

## Objectives

Cardiovascular diseases are a major cause of morbidity and accounted for 20.1% of all deaths in the United States in 2022.

We assessed trends in characteristics, regulatory designations and expedited development and review pathways for cardiovascular drugs approved by the Food and Drug Administration (FDA) from 1980 to 2024.

## Methods

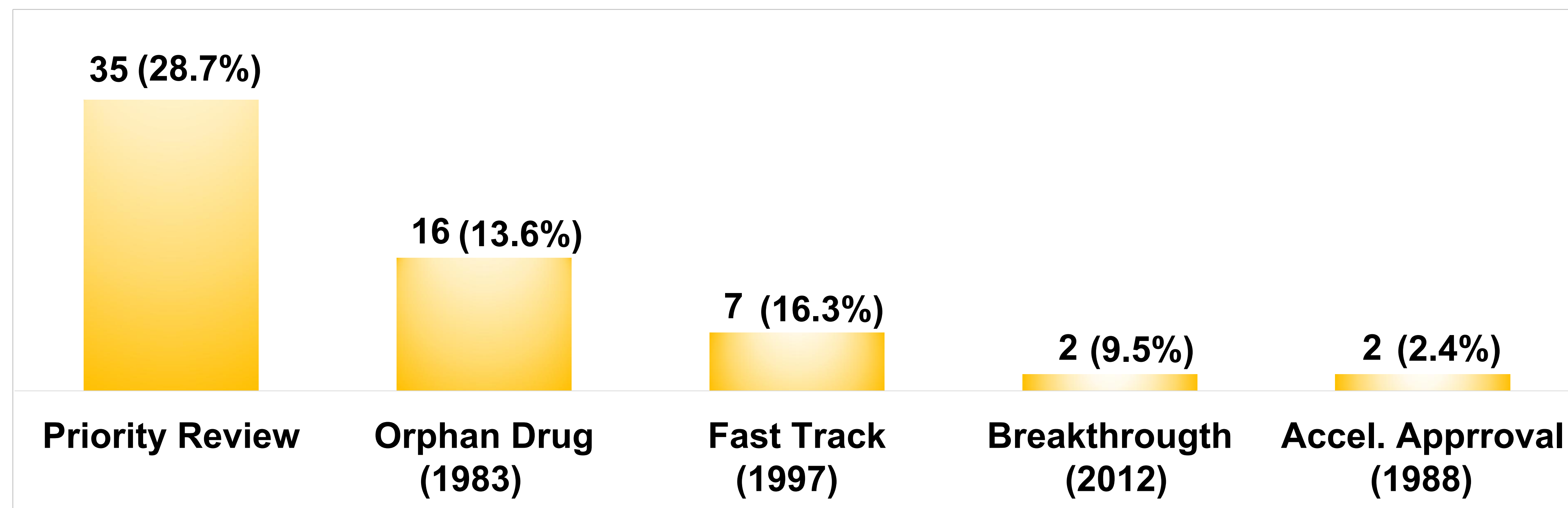
We collected information for cardiovascular new molecular entities (NME) and new therapeutic biologics license applications (BLA) approved by the FDA between 1980 and 2024 from the FDA publicly available databases Orange Book and Purple Book. We analyzed the data using descriptive statistics.

## Results

The FDA approved 122 cardiovascular drugs in 1980-2024, of which 101 (82.8%) remain in the market as of December 31, 2024. The approvals included 117 (95.9%) NME and 5 (4.1%) BLA. All BLA were approved after 2014. Cardiovascular drugs represented 8.3% of all the new drug approvals in the study period.

## Results

Figure 1. Cardiovascular Approvals Designations/Pathways, 1980–2024



There were 34 (27.6%) cardiovascular drugs classified as first-in-class, 16 (13.6%) received orphan designation, 7 (16.3%) underwent fast-track review to expedite drug development, 2 (9.5%) breakthrough therapy designation, and 2 (2.4%) accelerated approval (Figure 1).

The highest number of approvals occurred in 1980-1989 (Figure 2). The number of approvals of cardiovascular drugs were an average  $\pm$  standard deviation of  $4.0 \pm 2.2$  in the 1980s, declined to  $1.4 \pm 1.2$  in the 2010s, and increased to  $2.2 \pm 2.2$  in 2020-2024.

Cardiac therapy (28, 22.9%), agents acting on the renin-angiotensin system (22, 18%), and lipid modifying agents (21, 17.2%) concentrated 58.2% of the approvals (Table 1).

Figure 2. Trends in FDA Cardiovascular Approvals, 1980–2024

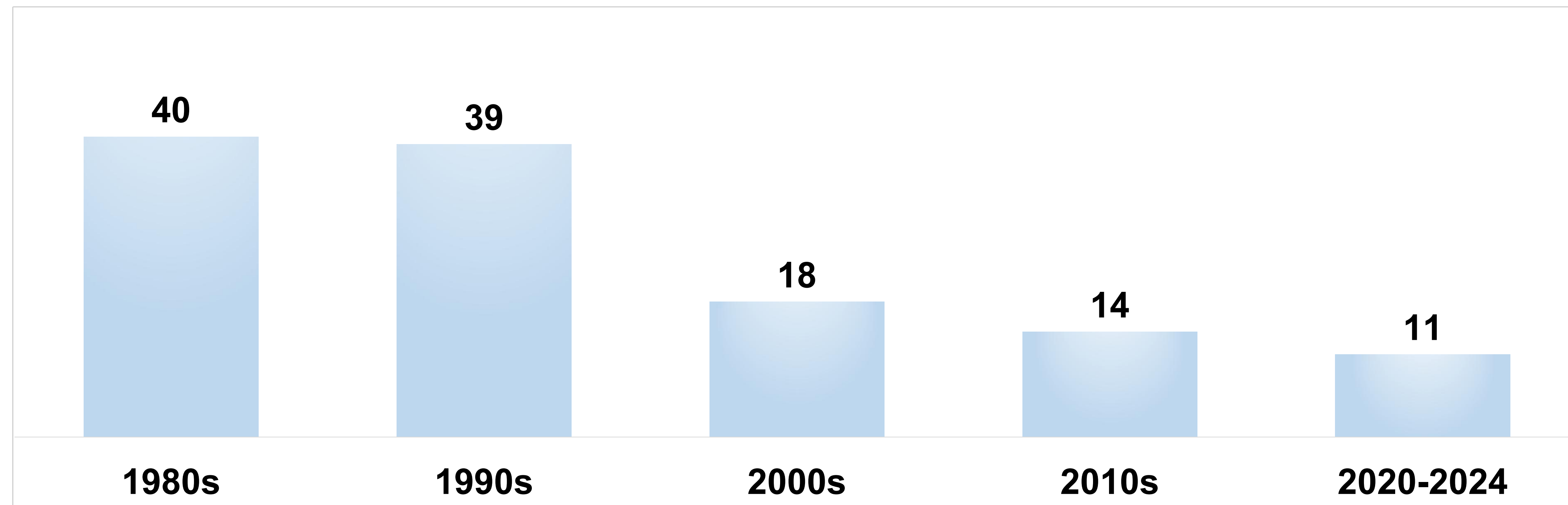


Table 1. Cardiovascular Drug Approvals by Therapeutic Class, 1980–2024

Therapeutic Class	1980s	1990s	2000s	2010s	2020s	Total (%)
Cardiac Therapy	11	8	4	2	3	28 (22.9%)
Agents Acting on Renin-Angiotensin Syst.	4	14	2	2	-	22 (18.0%)
Lipid Modifying Agents	2	6	5	5	3	21 (17.2%)
Beta Blocking Agents	8	3	1	-	1	13 (10.6%)
Calcium Channel Blockers	5	6	1	-	-	12 (9.8%)
Diuretics	3	1	3	-	1	8 (6.6%)
Endothelin Receptor Antagonist	-	-	2	1	1	4 (3.3%)
Antiadrenergic Agents, Peripherally Acting	4	-	-	-	-	4 (3.3%)
Other	3	1	0	4	2	10 (8.2%)
Total	40	39	18	14	11	122 (100%)

## Conclusions

Most cardiovascular drugs approved by the FDA in 1980-2024 did not represent an improvement over the therapies already marketed.

The annual averages of FDA cardiovascular drugs approvals declined over the study period.

Cardiovascular drug development remains critical to addressing unmet medical needs in this therapeutic area.