

Mental Illnesses

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES

Pharmaceutical Research Companies Are Developing 197 Medicines to Treat Mental Illnesses

America's pharmaceutical research companies are currently developing 197 medicines to help the nearly 60 million Americans today suffering from some form of mental illness—from Alzheimer's disease to depression to schizophrenia to dependence on alcohol or drugs. All of the medicines are either in clinical trials or awaiting review by the Food and Drug Administration.

Over the past half century, pharmaceutical research has helped transform mental illnesses from misunderstood causes of shame and fear into highly treatable conditions. For example, medicines for treating depression are helping thousands of people suffering from this disease to live productive lives. Breakthrough schizophrenia medicines enable most patients to be treated in the community, and medicines for Alzheimer's disease are helping elderly people maintain their independence longer outside of nursing homes.

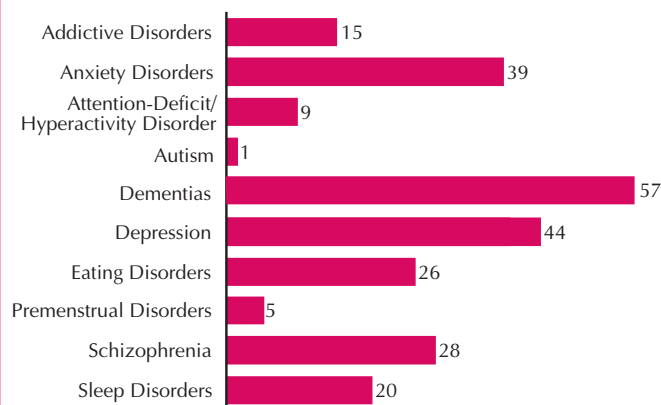
Despite the progress, mental illnesses continue to exact a heavy human and economic toll. The National Institute of Mental Health estimates that 1 in 4 American adults suffer from a diagnosable mental disorder. According to the World Health Organization, some 450 million people worldwide suffer from a mental health disorder. Mental illness, including suicide, accounts for more than 15 percent of the burden of disease in established market economies, which is more than the disease burden caused by all cancers. The total cost (direct and indirect costs) of treating mental illnesses in the United States is \$205 billion a year, according to the National Institute of Mental Health.

New medicines today in the research and development pipeline offer hope of reducing the human and economic costs of mental illnesses. They include: 44 for depression, which affects nearly 21 million Americans; 15 for addictive disorders, including dependence on alcohol, tobacco or illicit drugs; 39 medicines for anxiety disorders, which affect more than 40 million adults ages 18 and older; 57 for dementias, including Alzheimer's disease, which affects about 4.5 million Americans; and 28 for schizophrenia, which strikes some 2.4 million American adults each year. Other potential medicines target attention deficit/hyperactivity disorder, autism, eating disorders, premenstrual disorders and sleep disorders.

Examples of some medicines now being tested to treat mental illnesses include:

- A medicine that modulates the transmission of gamma-aminobutyric acid (GABA). By normalizing the action of

MEDICINES IN DEVELOPMENT FOR MENTAL ILLNESSES*



* Some medicines are in development for more than one disorder.

GABA in the brain, the medicine may reduce the abnormal neuronal activity associated with anxiety and panic attacks.

- A medicine that treats both the positive symptoms (distortion or excess of normal function) and negative symptoms (reduction or loss of normal function) associated with schizophrenia.
- A therapeutic vaccine designed to fight cocaine addiction by inducing antibodies (immune system proteins) that block the uptake of cocaine into the brain.

Researching and developing new medicines remains a risky investment and lengthy process—costing, on average, over \$800 million and taking between 10 and 15 years to bring a new medicine to patients. But advances in our understanding of mental illnesses and how to treat them have allowed America's pharmaceutical companies to conduct the cutting-edge research needed to reduce the destructive toll of these disorders and to allow more patients to lead healthier, happier, more productive lives.

Billy Tauzin
President and CEO
PhRMA

Medicines in Development for Mental Illnesses

ADDICTIVE DISORDERS

Product Name	Sponsor	Indication	Development Status*
468816 (glycine antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	smoking cessation	Phase II (888) 825-5249
abuse-resistant oxycodone	Elite Pharmaceuticals <i>Northvale, NJ</i>	drug abuse	Phase I (201) 750-2646
Acomplia [®] rimonabant	sanofi-aventis <i>Bridgewater, NJ</i>	smoking withdrawal (see also eating disorders)	application submitted (800) 633-1610
ADX 10061	Addex Pharmaceuticals <i>Geneva, Switzerland</i>	smoking withdrawal	in clinical trials www.addexpharma.com
DAS-431 (intravenous)	DrugAbuse Pharmaceutical <i>Lexington, MA</i>	cocaine dependence (see also dementias)	Phase II (781) 674-2050
Depotrex [®] depot naltrexone microcapsules	Biotek <i>Woburn, MA</i>	opiate/alcohol dependence	Phase II (781) 938-0938
GBR 12909 (vanoxerine)	Novo Nordisk <i>Princeton, NJ</i>	cocaine dependence	in clinical trials (609) 987-5800
lobeline	Yaupon Therapeutics <i>Radnor, PA</i>	methamphetamine addiction	Phase I (610) 975-9290
lofexidine	US Worldmeds <i>Louisville, KY</i> National Institute on Drug Abuse <i>Bethesda, MD</i>	opiate dependence	Phase III (502) 753-2094
nalmefene HCl	Somaxon Pharmaceuticals <i>San Diego, CA</i>	pathological gambling and other impulse control disorders	Phase II/III (858) 509-3670
		nicotine dependence, smoking cessation	Phase II (858) 509-3670
Naltrel [®] naltrexone depot for injectable	DrugAbuse Pharmaceutical <i>Lexington, MA</i>	alcohol dependence	Phase III (781) 674-2050
		heroin dependence, opiate dependence	Phase II (781) 674-2050
NicVAX [™]	Nabi Biopharmaceuticals <i>Boca Raton, FL</i>	nicotine addiction	Phase II (800) 685-1766
Probupine [™] bupenorphine	Titan Pharmaceuticals <i>South San Francisco, CA</i>	opioid dependence	Phase II (650) 244-4990
TA-CD (therapeutic vaccine)	Xenova Group <i>Slough, United Kingdom</i>	cocaine dependence	Phase II www.xenova.com
varenicline	Pfizer <i>New York, NY</i>	smoking cessation	application submitted (860) 732-5156

* For more information about a specific medicine in this report, please call the telephone number listed.

ANXIETY DISORDERS

Product Name	Sponsor	Indication	Development Status
163090 (presynaptic mixed 5HT1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	anxiety (see also depression)	Phase I (888) 825-5249
823296 (NK1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	anxiety (see also depression)	Phase I (888) 825-5249
876008 (CRF1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	anxiety (see also depression)	Phase I (888) 825-5249
ABT-089	Abbott Laboratories <i>Abbott Park, IL</i>	anxiety (see also ADHD, dementias, schizophrenia)	Phase I (847) 937-6100
AC 5216	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	anxiety (see also depression)	Phase II (888) NOW-NOVA
AFQ 056	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	anxiety	Phase II (888) NOW-NOVA
AZ-002	Alexza Pharmaceuticals <i>Palo Alto, CA</i>	acute panic attacks	Phase I completed (650) 687-3900
casopitant (NK1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	anxiety (see also depression)	Phase II (888) 825-5249
CP 316311	Pfizer <i>New York, NY</i>	anxiety (see also depression)	Phase II (860) 732-5156
cycloserine	Pfizer <i>New York, NY</i>	obsessive-compulsive disorder (see also schizophrenia)	Phase III (860) 732-5156
Cymbalta [®] duloxetine	Eli Lilly <i>Indianapolis, IN</i>	generalized anxiety disorder	Phase III (317) 276-2000
Emend [®] aprepitant	Merck <i>Whitehouse Station, NJ</i>	anxiety	Phase II (800) 672-6372
Gabitril [®] tiagabine	Cephalon <i>Frazer, PA</i>	generalized anxiety disorder (see also sleep disorders)	Phase III (610) 344-0200
levetiracetam	UCB Pharma <i>Rochester, NY</i>	anxiety	Phase II (585) 475-9000
Lexapro [®] escitalopram	Forest Laboratories <i>New York, NY</i>	panic disorder, social anxiety disorder (see also premenstrual disorders)	application submitted (800) 947-5227
		----- obsessive-compulsive disorder	Phase III (800) 947-5227
lorazepam intranasal spray	Intranasal Therapeutics <i>Lexington, KY</i>	anxiety (see also sleep disorders)	Phase I (859) 252-5080
LY 354740	Eli Lilly <i>Indianapolis, IN</i>	anxiety	Phase II (317) 276-2000
LY 544344	Eli Lilly <i>Indianapolis, IN</i>	generalized anxiety disorder	Phase III (317) 276-2000

ANXIETY DISORDERS

Product Name	Sponsor	Indication	Development Status
Lyrica™ pregabalin	Pfizer <i>New York, NY</i>	generalized anxiety disorder	application submitted (860) 732-5156
		panic disorder, social phobia	Phase III (860) 732-5156
midazolam intranasal spray	Intranasal Therapeutics <i>Lexington, KY</i>	preprocedural anxiety (see also dementias)	Phase I (859) 252-5080
MKC 242	MediciNova <i>San Diego, CA</i>	generalized anxiety disorder	Phase II (858) 373-1500
Neurontin® gabapentin	Pfizer <i>New York, NY</i>	social anxiety phobia (see also depression)	in clinical trials (860) 732-5156
ONO 2333Ms	ONO Pharma USA <i>Hackensack, NJ</i>	anxiety (see also depression)	Phase I (201) 342-8228
pagoclone	Indevus Pharmaceuticals <i>Lexington, MA</i>	panic disorder	Phase III (781) 861-8444
		generalized anxiety disorder	Phase II (781) 861-8444
PH94B	Pherin Pharmaceuticals <i>Redwood City, CA</i>	social anxiety disorder (social phobia)	Phase II (650) 568-1587
Prozac® fluoxetine	Eli Lilly <i>Indianapolis, IN</i>	panic disorder, post-traumatic stress disorder (see also depression)	Phase III (317) 276-2000
PRX 00023	Predix Pharmaceuticals <i>Lexington, MA</i>	generalized anxiety disorder (see also ADHD, depression)	Phase III (781) 372-3260
		anxiety disorders	Phase II (781) 372-3260
R7090	Roche <i>Nutley, NJ</i>	anxiety	Phase I (973) 235-5000
RG 1068 (synthetic human secretin)	Repligen <i>Waltham, MA</i>	obsessive-compulsive disorder (see also schizophrenia)	Phase I (781) 250-0111
Risperdal® risperidone	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	obsessive-compulsive disorder (see also schizophrenia)	in clinical trials (800) 817-5286
SAX-187	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	acute anxiety	Phase I (610) 902-1200
SEP174559	Sepracor <i>Marlborough, MA</i>	anxiety	Phase I (508) 481-6700
SLV 308	Solvay Pharmaceuticals <i>Marietta, GA</i>	panic disorder (see also depression)	Phase II (770) 578-9000
TGWOOAD/AA	Fabre Kramer Pharmaceuticals <i>Houston, TX</i>	anxiety, social phobia	Phase II (713) 975-6900

ANXIETY DISORDERS

Product Name	Sponsor	Indication	Development Status
Topamax® topiramate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	post-traumatic stress disorder (see also depression)	in clinical trials (800) 817-5286
TP-003	Merck <i>Whitehouse Station, NJ</i>	anxiety	Phase I (800) 672-6372
vestipitant and paroxetine combination	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	anxiety (see also depression)	Phase II (888) 825-5249
YKP 3089	SK Bio-Pharmaceutical <i>Fairfield, NJ</i>	anxiety	Phase I (973) 227-3939
Zoloft® sertraline	Pfizer <i>New York, NY</i>	generalized anxiety disorder (see also eating disorders)	in clinical trials (860) 732-5156

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

Product Name	Sponsor	Indication	Development Status
372475 (triple reuptake inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	attention-deficit/hyperactivity disorder (ADHD) (see also depression)	Phase II (888) 825-5249
ABT-089	Abbott Laboratories <i>Abbott Park, IL</i>	ADHD (see also anxiety, dementias, schizophrenia)	Phase II (847) 937-6100
Emsam® selegiline transdermal system	Somerset Pharmaceuticals <i>Tampa, FL</i>	ADHD (see also dementias)	Phase I
modafinil (Orphan Drug)	Cephalon <i>Frazer, PA</i>	ADHD (see also dementias, sleep disorders)	application submitted (619) 344-0200
NRP104	New River Pharmaceuticals <i>Radford, VA</i> Shire Pharmaceutical <i>Wayne, PA</i>	ADHD	application submitted (540) 633-7978 (434) 595-8800
PRX 00023	Predix Pharmaceuticals <i>Lexington, MA</i>	ADHD (see also anxiety, depression)	Phase II (781) 372-3260
SGS 742	Saegis Pharmaceuticals <i>Half Moon Bay, CA</i>	ADHD (see also dementias)	Phase II (650) 560-0210
SPD 465	Shire Pharmaceutical <i>Wayne, PA</i>	ADHD	Phase III (484) 595-8800
SPD 503	Shire Pharmaceutical <i>Wayne, PA</i>	ADHD	Phase III (484) 595-8800

AUTISM

Product Name	Sponsor	Indication	Development Status
Ampalex® CX 516	Cortex Pharmaceuticals <i>Irvine, CA</i>	autism (see also dementias, schizophrenia, sleep disorders)	Phase II (949) 727-3157

DEMENTIAS

Product Name	Sponsor	Indication	Development Status
189254 (histamine H3 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Shionogi USA <i>Florham Park, NJ</i>	dementia	Phase I (888) 825-5249 (973) 966-6900
742457 (5HT6 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	dementia	Phase II (888) 825-5249
ABT-089	Abbott Laboratories <i>Abbott Park, IL</i>	Alzheimer's disease (see also anxiety, ADHD, schizophrenia)	Phase II (847) 937-6100
ABT-239	Abbott Laboratories <i>Abbott Park, IL</i>	cognition disorder	Phase I (847) 937-6100
ABT-834	Abbott Laboratories <i>Abbott Park, IL</i>	cognition disorder	Phase I (847) 937-6100
AC 3933	Dainippon Sumitomo Pharma <i>Otsuka, Japan</i>	dementia	Phase II www.ds-pharma.co.jp
Agilect® rasagiline mesylate	Teva Pharmaceuticals USA <i>North Wales, PA</i>	Alzheimer's disease	Phase II (215) 591-3000
AL-108	Allon Therapeutics <i>Vancouver,</i> <i>British Columbia</i>	Alzheimer's disease	Phase I (604) 736-0634
AL-208	Allon Therapeutics <i>Vancouver,</i> <i>British Columbia</i>	mild cognitive impairment	Phase I (604) 736-0634
ALZHEMED™	Neurochem <i>Laval, Quebec</i>	Alzheimer's disease	Phase III (450) 680-4500
Ampalex® CX 516	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease (see also autism, schizophrenia, sleep disorders)	Phase II completed (949) 727-3157
Aricept® donepezil hydrochloride	Eisai <i>Ridgefield Park, NJ</i>	vascular dementia	application submitted (888) 274-2378
		mild cognitive impairment, severe Alzheimer's disease	Phase III (888) 274-2378
Avandia® XR rosiglitazone maleate XR	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase II (888) 825-5249

DEMENTIAS

Product Name	Sponsor	Indication	Development Status
bapineuzumab (AAB-001)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Alzheimer's disease	Phase II (610) 902-1200
C 7617	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase I (800) 672-6372
C 9136	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase II (800) 672-6372
CERE-110 (growth factor gene therapy)	Ceregene <i>San Diego, CA</i>	Alzheimer's disease	Phase I (858) 458-8800
Corlux™ mifeprostone	Corcept Therapeutics <i>Menlo Park, CA</i>	Alzheimer's disease (see also depression, eating disorders)	Phase II (650) 327-3270
CX717	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease	Phase II (949) 727-3157
DAS-431	DrugAbuse Pharmaceuticals <i>Lexington, MA</i>	cognition disorder (see also addictive disorders)	Phase I (781) 674-2050
Emsam® selegiline transdermal system	Somerset Pharmaceuticals <i>Tampa, FL</i>	Alzheimer's disease (see also ADHD)	Phase III
		----- cognition disorder	Phase II
Exelon® TDS rivastigmine tartrate	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	dementia, vascular dementia	Phase III (888) NOW-NOVA
FK962	Astellas Pharma US <i>Deerfield, IL</i>	Alzheimer's disease	Phase II (800) 727-7003
Flurizan™ (MPC-7869)	Myriad Genetics <i>Salt Lake City, UT</i>	Alzheimer's disease	Phase III (801) 584-3600
GTS 21	Athenagen <i>South San Francisco, CA</i>	Alzheimer's disease	Phase I (650) 869-7600
IPL455,903 (HT-0712)	Inflazyme Pharmaceuticals <i>Vancouver, British Columbia</i> Helicon Therapeutics <i>Farmingdale, NY</i>	age-associated memory impairment	Phase II (604) 279-8511 (631) 370-8818
Ketasyn® AC-1202	Accera <i>Broomfield, CO</i>	Alzheimer's disease	Phase II (303) 439-0004
ladostigil hemitartrate	Teva Pharmaceuticals USA <i>North Wales, PA</i>	Alzheimer's disease	Phase II (215) 591-3000
LY450139	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase II (317) 276-2000
Marinol® dronabinol	Solvay Pharmaceuticals <i>Marietta, GA</i>	dementia (see also depression, eating disorders)	Phase II (770) 578-9000
MEM-1003	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease (see also depression)	Phase II (201) 802-7100
		----- mild cognitive impairment, vascular dementia	Phase I (201) 802-7100

DEMENTIAS

Product Name	Sponsor	Indication	Development Status
MEM-1414	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease, mild cognitive impairment, vascular dementia	Phase I (201) 802-7100
MEM-3454	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease	Phase I completed (201) 802-7100
Memryte™ leuprolide acetate	DURECT <i>Cupertino, CA</i> Voyager Pharmaceuticals <i>Raleigh, NC</i>	Alzheimer's disease	Phase III (408) 777-1417
midazolam intranasal spray	Intranasal Therapeutics <i>Lexington, KY</i>	dementias (see also anxiety)	Phase I (859) 252-5080
modafinil	Cephalon <i>Frazer, PA</i>	Alzheimer's disease (see also ADHD, sleep disorders)	Phase II (619) 344-0200
MX-4509	Migenix <i>San Diego, CA</i>	Alzheimer's disease	Phase I completed (858) 793-7800
Namenda memantine	Forest Laboratories <i>New York, NY</i>	mild Alzheimer's disease	application submitted (800) 947-5227
nefiracetam	Daiichi Sankyo <i>Parsippany, NJ</i>	dementia	Phase II (973) 359-2600
neramexane	Forest Laboratories <i>New York, NY</i>	moderate to severe Alzheimer's disease	Phase III (800) 947-5227
NGX267	TorreyPines Therapeutics <i>La Jolla, CA</i>	Alzheimer's disease	Phase I (858) 623-5665
NS 2330	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Alzheimer's disease	Phase II (203) 798-9988
phenserine tartrate	Axonyx <i>New York, NY</i>	Alzheimer's disease	Phase III (212) 645-7704
		----- mild cognitive impairment	in clinical trials (212) 645-7704
PN401	Wellstat Therapeutics <i>Gaithersburg, MD</i>	Alzheimer's disease	Phase I (240) 631-2500
PRX-03140	Predix Pharmaceuticals <i>Lexington, MA</i>	Alzheimer's disease	Phase I (781) 372-3260
Reminyl® galantamine tablet (extended release)	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	mild cognitive impairment, vascular dementia	Phase III (800) 817-5286
R-phenserine	Axonyx <i>New York, NY</i>	Alzheimer's disease	Phase I (212) 645-7704
SGS 518	Saegis Pharmaceuticals <i>Half Moon Bay, CA</i>	cognitive impairment associated with schizophrenia	Phase II (650) 560-0210
SGS 742	Saegis Pharmaceuticals <i>Half Moon Bay, CA</i>	Alzheimer's disease, mild cognitive impairment (see also ADHD)	Phase II (650) 560-1210

DEMENTIAS

Product Name	Sponsor	Indication	Development Status
SR 57667	sanofi-aventis <i>Bridgewater, NJ</i>	Alzheimer's disease	Phase II (800) 633-1610
SR 57746 xaliproden	sanofi-aventis <i>Bridgewater, NJ</i>	Alzheimer's disease	Phase III (800) 633-1610
SRA-333 lecozotan	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	mild to moderate dementia of the Alzheimer's type	Phase II (610) 902-1200
T-817MA	Toyama Chemical <i>Tokyo, Japan</i>	Alzheimer's disease	Phase I
Tanakan® (EGb 781)	Ipsen <i>Milford, MA</i>	mild cognitive impairment related to age	Phase III (508) 478-8900
TC-1734	Targacept <i>Winston-Salem, NC</i>	cognitive impairment, including Alzheimer's disease and cognitive deficits in schizophrenia	Phase II (336) 480-2100
TH 9507	Theratechnologies <i>Montreal, Quebec</i>	mild cognitive impairment	Phase II (514) 336-7800
TTP488	TransTech Pharma <i>High Point, NC</i>	Alzheimer's disease	Phase II (336) 841-0300

DEPRESSION

Product Name	Sponsor	Indication	Development Status
163090 (presynaptic mixed 5HT1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also anxiety)	Phase I (888) 825-5249
372475 (triple reuptake inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also ADHD)	Phase II (888) 825-5249
823296 (NK1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also anxiety)	Phase I (888) 825-5249
876008 (CRF1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also anxiety)	Phase I (888) 825-5249
Abilify® aripiprazole	Bristol-Myers Squibb <i>Princeton, NJ</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	bipolar disorder (intramuscular) (see also schizophrenia) ----- bipolar depression, unipolar depression	application submitted (212) 546-4000 ----- Phase III (212) 546-4000
AC 5216	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	depression (see also anxiety)	Phase II (888) NOW-NOVA
asenapine	Organon USA <i>Roseland, NJ</i> Pfizer <i>New York, NY</i>	bipolar disorder (see also schizophrenia)	Phase III (973) 325-4500 (860) 732-5156

DEPRESSION

Product Name	Sponsor	Indication	Development Status
bifeprunox	Solvay Pharmaceuticals <i>Marietta, GA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	bipolar disorder (see also schizophrenia)	Phase III (770) 578-9000 (610) 902-1200
casopitant (NK1 antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also anxiety)	Phase II (888) 825-5249
Corlux™ mifepristone	Corcept Therapeutics <i>Menlo Park, CA</i>	depression (see also dementias, eating disorders)	Phase II (650) 327-3270
CP 316311	Pfizer <i>New York, NY</i>	depression (see also anxiety)	Phase II (860) 732-5156
CRF receptor antagonist	Bristol-Myers Squibb <i>Princeton, NJ</i>	depression	Phase II (212) 546-4000
desvenlafaxine succinate	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	major depressive disorder	application submitted (610) 902-1200
DOV 21,947	DOV Pharmaceutical <i>Hackensack, NJ</i>	depression	Phase I (201) 968-0980
DOV 10,2677	DOV Pharmaceutical <i>Hackensack, NJ</i>	depression	Phase I (201) 968-0980
gepirone ER	Fabre Kramer Pharmaceuticals <i>Houston, TX</i>	major depression	application submitted (713) 975-6900
Lamictal® lamotrigine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	bipolar disorder (acute treatment)	Phase III (888) 825-5249
Marinol® dronabinol	Solvay Pharmaceuticals <i>Marietta, GA</i>	affective disorders (see also dementias, eating disorders)	in clinical trials (770) 578-9000
mecamylamine HCl	Targacept <i>Winston-Salem, NC</i>	depression (add-on therapy)	Phase II (336) 480-2100
MEM 1003	Memory Pharmaceuticals <i>Montvale, NJ</i>	bipolar disorder (see also dementias)	in clinical trials (201) 802-7100
milnacipran	Cypress Biosciences <i>San Diego, CA</i>	depression	Phase III (858) 452-2323
Mirapex® pramipexole	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Pfizer <i>New York, NY</i>	depression	Phase II (203) 798-9988 (860) 732-5156
Neurontin® gabapentin	Pfizer <i>New York, NY</i>	bipolar disorder (see also anxiety)	Phase III (860) 732-5156
ONO 2333Ms	ONO Pharma USA <i>Hackensack, NJ</i>	depression (see also anxiety)	Phase I (201) 342-8228
ORG 34517	Organon USA <i>Roseland, NJ</i>	depression	Phase II (973) 325-4500

DEPRESSION

Product Name	Sponsor	Indication	Development Status
Prozac [®] fluoxetine	Eli Lilly <i>Indianapolis, IN</i>	dysthymic disorder (see also anxiety)	Phase III (317) 276-2000
PRX 00023	Predix Pharmaceuticals <i>Lexington, MA</i>	depression (see also anxiety, ADHD)	Phase II (781) 372-3260
radafaxine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also eating disorders)	Phase II (888) 825-5249
RG 2417	Repligen <i>Waltham, MA</i>	bipolar disorder	Phase II (781) 250-0111
RGH-188	Forest Laboratories <i>New York, NY</i>	bipolar mania (see also schizophrenia)	Phase I (800) 947-5227
SEP-225289	Sepracor <i>Marlborough, MA</i>	depression	Phase I (508) 481-6700
SLV 308	Solvay Pharmaceuticals <i>Marietta, GA</i>	depression (see also anxiety)	Phase II (770) 578-9000
Symbyax [®] olanzapine/ fluoxetine combination	Eli Lilly <i>Indianapolis, IN</i>	depression	Phase III (317) 276-2000
TGBA01AD	Fabre Kramer Pharmaceuticals <i>Houston, TX</i>	major depression	Phase II (713) 975-6900
Topamax [®] topiramate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	bipolar disorder (mania) (see also anxiety)	Phase III (800) 817-5286
Trileptal [®] oxcarbazepine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	bipolar disorder	in clinical trials (888) NOW-NOVA
VEC-162	Vanda Pharmaceuticals <i>Rockville, MD</i>	depression (see also sleep disorders)	in clinical trials (240) 599-4500
vestipitant and paroxetine combination	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	depression (see also anxiety)	Phase II (888) 825-5249
Vestra [™] reboxetine	Pfizer <i>New York, NY</i>	depression	application submitted (860) 732-5156
vilazodone	Merck KGaA <i>Darmstadt, Germany</i>	depression	Phase III www.merck.de
VPI 013 (OPC 14523)	Vela Pharmaceuticals <i>Lawrenceville, NJ</i>	depression	Phase II (609) 895-8352
Wellbutrin-XL bupropion (controlled-release formulation, once-daily dosing)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	seasonal affective disorder	application submitted (888) 825-5249

DEPRESSION

Product Name	Sponsor	Indication	Development Status
YKP 10A	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> SK Bio-Pharmaceuticals <i>Fairfield, NJ</i>	depression	Phase II (800) 817-5286 (973) 227-3939
Zonegran® zonisamide	Eisai <i>Ridgefield Park, NJ</i>	depression (manic episodes) (see also eating disorders)	Phase II (888) 274-2378

EATING DISORDERS

Product Name	Sponsor	Indication	Development Status
856464 (melanin-concentrating hormone antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	obesity	Phase I (888) 825-5249
869682 (sodium-dependent glucose transport inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	obesity	Phase II (888) 825-5249
AC 162352	Amylin Pharmaceuticals <i>San Diego, CA</i>	obesity	Phase I (858) 552-2200
Acomplia® rimonabant	sanofi-aventis <i>Bridgewater, NJ</i>	obesity and metabolic risk factors (see also addictive disorders)	application submitted (800) 633-1610
APD 356	Arena Pharmaceuticals <i>San Diego, CA</i>	obesity	Phase II (858) 453-7200
Axokine® ciliary neurotrophic factor	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	obesity	Phase III (914) 345-7400
Byetta® exenatide	Amylin Pharmaceuticals <i>San Diego, CA</i> Eli Lilly <i>Indianapolis, IN</i>	obesity	in clinical trials (858) 552-2200 (317) 276-2000
CB1 receptor antagonist	Bristol-Myers Squibb <i>Princeton, NJ</i>	obesity	Phase I (212) 546-4000
cetilistat	Alizyme <i>Cambridge, United Kingdom</i>	obesity	Phase III www.alizyme.com
Corlux™ mifeprostone	Corcept Therapeutics <i>Menlo Park, CA</i>	weight gain associated with use of olanzapine (see also dementias, depression)	Phase II (650) 327-3270
CP 945598	Pfizer <i>New York, NY</i>	obesity	Phase I (860) 732-5156
Glyset® miglitol	Pfizer <i>New York, NY</i>	obesity	Phase II (860) 732-5156
GT 389255	Peptimmune <i>Cambridge, MA</i>	obesity	Phase II (617) 715-8000

EATING DISORDERS

Product Name	Sponsor	Indication	Development Status
Marinol® dronabinol	Solvay Pharmaceuticals <i>Marietta, GA</i>	anorexia nervosa (see also dementias, depression)	Phase I (770) 578-9000
MK-0364	Merck <i>Whitehouse Station, NJ</i>	obesity	Phase II (800) 672-6372
MK-0493	Merck <i>Whitehouse Station, NJ</i>	obesity	Phase II (800) 672-6372
peptide YY 3-36	Nastech Pharmaceutical <i>Bothell, WA</i>	obesity	Phase II (425) 908-3600
radafaxine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	obesity (see also depression)	Phase I (888) 825-5249
RC 1291	Sapphire Therapeutics <i>Bridgewater, NJ</i>	anorexia	Phase II (908) 231-1435
S 2367	Shionogi USA <i>Florham Park, NJ</i>	obesity	Phase I (973) 966-6900
SLx 4090	Surface Logix <i>Brighton, MA</i>	obesity	Phase I (617) 746-8500
Symlin® pramlintide	Amylin Pharmaceuticals <i>San Diego, CA</i>	obesity	Phase II (858) 552-2200
urocortin	Neurocrine Biosciences <i>San Diego, CA</i>	obesity	Phase I (858) 617-7600
Zofran® ondansetron	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> University of Minnesota <i>Minneapolis, MN</i>	bulemia nervosa	in clinical trials (888) 825-5249
Zoloft® sertraline	Pfizer <i>New York, NY</i>	obesity (see also anxiety)	in clinical trials (860) 732-5156
Zonegran® zonisamide	Eisai <i>Ridgefield Park, NJ</i>	obesity (see also depression)	Phase II (888) 274-2378

PREMENSTRUAL DISORDERS

Product Name	Sponsor	Indication	Development Status
Effexor® XR venlafaxine	Solvay Pharmaceuticals <i>Marietta, GA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	premenstrual dysphoric syndrome	in clinical trials (770) 578-9000 (610) 902-1200
Lexapro® escitalopram	Forest Laboratories <i>New York, NY</i>	premenstrual dysphoric syndrome (see also anxiety)	in clinical trials (800) 947-5227
Lybrel™ levonorgestrel/EE	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	premenstrual dysphoric disorder	Phase III (610) 902-1200
PH80	Pherin Pharmaceuticals <i>Redwood City, CA</i>	premenstrual syndrome	Phase II (650) 568-1587

PREMENSTRUAL DISORDERS

Product Name	Sponsor	Indication	Development Status
YAZ 3 mg drospirenone/ 20 mcg ethinyl estradiol	Berlex <i>Montville, NJ</i>	premenstrual dysphoric disorder	application submitted (888) BERLEX-4

SCHIZOPHRENIA

Product Name	Sponsor	Indication	Development Status
644784 (dual acting COX-2 inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	schizophrenia	Phase I (888) 825-5249
773812 (mixed 5HT- dopaminergic antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	schizophrenia	Phase II (888) 825-5249
Abilify® aripiprazole	Bristol-Myers Squibb <i>Princeton, NJ</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	schizophrenia (intramuscular)	application submitted (212) 546-4000 (301) 999-0030
		schizophrenia (oral disintegrating tablet)	application submitted (212) 546-4000 (301) 999-0030
ABT-089	Abbott Laboratories <i>Abbott Park, IL</i>	schizophrenia (see also anxiety, ADHD, dementias)	Phase II (847) 937-6100
ACP 103	ACADIA Pharmaceuticals <i>San Diego, CA</i>	psychotic disorders (see also sleep disorders)	Phase II (858) 558-2871
ACP 104	ACADIA Pharmaceuticals <i>San Diego, CA</i>	schizophrenia	Phase II (858) 558-2871
Ampalex® CX 516	Cortex Pharmaceuticals <i>Irvine, CA</i>	schizophrenia (see also autism, dementias, sleep disorders)	Phase II (949) 727-3157
asenapine	Organon USA <i>Roseland, NJ</i> Pfizer <i>New York, NY</i>	psychotic disorders (see also depression)	Phase III (973) 325-4500 (860) 732-5156
AZ-004	Alexza Pharmaceuticals <i>Palo Alto, CA</i>	acute agitation in schizophrenia	Phase I completed (650) 687-3900
bifeprunox	Solvay Pharmaceuticals <i>Marietta, GA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	schizophrenia (see also depression)	Phase III (770) 578-9000 (610) 902-1200
C 9054	Merck <i>Whitehouse Station, NJ</i>	psychotic disorders	Phase II (800) 672-6372
CX 691	Cortex Pharmaceuticals <i>Irvine, CA</i>	schizophrenia	Phase II (949) 727-3157

SCHIZOPHRENIA

Product Name	Sponsor	Indication	Development Status
cycloserine	Pfizer <i>New York, NY</i>	psychotic disorders (see also anxiety)	Phase II (860) 732-5156
GRI 1 (GlyT-1)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	schizophrenia	Phase I (801) 583-4939
iloperidone	Vanda Pharmaceuticals <i>Rockville, MD</i>	schizophrenia	Phase III (240) 599-4500
Lonasen® blonanserin	Dainippon Sumitomo Pharma <i>Otsuka, Japan</i>	schizophrenia	Phase II www.ds-pharma.co.jp
ocaperidone	Neuro3d Mulhouse, France	schizophrenia	Phase II www.nuero3d.fr
		psychotic disorders	Phase I www.nuero3d.fr
P 101	Potomac Pharma <i>Bethesda, MD</i>	schizophrenia	Phase II
paliperidone	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	schizophrenia	application submitted (800) 817-5286
R1678	Roche <i>Nutley, NJ</i>	schizophrenia	Phase I (973) 235-5000
RG 1068 (synthetic human secretin)	Repligen <i>Waltham, MA</i>	schizophrenia (see also anxiety)	Phase II (781) 250-0111
RGH-188	Forest Laboratories <i>New York, NY</i>	schizophrenia (see also depression)	Phase I (800) 947-5227
Risperdal® risperidone	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	psychotic disorders (see also anxiety)	application submitted (800) 817-5286
sabcomeline	Minster Pharmaceuticals <i>Essex, United Kingdom</i>	schizophrenia	Phase II www.minsterpharma.com
SCA-136	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	schizophrenia	Phase II (610) 902-1200
talnetant	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	schizophrenia	Phase II (888) 825-5249
TGOFO2N	Fabre Kramer Pharmaceuticals <i>Houston, TX</i>	schizophrenia	Phase II (713) 975-6900
YKP 1358	SK Bio-Pharmaceuticals <i>Fairfield, NJ</i>	schizophrenia	Phase I (973) 227-3939

SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
ACP 103	ACADIA Pharmaceuticals <i>San Diego, CA</i>	insomnia (see also schizophrenia)	Phase I (858) 558-2871
Ampalex [®] CX 516	Cortex Pharmaceuticals <i>Irvine, CA</i>	sleep disorders (see also autism, dementias, schizophrenia)	Phase II (949) 727-3157
Gabitril [®] tiagabine	Cephalon <i>Frazer, PA</i>	insomnia (see also anxiety)	Phase II (610) 344-0200
Gaboxadol GABA-A receptor agonist	Merck <i>Whitehouse Station, NJ</i>	sleep disorders	Phase III (800) 672-6372
indiplon (immediate release)	Pfizer <i>New York, NY</i> Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	application submitted (860) 732-5156 (858) 617-7600
indiplon (modified release)	Pfizer <i>New York, NY</i> Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	application submitted (860) 732-5156 (858) 617-7600
lorazepam intranasal spray	Intranasal Therapeutics <i>Lexington, KY</i>	sleep disorders (see also anxiety)	Phase I (859) 252-5080
LY 156,735 (PD 6735)	Phase 2 Discovery <i>Cincinnati, OH</i>	sleep disorders	Phase II (513) 475-6618
M 100907	sanofi-aventis <i>Bridgewater, NJ</i>	insomnia	Phase II (800) 633-1610
modafinil	Cephalon <i>West Chester, PA</i>	sleep disorders (see also ADHD, dementias)	Phase III (619) 344-0200
NBI 75043	Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	Phase I (858) 617-7600
NG2-73	Neurogen <i>Branford, CT</i>	insomnia	Phase II (203) 488-8201
orexin receptor antagonist	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	sleep disorders	Phase II (650) 624-6900
ORG 50081	Organon USA <i>Roseland, NJ</i>	sleep disorders	Phase II (973) 325-4500
PD 299685	Pfizer <i>New York, NY</i>	insomnia	Phase II (860) 732-5156
Rozerem [®] ramelteon	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	sleep disorders	Phase II (847) 383-3000
Silenor [™] doxepin HCl	Somaxon Pharmaceuticals <i>San Diego, CA</i>	insomnia	Phase III (858) 509-3670
SO-101	Somaxon Pharmaceuticals <i>San Diego, CA</i>	insomnia	Phase III (858) 509-3670

SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
TGAR01H	Fabre Kramer Pharmaceuticals <i>Houston, TX</i>	insomnia	Phase II (713) 975-6900
VEC-162	Vanda Pharmaceuticals <i>Rockville, MD</i>	insomnia (see also depression)	Phase II/III (240) 599-4500

The content of this survey has been obtained through industry sources and the “Adis R&D Insight” database based on the latest information. **Survey current as of May 2, 2006.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA’s web site.

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Alzheimer's disease—Progressive and rarely reversible chronic deterioration of all mental functions. Early manifestations include a decrease in attention span, impaired powers of concentration, some personality change and forgetfulness. As the disease progresses, there is a loss of computational ability, in addition to word-finding problems and difficulty with ordinary activities. Ultimately, there is severe memory loss, complete disorientation, social withdrawal and loss of independence.

anxiety disorders—A group of mental illnesses in which symptoms of anxiety (from mild unease to intense fear) are the main feature and there is overlap among specific syndromes.

Generalized anxiety disorder is diagnosed if a patient experiences unrealistic or excessive anxiety and worry (apprehensive expectation) about two or more life circumstances, e.g., worry about something bad happening to a loved one (who is not in danger) and worry about money (for no reason) for six months or longer. A diagnosis of **panic disorder** requires that panic attacks—sudden feelings of apprehension or fear accompanied by physical symptoms such as shortness of breath—occur with 4 out of 12 concomitant psychophysiological symptoms, that the attacks are severe enough and happen often enough to be disruptive or distressing to the individual, and that at least one attack was spontaneous, i.e., occurred in the absence of a phobic stimulus.

attention deficit/hyperactivity disorder—ADHD is a complex neurological impairment that results in an overactive behavior pattern and a difficulty concentrating. While it primarily affects children, a growing number of adults are being diagnosed with the disorder. Boys are afflicted some three times as often as girls. Children with ADHD are full of energy, fidgety, impulsive, reckless, irritable, emotionally immature and aggressive. Because their attention

span is short, they do not conform to orderly routine. ADHD often leads to anti-social acts and difficulty learning, although IQ is normal. No definite cause has been established, but some researchers now believe heredity plays a role.

autism—A group of disorders that cause severe and pervasive impairment in thinking, feeling, language, and the ability to relate to others. It is usually first diagnosed in early childhood and ranges from a severe form, called autism disorder, through pervasive development disorder, to a much milder form, Asperger syndrome.

dementia—Degeneration of central nervous system functions, such as memory and learning capacity. The natural decline of these functions with age is grossly exaggerated in dementia.

depression—A feeling of intense sadness, which may follow a recent loss or other sad event but is out of proportion to that event and persists beyond an appropriate length of time. **Major depressive disorder** (or major depression syndrome) includes an episode of depression defined as a persistent (for at least 2 weeks) mood disturbance, plus at least 4 of the following: sleep disturbance, changes in psychomotor activity, loss of ability to experience pleasure and interest, fatigue, feelings of worthlessness or guilt, difficulty in concentrating, and preoccupation with death or a wish to die. Major depression is associated with impairment in social functioning. If criteria for major depression have been met but in addition an episode of mania has ever occurred, then the diagnosis becomes **bipolar disorder** (or manic-depressive illness). The essential feature of mania is a distinct period when the predominant mood is either elevated, expansive, or irritable, with associated symptoms including hyperactivity, pressure of speech, flight of ideas, inflated self-

esteem, decreased need for sleep, distractibility and excessive involvement in activities that often are flamboyant, bizarre or disorganized.

obesity—The accumulation of excessive body fat. Generally, people whose weight is 20 percent or more over the midpoint of their weight range on a standard height-weight table are considered obese.

obsessive-compulsive disorder—A neurosis characterized primarily by recurrent and persistent thoughts that are intense, disgusting, frightening, absurd or otherwise alien, accompanied by ritualized, repetitive behavior that is usually irrational and bizarre.

premenstrual syndrome (PMS)/premenstrual dysphoric disorder (PMDD)

—**PMS** refers to the variation of physical and mood symptoms that appear during the last one or two weeks of the menstrual cycle and disappear by the end of a full flow of menses. Psychiatrists and other mental health workers tend to use the term **PMDD** to describe a specific set of mood symptoms that interfere with social or role functioning that are also present the week before menses and remit a few days after the start. PMS looks more at physical symptoms such as bloating, breast tenderness and appetite change. PMDD has as part of its definition symptoms such as depressed mood, anxiety or tension, irritability, concentration difficulties, overeating or food cravings, and feeling overwhelmed.

psychosis—Severe mental disorders in which the individual loses contact with reality. Symptoms include delusions, hallucinations, thought disorders, loss of emotion, mania and depression.

schizophrenia—The most common form of psychotic illness characterized by disturbances in thinking, emotional reaction and behavior. It is disabling and has a prolonged course that almost always results in chronic ill health and some degree of personality change.

SELECTED FACTS ABOUT MENTAL ILLNESSES AND ADDICTIVE DISORDERS

Overview

- Worldwide, some 450 million people suffer from a mental health disorder.¹ Many people suffer from more than one mental disorder at a given time. Mental illness, including suicide, accounts for more than 15 percent of the burden of disease in established market economies, which is more than the disease burden caused by all cancers.²
- An estimated 26.2 percent of Americans age 18 and older (57.7 million people) suffer from a diagnosable mental disorder in a given year. That's about 1 in 4 adults.²
- In 2003, 31,484 people committed **suicide** in the United States—86 suicides per day or one suicide every 17 minutes.³ More than 90 percent of those who commit suicide have a diagnosable mental disorder, commonly a depressive disorder or a substance abuse disorder.⁴ Suicide was the eleventh leading cause of death in this country in 2002.⁵
- Males are four times more likely to die from **suicide** than females, although females attempt suicide during their lifetime about three times as often as males.³
- **Suicide** is the third leading cause of death among young people ages 15 to 24; only accidents and homicides occur more frequently. In 2003, nearly 4,000 suicides were completed by people between the ages of 15 and 24. Firearms, the most commonly used suicide method among youth, were used in 52 percent of youth suicides.³
- While the elderly (age 65 and older) make up 12.4 percent of the population, they account for almost 17 percent of all **suicides**. In 2003, about 14 elderly adults committed suicide each day, resulting in 5,248 suicides. Of those, 85 percent were men. Firearms were used in 73 percent of suicides committed by the elderly. One of the leading causes of suicide among the elderly is **depression**, often undiagnosed and untreated.³
- The total yearly cost for mental illness in both the private and public sectors in the United States is \$205 billion. Some \$92 billion goes to direct treatment costs, with \$105 billion due to lost productivity and \$8 billion resulting from crime and welfare costs. The allocation for the cost of untreated and mistreated mental illness to U.S. businesses, the government, and families has grown to \$113 billion annually.⁴

Addictive Disorders

- Some 22.5 million people age 12 or older in 2004 were classified with past year **substance dependence or abuse** (9.4 percent of the population). Of these, 3.4 million were classified with dependence on or abuse of both alcohol and illicit drugs, 3.9 million were dependent on or abused illicit drugs but not alcohol, and 15.2 million were dependent on or abused alcohol but not illicit drugs.⁶
- In 2004, 121 million Americans age 12 or older (50.3 percent) were current alcohol drinkers. Some 55 million people (22.8 percent) participated in binge drinking, defined as five or more drinks on at least one occasion in the 30 days prior to the 2004 National Survey on Drug Use and Health (NSDUH). The highest prevalence of binge and heavy drinking that year was for young adults ages 18 to 25.⁶
- In 2004, 19.1 million Americans, or 7.9 percent of the population age 12 or older, were current **illicit drug users**. (Current drug use means use of an illicit drug during the month prior to the NSDUH survey.) Marijuana was the most commonly used illicit drug that year, with a rate of 6.1 percent (14.6 million current users). Of the 2 million current **cocaine** users, 467,000 used crack. Hallucinogens were used by 929,000 people, and 166,000 people used **heroin**.⁶
- In 2004, 21.4 million adults age 18 or older suffered from **serious psychological distress (SPD)**—a high level of distress due to any type of mental problem. That represented almost 10 percent of all adults, a rate that increased from 8.3 percent in 2002. SPD was highly correlated with **substance dependence or abuse**. Among adults with SPD in 2004, 21.3 percent (4.6 million) were dependent on or abused alcohol or illicit drugs, while the rate among adults without SPD was 7.9 percent.⁶
- In 2004, 70.3 million Americans were current users of a **tobacco** product—that's 29.2 percent of the population age 12 and older. Nearly 60 million smoked cigarettes, nearly 14 million smoked cigars, more than 7 million used smokeless tobacco, and nearly 2 million smoked tobacco in pipes. ⁶

SELECTED FACTS ABOUT MENTAL ILLNESSES AND ADDICTIVE DISORDERS

Addictive Disorders (continued)

- According to the 2006 National Drug Threat Assessment, the economic cost of **drug abuse** to the United States was nearly \$181 billion in 2002.⁷ The most recent estimate of the overall economic cost of **alcohol abuse** was \$185 billion in 1998, including the costs of lost productivity and health-care expenditures.⁸
-

Anxiety Disorders²

- **Anxiety disorders**, which include **panic disorder**, **obsessive-compulsive disorder**, **post-traumatic stress disorder**, **generalized anxiety disorder**, and **phobias**, affect more than 40 million adults ages 18 and older, or about 18.1 percent of people in this age group in a given year.
 - About 6.8 million American adults ages 18 and older, or about 3.1 percent of people in this age group, have **generalized anxiety disorder (GAD)** each year. The median age of onset is 31.
 - Some 2.2 million U.S. adults age 18 and older, or about 1 percent of people in that age group, have obsessive-compulsive disorder (OCD) in a given year. The median age of onset is 19.
 - Approximately 6 million Americans ages 18 and older have **panic disorder**, or about 2.7 percent of people in that age group.
 - About 7.7 million U.S. adults age 18 and older, or about 3.5 percent of that age group, have post-traumatic stress disorder (PTSD) in a given year. PTSD can develop at any age, but the median age of onset is 23.
 - About 15 million American adults ages 18 and older, or about 6.8 percent of people in this age group, have **social phobia** yearly. The disorder typically begins around age 13.
-

Attention-Deficit/Hyperactivity Disorder (ADHD)

- The estimated prevalence among children of **ADHD**, the most common psychiatric condition affecting children, ranges from 5 percent to 10 percent. As many as half of the children with ADHD are never diagnosed. Up to 40 percent of children diagnosed with ADHD have relatives with the same type of problem.⁴
 - **ADHD** usually becomes evident in preschool or early elementary years. The median age of onset is seven years, although the disorder can persist into adolescence and occasionally into adulthood.²
-

Dementias

- As many as 6.8 million people in the United States have **dementia**, and at least 1.8 million of them are severely affected. Some studies have found that almost half of all people age 85 and older have some form of dementia. Although it is common in very elderly individuals, dementia is not a normal part of the aging process.⁹
 - **Alzheimer's disease (AD)**, the most common cause of dementia among people age 65 and older, affects about 4.5 million Americans. The duration of illness, from onset of symptoms to death, averages eight years, but some people with AD may live as many as 20 years. By 2050, the number of people with AD could range from 11.3 million to 16 million.¹⁰
 - In a recent Mayo Clinic study, researchers found that 12 percent of those ages 70 to 89 have **mild cognitive impairment (MCI)**, the transitional stage between normal aging and dementia. The prevalence of MCI increased with age, affecting 9 percent of those ages 70 to 79 and nearly 18 percent of those 80 to 89.¹¹ **MCI** progresses into Alzheimer's disease at a rate of up to 15 percent per year.¹⁰
 - **Vascular dementia**, the second most common cause of dementia after Alzheimer's disease, accounts for up to 20 percent of all dementias. It is caused by brain damage from cerebrovascular or cardiovascular problems, usually strokes. In many cases, vascular dementia may coexist with AD. The incidence of vascular dementia increases with advancing age and is similar in men and women.⁹
 - National direct and indirect costs of caring for individuals with **AD** are at least \$100 billion.¹⁰
-

Depression

- **Mood disorders**, which include **major depressive disorder**, **dysthymic disorder**, and **bipolar disorder**, affect nearly 21 million U.S. adults, or about 9.5 percent of the U.S. population age 18 and older in a given year. The median age of onset for mood disorders is age 30. These disorders often co-occur with **anxiety disorders** and **substance abuse**.²

SELECTED FACTS ABOUT MENTAL ILLNESSES AND ADDICTIVE DISORDERS

Depression (continued)

- **Depression** affects as many as 1 in every 33 children and 1 in 8 adolescents in the United States. Recent studies have shown that greater than 20 percent of adolescents in the general population have emotional problems, and one-third of adolescents attending psychiatry clinics suffer from depression.⁴
- **Major depression** is the leading cause of disability (measured by the number of years lived with a disabling condition) worldwide among persons age 5 and older. For women throughout the world, including those in established market economies, depression is the leading cause of Disability Adjusted Life Years, or DALYs, which measure lost years of healthy life. In established market economies, **schizophrenia** and **bipolar disorder** are also among the top 10 causes of DALYs for women.²
- **Major depressive disorder** is the leading cause of disability in the United States for ages 15-44, affecting nearly 15 million American adults (about 6.7 percent of the U.S. population age 18 and older) in a given year. The disorder can develop at any age, but the median age at onset is 32. Major depressive disorder is more prevalent in women than in men.²
- **Dysthymic disorder** (chronic, mild depression) affects some 1.5 percent of the U.S. population age 18 and older (about 3.3 million people) in a given year. The median age of onset is 31. ²
- **Bipolar disorder** affects about 5.7 million American adults, or about 2.6 percent of the U.S. population age 18 and older yearly. The median age of onset for this disorder is age 25.²
- **Depression** ranks among the top three workplace problems. **Clinical depression** alone costs the United States \$43.7 billion annually, including workplace costs for absenteeism and lost productivity (\$23.8 billion), direct costs for treatment and rehabilitation (\$12.4 billion), and lost earnings due to depression-induced **suicides** (\$7.5 billion).⁴

Eating Disorders

- Approximately 1 percent of adolescent girls develop **anorexia nervosa**, and 1 in 10 cases leads to death from starvation, cardiac arrest, or **suicide**. ⁴
- Approximately 127 million adults in the United States are **overweight**, 60 million **obese**, and 9 million **severely obese**. Today, 64.5 percent of U.S. adults age 20 and older are overweight and 30.5 percent are obese. Severe obesity prevalence is now 4.7 percent, up from 2.9 percent reported in the 1988-1994 National Health and Nutrition Survey.¹²
- Approximately 30.3 percent of children ages 6 to 11 are **overweight** and 15.3 percent are **obese**. For adolescents ages 12 to 19, 30.4 percent are overweight and 15.5 percent are obese. Overweight prevalence is higher in boys (32.7 percent) than in girls (27.8 percent). In adolescents, overweight prevalence is about the same for girls (30.2 percent) and boys (30.5 percent).¹²
- **Obesity** is the second leading cause of unnecessary deaths in this country, causing at least 300,000 excess deaths annually.¹²
- The economic costs of **overweight** and **obesity** are comparable to the costs of cigarette smoking. The annual cost of overweight and obesity in the United States is estimated to be nearly \$123 billion in direct (\$64.1 billion) and indirect (\$58.8 billion) costs. Obesity and obesity-related conditions or ailments result in at least \$62.7 million in doctors' visits and \$39.3 million in lost workdays each year.¹³

Premenstrual Disorders

- **Premenstrual syndrome (PMS)** is estimated to affect up to 75 percent of women during their childbearing years. It occurs more often in women between their late 20s and early 40s, those with at least one child, those with a family history of a **major depressive disorder**, or women with a past medical history of either postpartum depression or an **affective mood disorder**. Up to 60 percent of women with severe PMS have an underlying psychiatric disorder.¹⁴
- **Premenstrual dysphoric disorder (PMDD)** is a more severe form of PMS, affecting up to 8 percent of women in their reproductive years. An estimated 40 percent of women who seek treatment for PMDD actually have a premenstrual exacerbation of an underlying mood disorder rather than PMDD.¹⁵

SELECTED FACTS ABOUT MENTAL ILLNESSES AND ADDICTIVE DISORDERS

Schizophrenia

- **Schizophrenia** strikes some 2.4 million American adults, or about 1.1 percent of the U.S. population age 18 and older, in a given year, affecting men and women with equal frequency. The disorder first appears in men in their late teens or early 20s, while women are generally affected in their 20s or early 30s.² Schizophrenia is rare in children under 12, but it occurs in about three out of every 1,000 adolescents.⁴

Sources:

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4. National Mental Health Association, www.nmha.org
5. U.S. Centers for Disease Control and Prevention, www.cdc.gov
6. Substance Abuse & Mental Health Services Administration, Office of Applied Studies, www.oas.samhsa.gov
7. U.S. Department of Justice, www.usdoj.gov
8. National Institute on Alcohol Abuse and Alcoholism www.niaaa.nih.gov
9. National Institute of Neurological Disorders and Stroke, www.ninds.nih.gov
10. Alzheimer's Association, www.alz.org
11. SeniorJournal.com, www.seniorjournal.com
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13. ObesityinAmerica.org, [The Endocrine Society and Hormone Foundation], www.obesityinamerica.org
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THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

It takes 10-15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

Discovery/ Preclinical Testing		Clinical Trials			FDA	Phase IV
		Phase I	Phase II	Phase III		
Years	6.5	1.5	2	3.5	1.5	
Test Population	Laboratory and animal studies	20 to 100 healthy volunteers	100 to 500 patient volunteers	1,000 to 5,000 patient volunteers	Review process/ approval	Additional post-marketing testing required by FDA
Purpose	Assess safety, biological activity and formulations	Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use		
Success Rate	5,000 compounds evaluated	5 enter trials			1 approved	

THE DRUG DEVELOPMENT AND APPROVAL PROCESS

The U.S. system of new drug approvals is perhaps the most rigorous in the world.

It takes 10–15 years, on average, for an experimental drug to travel from lab to U.S. patients, according to the Tufts Center for the Study of Drug Development, based on drugs approved from 1994 through 1998. Only five in 5,000 compounds that enter preclinical testing make it to human testing. And only one of those five is approved for sale.

On average, it costs a company \$802 million to get one new medicine from the laboratory to U.S. patients, according to a November 2001 report by the Tufts Center for the Study of Drug Development.

Once a new compound has been identified in the laboratory, medicines are developed as follows:

Preclinical Testing. A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety.

Investigational New Drug Application (IND). After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND becomes effective if FDA does not disapprove it within 30 days. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. All clinical trials must be reviewed and approved by the Institutional Review Board (IRB) where the trials will be conducted. Progress reports on clinical trials must be submitted at least annually to FDA and the IRB.

Clinical Trials, Phase I. These tests involve about 20 to 100 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized, and excreted as well as the duration of its action.

Clinical Trials, Phase II. In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug's effectiveness.

Clinical Trials, Phase III. This phase usually involves 1,000 to 5,000 patients in clinics and hospitals. Physicians monitor patients closely to confirm efficacy and identify adverse events.

New Drug Application (NDA)/Biologic License Application (BLA). Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more. The average review time for the 36 new therapeutics approved by the FDA in 2004 was 18.1 months.

Approval. Once FDA approves an NDA or BLA, the new medicine becomes available for physicians to prescribe. A company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional trials (Phase IV) to evaluate long-term effects.

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. PhRMA member companies invested an estimated \$39.4 billion in research and development in 2005.

New Medicines in Development for Mental Illnesses is presented by PhRMA in cooperation with the following organizations:

American Academy of Child and Adolescent Psychiatry
American Academy of Physician Assistants
American Association for Geriatric Psychiatry
American Council on Alcoholism
American Nurses Association
American Psychiatric Association
American Society of Clinical Psychopharmacology
Anxiety Disorders Association of America
CHADD: Children & Adults with Attention-Deficit/Hyperactivity Disorder
Depression and Bipolar Support Alliance
DRADA—Depression & Related Affective Disorders Association
Interamerican College of Physicians & Surgeons
International Psychogeriatric Association
NARSAD: The Mental Health Research Association
National Alliance for Hispanic Health
National Alliance for the Mentally Ill (NAMI)
National Association of Anorexia Nervosa and Associated Disorders—ANAD
National Black Nurses Association
National Eating Disorders Association
National Foundation for Depressive Illness
National Medical Association
National Mental Health Association

Being listed in this report in no way implies that the above-mentioned organizations endorse or recommend the use of any of the products in development contained in this publication. For further information, patients should consult their physicians or health care providers.



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