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CNS Drugs Take Longer to Develop, Win Approval

By Bill Myers

Drugs targeting the central nervous system take significantly longer to develop and get approved than other meds, according to a new analysis.

Tufts University's Center for Drug Development analyzed 509 drugs and biologics tested and approved since 2000 and found that CNS drugs took 20 percent longer to develop and about 19 months (36 percent) longer on average than other meds to win FDA approval after clinical trials.

There was an upswing in more recent years, according to the report: CNS drugs were approved at a 6 percent faster clip than other drugs between 2012 and 2017. But it's unclear whether that's a new trend or an anomaly.

Study author Joseph A. DiMasi, the center's director of economic analysis, attributes the change to sponsors shifting their focus to unmet needs, such as treatments for muscular dystrophy, ALS and spinal muscular atrophy.

But he notes that six of the nine drugs that hit the market in the past five years had orphan status, so they may be skewing the short-term picture to make it seem like the pace is picking up when it's not.

Some of the report's other findings:

- Central nervous system drugs are less likely than other meds to win fast-track approval. Some 28 percent of brain disorder drugs earned a priority rating between 2000 and 2017, compared to more than 51 percent of all other drugs.
- The FDA approved 57 central nervous system drugs or biologics between 2000 and 2017, compared to 450 other kinds of drugs/ biologics.
- On average, it took 8.2 years to develop and approve anti-psychotics and 12.6 years to develop and approve treatments for multiple sclerosis. It took an average of 11.6 years to get multiple sclerosis drugs through clinical trials but they also had the fastest post-clinical approval times — on average, just under a year — compared to other central nervous system drugs.

DiMasi says he's concerned about the time lag in getting these drugs approved, especially since it's projected that brain disorders will account for 15 percent of the world's disease burden by the end of 2020. But he notes the major holdup is science not policy, stressing that researchers still don't have a full understanding of how the brain works and it's hard to focus on clinical endpoints because so many rely on patients subjective experiences.

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—Joseph A. DiMasi, director of economic analysis, Tufts University's Center for Drug Development

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Indeed, Christopher Randolph, chief scientific officer at MedAvante-ProPhase, says sponsors have increasingly focused on slowing or stopping neurodegenerative diseases such as Alzheimer's. That automatically means they're likely to take longer to test drugs.

"If you had a treatment that you thought would improve agitation in Alzheimer's disease, that's a short trial, you can do that in a few months. But if you're trying to slow down the underlying progression of the disease, you need a lot more time," he tells *CenterWatch*.

There are a handful of trials pending testing whether proposed drugs can help prevent Alzheimer's disease among patients who, say, have a family history of dementia but are otherwise asymptomatic. That means scientists are committing themselves to years' long waits to see if symptoms develop, Randolph says, noting that "to be able to detect a signal like that, you need fairly large sample sizes and long trials."

Link to study here: https://csdd.tufts.edu/.