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Investing in the life sciences industry without an understanding of the key regulatory factors that could determine a product’s success or failure could cost you millions of dollars.

As the industry readies itself for the 2019 edition of the annual pilgrimage to the J.P. Morgan Healthcare Conference in San Francisco, our market-leading Global Regulatory Team has prepared a series of updates covering the following topic areas that we hope will help guide your 2019 investment decisions.

- Drug pricing and reimbursement
- Regulatory changes in Europe
- Medical device and technology
- Digital health
- Data privacy and cybersecurity
- Value-based purchasing
- Cell and gene therapies
- CFIUS reporting obligations

In this first edition, we explore the pre-commercial drug investment risks related to pricing and reimbursement.

Pre-commercial drug investment risks: Will insurers pay for this product?

Investors continue to be drawn to the pharmaceutical industry, particularly as novel therapies like gene and cell therapies and potential blockbuster treatments for cancers and Alzheimer’s disease proceed through U.S. Food and Drug Administration (FDA) approval. It may be tempting to focus primarily on a drug’s clinical trial results and expected market value when making investment decisions. Yet, the value of the projected market is entirely dependent on the product’s coverage, reimbursement, and pricing profile. The specifics will differ by product, but an investor ignores such matters at their own peril. The following three key questions can help to
get the conversation started.

1. Does the drug have multiple possible indications?

A pre-commercial product often has multiple possible uses in development. Where that is the case, it is important to think through each possible indication's coverage, reimbursement, and pricing profile, and the order in which the uses are expected to be commercialized. The first indication approved and launched can lock in and limit the coverage, reimbursement, and pricing options available for subsequent indications. Investors need to consider whether subsequent uses can be commercialized using different FDA approvals or different product presentations (different concentrations, strengths, or routes of administration, for example) to generate the possibility for market differentiation and flexibility down the road.

**Why it matters:** If the product under consideration is being valued based on the possibility of multiple indications, you need to test whether your market valuation of the follow-on indications takes into account any coverage, reimbursement, and pricing constraints that the first or other earlier indications may create.

2. Is the drug going to be self-administered, physician-administered, or both?

The Medicare program has different rules regarding the coverage and reimbursement of drug products, which generally depend on whether a drug is going to be physician-administered or self-administered. And even if you don't expect a large Medicare market, the Medicare rules tend to drive how Medicaid and the commercial markets approach a product.
Physician-administered drugs are more likely to be covered under the Medicare Part B benefit and reimbursed at a rate based on average sales price (ASP); in general, the average commercial price in the quarter, as calculated and reported by a product’s manufacturer to the Centers for Medicare and Medicaid Services (CMS). The market for physician-administered drugs generally consists of physicians and other health care providers, who “buy” the drug and then “bill” the relevant payer for the drug, and in the case of Medicare, get reimbursed at a rate based on the product’s ASP. The Department of Health and Human Services (HHS) is seriously considering reforms to this approach in the Medicare program, including a mandatory demonstration project that would link payment rates to international prices, which could create additional uncertainty about reimbursement over the next few years.

Medicare assigns a billing and payment code to each drug product, and all versions of the product marketed under a given New Drug Application (NDA) or Biologics License Application (BLA) are assigned to that code and reimbursed using a weighted average of the ASP for those versions. If different presentations of that product are not parity-priced at the milligram level, for example, that means that the reimbursement rate for the code will be higher relative to market price for some versions of the drug and lower for others. That is why, as noted above, it is important to think about whether a given product will have different uses and prices, as in the case of a Part B drug, which can wreak havoc on its reimbursement, with a knock-on effect to customer demand.

Self-administered drugs, in contrast – such as drugs dispensed by a retail, mail, or specialty pharmacy – are more likely to be covered under the Medicare Part D benefit. For most classes of drugs, Part D plans have considerable discretion with respect to which drugs they cover, meaning that a pharmaceutical manufacturer may need to negotiate with Part D plans to obtain coverage for its drug, typically by offering a rebate. Even when a Part D plan covers a drug, for most classes of drugs, the plan has flexibility to impose utilization management restrictions on the drug, potentially creating access barriers. Each Part D plan has its own payment and patient cost-sharing structures, subject to annual CMS approval.
**Both?** Occasionally, a product can have one version that is a Part B drug and another that is a Part D drug. In that case, the drug may be reimbursed at distinct rates under the Part B and Part D programs. The prices that the manufacturer has to report to CMS (which, in turn, impact drug reimbursement under the Medicare and Medicaid programs) may, in some instances, reflect a “blend” of the pricing in the two programs. Additionally, the drug will likely be subject to distinct patient cost-sharing and utilization management rules in the two programs. This all presumes a manufacturer can maintain coverage for a drug under both Part B and Part D; if utilization of the Part D-covered version of the drug surpasses the Part B-covered version among Medicare beneficiaries, the drug could lose coverage under Part B.

**Why it matters:** The status of the drug as Part B or Part D, as well as CMS coding decisions, may impact Medicare payment, patient cost sharing, and overall access to the drug. These considerations are relevant for any evaluation of a target and its drug candidates.

**3. Does the pricing strategy account for Medicaid, Medicare, and other governmental program pricing requirements?**

There are multiple governmental health care programs – including Medicaid, Medicare, the Secretary of Veterans Affairs Federal Supply Schedule (VA/FSS) program, and the 340B Drug Pricing Program – and the coverage and pricing requirements in these programs are interlinked. For instance, many manufacturers participate in the Medicaid drug rebate program (MDRP) – a program under which manufacturers pay a rebate on all units paid for by state Medicaid programs, and state Medicaid programs must cover the drug for Medicaid enrollees – because participation in the MDRP is a condition for coverage of a drug under the Medicare Part B program.

Manufacturers that join the MDRP are also required to participate in the Secretary of Veterans Affairs Federal Supply Schedule (VA/FSS) program and the 340B Drug Pricing Program. Under the 340B program, a manufacturer agrees to sell its products to certain safety-net providers at no more than a statutorily-defined “ceiling price.” This ceiling price, like the Medicaid drug rebate amount and the Medicare ASP-based reimbursement rate, is determined based on commercial pricing data that manufacturers must report to CMS. The VA/FSS program imposes a different type of ceiling price on certain sales to the federal government and has its own set of price reporting requirements.

**Why it matters:** While a pre-commercial target company is not likely participating in these government health care programs, the coverage and price reporting requirements under each of these programs will significantly impact a drug’s reimbursement rates and overall commercial
strategy. Advance planning and financial modeling of these impacts is critical to accurately evaluating the profitability of the target.

Our Global Regulatory Team

We help organizations navigate the world’s multiplying regulatory regimes as they cross industries and borders alike. At Hogan Lovells, we believe that regulation is neither a force to be feared nor an obstacle to be overcome. Regulation is simply a reality of doing business today, and the organizations that understand it holistically and navigate it well are the ones that will succeed. Our team helps industry understand, anticipate, and influence the shifting – and often volatile – regulatory landscape. We partner with your business to create smart, operational solutions that mitigate risk, create new opportunities, and power your enterprise to advance.

Our Global Life Sciences and Health Care Team

Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires a partner with a holistic, collaborative approach and a global perspective. For life sciences innovators of all sizes, anywhere in the world, Hogan Lovells is that partner – from cutting-edge start-ups and boutique venture funds to world-renowned research institutions and health systems to global biopharmaceutical conglomerates. With more than 500 life sciences and health care lawyers around the world, we provide a seamless experience everywhere you do business. And no matter the challenge – from creation to commercialization of a life-saving therapy, regulatory compliance to an international patent dispute, the formation of a strategic alliance to a complex, global merger – we’ve been there before and we understand how to prepare you for what happens next, helping you to anticipate risks and address future issues before they arise.

Contacts

Alice Valder Curran
Partner

Christopher H. Schott
Partner

Elizabeth (Beth) Halpern
Partner

Margaux J. Hall
Counsel