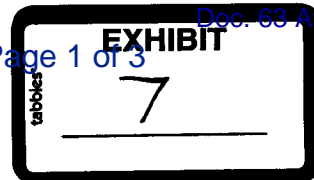


2002
January

New Drug Approvals In 2001

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES



Pharmaceutical Companies Added 32 New Treatments to the Nation's Medicine Chest in 2001

In 2001, pharmaceutical and biotechnology companies won approval for 24 new drugs and eight new biologics.

The new medicines approved by the Food and Drug Administration in 2001 include:

- 1 for HIV/AIDS, which affects 800,000 to 900,000 Americans
- 2 for arthritis, which afflicts more than 20 million Americans
- 3 for cancer, the second leading cause of death in the United States
- 2 for glaucoma, a leading cause of blindness
- 5 for heart disease, the leading killer of Americans
- 5 for infectious diseases, including bacterial, viral and fungal infections
- 1 for schizophrenia, which affects more than 2 million Americans
- 1 for Alzheimer's disease, which afflicts nearly half of all Americans 85 and older;
- 2 for migraine headaches, which affects about 10 percent of Americans and cost employers \$13 billion a year in lost work costs
- 2 vaccines to prevent hepatitis

Detailed descriptions of the medicines approved in 2001 are on page 9.

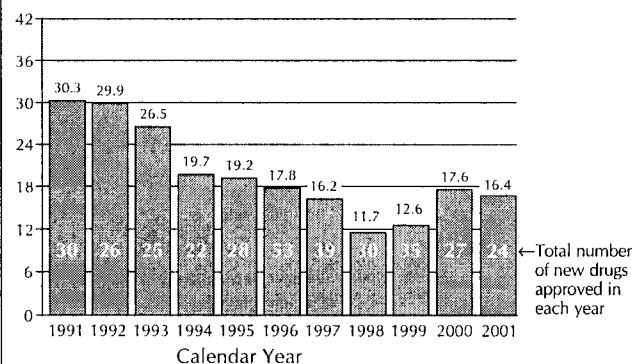
All together, the new medicines made available this year treat or prevent 32 diseases with an annual cost to society of more than \$250 billion and a terrible human cost to patients and their families.

Each approved medicine represents an average research and development cost of \$802 million, according to data from the Tufts Center for the Study of Drug Development. This represents a 250 percent increase in the cost of drug development in just over a decade. This new figure reflects the fact that each new drug requires more study and larger, more complex clinical trials. It also reflects the fact that companies are tackling many difficult diseases, such as sepsis, AIDS, and Alzheimer's. In 2001, companies that are members of the Pharmaceutical Research and Manufacturers of America (PhRMA) spent an estimated \$30.3 billion on R&D. This represents a 16.6 percent increase in research spending over the year 2000.

Drug development is not only expensive—it is a very lengthy process. According to Tufts, it takes an average of 10 to 15 years to bring a new medicine from the laboratory to the pharmacy. The tail end of this time is the time

MEAN APPROVAL TIMES FOR NEW DRUGS, 1991-2001

Mean approval time (months)



Source: U.S. Food and Drug Administration

required for the review of the company's application by the Food and Drug Administration. This year, the 24 drugs approved were reviewed in an average of 16.4 months. This represents a slight improvement over last year's times, but approval times for drugs in 1998 and 1999 were somewhat shorter. Additionally, eight new biologics were approved in 2001, and were reviewed in an average of 19.6 months.

Pharmaceutical companies have more than a thousand promising new treatments in the pipeline and, with the mapping of the human genome, this number is expected to increase substantially. Expedient and efficient reviews are essential so that patients may have timely access to safe and effective new medicines. For this reason, PhRMA will work with the FDA and with Congress this year to reauthorize the Prescription Drug User Fee Act, which sunsets on October 1, 2002. User fees now pay the salaries of 900 highly qualified drug reviewers and, if the law is not renewed promptly, FDA will have to dismiss a large number of reviewers.

The 32 medicines approved this year will add to the arsenal of formidable weapons America's pharmaceutical companies have developed against disease. The medicines in the pipeline promise an even healthier tomorrow.

Alan F. Holmer
President and CEO
PhRMA

| Product | Company | Indication/Use | NDA Received | FDA Approved | Review Time | Foreign Availability* |
|--|---|--|--------------|--------------|-------------|---|
| Travatan™ travoprost ophthalmic solution (P) | Alcon Laboratories Fort Worth, TX | reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension | 7/7/00 | 3/16/01 | 8.3 months | USA first marketing |
| <i>For more information contact: Mary Dulle, (817) 551-8058</i> | | | | | | |
| Viread™ tenofovir disoproxil fumarate (P) | Gilead Sciences Foster City, CA | treatment of HIV infection | 5/1/01 | 10/26/01 | 5.9 months | USA first marketing |
| <i>For more information contact: Amy Flood, (650) 522-5643</i> | | | | | | |
| Yasmin® drospirenone and ethinyl estradiol (S) | Berlex Laboratories Montville, NJ | low-dose monophasic oral contraceptive | 5/17/99 | 5/11/01 | 23.8 months | 9 countries including: 2000 Germany 2001 Denmark 2001 Norway 2001 Sweden 2001 Netherlands 2001 Ireland |
| <i>For more information contact: Kim Schillace, (973) 487-2461</i> | | | | | | |
| Zometa™ zoledronic acid for injection (P) | Novartis Pharmaceuticals East Hanover, NJ | treatment of hypercalcemia of malignancy | 12/21/99 | 8/20/01 | 20.0 months | more than 30 countries including: European Union Brazil Switzerland Canada Australia |
| <i>For more information contact: Gloria Stone, (973) 781-5587</i> | | | | | | |

New Biologic Approvals in 2001

| Product | Company | Indication/Use | BLA Received | FDA Approved | Review Time | Foreign Availability* |
|---|--|--|--------------|--------------|-------------|------------------------|
| Aranesp™ darbepoetin alfa (S) | Amgen Thousand Oaks, CA | treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis | 12/28/99 | 9/17/01 | 20.7 months | unavailable |
| <i>For more information contact: Amgen, (805) 447-1000</i> | | | | | | |
| Campath® alemtuzumab (P) | Berlex Laboratories Montville, NJ ILEX Oncology San Antonio, TX Millennium Pharmaceuticals Cambridge, MA | treatment of B-cell chronic lymphocytic leukemia | 12/23/99 | 5/7/01 | 16.5 months | USA first marketing |
| <i>For more information contact: Kimberley Jordan, (Berlex), (973) 487-2592</i> | | | | | | |

| Product | Company | Indication/Use | BLA Received | FDA Approved | Review Time | Foreign Availability* |
|--|--|---|--------------|--------------|-------------|-----------------------|
| DigiFab™ digoxin immune Fab (ovine) (S) | Protherics Brentwood, TN | treatment for digoxin toxicity | 8/3/99 | 8/31/01 | 24.9 months | 2000 Sri Lanka |
| <i>For more information contact: Suzanne Ward, (615) 963-4528</i> | | | | | | |
| Kineret™ anakinra (S) | Amgen Thousand Oaks, CA | reduction of signs and symptoms of moderate to severe active rheumatoid arthritis | 12/28/99 | 11/14/01 | 22.6 months | unavailable |
| <i>For more information contact: Amgen, (805) 447-1000</i> | | | | | | |
| Nabi-HB™ Hepatitis B immune globulin (human) (S) | Nabi Boca Raton, FL | hepatitis B | 12/16/99 | 10/23/01 | 22.2 months | unavailable |
| <i>For more information contact: Nabi, (561) 989-5800</i> | | | | | | |
| PEG-Intron™ peginterferon alfa-2b (S) | Schering-Plough Kenilworth, NJ | treatment of chronic hepatitis C | 12/23/99 | 1/19/01 | 12.9 months | 2001 European Union |
| <i>For more information contact: Robert J. Consalvo, (908) 298-7409</i> | | | | | | |
| Twinrix® Hepatitis A inactivated and Hepatitis B (recombinant) vaccine (S) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | prevention of hepatitis A & B in adults | 2/1/99 | 5/11/01 | 27.3 months | unavailable |
| <i>For more information contact: Ramona DuBose, (919) 483-2839</i> | | | | | | |
| Xigris™ drotrecogin alfa (activated) (P) | Eli Lilly Indianapolis, IN | reduction of mortality in adults with severe sepsis at high risk of death | 1/26/01 | 11/21/01 | 9.9 months | USA first marketing |
| <i>For more information contact: Dan Collins, (media only), (317) 277-2688 and Holger Schilske, M.D., (317) 277-5505</i> | | | | | | |

The content of this survey has been obtained through government and industry sources. The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly.

PhRMA Internet address: <http://www.phrma.org>

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