

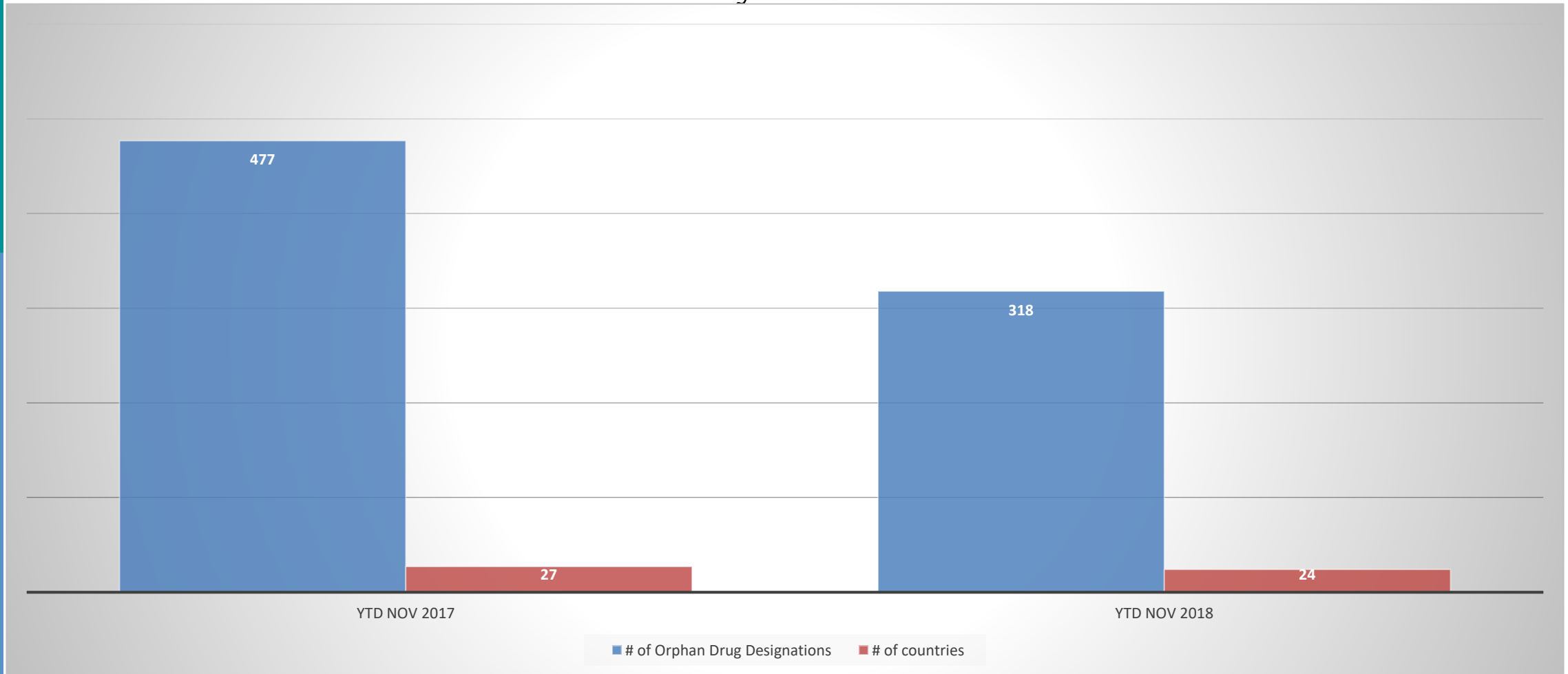
# Orphan Drug Designations in the USA 2018

K&A Schaefer Consulting

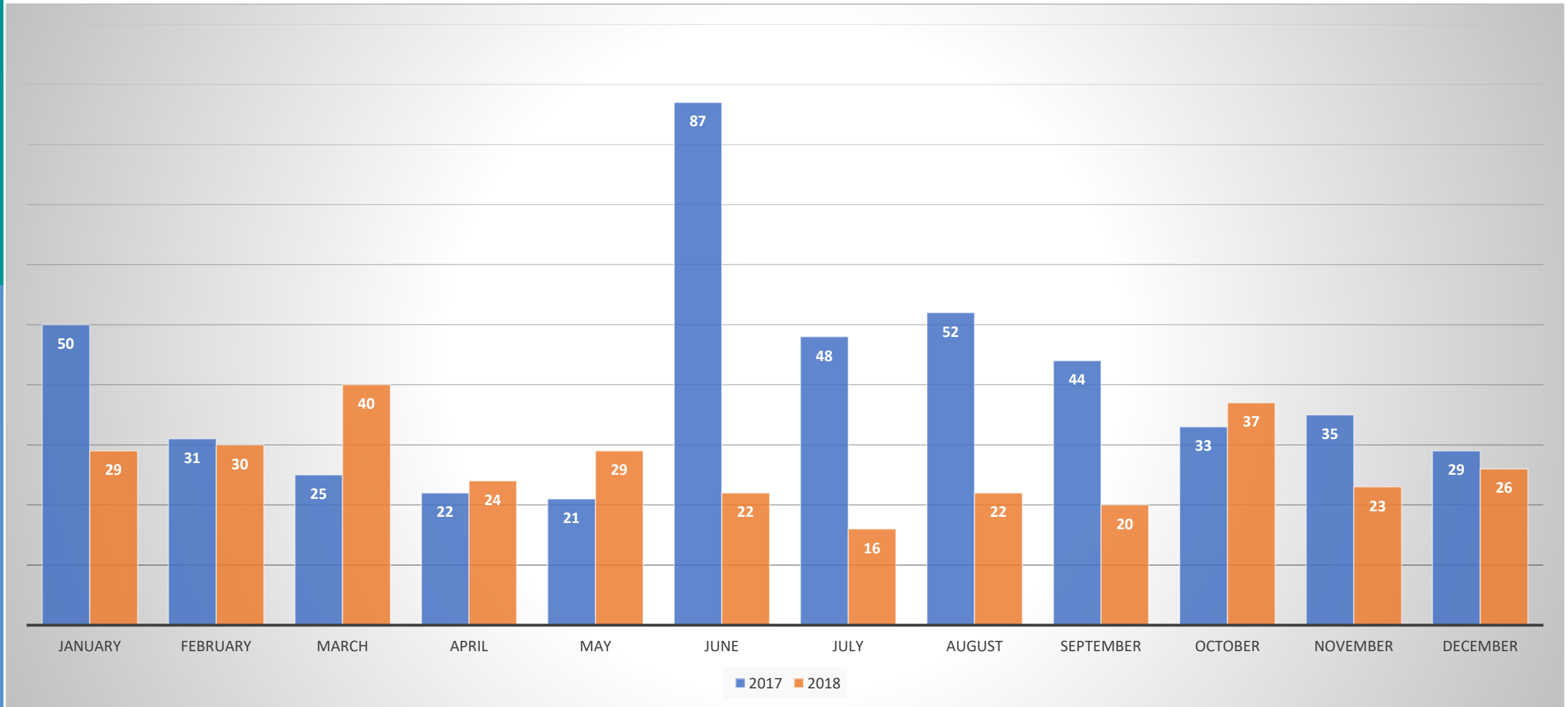
## Summary 2018

- In 2018 FDA approved 318 Orphan Drug Designations
  - In 2017 a total of 477 have been approved
  - For FY2018 33% less designations have been approved compared to last year.
- Companies from a total of 24 countries received at least one Orphan Drug Designation from the FDA in 2018
  - 70% (-1% compared to YTD November 2018) of all Orphan Drug Designations come from the USA
  - In 2017 Orphan Drug Designations from 27 countries were approved by FDA
- FY a total of 260 companies received at least one Orphan Drug designation. The majority of companies received one designation (87%), which is 2% lower than last month
  - 22 companies received two designations FY2018,
  - 8 companies received three designations
  - 2 company received approval for four designations
  - 2 company received approval for five designations
  - 1 company received approval for six designations

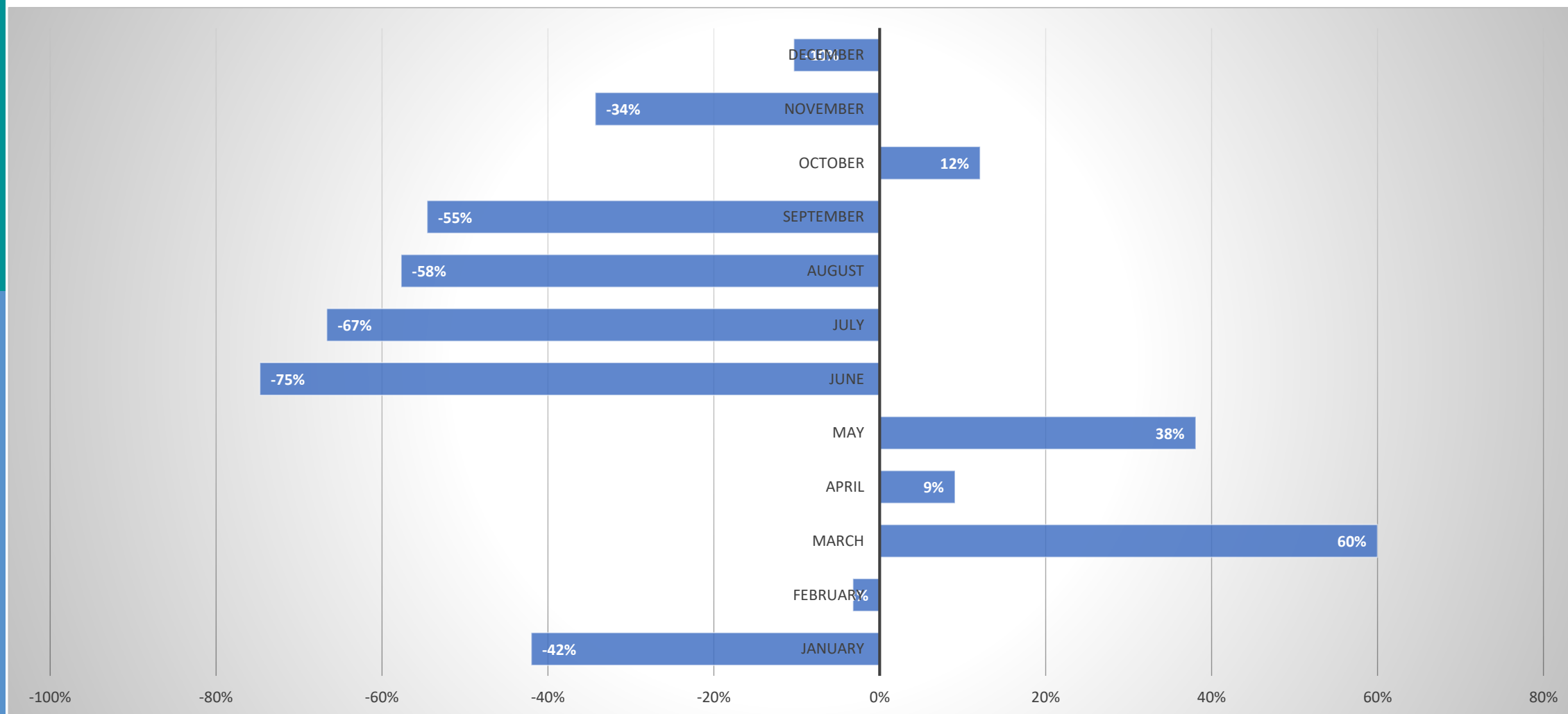
## The Total Number Of Orphan Drug Designations declined by 33% FY 2018



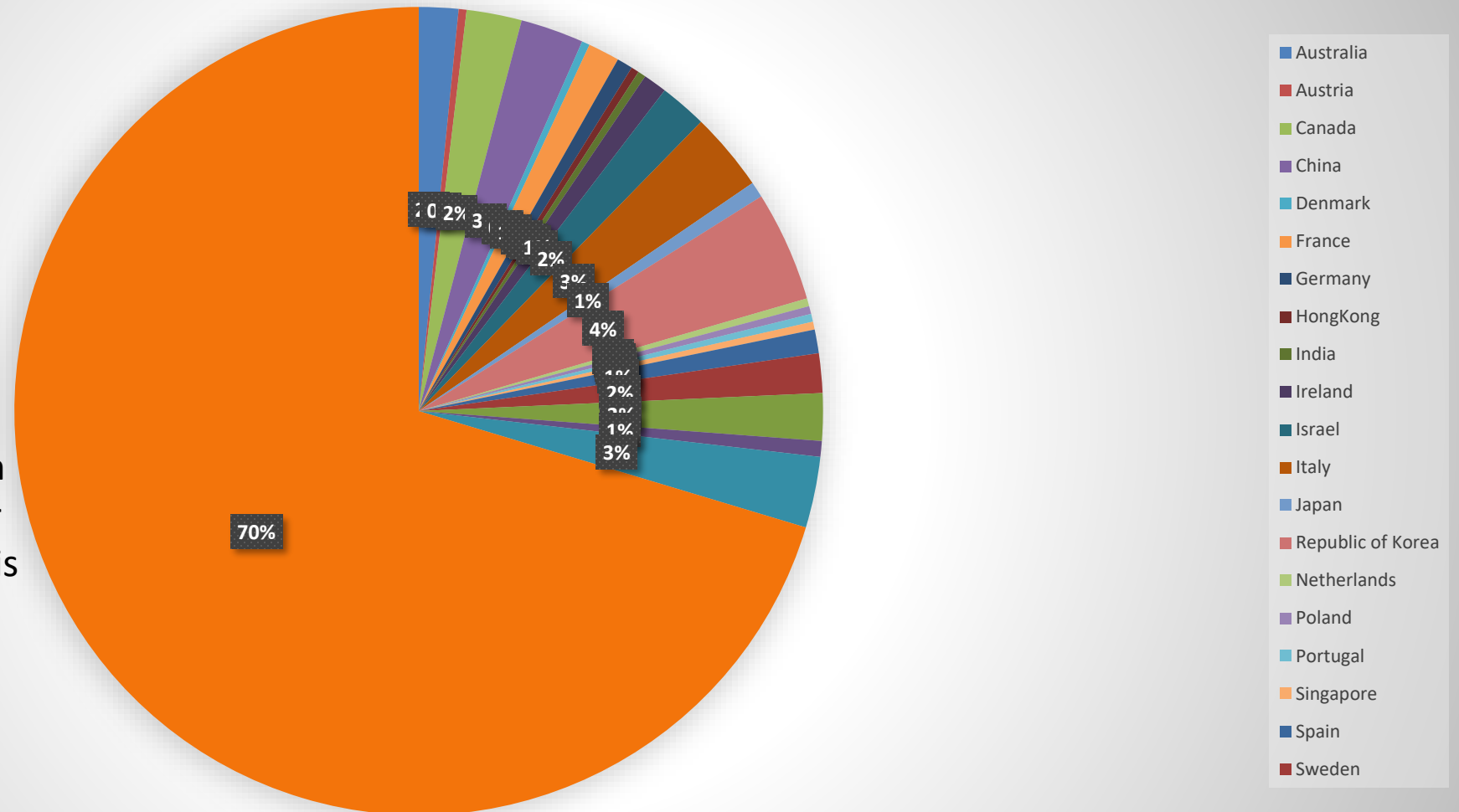
## Designations 2017 vs 2018 on a monthly basis



## Development 2017 vs 2018 on a monthly basis in %

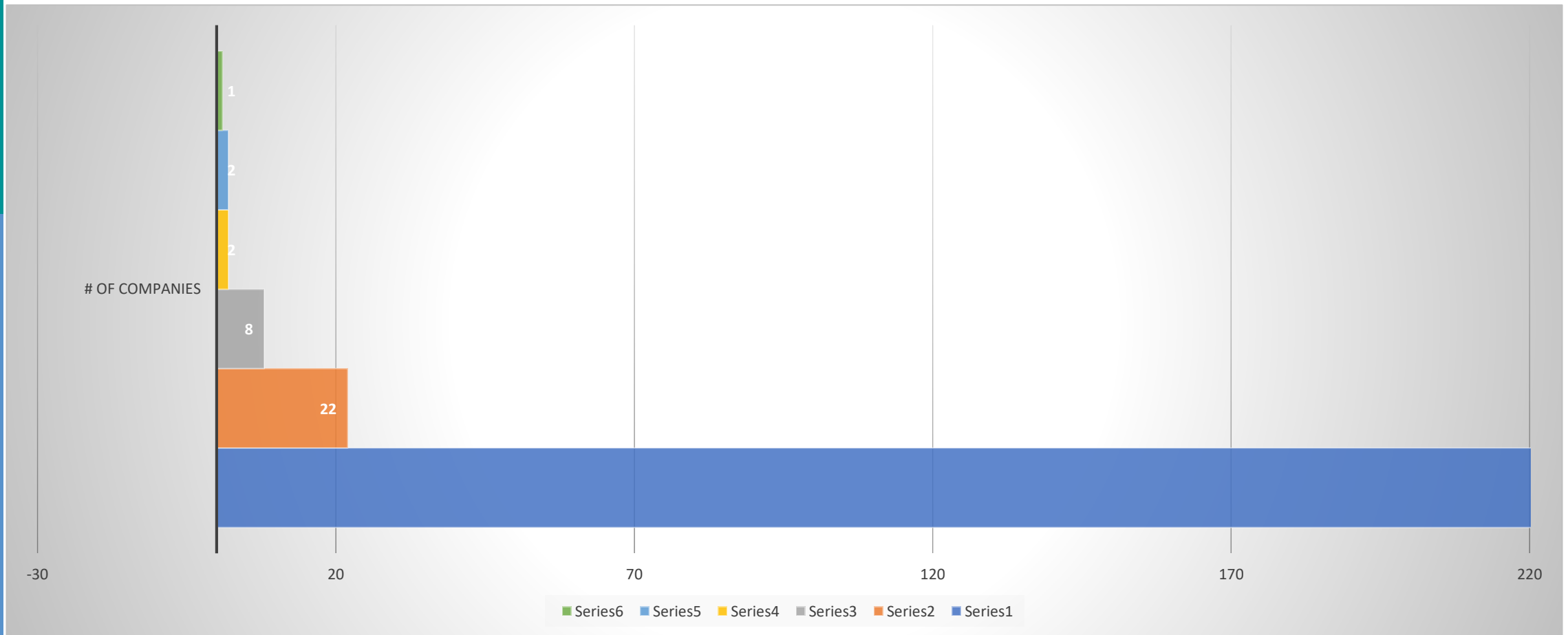


## The Vast Majority Of Orphan Drug Designations Are From The USA



Percentage of Orphan Drug Designations for US based companies is 1% lower than YTD November

# 87% Of All Companies (-2% vs last month) Received Approval for One Orphan Drug Designation for FY2018



## Development of Orphan Drug Designations over time

