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Editorial

New Drug Approvals by FDA from 2013-2017

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The pharmaceutical sector is a very challenging industry. It involves huge investments, strong regulations, and low output in terms of new drugs. Bringing a drug into the market is an arduous task, and involved testing from preclinical safety to clinical trials. With its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat, FDA (U.S. Food and Drug Administration) provides scientific and regulatory advice needed to bring new therapies to market.

Drug products include both small molecules and biological products. Approval of new molecular entities (NMEs) is authorized under Part 314 (Title 21, Chapter 1, Subchapter D, Part 314, subpart B) of the Electronic Code of Federal Regulations and approval of biological products is authorized under Part 601 (Title 21, Chapter 1, Subchapter F, Part 601, subpart C) of the Electronic Code of Federal Regulations [1,2]. For simplicity, the term "drugs" will be used to refer to both new molecular entities and biological products in this manuscript. Novel drugs can represent important new therapies for advancing patient care. During past five years (2013 - 2017), the U.S. Food and Drug Administration (FDA), has approved a total of 191 new entities, with 46 approvals in 2017 being the highest in last five years [3-7] (Figure 1). The present article reviews the drugs approved during last five years by FDA. Percentage of FDA approved drugs falling into various classes is depicted in figure 2 and 3.

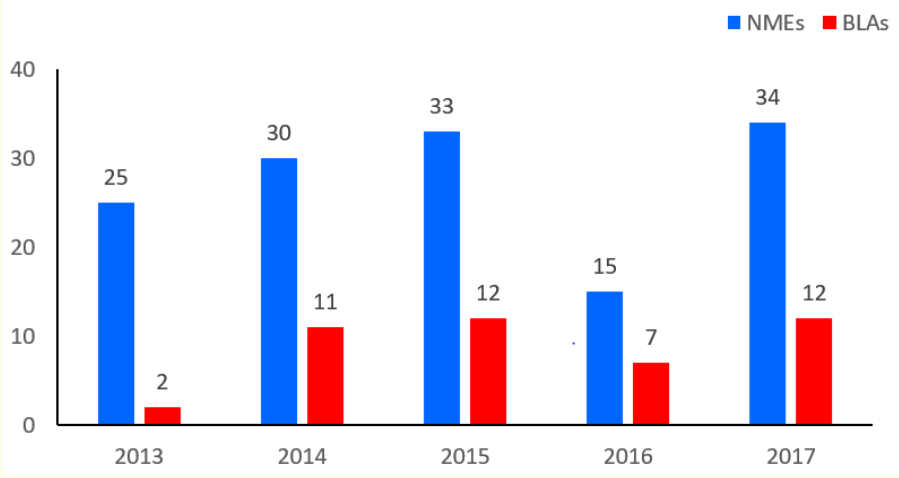

Figure 1: *New drugs approved from 2013-2017. (NMEs: New Molecular Entities, BLAs: Biologics License Applications).*

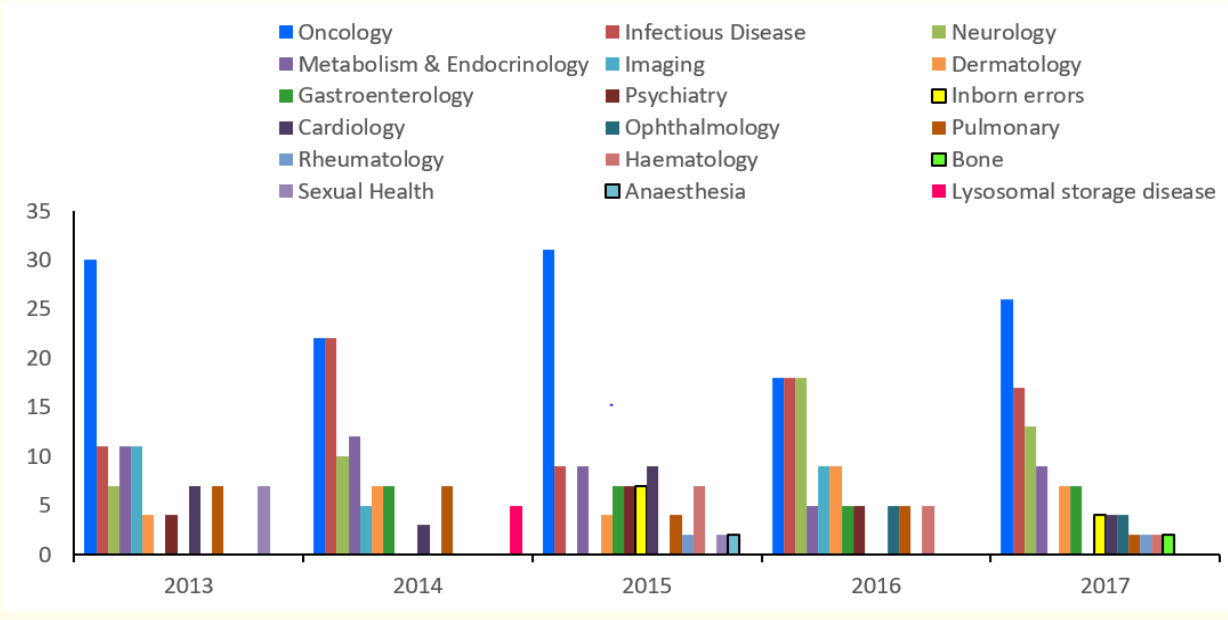

Figure 2: *Percentage of new drugs approved under various therapeutic classes from 2013-2017.*

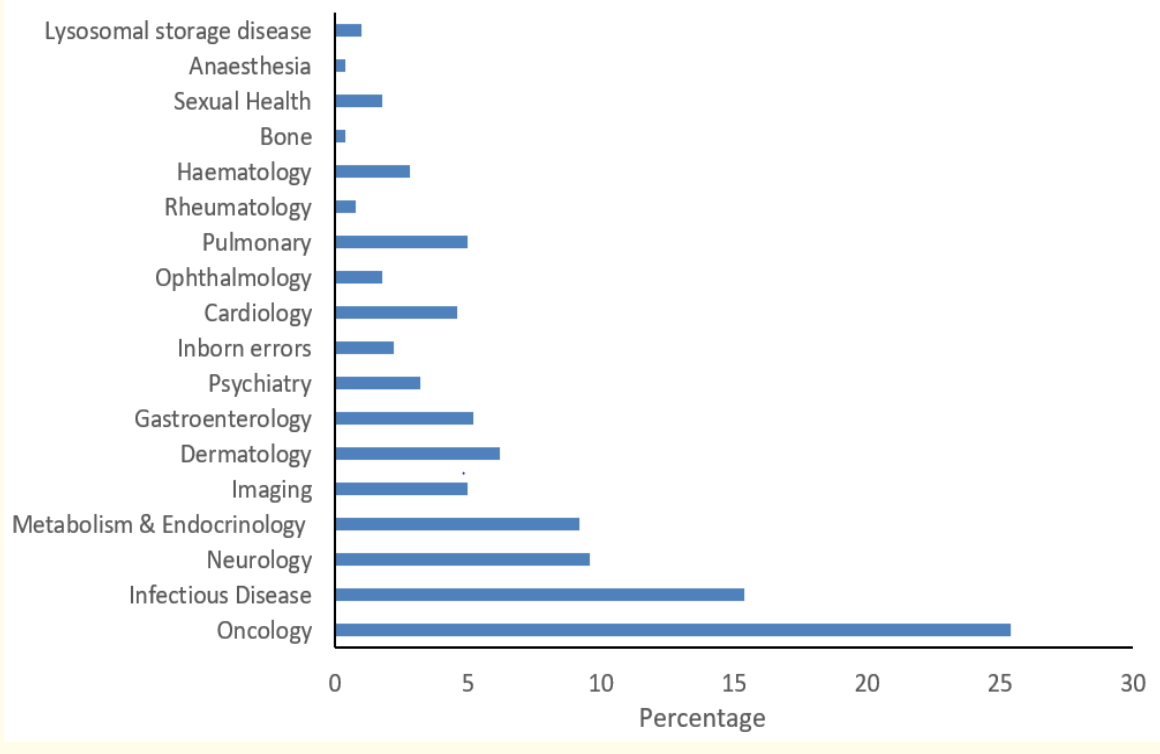

Figure 3: *Percentage of new drugs approved under various therapeutic classes in 5 years.*

By therapeutic area, cancer drugs continue to dominate the CDER approval list with 25% of the total drugs approved. Cancer remains as one of the leading causes of death in the world, which places a heavy burden on health services and society. On average, fewer than two new oncology focused drugs entered the marketplace in the period ranging from 1951 through the 1980s. Thereafter, the number of new drugs targeting cancer increased dramatically, doubling in the 1990s and more than doubling again in following years. In the current decade, about ten new drugs have been introduced each year [8]. Anticancer drugs are estimated to account for 12% of total direct cancer care costs and 5% of total drug costs worldwide [9].

The second therapeutic area in which the maximum percentage of approved drugs fall is infectious diseases comprising of 15% of total approvals. Drugs targeting infectious diseases have greatly improved public health. The number of new drugs targeting infectious disease peaked during the 1990s and declined rapidly thereafter. Molecules targeting bacterial pathogens represent the most common component of anti-infectives followed by antivirals and antifungals. Focusing on antibacterial agents, an increase in new NMEs predominated from the 1960s through to the 1990s, dropping sharply thereafter. Obsolescence and resistance has eliminated one-third of these drugs. Consequently, the arsenal of antibiotics peaked in 2000 and is declining [10]. Increased approvals in this therapeutic area during last five years shows renewed interest to treat diseases in this domain.

Neurology drugs comprised 10% of total approvals. Neuroscience remains a great challenge and opportunity in terms of new drug discovery and development. An assessment reveals a low steady rate of new FDA approvals, which is interrupted by two bursts in activity, first in the 1950s and then in the 1990s. These trends are reflected in the approvals for NMEs targeting multiple indications in this field, including seizure, Parkinson's disease and neuromuscular disorders [11]. The number of approvals in the last five years, especially 4 approvals in 2016, shows the increased interest of various pharmaceutical companies in this area.

Rest of the therapeutic areas saw drug approvals at less than 10% of total approvals.

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