

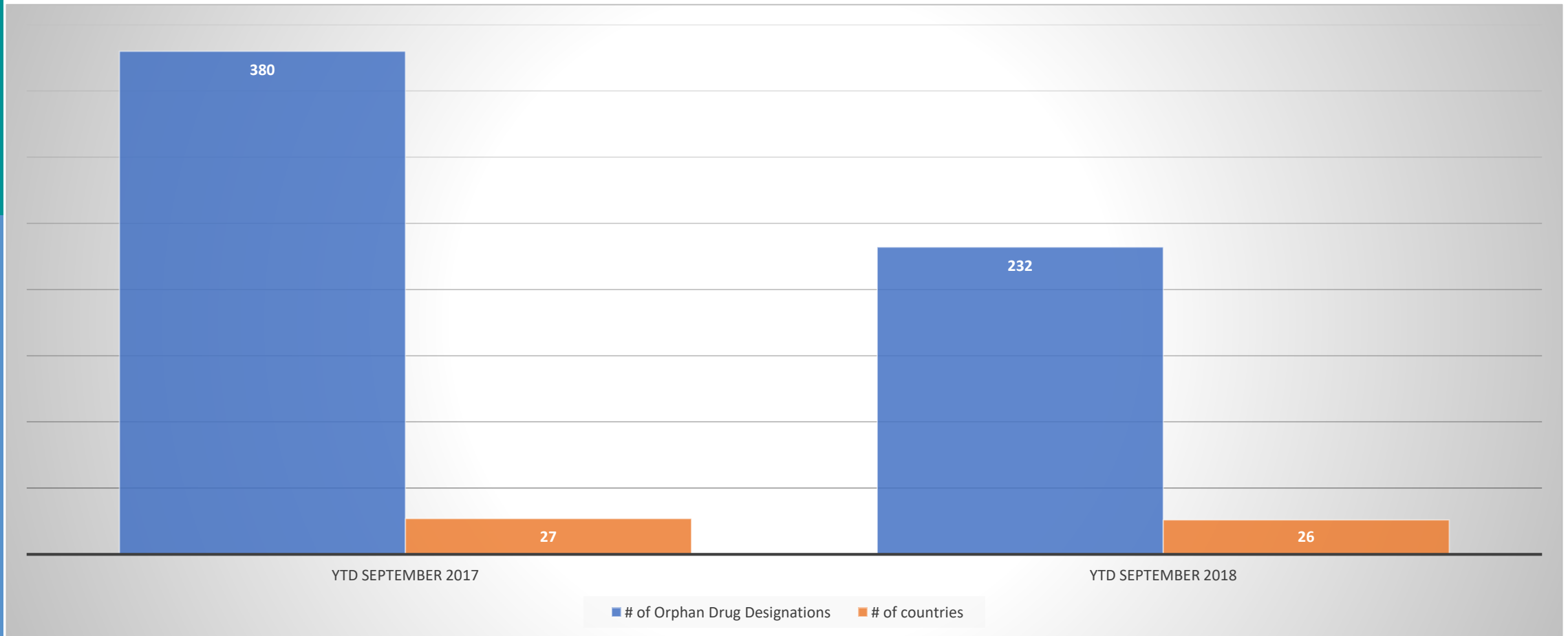
# Orphan Drug Designations in the USA YTD September 2018

K&A Schaefer Consulting

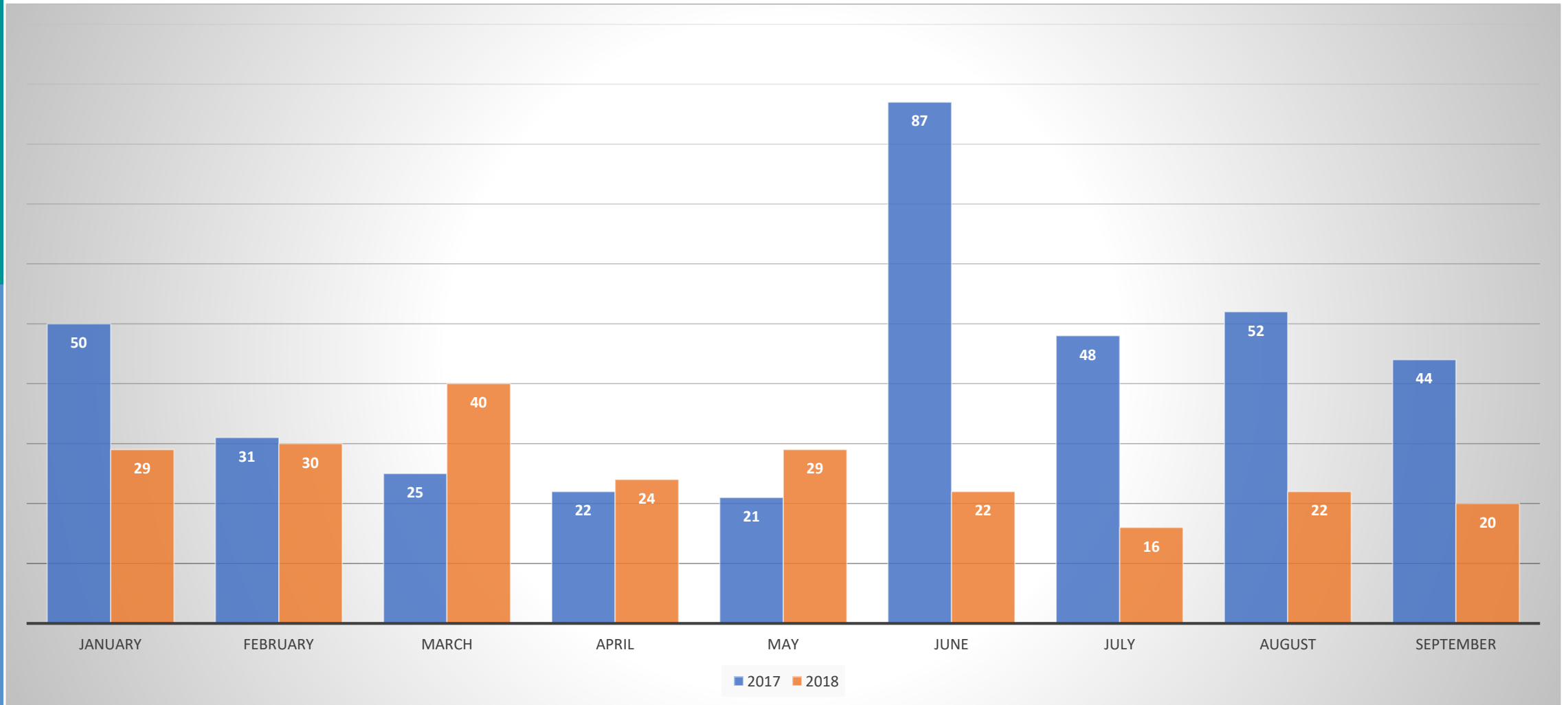
## Summary YTD September 2018

- YTD September 2018 FDA approved 232 Orphan Drug Designations
  - In the same timeframe of 2017 a total of 380 have been approved
  - YTD September 2018 39% less designations have been approved compared to last year. This is a further decline from the 37% in August
- Companies from a total of 26 countries received at least one Orphan Drug Designation from the FDA in 2018
  - 72% (unchanged) of all Orphan Drug Designations come from the USA
  - In 2017 Orphan Drug Designations from 27 countries were approved by FDA
- The majority of companies received one designation (90%), 2% down from July
  - 14 companies received two designations YTD September 2018,
  - 4 companies received three designations and
  - 2 company received approval for four designations

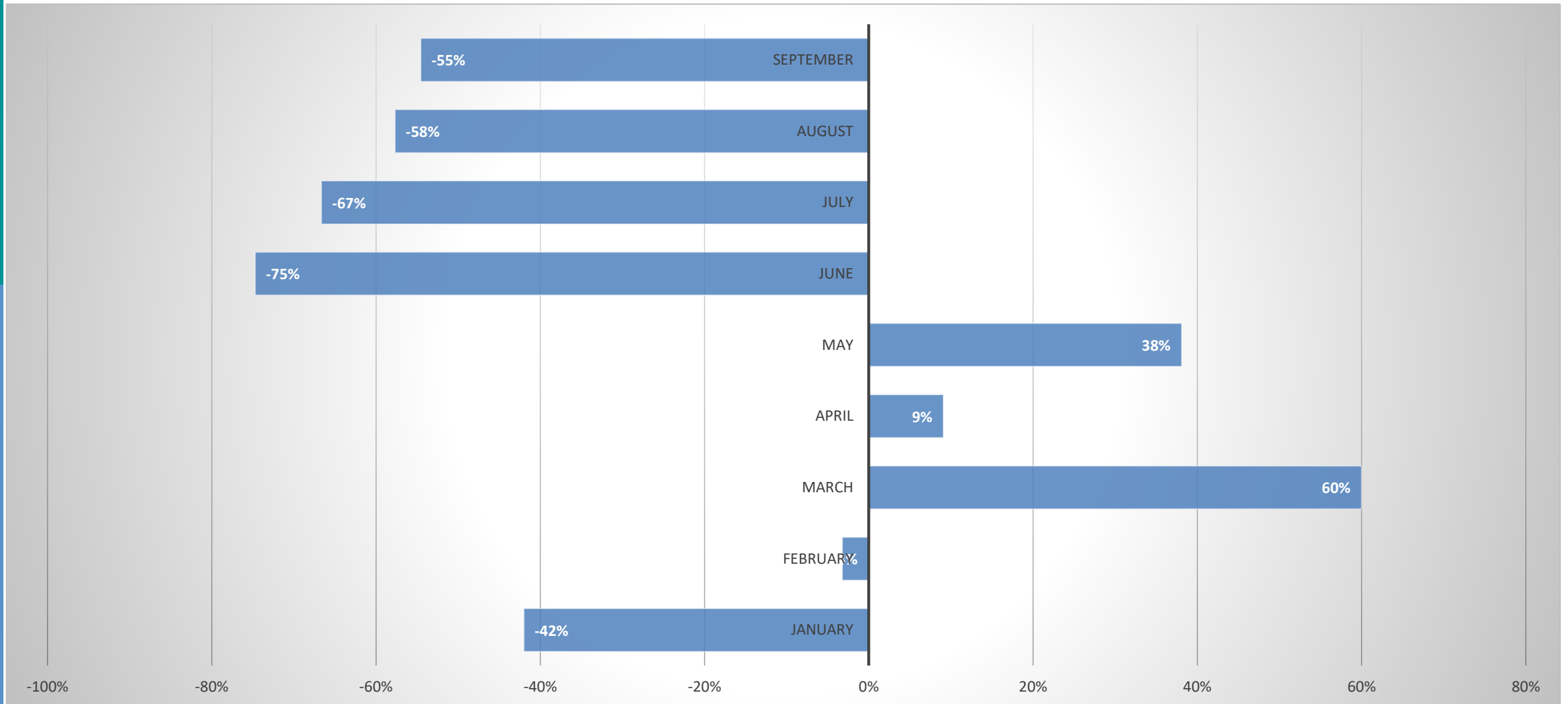
## The Total Number Of Orphan Drug Designations declined by 39% YTD September 2018



## Designations 2017 vs 2018 on a monthly basis

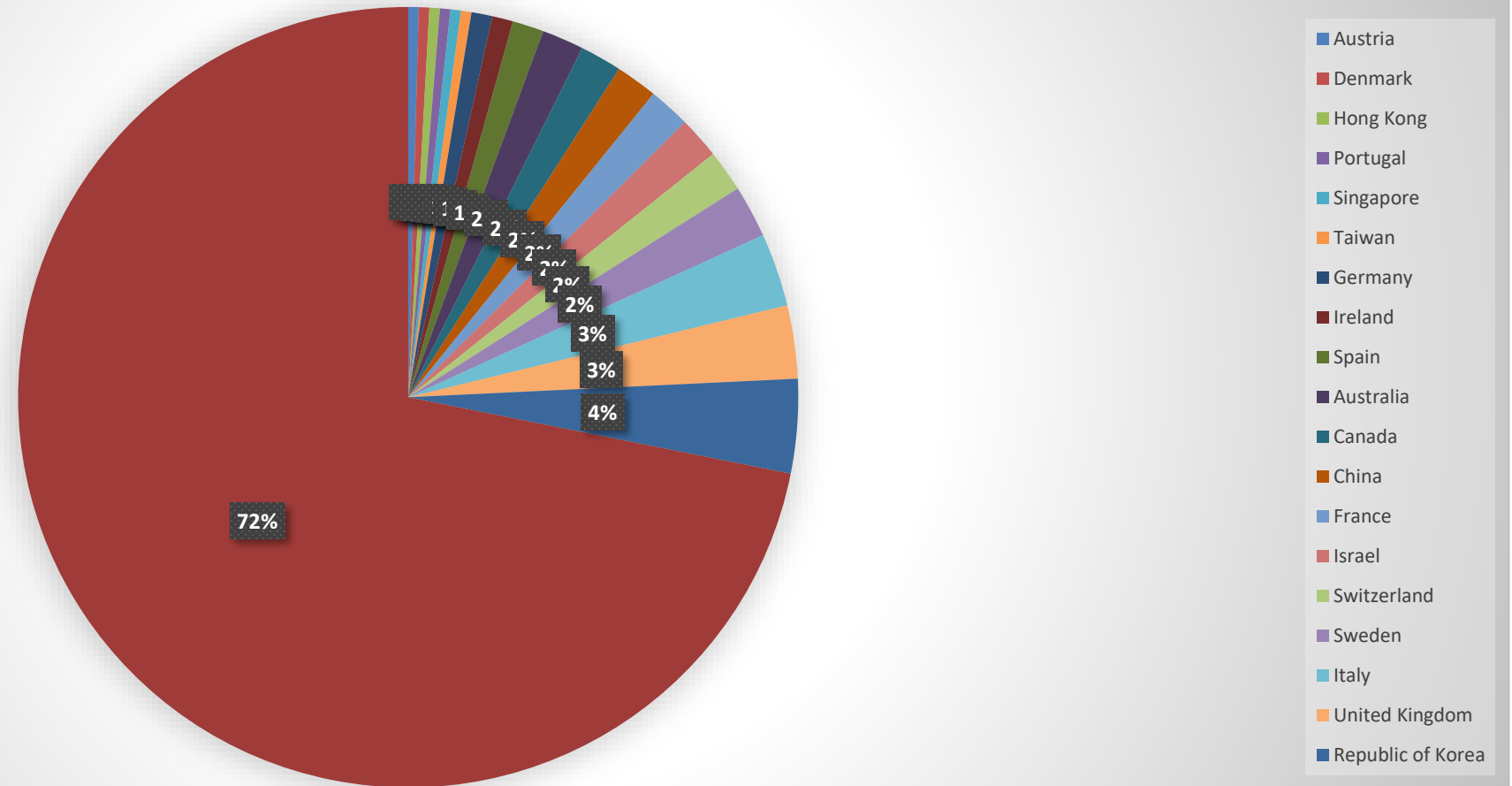


## Development 2017 vs 2018 on a monthly basis in %



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

# of Designations



Percentage of Orphan Drug Designations for US based companies is unchanged

## 90% Of All Companies Received Approval for One Orphan Drug Designation YTD September 2018

