Using the FDA’s Modernization Act, Section 114 to Promote the Economic Value of New Drugs to Payers

Explore how major pharmaceutical and biotechnology companies are leveraging Section 114 in their interactions with formulary decision-makers.

Methodology

A web-based survey was presented to 35 outcomes directors asking them about their experiences with, and interpretations of, Section 114 and whether the advent of comparative effectiveness research will affect the use of Section 114 promotions.

Results

16 of the 35 experts completed the survey (46%) with 81% stating they always or frequently consider using Section 114 when making promotional claims for drugs. 75% said the FDA should issue a guidance on how to make such promotions to payers, especially what qualifies as “health care economic information” and “competent and reliable scientific evidence.”

The Takeaway

The survey reflects high levels of awareness of Section 114 among outcomes directors. It shows that respondents expect to see an increase in the use of Section 114 for promotional purposes. And it seems clear that more guidance is warranted from the FDA, given the rise in comparative effectiveness research.