Innovation in Psychiatric Drug Development:

A Quantitative Analysis of FDA-Approved Psychiatric Drugs, 2012–2024

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Abstract

Objective: Psychiatric drug development is critical for addressing the global burden of mental illness, but the degree of recent innovation is not well understood. Prior studies have highlighted concerns over the stagnation of new therapeutic approaches, particularly compared to other medical specialties. What is the degree of innovation in psychiatric drug development?

Method: This observational study cross-referenced 3 drug development databases to identify new and existing therapeutics approved for psychiatric indications between January 1, 2012, and December 31, 2024. To assess each drug's degree of innovation, the primary outcome was the proportion of drugs classified as "first-in-class" with secondary measures including US Food and Drug Administration (FDA) priority review status, orphan drug designations, inclusion on the WHO's Model List of Essential Medicines, and therapeutic benefit and clinical usefulness ratings by experts.

Results: A total of 22 new psychiatric drugs and supplemental indications were identified. Of these, 7 (31.8%) were categorized as first-in-class, 2 (9.1%) were considered an advance-in-class, and 13 (59.1%) were considered addition-to-class. Three drugs (13.6%) received FDA priority review, 1 (4.5%) was designated as an orphan drug, and 0 were included on the WHO's Model List of Essential Medicines. For clinical utility, of drugs with available data, none of them received a rating of "clinically helpful," and 3/22 (13.6%) were rated "clinically not helpful."

Conclusion: Innovation in psychiatric drug development in the past 13 years was limited, with most new drugs representing incremental advances rather than groundbreaking innovations. Compared to other medical fields, psychiatric drug development appears to lag in terms of novelty and clinical impact.

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Drug development in psychiatry has changed the prognosis of diseases that affect millions of Americans each year. An estimated 16.7% of the adult US population has at least 1 prescription for a drug for a psychiatric condition each year; spending on these drugs is one component of the $317 billion estimated annual economic burden of serious mental illnesses in US adults.[1,2] Use of psychiatric medications has increased over time, with prescriptions per outpatient visit among adolescents increasing by 10% from 2006 to 2019.[3] These drugs are not cheap to develop; the median capitalized research and development (R&D) investment to introduce a new drug to the market is $985.3 million, and the National Institutes of Health funding toward development of approved drugs from 2010 to 2019 was $247.3 billion.[4,5] Approximately 14% of R&D expenditures in the pharmaceutical industry are dedicated to disorders of the mind and brain; it is not known how these massive investments translate directly into clinical impact.[6]

While drug development technology has rapidly accelerated the pace of discovery in recent years, particularly in the realms of gene editing[7] and biologics,[8] it is unclear as to whether this progress in new development techniques has provided benefits in psychiatry. Though there have been a multitude of newly approved psychiatric drugs in the last dozen years, their mechanisms are largely based on the same or similar putative methods of action of older drugs, rather than acting on novel therapeutic targets.[9–11] There is evidence that the additive clinical benefits of such "me-too" drugs are, generally, quite limited.[12] Meanwhile, there remain no Food and Drug Administration (FDA)–approved treatments for such prevalent and life-upending mental

Clinical Points

- From 2012 to 2024, 21 new psychiatric pharmacotherapies and 1 supplemental indication were approved; only ~32% new psychiatric pharmacotherapies were first-in-class. Innovation and volume in psychiatric pharmacotherapy development lag behind specialties such as dermatology and oncology.
- Real-world added benefit of new psychiatric pharmacotherapies was modest: Just 2 new pharmacotherapies earned "high" added therapeutic benefit ratings from independent agencies across North America and Europe, with most rated low benefit or not rated. Despite great need, expedited FDA approvals of psychiatric pharmacotherapies are uncommon.

health disorders as anorexia nervosa and gambling disorder. One salient contributor to this apparent focus on low-risk forms of innovation while many highly prevalent psychiatric disorders having no effective pharmacologic treatments is that psychiatric drug development has a relatively low success rate when compared to drug development in other fields of medicine; over 93% of potential psychiatric therapies brought to phase 1 clinical trials will fail to reach regulatory approval.[13] While many have written on the perceived stagnation of psychiatric drug development and a subjective lack of recent breakthroughs, this phenomenon, if true, is poorly quantified.[14,15]

Here, we present an empirical study of innovation in psychiatric drug development, examining the effectiveness and innovativeness of all FDA-approved psychiatric drugs developed from 2012 to 2024. Through this quantitative characterization and comparison with other medical fields, we seek to provide insight into the state of research in the field and to provide a baseline for comparing future progress.

METHODS

To determine novel psychiatric drugs and indications, we cross-referenced 3 databases in a systematic manner similar to Kamat et al[16]: WIRB-Copernicus Group Clinical Services CenterWatch (a clinical research organization partner that provides updated databases identifying drug approvals)[17]; annual biologic approval lists by the US FDA Center for Biologics Evaluation and Research[18]; and annual new molecular entity approval lists by the FDA Center for Drug Evaluation and Research.[19] Drugs were included if they were either first approved or approved for use in a new psychiatric condition between January 1, 2012, and December 31, 2024, a study period chosen to facilitate comparability with innovation studies in adjacent fields of medicine that used similar time periods. We excluded drugs that received simple reformulations (eg, an extended-release form of an existing medication) or combinations with exclusively previously approved drugs during the study period. Because human participants were not involved and all data are publicly available in this study, procedures were exempt from institutional review board review. We followed a STROBE reporting guideline in sharing results from this repeated cross-sectional study.[20]

We compiled a list of new and supplemental new psychiatric indications approved by the FDA from January 1, 2012, to December 31, 2024, using the aforementioned databases. Our compiled data were first approved by 2 board-certified and practicing psychiatrists with expertise in psychiatric drug development (D.S. and M.O.). Second, we categorized each drug and supplemental indication into 1 of 5 established therapeutic areas: mood disorders, schizophrenia or other psychotic disorders, attention-deficit/hyperactivity disorder, sleep-related disorders, or other disorders (eg, substance use disorders, hypoactive sexual desire disorder, and Tourette disorder). Third, to estimate each drug and supplemental indication's degree of innovation (and to serve as an imperfect proxy for overall drug effectiveness), we used the Orphan Drug Product designation database, the FDA's expedited development and/or regulatory review programs, the World Health Organization's (WHO) Model List of Essential Medicines, and 5 innovation designation measures.

Innovation Measures Determination

The primary measure of innovation was FDA innovation designation (ie, first-in-class, advance-in-class, or addition-to-class). In alignment with Lanthier et al,[21] we defined drugs deemed "first-in-class" as being new molecular entities used in a novel indication or with a novel putative mechanism of action, "addition-to-class" as being new molecular entities for an already-covered indication or with a similar mechanism of action to others that received a priority review designation for any approvals during the study period, and "advance-in-class" as being new molecular entities for an already-covered indication or with a similar mechanism of action to others that did not warrant FDA priority review designation during the study period.[22]

Secondary measures of innovation included clinical usefulness and therapeutic benefit ratings conducted by Prescrire, the Human Drug Advisory Panel, the Federal Joint Committee, and the National Authority for Health. Clinical usefulness ratings by Prescrire,[23] an independent drug assessor based in France, were found by accessing Prescrire's monthly medical journal to determine if each drug and supplemental indication was "clinically useful," "clinically not useful," or "judgment reserved" (ie, no information was available). Innovation was also characterized using therapeutic benefit ratings conducted

by the Human Drug Advisory Panel, a committee of 6 drug therapy and clinical research experts based in Canada[24]; the Federal Joint Committee, a legal healthcare entity supervised by the Federal Ministry of Health of Germany[25]; and the National Authority for Health, an independent health group based in France.[26] For each of these last 3 secondary measures, information about each drug from these databases was used to decide if each drug's added therapeutic benefit was "low," "high," or "N/A" (ie, no information was available). Using these innovation measures, we described annual psychiatric drug approvals within the specified period.

RESULTS

We identified 21 new approved drugs and 1 new supplemental indication of an existing drug approved by the FDA for psychiatric indications over the study period (Table 1). Three (13.6%) of these were combinations or reformulations of existing drugs (Table 2). Eleven (50.0%) were treatments for mood disorders, 6 (27.3%) were for psychotic disorders, 2 (9.1%) were for attention-deficit/hyperactivity disorder, 3 (13.6%) were for sleep disorders, and 3 (13.6%) were for other disorders (n > 22 because some drugs had multiple approvals). Of these other disorders, 1 drug (4.5%) was classified as a treatment for Tourette disorder, and 2 (9.1%) were classified as treatments for hypoactive sexual desire disorder. In terms of innovation, 13 drugs (59.1%) were categorized as addition-to-class, 2 (9.1%) were categorized as advance-in-class, and 7 (31.8%) were categorized as first-in-class (Supplementary Figure 1).

As for secondary measures of innovation, 4 drugs (18.2%) received expedited FDA approval; of these 4 drugs, 3 (13.6%) were designated by the FDA as "breakthrough" drugs. One drug (4.5%), aripiprazole, was designated as an "orphan drug" by the FDA prior to our study period for Tourette disorder treatment and was included on the WHO's Model List of Essential Medicines. Additionally, at the time of analysis, therapeutic benefit ratings had been conducted by Canada's Human Drug Advisory Panel, Germany's Federal Joint Committee, and France's National Authority for Health, as well as by the independent drug assessor Prescrire, for the subset of 19 new drugs approved before 2023 (ie, all except for zuranolone, gepirone, and xanomeline and trospium chloride). Of these ratings, only 1 organization (the French National Authority for Health) ranked 2 drugs with a new formulation or indication—aripiprazole for Tourette disorder and lurasidone for major depressive episodes in bipolar I disorder—as having a high added therapeutic benefit. All other drugs were not rated or received a rating of "low" in regard to added therapeutic benefit (including aripiprazole when reviewed by the German Federal Joint Committee and the Canadian Human Drug Advisory Panel). Prescrire rated 3 drugs (13.6%) as "clinically not useful," while the remaining 16 drugs (72.7%) received no rating (Supplementary Table 1).

DISCUSSION

To our knowledge, this study is the first to quantitatively characterize innovation in psychiatric drug development. Using FDA innovation designations, clinical usefulness ratings, and added therapeutic benefit ratings, we gauged the degree of innovation of all psychiatric drugs approved from 2012 to 2024. We report 3 main findings. First, of the 21 new approved drugs and 1 new supplemental indication of existing drugs approved by the FDA for psychiatric indications, 7 were categorized as "first-in-class." However, the remaining 15 approved drugs or supplemental indications received innovation designations of "advance-in-class" or "addition-to-class," demonstrating that over 65% of psychiatric drugs developed over the period of interest exhibited a comparatively low degree of innovation. Second, only 2 of the 20 new approved drugs or supplemental indications (aripiprazole for Tourette disorder and lurasidone for major depressive episodes in bipolar I disorder when reviewed by the French National Authority for Health) received a benefit rating of "high."[27,28] Third, a high proportion of the newly approved drugs or supplemental indications during this time period were either combination therapies or new applications of existing drugs.

It is evident that innovation in psychiatric drug development lags drug development in peer specialties.[29] For example, in the period 2012–2022, 52 new drug applications and 26 new supplemental indications were approved by the FDA for use in the field of dermatology.[16] This total of 78 new approved dermatologic therapies is almost 4 times the number of psychiatric therapies approved in the similar (and slightly longer) time period of our study. Of these novel dermatologic drugs, about 39% were rated "clinically useful" or "high" in terms of added therapeutic benefit; of the novel dermatologic supplemental indications, around 30% received these positive ratings. Additionally, while just 32% of psychiatric drugs approved over our study period were considered innovative (ie, first-in-class), 46% of dermatologic drugs approved over a similar period were considered innovative by the same metric. Innovation in psychiatric drug development has also lagged behind drug innovation in oncology. In a study characterizing 85 approved oncologic drugs approved between the years 2006 and 2018, a period of the same length (yet slightly earlier than) the one assessed in our study, 60% were found to be innovative by the same innovation metric.[30]

Table 1.

Newly FDA-Approved Pharmacotherapies for Psychiatric Indications, 2012–2024

Brand name	Generic name	Approved for	Date of approval	First psychiatric approval?	Mechanism of action	Method of administration	Orphan Drug Product database	WHO's Model List of Essential Medicines	FDA expedited review	FDA innovation designation
Latuda	Lurasidone	Major depressive episode in bipolar I disorder (previously schizophrenia) (subsequently pediatric/ adolescent indications of above, and made available as long-acting injectable)	June 2013	N	Dopamine receptor antagonist, serotonin receptor antagonist	Oral/injection	N	N	N	Addition-to-class
Fetzima	Levomilnacipran	MDD	July 2013	Y	Norepinephrine-serotonin reuptake inhibitor	Oral	N	N	N	Addition-to-class
Brintellix/ Trintellix	Vortioxetine	MDD	September 2013	Y	Serotonin transport inhibitor	Oral	N	N	N	Addition-to-class
Belsomra	Suvorexant	Insomnia	August 2014	Y	Orexin receptor antagonist	Oral	N	N	N	Addition-to-class
Abilify	Aripiprazole	Tourette disorder (previously schizophrenia, manic and mixed episodes in bipolar I disorder, MDD (adjunct), irritability in pediatric ASD (subsequently available in long-acting injectable form and as pill + sensor)	December 2014	N	Dopamine receptor partial agonist, serotonin receptor antagonist	Oral/injection	Y	Y	N	Addition-to-class
Rexulti	Brexpiprazole	MDD, schizophrenia, agitation associated with Alzheimer disease	July 2015	Y	Dopamine receptor partial agonist, serotonin receptor antagonist	Oral	N	N	N	Addition-to-class
Addyi	Flibanserin	HSDD	August 2015	Y	Serotonin receptor agonist, serotonin receptor antagonist	Oral	N	N	N	First-in-class
Vraylar	Cariprazine	Schizophrenia, manic or mixed episodes associated with bipolar I disorder and for bipolar depression (subsequently as adjunct for MDD)	September 2015	Y	Dopamine receptor partial agonist	Oral	N	N	N	Addition-to-class

(continued)

Table 1 (continued).

Brand name	Generic name	Approved for	Date of approval	First psychiatric approval?	Mechanism of action	Method of administration	Orphan Drug Product database	WHO's Model List of Essential Medicines	FDA expedited review	FDA innovation designation
Nuplazid	Pimavanserin	Hallucinations and delusions associated with Parkinson disease psychosis	April 2016	Y	Serotonin receptor inverse agonist	Oral	N	N	BT, PR	First-in-class
Vyleesi	Bremelanotide	HSDD	June 2018	Y	Melanocortin receptor agonist	Injection	N	N	N	Addition-to-class
Spravato	Esketamine	TRD (subsequently depressive symptoms with acute suicidal ideation or behavior)	March 2019	Y	NMDA receptor antagonist	Nasal spray	N	N	FT, BT, PR (TRD); BT (depressive symptoms with acute suicidal ideation or behavior)	First-in-class
Zulresso	Brexanolone	Postpartum depression	March 2019	Y	GABA-A modulator	Injection	N	N	BT, PR	First-in-class
Caplyta	Lumateperone	Schizophrenia (subsequently depressive episodes associated with bipolar I or II disorder)	December 2019	Y	Mixed dopamine/serotonin antagonism	Oral	N	N	N	First-in-class
Dayvigo	Lemborexant	Insomnia	December 2019	Y	Orexin receptor antagonist	Oral	N	N	N	Addition-to-class
Azstarys	Serdexmethylphenidate-dexmethylphenidate	ADHD	March 2021	Y[a]	Dopamine-norepinephrine reuptake inhibitor	Oral	N	N	N	Addition-to-class
Qelbree	Viloxazine	ADHD	April 2021	Y	Norepinephrine reuptake inhibitor	Oral	N	N	N	Addition-to-class
Lybalvi	Olanzapine-samidorphan	Schizophrenia, manic and mixed episodes associated with bipolar I disorder	May 2021	Y[a]	Dopamine receptor antagonist, serotonin receptor antagonist	Oral	N	N	N	Addition-to-class
Quviviq	Daridorexant	Insomnia	January 2022	Y	Orexin receptor antagonist	Oral	N	N	N	Addition-to-class
Auvelity	Dextromethorphan and bupropion	MDD	August 2022	Y[a]	NMDA receptor antagonist	Oral	N	N	BT, PR	Advance-in-class
Zurzuvae	Zuranolone	Postpartum depression	August 2023	Y	GABA-A modulator	Oral	N	N	FT, PR	Advance-in-class
Exxua	Gepirone	MDD	September 2023	Y	Serotonin receptor partial agonist	Oral	N	N	N	First-in-class
Cobenfy	Xanomeline and trospium chloride	Schizophrenia	September 2024	Y	Muscarinic receptor agonist	Oral	N	N	N	First-in-class

[a]Combination drug that had 1 component already FDA-approved and 1 novel component.

Abbreviations: ADHD = attention deficit hyperactivity disorder, ASD = autism spectrum disorder, BT = breakthrough therapy designation, FDA = Food and Drug Administration, FT = fast track designation, HSDD = hypoactive sexual desire disorder, MDD = major depressive disorder, PR = priority review designation, TRD = treatment-resistant depression, WHO = World Health Organization.

While the reasons behind this relative lack of innovation in psychiatric drugs remain poorly characterized, the comparative absence of clear biomarkers in psychiatry (for target selection, prognostication, etc) plays a role, effectively limiting our understanding of why early-phase findings often fail to engender desired outcomes in later-phase trials. Without many clear-cut targets, it follows that the mechanisms of action of approved drugs and supplemental indications are often not as clear in psychiatry compared to other specialties.[31] While characterizing efficacy in terms of clinical outcomes is a feature conserved across trials in psychiatry and, for example, dermatology, it is comparatively difficult to visualize the methods of action of approved treatments on a neuronal systems level. Another important reason for this discrepancy may be increasing market saturation with off-patent and relatively cheap, if not particularly effective, medications for many high-prevalence psychiatric disorders; such saturation raises the bar for demonstrated efficacy of new treatments, as it is challenging for another "me-too" addition-to-class drug to succeed in a market landscape where cheaper and similarly effective alternatives are already available. That many patients are harmed financially by their psychiatric conditions may also contribute, despite recent research indicating that "different classes of psychiatric drugs have been among the industry's most profitable products during the last several decades."[32–34]

Interpretations of this study should be considered within the scope of its limitations. Because this study focuses on the period 2012 through the end of 2024, improvements in psychiatric drug development that occurred in early 2025, as well as pending drug trials and approvals (eg, psychedelics), are not reflected in our work. Additionally, certain aspects of innovation in psychiatry—namely, combination drugs and regimens, delivery vehicles, and augmentation strategies—are not included in this study but may serve as alternative indicators of progress in psychiatric drug development. Further, this study measures innovation based on approved products only, without accounting for innovation occurring at earlier stages of psychiatric drug development. At early phases, psychiatric drug development may be similarly innovative to other fields, but because of the low reproducibility between phases, later phases of psychiatric drug development (ie, at the stage of approved products) may not appear as comparably innovative. Finally, this study does not capture downstream advances in care precision, quality, and access. These advances, such as the rise of precision psychiatry, new forms of psychotherapy, and improved quality of care, may be ultimately just as impactful to patients as development of any new pharmacologic therapies.[35–38]

Table 2.
Characteristics of New Psychiatric Drugs and Supplemental New Indications Approved by the FDA, 2012–2024[a]

Characteristic	New drugs and supplemental new indications (n = 22), No. (%)
FDA expedited or regulatory program	
Accelerated approval	0 (0.0)
Breakthrough	3 (13.6)
Fast track	1 (4.5)
Priority review[b]	4 (18.2)
Orphan status	
Yes	1 (4.5)
No	21 (95.5)
WHO essential medicine[b]	
Yes	1 (4.5)
No	21 (95.5)
Drug type	
Small molecule	22 (100.0)
Biologic	0 (0.0)
Therapeutic area	
Mood disorders	11 (50.0)
Psychotic disorders	6 (27.3)
Attention-deficit/hyperactivity disorders	2 (9.1)
Sleep disorders	3 (13.6)
Other disorders	3 (13.6)
Degree of innovation (innovation designation)	
First-in-class	7 (31.8)
Advance-in-class	2 (9.1)
Addition-to-class	13 (59.1)
Clinical usefulness[b]	
Judgment reserved	19 (86.4)
Clinically not useful	3 (13.6)
Clinically useful	0 (0)
Added therapeutic benefit rating[b]	
Germany	
Low	5 (22.7)
High	0 (0.0)
N/A	17 (77.3)
Canada	
Low	8 (36.4)
High	0 (0.0)
N/A	14 (63.6)
France	
Low	3 (13.6)
High	2 (9.1)
N/A	17 (77.3)

[a]Data are from WIRB-Copernicus Group Clinical Services CenterWatch, annual biologic approval lists by the US Food and Drug Administration (FDA) Center for Biologics Evaluation and Research, annual new molecular entity approval lists by the FDA Center for Drug Evaluation and Research, the Orphan Drug Product designation database, the FDA's expedited development and/or regulatory review programs, the World Health Organization's Model List of Essential Medicines, Prescrire, the Human Drug Advisory Panel, the German Federal Joint Committee, and the French National Authority for Health.
[b]2024 data not available at the time of analysis.

Despite these limitations, this study is, to our knowledge, the first to quantitatively characterize innovation in drug development in psychiatry, placing this period of development in the context of peer specialties with available comparator studies. We show

that innovation in psychiatric drug development from January 1, 2012, to December 31, 2024, was limited in the context of other fields in medicine. Future research is merited to increase this innovation and lessen the burden of suffering from psychiatric disease on the over 20% of Americans who live with these diseases each day.[39]

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The Journal of Clinical Psychiatry

Supplementary Material

Article Title: Innovation in Psychiatric Drug Development: A Quantitative Analysis of FDA-Approved Psychiatric Drugs, 2012–2024

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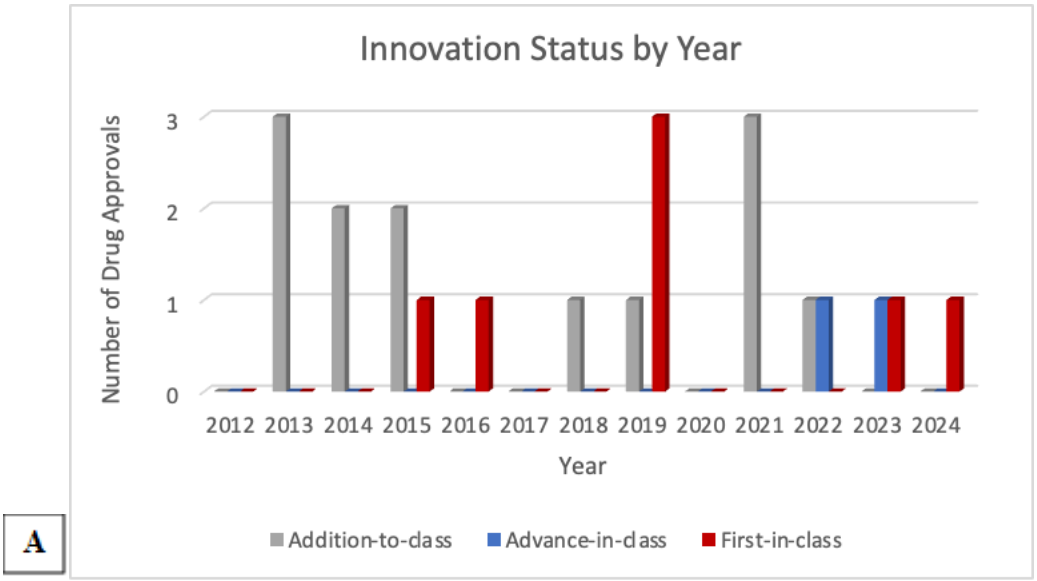
LIST OF SUPPLEMENTARY MATERIAL FOR THE ARTICLE

1. **Figure 1** Annual Approval of Psychiatric Drugs and Supplemental New Indications 2012-2024, by Measure of Innovation
2. **Table 1** Ratings of FDA-Approved Pharmacotherapies for Psychiatric Indications, 2012-2024

DISCLAIMER

This Supplementary Material has been provided by the authors as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

Supplementary Figure 1: Annual approval of psychiatric drugs and supplemental new indications 2012-2024, by measure of innovation.



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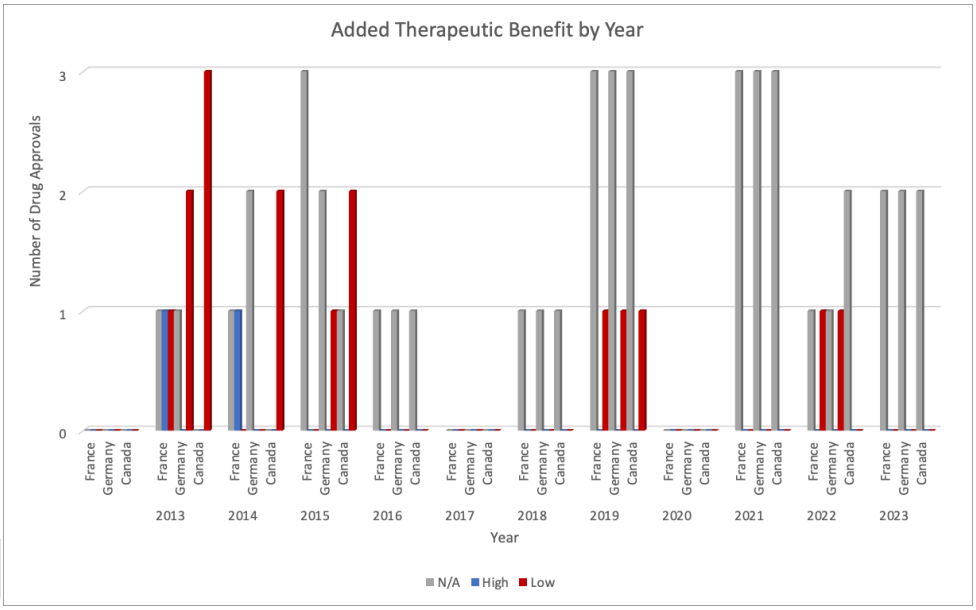

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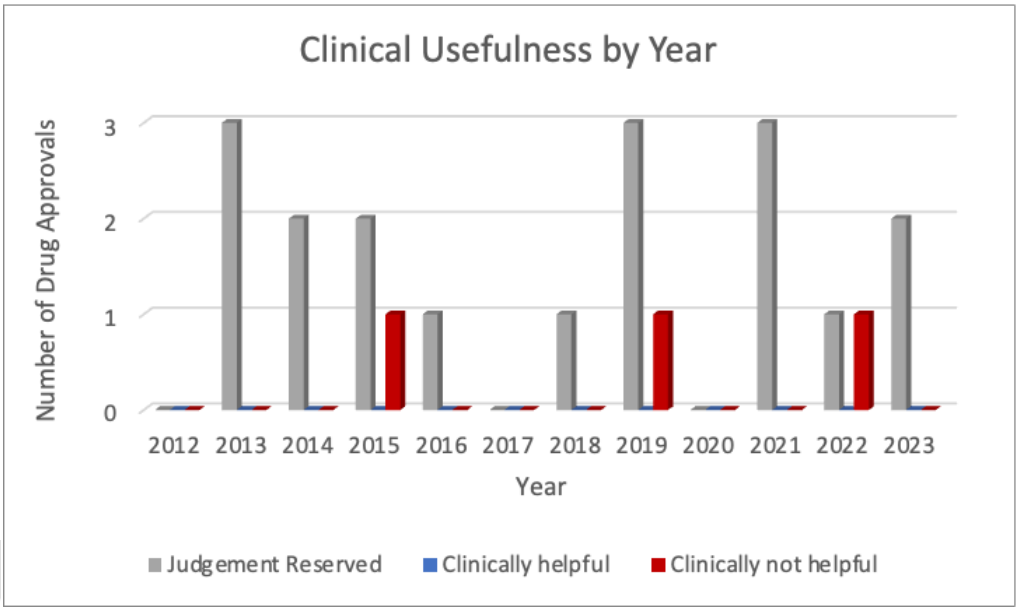

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Note: Data are from WIRB-Copernicus Group Clinical Services CenterWatch, annual biologic approval lists by the U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research, annual new molecular entity approval lists by the FDA Center for Drug Evaluation and Research, the Orphan Drug Product designation database, the FDA's expedited development and/or regulatory review programs, the World Health Organization's Model List of Essential Medicines, Prescrire, the Human Drug Advisory Panel, the German Federal Joint Committee, and the French National Authority for Health. *For figures 1B and 1C, 2024 data was not available at time of analysis and so is not displayed.

Supplementary Table 1: Ratings of FDA-approved pharmacotherapies for psychiatric indications, 2012-2024.

Brand Name	Generic Name	Prescrire (France) Rating	National Authority for Health (France) Rating	Federal Joint Committee (Germany) Rating	Human Drug Advisory Panel (Canada) Rating
Latuda	Lurasidone	Judgement reserved*	High***	Low***	Low***
Fetzima	Levomilnacipran	Judgement reserved*	N/A*	N/A*	Low***
Brintellix/Trintellix	Vortioxetine	Judgement reserved*	Low***	Low***	Low***
Belsomra	Suvorexant	Judgement reserved**	N/A**	N/A**	Low***
Rexulti	Brexipiprazole	Judgement reserved*	N/A*	N/A*	Low***
Addyi	Flibanserin	Judgement reserved**	N/A**	N/A**	Low***
Vraylar	Cariprazine	Clinically not useful***	N/A*	Low***	N/A*
Abilify	Aripiprazole	Judgement reserved**	High***	N/A**	Low***
Nuplazid	Pimavanserin	Judgement reserved**	N/A**	N/A**	N/A**
Vyleesi	Bremelanotide	Judgement reserved**	N/A**	N/A**	N/A*
Spravato	Esketamine	Clinically not useful***	Low***	Low***	N/A*
Zulresso	Brexanolone	Judgement reserved*	N/A*	N/A*	N/A*
Caplyta	Lumateperone	Judgement reserved**	N/A**	N/A**	N/A**
Dayvigo	Lemborexant	Judgement reserved**	N/A**	N/A**	Low***
Azstarys	Serdexmethylphenidate-dexmethylphenidate	Judgement reserved**	N/A**	N/A**	N/A**
Qelbree	Viloxazine	Judgement reserved*	N/A*	N/A*	N/A*
Lybalvi	Olanzapine-samidorphan	Judgement reserved**	N/A**	N/A**	N/A*
Quviviq	Daridorexant	Clinically not useful***	Low***	Low***	N/A*
Auvelity	Dextromethorphan & Bupropion	Judgement reserved**	N/A**	N/A*	N/A*
Zurzuvae	Zuranolone	Judgement reserved**	N/A**	N/A**	N/A**
Exxua	Gepirone	Judgement reserved**	N/A**	N/A**	N/A**
Cobenfy	Xanomeline & Trospium Chloride	Judgement reserved**	N/A**	N/A**	N/A**

Judgement Reserved or N/A - *	No rating was found, but the drug was approved in the provided country.
Judgement Reserved or N/A - **	No rating was found, and the drug was not approved in the provided country.
Clinically not useful/Clinically useful or Low/High - ***	A rating was found, and the drug was approved in the provided country.