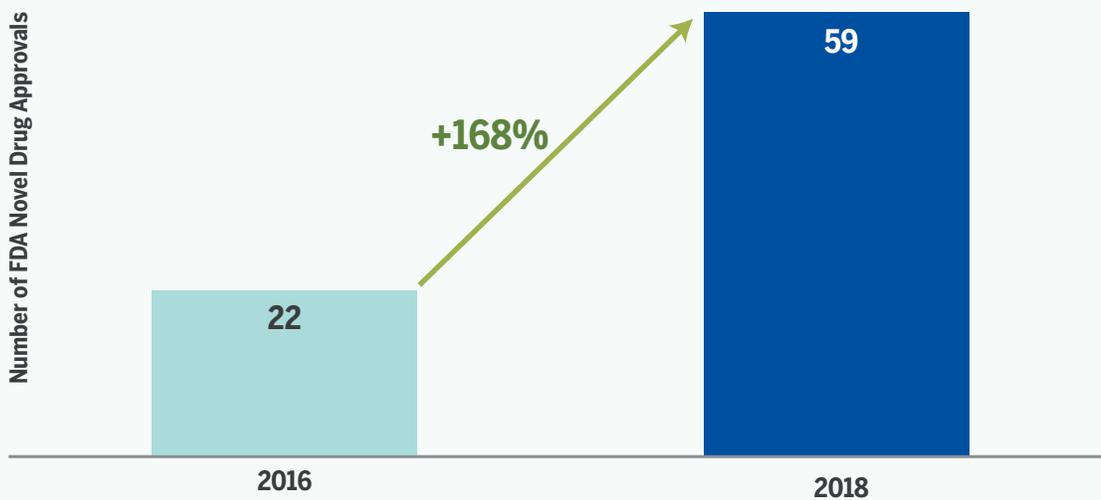


The FDA Comes Around

Innovation in the health care sector is accelerating due in part to a more accommodating regulatory environment for new approaches to medical treatment. Tracking which companies are participating in novel drug manufacturing may be important for health care investors.

The FDA is Increasingly Fostering Innovation



Source: www.FDA.gov.

Note: According to the FDA, novel drugs are "innovative products that serve previously unmet medical needs or otherwise significantly help to advance patient care and public health."

- In an effort to foster competition through innovation, the Food and Drug Administration (FDA) has approved 168% more novel drugs in 2018 than in 2016.
- Often perceived as a regulatory roadblock, the FDA has become a facilitator of innovation by trying to reduce the regulatory burden on new and novel drugs and devices that address unmet medical needs.
- The FDA is also collaborating with companies in a more proactive way during the development process. The agency is offering more guidance and engaging in more interactive exchanges with companies prior to a product filing. In certain cases, submissions are permitted on a rolling basis as data or modules are completed, as opposed to one complete submission at the end of data collection and analysis.
- We believe that what is taking place in health care is not only hopeful to consumers and patients, but also attractive from an investment perspective. Novel drug manufacturers and medical device companies as well as those businesses that sell products and services to aid in new product innovation are potential beneficiaries.

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