Pre- and Post-Market Studies

Drug companies and Congress are urging FDA to approve medical treatments based on inconclusive pre-market studies, and aren't requiring better studies until after the products are already approved (post-market studies).

Does this come at the cost of patient safety?

GAO* said: most post-market drug studies requested or required by FDA were **"delayed or overdue."**

For devices, GAO said only **1 in 5** post-market studies required since 2007 had been **completed**.

	Pre-Market Studies	Post-Market Studies
Usually paid for by the manufacturer	✓	✓
Usually supposed to last at least a year		✓
Usually include patients with no other diseases	✓	
Must show a clear benefit for diverse patients by studying all sexes, ages, and major racial groups		
Companies have an incentive to delay or avoid releasing the results of these studies		✓
Participants usually have to pay for the product		✓

*Government Accountability Office

National Center for Health Research
center4research.org

June 2016