time highs, and regulatory interest from the Federal Trade Commission, the Food and Drug Administration, the Securities and Exchange Commission, and the Office of Inspector General for the Department of Health and Human Services, interest, acquiring companies must exercise extreme diligence and due care in structuring, documenting and consummating acquisitions.

Conventional challenges with mergers and acquisitions include identification of suitable complementary targets, due diligence development and risk assessment, valuation and payment, optimal structure, liability exposure and tax treatment, assumed and excluded assets and liabilities, representations and warranties, pre-closing and post-closing covenants, closing timelines and conditions and termination. There exists a well-established body of principles, terms and documents addressing these problems.

In addition to these traditional risks associated with acquisitions, medical device manufacturers present unique perils. For example, while intellectual property represents a meaningful driver of device manufacturer value, potential liabilities for exposure, damages and duration to the acquirer are persistent, immense and enduring. Similarly, the FDA has announced an ongoing emphasis on enforcement of manufacturing standards and quality, jeopardizing the value of product lines, operations and revenue streams acquired. Device targets present distinctive threats for adverse events, recalls and products liability. The SEC meanwhile expresses renewed interests in "channel stuffing" and similar distribution excess, triggering costly class action shareholder litigation over fraudulent revenue recognition. Finally, the offer, distribution and sale of medical device products and services is governed by complex federal and state statutory and regulatory requirements, including attention to financial ownership, referral relationships and off-label promotion.

Fortunately, Burr has extensive, long-standing experience in structuring, documenting and consummating medical device mergers and acquisitions. In addition to identifying these risks, Burr's comprehensive team provides value-added solutions. For example, Burr has successfully structured transactions preserving critical provider and regulatory assets while eluding legacy financial and tax liabilities. Also, Burr has documented acquisitions to effectively isolate material regulatory risks through a series of targeted indemnities, replenished escrows, and representation and warranty insurance packages. Lastly, Burr has efficiently deployed resources to consummate device acquisitions on time and at value.

Because of their experience, Burr lawyers are frequently invited to present at continuing education seminars and conferences. Chet Hosch recently spoke at a program on medical device corporate strategy. Chet's slide deck on the legal perspective of device mergers and acquisitions can be accessed here.

If you would like more information, please contact:

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