



Trends in Cardiovascular Drugs and Medical Devices Approved by FDA (1980-2021)

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Background

Heart disease is the leading cause of death in the US. Studies assessing trends in cardiovascular drug approvals and medical device authorization are lacking.

This study compared trends in approvals of cardiovascular new molecular entities (NME), new therapeutic biologics (BLA), and new medical device premarketing authorization (PMA) approved by the FDA in 1980-2021. We also assessed differences in the characteristics of cardiovascular and other therapeutic classes new drugs and medical devices approved by the FDA in the study period.

Methods

This study included new drugs, BLA, gene and cell therapies, and medical device premarket authorizations approved by the FDA in 1980-2021.

We extracted regulatory information for new drugs and medical devices from the FDA website and drug therapeutic class information from the WHO Collaborating Center for Drug Statistics Methodology Anatomical Therapeutic Chemical (ATC) Classification System. We updated all study data through December 31, 2021

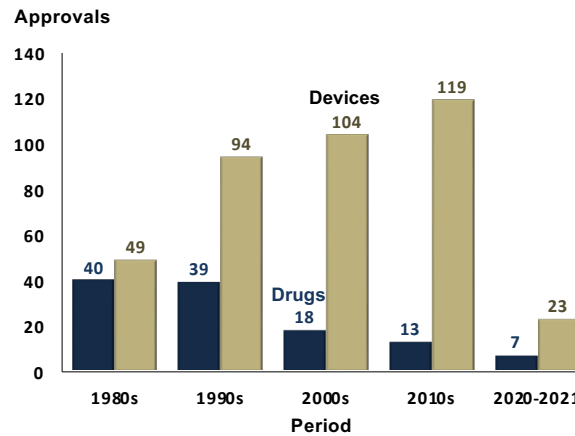
Results

The FDA approved 117 (9.6% of drug approvals) cardiovascular drugs and authorized 389 (26.4%) new cardiovascular medical device PMA in the period 1980-2021.

The FDA granted priority review designation to 34 (5.1%) new cardiovascular drugs, orphan drug designation to 14 (3.6%), breakthrough therapy designation to 1 (1.0%), accelerated approval to 4 (2.9%), and fast track approval to 7 (3.4%) .

Results

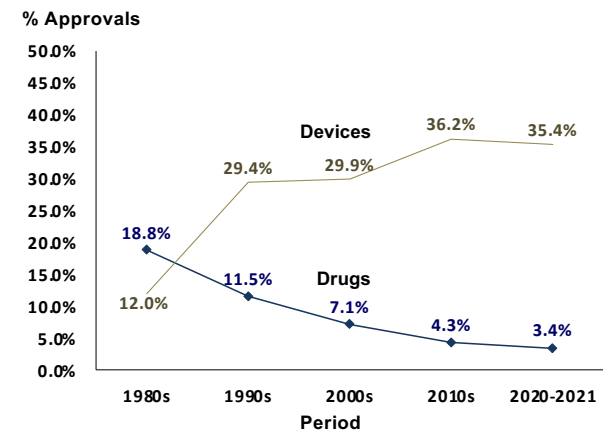
Figure 1. New Cardiovascular Drugs and Devices 1980-2021



The FDA approved 43 (11.1%) new cardiovascular PMA using expedited review or breakthrough designations. Additionally, new Implantable cardiovascular devices represented 44.5% of all new implantable premarketing authorizations, and life-sustaining support cardiovascular devices presented 93.6% of all new life-sustaining support PMA.

Average annual number of new cardiovascular drugs declined 4 from 4.0 (n=40, 18.8% of total approvals) in the 1980s to 1.3 (13, 4.3%) in the 2010s, while the Average annual number of new cardiovascular premarket authorizations increased from 4.9 (49, 12.0%) in the 1980s to 11.9 (119, 36.2%) in the 2010s.

Figure 2. New Cardiovascular Drugs and Devices, as a Percentage of all Approvals, 1980-2021



Conclusions

In the period 1980-2021, cardiovascular drugs represented was less than one in ten new drugs, while new cardiovascular devices accounted for one fourth of all medical device premarketing authorizations. Over time, there was a decline in the number of new cardiovascular drugs, while there was an increase in the number of new cardiovascular devices.

More studies are necessary to assess the benefit for patients from new drugs and medical devices in comparison with the existing alternatives available in the market.