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Research based pharmaceutical company members of the New York Health Products received 25 FDA approvals in 2005 for prescription medicines to successfully treat the ailments and diseases that affect our quality of life.

Scientists' knowledge of disease is growing rapidly and today researchers in America's top pharmaceutical companies are tackling diseases more complex than ever before. New medicines this year treat diseases from the very common to the most rare. Some are the first treatment option available for a condition, others improve care for treatable diseases.

The process for developing a new drug for market is expensive and takes years to complete. Teams of chemists, pharmacologists, physicists, and biologists working in pharmaceutical companies across America, start by screening thousands of compounds for potential drug development and weighing basic concerns - Is a new drug likely to be more effective than current therapies? Will it be possible to manufacture? Does it have a reasonable dose range and delivery system? – before determining if a potential drug is viable for continued development.

Once a viable drug candidate has been identified in the laboratory, it begins years of testing, undergoing a series of arduous steps including pre-clinical tests, FDA applications, three phases of clinical trials in humans, and approvals before it can be declared ready for market. And pharmaceutical companies do not stop there, once approved, continued study is often undertaken to assess any long term effects the drug may produce and monitor results in the population at large.

The pharmaceutical company members of the New York Health Products Council have all devoted countless hours and substantial resources into developing the 25 new drugs listed below that have received approval from the FDA this past year. Please visit the company web sites at the end of this release for more information.

ADHD

Health Canada has approved **CONCERTAR** (methylphenidate HCl) extended-release tablets for use in adolescents (age 13 to 18) with Attention Deficit Hyperactivity Disorder (ADHD). Until now Concertar was approved only for the treatment of ADHD in children aged six to 12 years.

In a clinical study of adolescents aged 13 to 18 years, Concertar significantly reduced ADHD symptoms. As a one-dose-per-day medication it controls symptoms of ADHD throughout the day, taking away the "ups and downs" in behavior associated with multiple dosing.

Approximately four to eleven percent of school-aged children/adolescents are affected by ADHD, which totals up to an estimated half million children/adolescents in Canada alone. ADHD is characterized by three core symptoms – inattention, hyperactivity and impulsivity. *August 11, 2005; Janssen-Ortho Inc.*

ALZHEIMERS

A once-daily treatment for the symptoms of mild to moderate Alzheimer's disease has been approved by the U.S. Food and Drug Administration. **RAZADYNET ER**, - which contains galantamine hydrobromide, first approved by the FDA in 2001 as a twice-daily medication under the name Reminylr - has been proven in clinical trials to provide comparable efficacy, safety and tolerability with the convenience of once-daily dosing, showing significantly better overall cognition (thinking and memory) and daily activities compared to patients taking a placebo.

Alzheimer's disease is a progressive, degenerative disorder that attacks the brain's nerve cells, or neurons, resulting in loss of memory, thinking and language skills, and behavioral changes. Alzheimer's disease is the most common cause of dementia, or loss of intellectual function, among people aged 65 and older and the national cost for caring for individuals with Alzheimer's disease is estimated at \$100 billion annually. *May 2005; Ortho-McNeil Neurologics, Inc.*

ARTHRITIS

In 2005, two new drugs were approved by the U.S. Food and Drug Administration in the fight against psoriatic arthritis. Centocor, Inc.'s **REMICADER** (infliximab) was approved to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis.

Abbot Laboratories, received approval for **HUMIRA**[®] (adalimumab) for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis. Approval was based on results of the Adalimumab Effectiveness Psoriatic Arthritis Trial (ADEPT), which is the largest biologic trial in PsA. Humira[®] patients experienced significantly greater improvements in both joint and skin disease symptoms than placebo-treated patients at 24 weeks, with improvements seen as early as two weeks after initiation and continuing to improve over time.

An immune-mediated inflammatory disease, psoriatic arthritis affects approximately one million men and women in the U.S. and is often characterized by the complex symptoms of joint inflammation (arthritis) and skin lesions (psoriasis). *May 2005; Centocor, Inc.;*
October 2005; Abbott Laboratories

BIPOLAR DISORDER

The U.S. food and Drug Administration has approved **DEPAKOTE**[®] **ER** (divalproex sodium extended-release tablets) for the treatment of acute mania or mixed episodes associated with bipolar disorder, with or without psychotic features. Depakote[®] ER is the once-daily formulation of Depakote[®] (divalproex sodium delayed-release tablets) which has been the leading medication for the treatment of mania associated with bipolar disorder since its approval in 1995. Depakote[®] ER, taken once per day, helps provide more consistent levels of medication in the body, which is key to the successful treatment of mania.

Approximately 2.3 million American adults have bipolar disorder, also known as manic-depressive illness. Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. The symptoms can be severe and may include abnormally elevated mood, irritability, marked increase in energy, grandiose thinking, thought disorders and depression.

December 2005; Abbott Laboratories

BONE FRACTURES

A novel protein device that enhances bone healing has been approved by the U.S. Food and Drug Administration for use in open tibia shaft fractures in adults. **rhBMP-2/ACS** (recombinant human Bone Morphogenetic Protein-2/Absorbable Collagen Sponge) can be used after stabilization with an intramedullary nail (a metal rod inserted into the bone) by orthopedic surgeons to help improve fracture healing while reducing the chances of infection.

The data package Wyeth submitted to the FDA was based on one of the largest orthopedic fracture clinical trials ever conducted. It showed that the use of rhBMP-2/ACS 1.5mg/mL in more than 400 patients during surgery, significantly improved the probability of fracture healing as evidenced by a reduced need for secondary procedures when compared to the standard of care.

May 2004; Wyeth Pharmaceuticals

DIABETES

The U.S. Food and Drug Administration has approved the New Drug Application (NDA) for **ACTOplus met™** for the treatment of type 2 diabetes. Combining ACTOS® (pioglitazone HCl) and metformin, two widely used diabetes medications, in a single tablet, ACTOplus met may help patients reduce the number of pills they take each day.

According to the American Diabetes Association, diabetes affects more than 18 million people, and type 2 diabetes is the most common form of the disease. *August 2005; Takeda Pharmaceuticals North America, Inc.*

EPILEPSY

TOPAMAXR (topiramate) **Tablets** and **TOPAMAXR** (topiramate capsules) **Sprinkle Capsules** have been approved by the U.S. Food and Drug Administration as initial monotherapy in patients 10 years of age and older with partial-onset or primary generalized tonic-clonic seizures.

Topamaxr, which provides coverage for both partial-onset and primarily generalized tonic-clonic seizures, offers doctors an option in situations where differentiating between these seizure types is difficult.

Epilepsy is one of the most common neurological disorders, occurring in an estimated 2.7 million Americans. It is characterized by seizures, which are abnormal electrical discharges in the brain that temporarily disrupt normal brain function. Seizures are classified as "generalized," originating in both sides of the brain simultaneously, or "partial-onset," starting in one area of the brain. Each year in the United States, approximately 200,000 people are diagnosed with epilepsy for the first time. *June 2005; Ortho-Mcneil Neurologics, Inc.*

HIV

Two new formulations of HIV prescription medications respond to physician and patient needs of fewer pills to fight the disease. First to receive approval by the U.S. Food and Drug Administration was **INVIRASE**[®] (saquinavir mesylate) which reduced the pill count for each dose by more than half (from five to two, twice-daily).

Abbott Laboratories also received U.S. Food and Drug Administration approval for a new tablet formulation of its HIV protease inhibitor (PI) **KALETRA**[®] (lopinavir/ritonavir), which will allow adult patients to take fewer pills with no food or refrigeration requirements.

Invirase[®] and Kaletra[®] are not cures for HIV infection or AIDS nor do they prevent the transmission of HIV. *December 2004; Hoffman-La Roche, Inc.; October 2005; Abbott Laboratories*

INFECTIOUS DISEASE

The U.S. Food and Drug Administration has approved **TYGACILÄ** (tigecycline), a novel I.V. antibiotic with a broad spectrum of antimicrobial activity, including activity against the drug-resistant bacteria methicillin-resistant *Staphylococcus aureus* (MRSA).

Tygacil is indicated for the treatment of complicated intra-abdominal infections (cIAI) and complicated skin and skin structure infections (cSSSI) in adults. It can be used as an empiric monotherapy to treat a variety of cIAI and cSSSI, both hospital and community acquired, including complicated appendicitis, infected burns, intra-abdominal abscesses, deep soft tissue infections, and infected ulcers. It provides clinicians with a novel, broad-spectrum option that can be used at the onset of treatment when the specific bacteria present are not yet known.

Developed by Wyeth Pharmaceuticals it is the first antibiotic approved in a new class called glycylcyclines and is designed to overcome key mechanisms of resistance that have affected antibiotic use. Antibiotic resistance costs the U.S. between \$4 billion and \$5 billion annually. *June 15, 2005; Wyeth Pharmaceuticals*

INSOMNIA

Takeda Pharmaceuticals North America, Inc. announced that the U.S. Food and Drug Administration has approved the New Drug Application (NDA) for **ROZEREM**[™] (ramelteon) 8-mg tablets for the treatment of insomnia characterized by difficulty with sleep onset. It selectively targets two receptors located in the brain's suprachiasmatic nucleus (SCN), the portion that regulates 24-hour, or circadian, rhythms including the sleep-wake cycle.

Rozerem[™] is the first and only prescription sleep medication that has shown no evidence of abuse and dependence and, as a result, has not been designated as a controlled substance by the U.S. Drug Enforcement Administration. This designation allows physicians to prescribe Rozerem[™] for long-term use in adults.

Approximately 60 million people in the United States suffer from insomnia, yet the vast majority remains undiagnosed and untreated. Insomnia is characterized by difficulty falling asleep, difficulty staying asleep, or poor quality sleep, leading to impairment of next-day functioning. Insomnia has been linked to a variety of health problems, including obesity, diabetes, hypertension, heart disease and depression. According to the U.S. Surgeon General, nearly \$15 billion annually is spent on healthcare related to insomnia, while \$50 billion is lost in productivity. *July 2005; Takeda Pharmaceuticals North America, Inc.*

KIDNEY DISEASE

The U.S. Food and Drug Administration has approved **ZEMPLAR®** (paricalcitol) **Capsules**, an oral, activated vitamin D therapy for prevention and treatment of secondary hyperparathyroidism (SHPT) in stages three and four chronic kidney disease (CKD) patients, before need for dialysis or transplantation.

The capsules are an oral formulation of Zemplar® Injection, which was introduced in 1998 and is the most widely-used activated vitamin D for the prevention and treatment of SHPT among dialysis patients. Zemplar® Capsules were designed to reduce parathyroid hormone levels (PTH), a key indicator of treatment efficacy, with minimal impact on calcium and phosphorus levels in a convenient oral form.

SHPT is a major complication associated with CKD that can detrimentally impact bones and other vital organs, including the heart, muscles and nerves if left untreated. It can occur when kidneys lose their ability to activate vitamin D obtained through diet and other sources. One in nine adults in the U.S., or 20 million people, have CKD and another 20 million are at risk for developing CKD from underlying causes such as diabetes and hypertension. *May 2005; Abbott Laboratories*

MACULAR DEGENERATION

The first medication in a new class of ophthalmic drugs to specifically target vascular endothelial growth factor (VEGF) has been approved by the U.S. Food and Drug Administration.

MACUGEN® (pegaptanib sodium injection) has been approved for the treatment of neovascular (wet) age-related macular degeneration (AMD), an eye disease associated with aging that destroys central vision.

Macugen® is the first anti-angiogenic treatment approved in ophthalmology, specifically addressing an underlying cause of blindness in age-related macular degeneration. It is the first therapy indicated for the treatment of all types of neovascular AMD, regardless of lesion subtype or size.

AMD is the leading cause of irreversible severe vision loss in patients older than 50 years of age in developed countries. There are 50 million people in the United States living with some form of AMD, with more than 1.6 million experiencing the active blood vessel growth and blood vessel leakage associated with neovascular AMD. There are over 200,000 new cases of neovascular AMD each year and this number is expected to increase significantly as the baby boom generation ages and overall life expectancy increases. Presently, over 500,000 people worldwide lose their sight annually from the disease. *December 2004; Pfizer, Inc. and Eyetech Pharmaceuticals, Inc.*

OSTEOPOROSIS

Once-monthly oral **BONIVA**[®] (ibandronate sodium) 150mg Tablets, has been approved by the U.S. Food and Drug Administration for the treatment of postmenopausal osteoporosis. It maintains and actually builds bone density.

A Surgeon General's Report elevates osteoporosis to a major public health threat on par with smoking and obesity. Forty-four million Americans over 50 years of age are affected by or at risk for osteoporosis, which causes bones to become weak and more likely to break, and can result in severe pain, deformity, disability, hospitalization and even death. *March 2005; Roche and GlaxoSmithKline*

OVERACTIVE BLADDER (OAB)

The past year saw two new drug approvals for people suffering from overactive bladder (OAB). **VESICARE**[®] (solifenacin succinate), manufactured by GlaxoSmithKline, has been approved by The U.S. Food and Drug Administration (FDA) for the treatment of OAB with symptoms of urgency, frequency and urge incontinence. In clinical studies, Vesicare[®] 5mg and 10mg showed clinical and statistical improvements in all symptoms of OAB. Specifically, once-daily Vesicare[®] was found to significantly reduce the number of incontinence episodes for patients during a 12-week study period.

Novartis' **ENABLEX**[®] (darifenacin) was also approved by the FDA for treatment of OAB with symptoms of urge urinary incontinence, urgency and frequency. A once-daily medication, it works by blocking the M3 receptor which is primarily responsible for bladder muscle contraction to reduce incontinence episodes, increase the amount of urine the bladder can hold, reduce the frequency of urination episodes, and decrease the pressure or urgency associated with the urge to urinate.

OAB is a medical condition that causes the bladder muscle to contract while the bladder is filling with urine, rather than when the bladder is full. Patients with OAB feel the urge to urinate more often, without advance warning, and when the bladder isn't completely full. It is estimated that OAB affects 17-20 million men and women in the United States. *November 2004; GlaxoSmithKline; December 2004; Novartis Pharmaceuticals Corporation*

PAIN MANAGEMENT

Developed by Pfizer, **LYRICA**[®] (pregabalin) capsules c-v was approved by the U.S. Food and Drug Administration to treat two distinct forms of neuropathic pain. It is indicated for the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN) and adjunctive treatment of partial onset seizures in adults with epilepsy.

Neuropathic pain, one of the most debilitating forms of pain, is caused by nerve damage that can result from underlying conditions, such as diabetes or shingles. Nearly half of the 18 million Americans with diabetes will develop some form of diabetic neuropathy over the course of their disease. PHN, which affects about 150,000 Americans each year, is a complication of shingles, a painful outbreak of rash or blisters on the skin caused by a reactivation of the same virus that causes chicken pox. Partial onset seizures represent over half of all seizures in patients with epilepsy, a chronic neurological condition affecting nearly three million Americans. *September 2005; Pfizer, Inc.*

PANIC DISORDER

Wyeth has announced the approval of **EFFEXOR XR** (venlafaxine HCl), by the U.S. Food and Drug Administration for the treatment of panic disorder in adults. Often associated with conditions such as depression or other anxiety disorders, Effexor XR, a serotonin-norepinephrine reuptake inhibitor, is also indicated for the treatment of adults with major depressive disorder, generalized anxiety disorder (GAD) or social anxiety disorder (SAD).

Panic disorder affects 2.4 million American adults annually. It is characterized by recurrent, unexpected panic attacks; i.e., a discrete period of intense fear or discomfort in the absence of real danger, where four of 13 specific symptoms such as accelerated heart rate, shortness of breath, trembling or fear of dying develop abruptly, reach a peak within 10 minutes, and are followed by at least one month of persistent concern about having another panic attack. *November 21, 2005; Wyeth Pharmaceuticals*

PERTUSSIS

A booster vaccine has been approved for individuals aged 10 to 19 years to prevent the spread of the highly contagious disease, pertussis (whooping cough). GlaxoSmithKline's **BOOSTRIX**® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)] received approval from the U.S. Food and Drug Administration and is indicated to be given as a single dose, adding a pertussis component to the routine tetanus/diphtheria booster currently administered to teens.

Adolescents are an important reservoir for pertussis and often the source of infection for infants for whom the disease can be deadly. Reported cases of pertussis have risen nearly 20-fold since 1976 with almost 20,000 cases reported in 2004, the highest number in more than 40 years. In addition, experts believe that the true incidence of the disease may be greater than one million cases per year with adolescents being hit particularly hard with a 743 percent increase reported in the last decade for this age group.

Pertussis, commonly known as whooping cough, is a highly contagious bacterial infection of the respiratory system that causes spasms of severe coughing that can last for up to 100 days. Spread through airborne droplets of an infected person's cough or sneeze, the first symptoms are similar to the common cold with a mild fever, runny nose and cough. A cost-benefit analysis for the use of a pertussis booster vaccine in adolescents projected that vaccination of people in the U.S. ages 10-19 during a 10-year period would prevent up to 1.8 million cases of pertussis and save as much as \$1.6 billion in direct and indirect costs. *May 2005; GlaxoSmithKline*

RESTLESS LEG SYNDROME

The first treatment for moderate-to-severe primary Restless Legs Syndrome (RLS), a chronic and disruptive neurological condition affecting approximately one in ten adults in the U.S., has been approved by the U.S. Food and Drug Administration. In clinical trials, patients taking **REQUIP**® (ropinirole HCl) Tablets experienced significantly improved symptoms and lower relapse rates compared with patients taking a placebo.

RLS is characterized by a compelling urge to move the legs and by uncomfortable or sometimes painful sensations in the legs. Symptoms of RLS generally occur at rest and are temporarily relieved by movement. People with RLS often have difficulty falling and staying asleep. Although its exact cause is unknown, researchers believe that the underlying cause of RLS may be related to dopamine, a chemical that carries the signals between nerve cells that control body movement. Requip® is a second-generation dopamine agonist that directly stimulates dopamine receptors in the brain.

May 2005; GlaxoSmithKline

SINUSITIS

The U.S. Food and Drug Administration approved a five-day, 750 mg once-daily regimen for **LEVAQUINR** (levofloxacin) tablets to treat acute bacterial sinusitis. The approval is based on a clinical study that found this shorter treatment regimen as effective as a traditional regimen of Levaquinr 500 mg for 10 days.

Sinusitis is one of the most common conditions seen by primary care physicians, and according to the National Ambulatory Medical Care Survey, is the fifth most common condition for which an antibiotic is prescribed. Each year in the United States there are an estimated 20 million cases of acute bacterial sinusitis. *August 2005; Ortho-McNeil, Inc*

SPINAL INFLAMMATION

REMICADER (infliximab) has been approved by the U.S. Food and Drug Administration as a treatment to reduce signs and symptoms in active ankylosing spondylitis (AS), a painful, progressive inflammatory condition of the spine that can result in fusion of the spinal vertebrae and structural damage to hips and other joints, which can lead to limited function and disability.

Patients in trials experienced not only rapid and sustained improvement of symptoms, including pain, stiffness and fatigue; they also experienced improvement in function and spinal mobility. *December 2004; Centocor, Inc.*

ULCERATIVE COLITIS

Centocor, Inc. has announced that **REMICADER** (infliximab) has been approved by the U.S. Food and Drug Administration for the treatment of ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD). Remicader is indicated for reducing signs and symptoms of the disease, as well as for achieving clinical remission and mucosal healing, and eliminating corticosteroid use in patients. To date, no therapy has ever been indicated for mucosal healing and eliminating the use of corticosteroids.

First approved in the U.S. for the treatment of Crohn's disease (CD) in 1998, Remicader remains the only anti-tumor necrosis factor (TNF-alpha) therapy indicated for the treatment of CD. Remicader is the only biologic indicated for the treatment of both types of inflammatory bowel diseases, CD and UC.

Ulcerative Colitis is a debilitating chronic disease affecting more than 500,000 Americans for whom there is no medical cure. Characterized by inflammation and ulceration of the inner lining of the colon, UC symptoms can often include unwanted weight loss, severe – sometime uncontrollable – bloody diarrhea, fatigue and frequent abdominal pain. *September 2005; Centocor, Inc.*

VASCULAR DISEASE

The U.S. Food and Drug Administration approved **REVATIO™** (sildenafil citrate) as a treatment for pulmonary arterial hypertension (PAH), a rare, aggressive and life-shortening vascular disease.

A long-term non-placebo controlled extension trial was conducted in which, at the end of one year, walk distance and functional class were stable and 94 percent of patients were still alive.

PAH is characterized by dangerously high pressure in the blood vessels that lead from the heart to the lung. It is estimated to affect approximately 100,000 people worldwide. Symptoms include difficulty breathing, dizziness and fatigue. Left untreated, patients have an average survival time of less than three years from the time of diagnosis. *June 2005; Pfizer, Inc.*

For further information contact member companies through their websites:

Abbott Laboratories – www.abbott.com

Centocor, Inc. – www.centocor.com

Eyetech Pharmaceuticals, Inc. – www.eyetech.com

Hoffman-La Roche inc. (Roche) – www.rocheuse.com

Janssen-Ortho Inc. – www.janssen-ortho.com

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. – www.jnj.com

Novartis Pharmaceuticals Corporation – www.us.novartis.com

Ortho-McNeil, Inc – www.ortho-mcneil.inc

Pfizer, Inc. – www.pfizer.com

Takeda Pharmaceuticals North America, Inc. – www.tpna.com

Wyeth Pharmaceuticals – www.wyeth.com