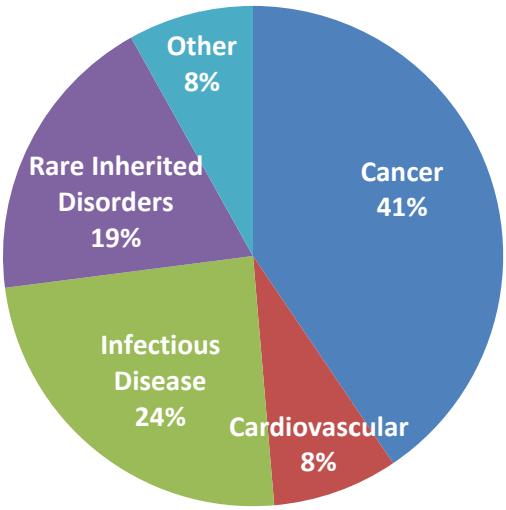
Science and Progress at the FDA

The "Advancing Breakthrough Therapies for Patients Act" was introduced in the Senate by Senators Bennet (D-CO), Hatch (R-UT), and Burr (R-NC) on March 26, 2012. Two months later, Congresswoman DeGette (D-CO) and Congressman Bilbray (R-CA) introduced the “Breakthrough Therapy Act” in the House of Representatives. The bills received bipartisan support, and were included as an amendment to the Food and Drug Administration Safety and Innovation Act (FDASIA), the latest iteration of the Prescription Drug User Fee bill. On July 9, 2012, the breakthrough therapy designation was signed into law.

A new drug may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease and preliminary clinical evidence suggests it provides a substantial improvement over existing therapies. Once a breakthrough therapy designation is granted, the FDA and drug sponsor work together to determine the most efficient path forward. **In just two years, 178 requests for Breakthrough Designation have been submitted, 44 designations have been granted, and 6 drugs have been approved from the program.**

Breakthrough Therapy Designations by Therapeutic Category



Breakthrough Therapies Approved by the FDA

Drug Name	Sponsor	Indication	PDUFA Deadline	Approval Date
Gazyva	Genentech	Chronic lymphocytic leukemia	12.20.13	11.1.13
Imbruvica	Pharmacyclics/J&J	Mantle cell lymphoma	2.28.14	11.13.13
Sovaldi	Gilead	Hepatitis C	12.8.13	12.6.13
Kalydeco	Vertex	Cystic fibrosis	3.27.14	2.21.14
Arzerra	Genmab/GlaxoSmithKline	Chronic lymphocytic leukemia	4.19.14	4.17.14
Zykadia	Novartis	Non-small cell lung cancer	8.24.14	4.29.14