the breakthrough-designated compounds, SD-101 is an orphan, and thus already fast-tracked in terms of regulatory review. But "we're hoping that [breakthrough] may expedite development plans as well," says Coull.

For now, then, breakthrough's impact on biotechs is patchy. "The true measure of success is going to be how active we are in working with the companies. If someone gets a breakthrough therapy and it's business as usual, then the breakthrough therapy is meaningless," said FDA's Pazdur in the *Forbes* interview.

Indeed, some suggest FDA is in danger of prioritizing too many candidates through its various expedited review programs. They question whether FDA has sufficient resources required to deal with over two dozen breakthroughs per year. "Someone else was on that calendar" that's cleared for breakthroughs, notes Avalere Health senior vice president Gillian Woollett. "If you're putting tons of resource behind something, other things have to fall by the wayside." And that raises a bigger public health question—whether FDA should be favoring to such an extent drug characteristics most likely to apply to those treating niche conditions, where well-defined patient groups and genetic markers make early clinical evidence more plausible. "The [breakthrough] program's great, on the face of it, but it's difficult to reconcile with public health" more broadly, says one commentator, who wants to remain anonymous. Shouldn't drug development programs be as efficient as possible and address unmet need as a matter of course, across any condition, severe or otherwise? At least the experience with breakthrough drugs may provide lessons for more efficient drug development across the board.

And although drug cost isn't part of FDA's remit, it is highly relevant to payers. Breakthrough-designated programs are likely to carry high prices. On one hand, this may facilitate payers' jobs by highlighting star treatments that show compelling additional benefit. "Breakthrough should have a big impact on the management of unmet need," suggests Pharmacyclics' Gayko. But too many star treatments, with prices to match, will have a big impact on budgets, too.

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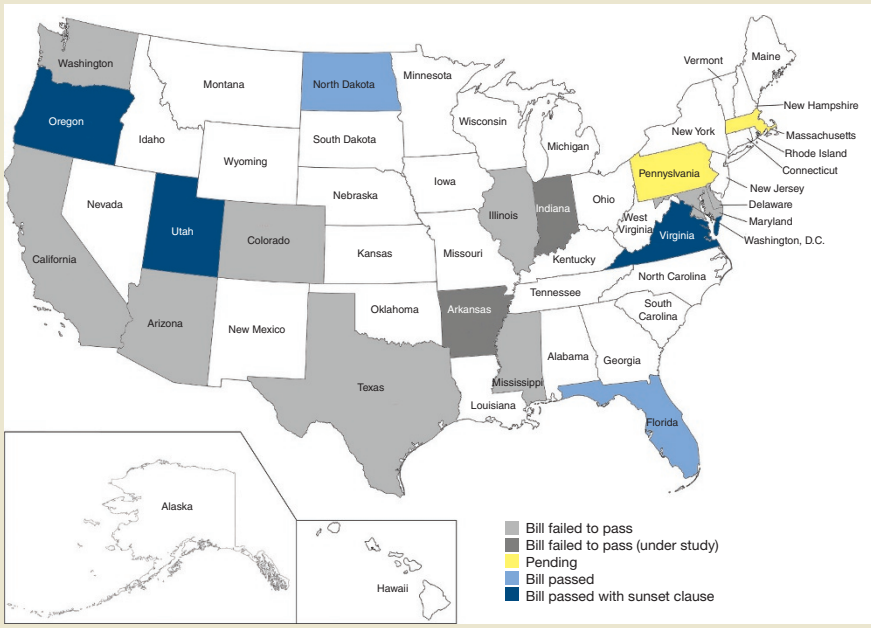

Biosimilars legislation state by state

California in October became the latest state to reject a controversial bill designed to stop automatic substitution of brand-name biologics for interchangeable biosimilars. The bill, backed by innovator biotechs such as Amgen and Genentech, pushes for biosimilars to be defined as interchangeable by the US Food and Drug Administration before pharmacists can substitute them as a default practice. The legislation has failed to pass in 11 states.