BIOBUSINESS BRIEFS

MARKET WATCH

Value of 2016 FDA drug approvals: reversion to the mean?

2014 and 2015 were extraordinary years for the biopharmaceutical industry, with records set in both the number and value of the new therapeutic drugs (NTDs) approved by the FDA. With 2016 figures now on the books (see *Nat. Rev. Drug Discov.*, **16**, 73–76; 2017), we have analysed the industry's latest output of NTDs. We define NTDs as new molecular entities approved by the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), but with two adjustments: we exclude diagnostic imaging agents and include combination products with at least one new molecular entity as an active ingredient. As described previously (*Nat. Rev. Drug Discov.* **13**, 331–332; 2014), we use projected peak annual sales of these NTDs as a proxy for value.

In 2016, the FDA approved 28 NTDs with aggregate projected peak annual sales of US$35 billion — about half the number and value of 2014 and 2015 approvals (FIG. 1). This was still well above the nadir seen in 2008, and it was on par with what was seen from 2010–2012.

The mean forecasted value per approval essentially held steady in 2016, and the median improved slightly. Mega-blockbuster products with more than $3 billion in peak annual sales made lower absolute and proportional projected contributions to value than in 2013–2015. However, because there were fewer low-value products in 2016 as well, the overall value per approval was nearly flat.

Oncology remains the predominant therapeutic area driving value, contributing about one-third of projected peak annual sales consistently since 2011. Contributions from other therapeutic areas vary more: for example, cardiovascular disease accounted for 19% of the value in 2015 but only 2% in 2016.

In 2016, one-quarter of NTDs had breakthrough therapy designation from the FDA, and these are expected to generate close to half of the value of all approvals ($16 billion of $35 billion). These numbers are similar to those seen in 2014 and 2015; 19% of approvals went to breakthrough therapy designees in both years, contributing 54% and 32% of the value, respectively.

Several factors may negatively affect the future number of approvals and their value. Two of these factors may be the spectre of increasing price pressure in the United States and the intensifying competition in many therapeutic areas, such as diabetes and oncology. Nevertheless, there are also reasons for optimism, including ongoing improvements in regulatory processes, a deeper knowledge of biological pathways and a growing armamentarium of modalities. We are cautiously optimistic that 2017 will eclipse 2016, although not return to 2015 levels.

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Competing interests statement
The authors declare competing interests: see Web version for details.

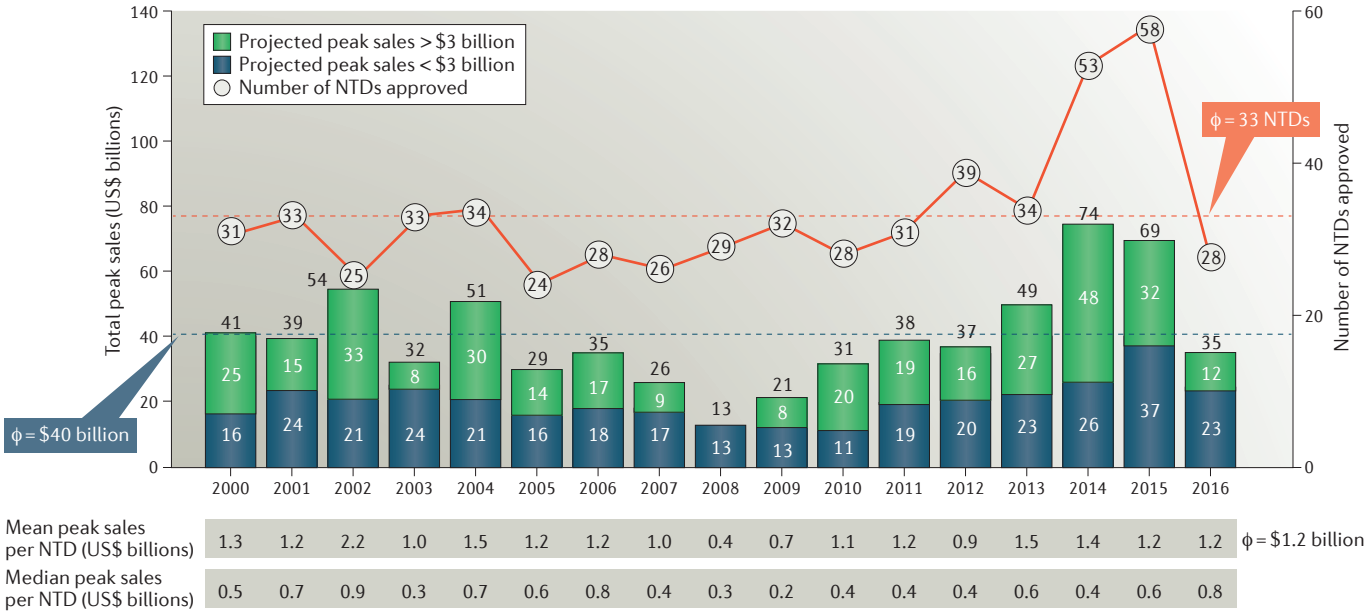

Figure 1 | **FDA drug approvals and projected aggregated peak sales: 2000–2016.** The graph shows the number and aggregate projected peak worldwide annual sales value of new therapeutic drugs (NTDs) by year of FDA approval. All values are inflation adjusted to 2016. Because of rounding, not all numbers add up to the totals shown. Sources: EvaluatePharma; FDA; Boston Consulting Group analysis.