CASE STUDY:

Launch Planning in an Ever-Evolving Policy and Regulatory Landscape

Magnolia market access

A MEDICAL KNOWLEDGE GROUP COMPANY

The Inflation Reduction Act (IRA) of 2022 has added another layer of complexity in product life cycle management

A development-stage biopharma company engaged Magnolia to help understand the impact that the IRA would have on their product development strategies, especially when considering that their product would have several indications and would likely be negotiated in the future in Medicare Part D. Our team developed a comprehensive packaging, licensing, and launch strategy to help the client understand how the IRA ties into other important regulations, and how appropriate planning could help avoid significant issues in the future.

National Council for Prescription Drug Programs (NCPDP)

- NCPDP sets guidelines for how manufacturers can obtain an NDC code and set pricing per billable unit
- The guidelines provide 3 categories for each unit–per gram, per mL, or per "each"
- Consideration should be given to what approach will provide the most flexibility for pricing, packaging, and rebating

Medicare Drug Rebate Program (MDRP)

- In order to offer drugs to federally insured patients, manufacturers have to offer their "best price" to any Medicaid patient under the MDRP
- MDRP regulations also set Medicaid rebate and line extension definitions
- Line extensions begin with the launch of an "initial" oral solid and carry forward and must be considered when making pricing and rebate decisions

IRA Medicare Drug Price Negotiation Program (MDPNP)

- MDPNP established a 7-year "clock" from launch of an initial product until it is eligible for negotiation (finalized at Year 9)
- Inclusion and exclusion criteria for which drugs are likely to be negotiated should be monitored to determine when to launch or license products
- Setting strategies to develop strong evidence to support your products clinical value will be important to maximize your fair price

Other launch factors resulting from the IRA

The provisions of the IRA could result in manufacturers using innovative approaches to product life cycle management, such as:

- Licensing NDAs to allow products with the same moiety to be treated separately under the MDRP and MDPNP
- Launching smaller, first indications outside of the US to avoid starting the negotiation "clock" on future, larger indications

Actions, Outcomes

Magnolia assisted the company by thinking through a holistic approach to product development activities as opposed to just focusing one key policy development. This involved:

- "Unpacking" how federal regulations regarding packaging, pricing, and contracting drive launch planning
- Understanding how NCPDP guidelines set pricing and packaging
- Recognizing the importance of the formulation of the first indication and the potential it is has to affect the pricing of line extensions in the future
- Understanding how the 7-year "clock" works for MDPNP negotiation and key inclusion/exclusion criteria that can determine whether a product will likely be negotiated