

FDA Perspective—DSM-5 and Drug Development

Mitchell Mathis, MD

Deputy Director, Division of Psychiatry Products
Food and Drug Administration



Discussion Points

- Historical Evolution of Indications
- Regulatory value of diagnostic categories
- Clinically meaningful pharmacologic treatment targets

Historical Indications

- Antipsychotics
 - “For the treatment of the manifestations of psychotic disorders”
- Antidepressants
 - “For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states”

Current Indications

- Much more specific
 - For the treatment of schizophrenia
 - For the treatment of major depressive disorder

Regulatory Value of DSM

- Phenomenology is part of psychiatric diagnosis
- Diagnostic system is useful
 - Clinical practice
 - Drug evaluation trials
- Not all coded disorders are legitimate drug targets

Clinically Meaningful Drug Targets

- Many of the coded diagnoses
 - Schizophrenia
 - Major depressive disorder
- Some legitimate pharmacologic targets are not coded
 - Clinically important aspects of a coded disorder
 - Irritability of autism
 - Agitation associated with schizophrenia/bipolar disorder
 - Cognitive impairment associated with schizophrenia

Summary

- There has been a historical evolution of labeled indications for psychiatric drugs
- FDA endorses *clinically meaningful* drug targets
 - May or may not be part of DSM-5
 - Relevance to the practice of psychiatry is important
- Always willing to consider arguments for new drug targets
 - Public health impact
 - Meaningful distinctions