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What's driving the surge in new-drug approvals?

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In 2012, new-drug approvals by the US Food and Drug Administration hit a ten-year high. Can the pharmaceutical industry make this trend last?

Much has been written about the pharmaceutical industry's R&D-productivity challenge during the past decade: the decline in new-drug approvals has raised discovery and development costs just as companies struggle to find new drugs to replace blockbusters that have lost (or will soon lose) their exclusivity. Yet by one important measure, the output of the pharmaceutical R&D process has accelerated significantly: the US Food and Drug Administration (FDA) approved 39 new drugs in 2012—the highest level in a decade.

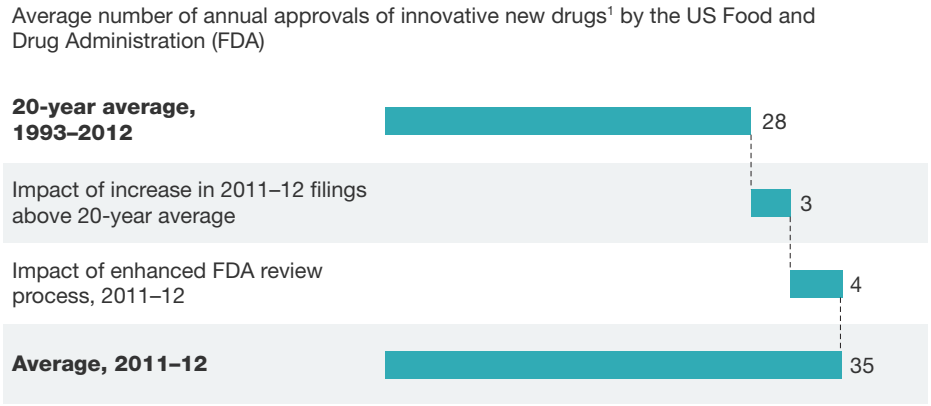
This promising surge has significant global implications, given the outsized role FDA approvals play in determining the industry's state. So is this a temporary uptick or the beginning of a phase of higher industry output and productivity? We believe that structural and operational changes within both the industry and the FDA have laid the foundation for an unusually high ongoing rate of drug approvals. The question is whether the global industry can seize the opportunity, as most innovative new drugs are approved in the United States first and then in other markets around the world.

Sustaining the surge

The number of new molecular entities—active drug ingredients never before marketed in the United States—that the FDA approves in a given year is an important measure of the pharmaceutical industry's health. During the past 20 years, an average of 28 innovative new drugs[1] were approved annually (exhibit). For much of the past decade, the number remained in the low to mid 20s, consistent with an industry-wide decline in R&D productivity. Yet in recent years, pharmaceutical companies have made serious efforts to improve their productivity and returns. Some are supplying drugs to combat diseases with high unmet needs. Others have aggressively

[1] New molecular entities or new biological entities.

Exhibit Several factors affect the recent increase in FDA approvals of innovative new drugs.



[1]New molecular entities or new biological entities.

Source: FDA public filings; McKinsey analysis

culled low-priority assets. Many have outsourced or shifted routine activities to lower-cost countries. And while countless things determine an industry's health, FDA approvals accelerated in 2011 and 2012, to a level about 24 percent above the long-term average.

We are cautiously optimistic that this development signals a turnaround in pharmaceutical R&D productivity. But three primary factors drive the acceleration in FDA approvals: the number of filings, the FDA approval rate, and regulatory review times. The new-drug approval rate is proportional to both the number of filings and the approval rate, but inversely proportional to review time. Our analysis found that while the top-quartile and median times to approval have remained relatively constant, approval times for the tail end of applications have recently decreased, partly as a result of higher approval rates for drugs submitted for the first time. The net result is that the distribution of approval times for 2011–12 was greater than or equal to the ten-year distribution, meaning that drugs were approved at faster-than-average rates during the past decade. We conclude that what drove the surge of new-drug approvals was an increase in the number of filings of new molecular entities by biopharmaceutical companies and a decrease in average review times. In other words, both the industry and the FDA played vital roles.

Under these circumstances, it is difficult to envision a significant *additional* uplift in the number of FDA approvals. However, the increased use of novel trial designs and regulatory approaches (such as the FDA's breakthrough-therapy designation) could meaningfully accelerate clinical-development programs. Such initiatives may decrease overall cycle times for the industry, which could sustain higher-than-average filing rates of new molecular entities into the medium term.

This article is drawn from *Regulatory Excellence: Achieving Public Health Impact Through Distinctive Regulatory Management Systems*, a new compendium from the McKinsey Center for Government (part of McKinsey's public-sector practice). This collection of articles examines effective regulatory systems now in place, as well as frameworks for new systems that could achieve excellence in other areas. For more, see the full compendium, on mckinsey.com. ▢

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