FDA regulation of laboratory developed tests: a long saga

15 DEC 2016
By:

The U.S. Food and Drug Administration’s approach to laboratory developed tests (LDTs) has had more plot twists than - and has gone on nearly as long as - some of TV’s most popular soap operas. In the latest turn of events, which aired shortly after the 2016 elections, the FDA announced that it would not be issuing final guidance documents that would have regulated LDTs as medical “devices,” and the laboratories performing them as medical device “manufacturers.”

Rather, according to an agency spokesperson, the agency has realized “just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right” and plans to “outline our view of an appropriate risk-based approach in the near future” in order to “help guide continued discussions.”

If you are just tuning in now, what follows is a brief recap of the past several decades, as well as prognostication on what the 2017 viewing season may bring.

Read the full article here.

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