Price Analysis of New Nervous System Drugs Marketed in the US (1980-2022)

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Background

Due to the complexity of the nervous system, there is a multitude of diseases and conditions that require pharmacological treatments. As a result, nervous system drugs are among the most used drugs in the US. However, the affordability of these drugs has become a significant concern due to their high cost, which affects patients and third-party payers, including Medicare and Medicaid and other public and private insurers. Despite their widespread utilization, there is a scarcity of studies evaluating the treatment cost of nervous system drugs over an extended period.

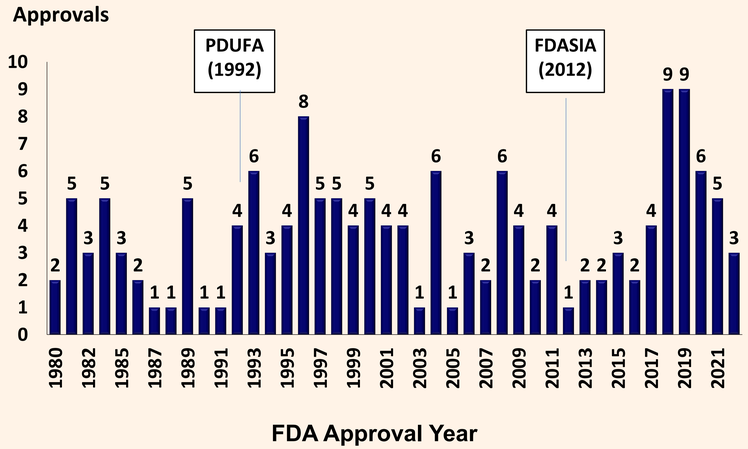
This study described the trends in drug treatment cost at the market entry of new nervous system drugs approved by the FDA in 1980-2022 and evaluated the potential factor explaining the drug treatment cost at market entry.

Methods

Regulatory information for new molecular entities (NME) was collected from the FDA website and the whole acquisition cost (WAC) from IBM Micromedex Red Book. We classified the drugs using the WHO Anatomical Therapeutic Chemical (ATC) Classification System. We estimated the drug treatment cost per year or duration defined on the drug label. The WAC was adjusted to 2022 dollars using the consumer price index. Descriptive statistics and multiple linear regression were performed.

Results

Figure 1. FDA New Nervous System Drug Approvals 1980-2022



The FDA approved 156 NSD (11.7% of all new drugs), including 150 NME and 6 BLA (Figure 1). The subtherapeutic classes with the largest number of approvals were psycholeptics (n=37, 23.7% of the total), psychoanaleptics (n=32, 20.5%), and analgesics (n=22, 14.1%). The median drug treatment cost at market entry increased from $1,018.10 (IQR= $915.05) for chronic use of NS approved in the 1980s to $15,573.95 in 2020-2022 (IQR=$14,396.35). Overall, the regression model explained 80% of the variance in the drug treatment cost of nervous system drugs at market entry (Table 1).

Table 1. Factors Explaining the Cost at Market Entry of New Nervous System Drugs, 1980-2022

Coefficients	Estimate	Std. Error	t value	Pr(>|t|)
Intercept	-1.626e+02	1.942e+01	-8.373	**5.43e-14**
Single Use	-2.076e+00	4.272e-01	-4.859	**3.14e-06**
Use in Cycles	-4.691e+00	4.351e-01	-10.781	**< 2e-16**
Approval Year	8.503e-02	9.745e-03	8.726	**7.34e-15**
Priority Review	6.599e-01	2.624e-01	2.515	**0.0131**
Anesthetics	-8.688e-01	5.516e-01	-1.575	0.1175
Anti-Parkinson Drugs	7.269e-01	5.434e-01	1.338	0.1831
Antiepileptics	7.413e-01	5.115e-01	1.449	0.1496
Psychoanaleptics	5.077e-01	4.756e-01	1.068	0.2876
Psycholeptics	4.827e-01	4.508e-01	1.071	0.2861
Marketed	-9.952e-02	8.002e-01	-0.124	0.9012
Biologic	-1.247e-01	6.402e-01	-0.195	0.8459
Orphan	7.281e-01	3.396e-01	2.144	**0.0338**

R-squared: 0.8083. Adjusted R-squared: 0.7904,
F-statistic: 45.1 on 13 and 139 DF, p-value: < 2.2e-16

FDA priority review (p=0.013), orphan designation and approval year (p<0.05), antiepileptics (p=0.14), psychoanaleptics, and psycholeptics (p=0.28), were positively associated with entry cost; while anesthetics (p=0.11) and biologic(p=0.8), were negatively associated.

Conclusions

The inflation-adjusted drug treatment cost at market entry of nervous system drugs significantly increased in 1980-2022. Several factors explain the variation in drug treatment cost of nervous system drugs at market entry.