EXHIBIT 2

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Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Longer clinical times are extending time to market for new drugs in U.S.

Recent trend offsets gains made by shorter approval times under PDUFA

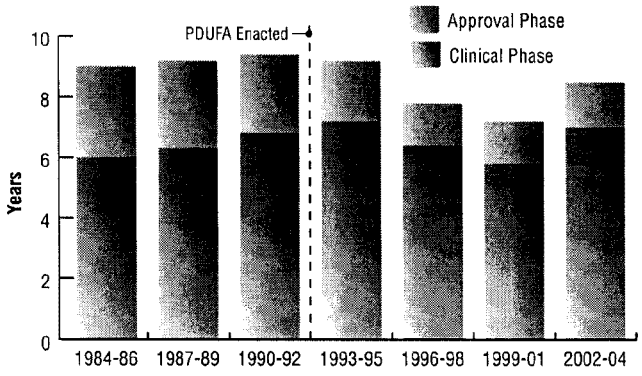
- Average clinical phase time increased 21% from a low of 5.8 years in 1999-01 to 7.0 years in 2002-04.
- After a spike in approvals in 1996-98, due in part to the FDA's clearing its backlog of applications, total approvals dropped 47% through 2002-04.
- Clinical times for priority drugs are at their longest since before enactment of PDUFA in 1992.
- In recent years, drugs for neuropharmacologic diseases have taken the longest to develop and bring to market.
- Clinical phase times have increased for most therapeutic areas between 1999-01 and 2002-04.
- Incentives for drug developers to market their products first in the U.S. remain high.

Average clinical times for new drugs approved for sale in the U.S. have lengthened in recent years after a decade of steady decline since passage of the *Prescription Drug User Fee Act of 1992* (PDUFA). As clinical times increased, the number of new drug approvals by the U.S. Food and Drug Administration (FDA) has fallen. Helping to explain these concurrent trends is the fact that as drug development becomes more complex and expensive, developers tend to concentrate available resources on fewer projects. Fewer development projects, in turn, lead to fewer new drug approvals.

Enacted to speed access to new medicines, PDUFA appears to have been instrumental in reducing clinical and approval times between 1993 and 2001. The challenge ahead, for industry as well as the FDA, is to further enhance the development of ever more complex medicines while improving assessments of drug safety and effectiveness. This *Tufts CSDD Impact Report* updates continuing Tufts CSDD analyses of the effect of the FDA's Strategic Action Plan and PDUFA III (enacted in October 2002) on new drug R&D.

Longer clinical development time slowed time to market for drugs approved in 2002-04

Clinical and Approval Times: 1984-2004

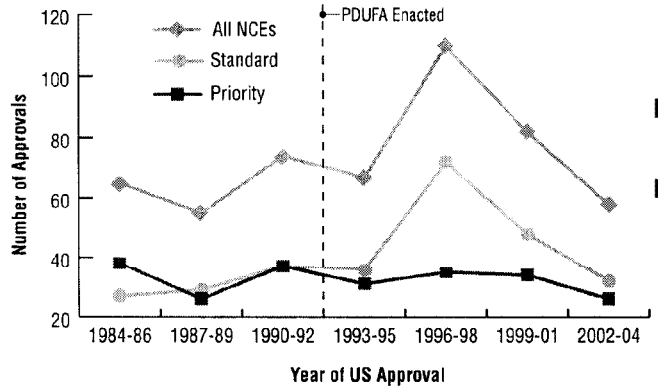


Source: Tufts Center for the Study of Drug Development

- Since PDUFA took effect in 1993, average clinical phase time declined initially, from a high of 7.2 years in 1993-95 to a low of 5.8 years in 1999-01, but increased markedly in 2002-04, to 7.0 years, an increase of 21%.
- During the same period, average approval time for NCEs fell from 2.0 in 1993-95 to 1.4 years in 1996-98, and has remained relatively stable through the three-year period ending 2004 (1.5 years).
- As a result of longer clinical times, overall time to reach the market for NCEs approved in 2002-04, from IND filing to NDA approval, increased by 18% from the previous three-year period.

Total drug approvals declined 47% between 1996-98 and 2002-04

Numbers of Priority, Standard, and All NCEs Approved: 1984-2004

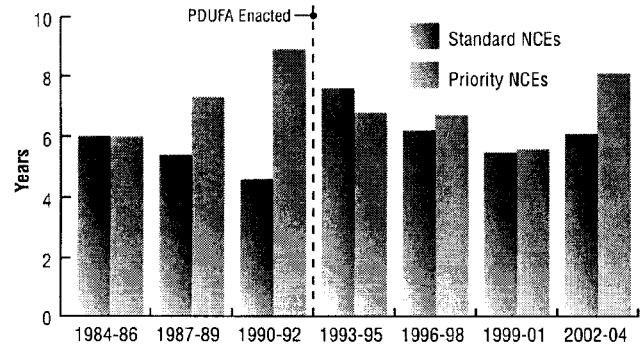


Source: Tufts Center for the Study of Drug Development

- After a spike in NCE approvals in 1996-98, due in part to the FDA's clearance of its backlog of applications, total approvals dropped 47% — from 110 in 1996-98 to 58 in 2002-04.
- Standard approvals during the same time dropped 56% — from 72 to 32.
- While the number of priority approvals in each three-year period since PDUFA took effect in 1993 remained relatively stable through 2001 that number dropped 34%, to 26, in 2002-04.

Clinical times for priority NCEs are at their longest since before enactment of PDUFA

Clinical Phases for Priority and Standard NCEs Approved: 1984-2004

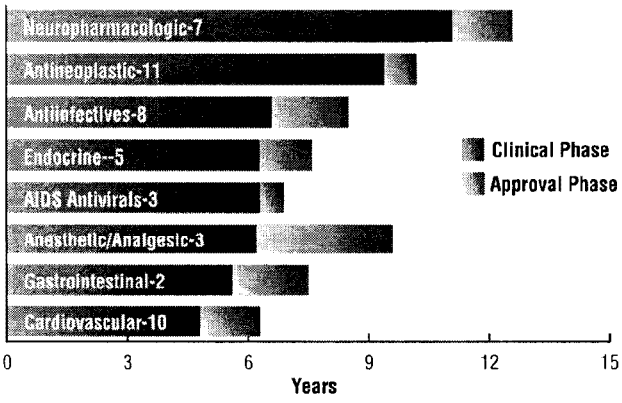


Source: Tufts Center for the Study of Drug Development

- Average clinical time for priority and standard NCEs, which had been declining since PDUFA enactment, reversed direction in 2002-04.
- Priority clinical time increased 45% — from 5.6 years in 1999-01 to 8.1 years in 2002-04.
- The gap between average standard and priority clinical times increased to 2 years in 2002-04.
- Average approval time for priority drugs also increased in 2002-04, by 33% — from 0.9 years in 1999-01 to 1.2 years in 2002-04 — while standard drug approval time remained similar. (See detail on page 4.)

Drugs for neuropharmacologic diseases take the longest to develop and bring to market

Clinical and Approval Times by Therapeutic Class: 2002-2004

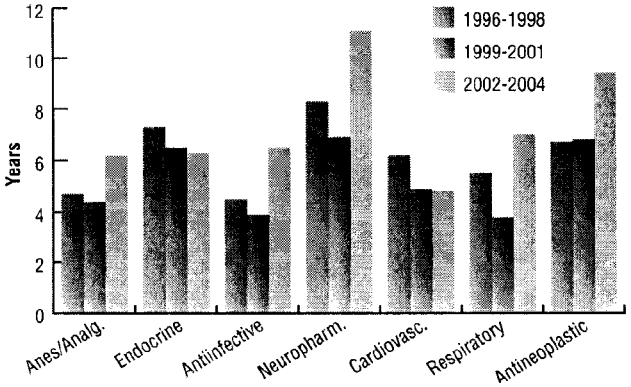


Source: Tufts Center for the Study of Drug Development

- Neuropharmacologic drugs take twice as long to develop and bring to market as cardiovascular drugs — 12.6 vs. 6.3 years.
- Clinical phase times for antiinfective, endocrine, AIDS antiviral, and anesthetic/analgesic agents averaged 6.4 years (range: 6.2 to 6.6 years).
- At the extremes, neuropharmacologic and antineoplastic agent clinical phase times were longer — 11.1 and 9.4 years, respectively — and gastrointestinal and cardiovascular agent times were shorter — 5.6 and 4.8 years, respectively.
- Average approval time varied considerably, from 0.6 years for AIDS antivirals to 3.4 years for anesthetic/analgesic drugs.

Average clinical phase time in 2002-04 increased for most therapeutic areas

Clinical Phases for NCEs Approved by Therapeutic Area: 1996-2004

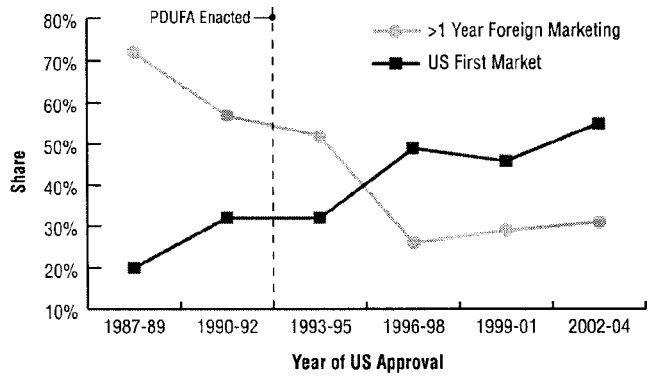


Source: Tufts Center for the Study of Drug Development

- Clinical times in 2002-04 reached a nine-year high for anesthetic/analgesic, antiinfective, neuropharmacologic, respiratory, and antineoplastic agents.
- Respiratory agents, as a group, experienced the largest jump in clinical times between 1999-01 and 2002-04 — 84%, from an average of 3.8 to 7.0 years. Antiinfectives and neuropharmacologic agents followed, with jumps of 67% and 61%, respectively.
- Clinical times for endocrine and cardiovascular agents decreased, on average, 1 year and 0.1 year, respectively, from 1999-01 to 2002-04.

Incentives for drug developers to market their products first in the U.S. remain high

Share of NCE Approvals by Location of Original Marketing



Source: Tufts Center for the Study of Drug Development

- The number of approved NCEs marketed first in the U.S. rose to an all time high of 55% in 2002-04, up from 20% in 1987-89.
- Only 31% of the new drugs approved in the U.S. in 2002-04 had more than one year of foreign marketing prior to U.S. approval.
- The attractiveness of the U.S. as a favored market for first launch of new medicines remains high due to the size and strength of the U.S. market and the generally favorable regulatory climate created by PDUFA.

Approval times for standard and priority NCEs (years)

	1984-86	1987-89	1990-92	1993-95	1996-98	1999-01	2002-04
Priority NCEs	3.0	2.6	1.7	1.5	1.0	0.9	1.2
Standard NCEs	3.0	3.1	3.4	2.5	1.6	1.7	1.8

Definition of terms

Approval phase time — Time from date of submission of an NDA or BLA to date of FDA approval.

BLA — Biologics license application. An application to FDA for a license to market a new biological product.

Clinical phase time — Time from filing of an IND, which is necessary to begin testing of a new compound in human subjects, to the submission of an NDA or BLA.

IND — Investigational new drug application. Notification by a drug sponsor to the FDA of its intent to conduct clinical studies on human subjects.

NCE — New chemical entity. A new therapeutic compound that has never been used or tested in human subjects.

NDA — New drug application. An application to FDA for a license to market a new drug.

PDUFA — *Prescription Drug User Fee Act of 1992*. Legislation passed by Congress authorizing the FDA to collect user fees for regulatory review of new drug applications. The FDA agreed to use the revenue generated from user fees to hire more reviewers to speed up the drug review process without compromising review quality. PDUFA was reauthorized in 1997 and again in 2002.

Priority drugs — NCEs considered by the FDA to offer high therapeutic value and earmarked for priority review. FDA's Center for Biologics Evaluation and Research (CBER) also grants review status but the criteria are somewhat different than FDA's Center for Drug Evaluation and Research (CDER), because the products must also be for serious or life-threatening illness.

Standard drugs — NCEs viewed as offering little or no therapeutic advantages over existing therapies and receiving lower review status by the FDA.

About the Tufts Center for the Study of Drug Development
The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics.

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