



## CASE STUDY: FDA FRACAS

### Ron Cohen

President and CEO, Acorda Therapeutics

HQ: Hawthorne, NY

Revenues: \$292 million

Industry: Biotechnology



**Challenge:** In 2010, just a few short weeks before Acorda was scheduled to present its new drug, Ampyra, designed to improve walking in patients with multiple sclerosis, to an FDA panel, Cohen learned the FDA was not inclined to approve the drug. Acorda had already spent nearly half a year preparing for the panel. "We had to abandon large segments of what we'd been doing for five months and revamp the whole thing, specifically to answer the objections in the document that we'd not expected," says Cohen. The stakes were as high as they could get. "If this drug did not succeed for us, the company would disappear."

**Solution:** To help prepare for the panel, Cohen had hired New Jersey-based consulting firm ECG, which then helped Acorda essentially graft a department onto the company that included physician experts, specialized FDA regulatory consultants, experts in specialized chemistry manufacturing and control, toxicology and pharmacokinetics, among other areas. ECG helped Acorda with every step of the process by coaching experts, assembling mock panels and offering critiques to help presenters be better prepared. So when they received the FDA's negative review document, they were able to quickly change gears and redirect the preparation to defend the points outlined by the FDA. "They were required to be coaches, impresarios and directors. They were psychologists for us at times," notes Cohen. "In that type of pressure cooker, there is always the potential for things to go off the rails. ECG helped us with that human element." Acorda's group successfully defended the drug's efficacy and it went to market; Ampyra is now the only FDA-approved therapy to improve walking in people with MS.

**Bottom line:** Acorda used an RFP process and had three different groups pitch for the project. "They were all quite good, but in the end, we made our decision the way I suspect most do: we picked the one most compatible with our character as a company, the one we felt most at home with," says Cohen. "That turned out to be an excellent decision."