



New drugs, but slow access — how to speed breakthroughs to patients

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The U.S. Food & Drug Administration (FDA) approved [46 novel drugs in 2017](#), a 21-year high. However, it could take as long as six months for some of these groundbreaking medicines to reach patients, as pharmaceutical review committees work their way through complex clinical information to determine how, when, and why a new drug should be prescribed.

The way things stand now, the insurers and pharmacy benefits managers (PBMs) that set copayments, premiums, and reimbursement rates do not receive reliable data about a new treatment until it is approved by the FDA.

But it can take months to assess that information and establish appropriate prescribing standards, meet state health insurance rate filings, fulfill Medicare and Medicaid requirements, and negotiate contracts with health care purchasers.

It also takes time to conduct an economic analysis and allocate funds to cover reimbursements, particularly now that some drugs can cost hundreds of thousands of dollars, blowing a hole in pharmaceutical budgets that were calculated 18 months earlier.

Meanwhile, patients suffer. When the breakthrough Hepatitis C drug [Sovaldi](#) was approved in December 2013, it was priced at \$84,000 for a course of treatment.

With some 4 million adults in the U.S. diagnosed with the deadly liver disease at the time, insurers had to scramble to figure out which patients would benefit from such an expensive drug, and how much they should budget to cover the cost.

Sovaldi was essentially a cure, replacing far less effective treatments, so the high price could be justified by the years of life gained by patients. But deciphering the data supporting that cost/benefit calculation took up to a year after approval for some payers — a year many patients could ill afford.

A bill introduced last year, [H.R. 2026](#), calls for shortening the lag-time between FDA approval and patient access to new drugs, called the Pharmaceutical Information Exchange (PIE) Act.

It would allow drug companies to share economic and scientific information on an investigational drug with insurers, pharmacy benefit managers, and other groups that establish prescribing and reimbursement policies 12 to 18 months ahead of FDA approval.

With such critical information in hand well in advance, appropriate coverage decisions and budget allocations would be in place as soon as a drug is approved.

The PIE Act contains strict guardrails to prevent this information from reaching patients, investors, and the public — only those involved in making decisions about payment and prescribing standards would have access. The PIE Act also requires that all shared information be truthful and based on competent and reliable scientific evidence.

In some ways, the bill replicates regulations the FDA is already starting to put in place. The [FDA Modernization Act of 1997](#), and the [21st Century Cures Act](#) passed in 2016, both authorized the FDA to allow pharmaceutical companies to share some economic and scientific data with drug formulary decision makers.

The agency produced draft guidance a year ago, but those guidelines do not have the force of law, as legislation would. The PIE Act would clarify exactly what kinds of information can be shared pre-approval and with whom, and would spell out restrictions.

The FDA is [streamlining its approval process](#) to expedite the advance of breakthrough drugs, so the stream of new medicines will almost certainly continue to grow.

First-in-class immunotherapies, personalized medicines, and gene therapies are also beginning to reach the market — the [first three gene therapies were approved last year](#) — making coverage, prescribing, and budgeting decisions even more challenging.

It is critical that Congress pass the PIE Act if patients are to have expedited access to these innovative treatments. For patients waiting for breakthrough medicines, every minute counts.

Susan A. Cantrell is the chief executive officer, Academy of Managed Care Pharmacy.

