Incentivizing Drug Development for Serious Mental Illness

A lack of incentives to invest in new treatments for serious mental illness is resulting in less new therapeutic options for patients.

Burden of Serious Mental Illness (SMI) in the US

- **U.S. adults with a SMI (2020)**: 14.2 million
  - 1% Schizophrenia
  - 6% Major depressive disorder
  - 3% Bipolar disorder

- **OR**: 1 in 20

Individuals with a SMI face a number of adversities:
- **Life-threatening illness**, including shorter life expectancy and heightened suicide rates
- **Significant challenges obtaining housing and employment**, and lost career opportunities
- **Increased rates of poverty, homelessness** and **interaction with the criminal justice system**

Lifetime societal costs are $1.85 million higher for an individual diagnosed with a SMI by age 25.

Unmet Need in Serious Mental Illness

People living with SMI often struggle to find an effective and tolerable treatment regimen due to the underlying heterogeneity and complex biology of mental health conditions.

Barriers to Innovation in Serious Mental Illness

- **Scientific and Research**
  - The complexity of studying the brain and the lack of biomarkers has led to:
    - Longer clinical development times
    - Lower clinical trial success rates
    - Slower regulatory (FDA) approval

- **Government Funding**
  - NIH funding for SMI research is disproportionately low considering the prevalence and significant burden of illness. For example, in 2021:
    - NIH funding for SMI research is $256 million for schizophrenia
    - $493 million for tuberculosis

- **Regulatory**
  - There is insufficient market protection for companies developing SMI treatments given the longer research timelines and ultimately higher costs to bring a drug to market.
  - The current design of the FDA’s accelerated approval program cannot be used for SMI where surrogate and intermediate endpoints have not been established, which limits expedited access to new drugs for these conditions

- **Health Systems**
  - Revenues may be limited by
    - **Lower sales volumes**
      - Fewer patients seek treatment compared to other diseases due to a complex mix of barriers
    - **Lower reimbursement**
      - Many patients who seek treatment are covered by Medicaid, which has some of the lowest reimbursement rates across all payer types

Policy Solutions

- **Increase Government Research Funding**
  - To improve fundamental knowledge of the brain and its basic mechanics, funding is needed to support:
    - **NIH BRAIN Initiative**

- **Support Public-Private Partnerships**
  - The Accelerating Medicines Partnership (AMP) program is a public-private partnership between the NIH, FDA, and other stakeholders that aims to produce better treatments and diagnostic tools in focused disease areas.

- **Regulatory Reform**
  - **Nutrition and Food Administration (FDA)** reforms are necessary to expedite the review and approval of brain-focused therapies

- **Address Health System Barriers**
  - Initiatives that improve the mental health care system can increase the number of patients who receive treatment for SMI.
  - Medicaid reform that aligns drug reimbursement with economic value has potential to increase innovation for drugs in high demand by Medicaid beneficiaries, including medications for SMI.

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