EDITOR'S DESK

BY MARC ISKOWITZ

Off-label and on the record

A MIDSUMMER WONK'S POLICY DREAM—As we closed this month's issue, our news staff kept eyes and ears attuned to a suddenly hot policy front. As of mid-July we had seen the high court avert a near disaster for healthcare reform, legislation that could bring change to FDA off-label enforcement and courtroom drama involving drug industry free speech.

In some respects, what didn't happen was just as interesting as what did. So let's look back while considering some of the what-if's.

First came the Supreme Court's late-June decision in *King* v. *Burwell*, which could have upended the Affordable Care Act if the Justices had ruled that the IRS had overstepped its authority in providing subsidies to people who buy insurance on exchanges.

Had a majority sided with King, "It would just be really devastating to many patients, as well as a setback for many of the gains we've seen," said Dora Hughes, a physician who spent 10 years at HHS before becoming a senior policy adviser for Sidley Austin. However, some ACA-related gains could not have become unraveled even in the latter scenario.

Could Rep. Fred Upton's signature bill become a legacy for life sciences?

In terms of the move to quality improvement, integrated health systems and risk sharing, she said, "Those are now interwoven into the way the federal government is doing business. Those transformations will continue to go forward."

As John Kamp, executive director at the Coalition for Healthcare Communication, pointed out, supposing *King* had gone the other way, "that's all the Congress would have been looking at, and we couldn't have gotten 21st Century Cures done. With *King* going the way it did, the impetus to move something in the House was very different."

Indeed, shortly after *King*, the House of Representatives passed the 21st Century Cures bill, whose main aim is to speed approvals but includes three important communications provisions: clarifying FDAMA 114's scope on healthcare economic information; calling on the FDA to issue a guidance within 18 months on truthful, non-misleading information; and clarifying that certified CME events are exempt from Sunshine reporting. (Our recaps appear on p. 12.)

Meanwhile, a New York federal courthouse was the scene of further July action, as the FDA defended—some say weakly—its off-label marketing policies as part of a hearing in *Amarin* v. *FDA*. The what-if's here: The judge may issue an order limiting the FDA's off-label enforcement or craft an opinion giving relief to Amarin while not undermining the FDA's overall authority.

As far as the Cures bill, the path toward Senate passage is trickier, predicted Hughes. "There's greater deference, or at least interest, in what the [Obama] administration's views are by Senate Democrats."

Sen. Lamar Alexander (R-TN)—who chairs the Senate Health, Education, Labor and Pensions Committee—does not have the same motivation as did Rep. Fred Upton (R-MI), chairman of the House Energy and Commerce Committee. Upton's term ends with this Congress.

It now appears that Alexander won't bring forward a bill until September or October, quite close to election year. And if that's the case, most of what's in the Cures bill could be tabled until the next FDA appropriations, or PDUFA, bill, said Kamp.

For more "suppose-so's," see our roundtable starting on p. 30. As you read what these possible changes to FDA's off-label policy may mean, ponder whether Rep. Upton's signature bill could become a legacy for life-science communicators, as well.

Agenda

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