

Competition

BD operates in the increasingly complex and challenging medical technology marketplace. Technological advances and scientific discoveries have accelerated the pace of change in medical technology, the regulatory environment of medical products is becoming more complex and vigorous, and economic conditions have resulted in a challenging market. Companies of varying sizes compete in the global medical technology field. Some are more specialized than BD with respect to particular markets, and some have greater financial resources than BD. New companies have entered the field, particularly in the areas of molecular diagnostics, safety-engineered devices and in the life sciences, and established companies have diversified their business activities into the medical technology area. Other firms engaged in the distribution of medical technology products have become manufacturers of medical devices and instruments as well. Acquisitions and collaborations by and among companies seeking a competitive advantage also affect the competitive environment. In addition, the entry into the market of low-cost manufacturers has created increased pricing pressures. BD competes in this evolving marketplace on the basis of many factors, including price, quality, innovation, service, reputation, distribution and promotion. The impact of these factors on BD's competitive position varies among BD's various product offerings. In order to remain competitive in the industries in which it operates, BD continues to make investments in research and development, quality management, quality improvement, product innovation and productivity improvement in support of its core strategies. See further discussion of the risks relating to competition in the medical technology industry in Item 1A. Risk Factors.

Third-Party Reimbursement

Reimbursement is an important strategic consideration in the development and marketing of medical technology. Obtaining coverage, coding and payment is critical to the commercial success of a new product or procedure. Difficulty in achieving market access can lead to slow adoption in the marketplace and inadequate payment levels that can continue for months or even years.

A majority of BD's customers rely on third-party payers, including government programs and private health insurance plans, to reimburse some or all of the cost of the procedures, products and services they provide. Vertical integration has created a very concentrated market among commercial third-party payers in the U.S. Global payers are increasingly focused on strategies to control spending on healthcare and reward improvements in quality and patient outcomes.

BD is actively engaged in identifying and communicating value propositions of its products for payer, provider, and patient stakeholders, and it employs various efforts and resources to attempt to positively impact coverage, coding and payment pathways. However, BD has no direct control over payer decision-making with respect to coverage and payment levels for BD products. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) and/or drug(s) utilized, the available budget, or a combination of these factors, and coverage and payment levels are determined at each payer's discretion. As BD's product offerings are diverse across a variety of healthcare settings, they are affected to varying degrees by the many payment pathways that impact the decisions of healthcare providers regarding which medical products they purchase and the prices they are willing to pay for those products. Therefore, changes in reimbursement levels or methods may either positively or negatively impact sales of BD products in any given country for any given product.

As government programs expand healthcare coverage for their citizens, they have at the same time sought to control costs by limiting the amount of reimbursement they will pay for particular procedures, products or services. In addition, most payers are seeking price predictability in order to mitigate future exposure to manufacturer price increases. This is coupled with an increase in high deductible private insurance plans, which transfer more pricing exposure and burden directly to the patient.

Many payers both in the U.S. and globally have developed specific payment and delivery mechanisms to support these cost control efforts and to focus on paying for value. These mechanisms include payment reductions, pay for performance measures, quality-based performance payments, restrictive coverage policies, bidding and tender mechanics, studies to compare the effectiveness of therapies and use of technology