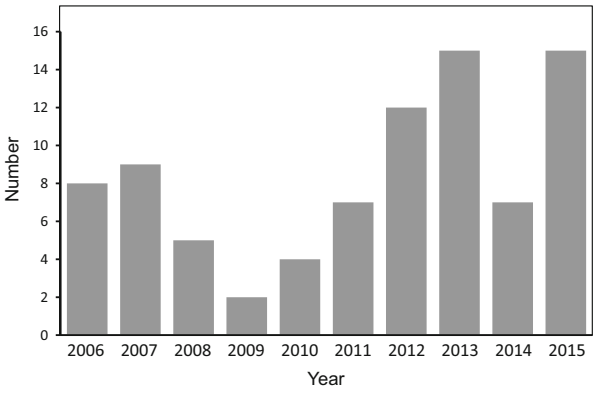

Fig. 6 Number of 1st-in-class drugs approved by the US Food and Drug Administration during the past 10 years

mold it into a linear process comprising a number of separate phases or process steps (target identification, tool production and assay development, hit finding and validation, hit-to-lead, lead optimization, preclinical development). Accepting a priori a highly increased attrition rate in the research phase, the assumption was that brute-force and ever larger numbers of projects and high-throughput experiments would drive productivity. Today, the pharmaceutical industry has largely taken a step back from this brute-force approach realizing that it rather hampered creativity, innovation, and ultimately productivity. Instead, the focus is now much more on science-driven approaches in areas of high unmet medical need where basic science has laid a good foundation for a sufficient mechanistic understanding to allow successful drug discovery. In addition, the industry has started to digest the recent revolutionary advances in technologies and genomics resulting in increased knowledge about complex biological systems and human pathophysiology. This is also reflected by the sharply rising numbers of approved breakthrough therapies by the US Food and Drug Administration (FDA) in 2013 and 2014. In addition, also the numbers of first-in-class drugs approved by the FDA have significantly increased in recent years (Fig. 6). Taking into account the long median time of about 20 years for drug discovery from target identification to regulatory approval (Eder et al. 2014), it appears that only now we are about to see the full impact of modern drug discovery approaches and of the information gained from sequencing the human genome on the productivity of the pharmaceutical industry. This will, no doubt, continue for many decades to come and further change the practice of medicine in significant and probably as yet unimaginable ways.

References

Algire GH, Chalkley HW (1945) Vascular reactions of normal and malignant tissues in vivo. 1. Vascular reactions of mice to wounds and to normal and neoplastic transplants. J Natl Cancer Inst 6:73–85

Arunlakshna O, Schild HO (1959) Some quantitative uses of drug antagonists. Br J Phamacol Chemother 14:48–58