Case Study: Regulatory Process & Policy

Advising decision-makers on PDUFA Reauthorization

Challenge

The Prescription Drug User Fee Act (PDUFA) authorizes FDA to collect fees from pharmaceutical companies to help fund the agency's drug review work. Every five years the Prescription Drug User Fee Act (PDUFA) gives the healthcare community the opportunity to both evaluate the performance of the Food & Drug Administration and reevaluate its priorities. Having the right guidance and voice in these discussions can give pharma companies a competitive advantage.

Solution

YourEncore experts, over the course of their careers, have earned a "seat at the table" for their technical understanding of FDA programs and how policy can impact innovation and new opportunities to advance the public health. These experts are respected and trusted by elected officials, patient groups, industry negotiators, and senior regulatory decision-makers.

Results

YourEncore experts continue to shape PDUFA legislation, including advice for 2017's PDUFA VI reauthorization.

Key priorities include:

- Better Integrate the Patient Perspective in Drug Development and Regulatory Decision-Making
- Enhance the Scientific Expertise, Processes, and Tools FDA Uses to Make Regulatory Decisions
- Promote Long-Term Stability of the PDUFA Program: Resource and Workforce Management

your encore