Washington Insider

BY JAMES G. DICKINSON

Social media's increasing volatility is shifting the balance of power in Washington in unexpected ways. Its impact on Capitol Hill and on the campaign trail is widely known, but would you expect lowly patient power on social media to shake the job of a high-level FDA center director?

That's what has been happening to FDA medical devices chief Jeffrey Shuren at the direction of a Philadelphia-area heart surgeon whose wife was devastated with cancer spread by an FDA-cleared device called a power morcellator. Patient activists say the FDA should ban the devices.

The surgeon, Dr. Hooman Noorchashm, deftly used social media to connect with other similarly injured patients, family members, lawyers, journalists, health professionals and activists, FDA officials and Capitol Hill staffers to not only bring about a labeling change for the device but also to force one manufacturer to quit the market.

Would you expect that patient power exerted through social media might shake the job of a high-level FDA center director?

But that didn't satisfy Noorchashm. He broadened his attack to include patients injured from the Essure permanent birth control device.

As his network grew, Noorchashm targeted Shuren for allegedly "being in bed with" industry through his support of device marketing without proof of safety and through Shuren's wife, Allison, and her legal work with device companies as a partner at the law firm Arnold & Porter.

All of this he spread throughout his network, blow by blow. The FDA was forced to issue a public statement, saying the agency "is committed to ensuring agency employees avoid conflicts of interest." Before he was appointed, Shuren "went through FDA's rigorous ethics review process to identify and avoid any potential conflicts of interest including in relation to his wife's law firm partnership," the FDA said.

That didn't mollify Noorchashm or his network. Their campaign to force Shuren from office is escalating at press time.

James G. Dickinson is the editor Dickinson's FDA Webview (fdaweb.com).

Omitting risk info is top reason for FDA warning

ABOUT 60% of FDA warning letters and untitled letters issued to pharmaceutical firms in the past two years cited omitted risk information in promotional materials, say J&J executives.

Kardashian West: FDA warning letter became national news

The FDA's most recent warning became national news when the agency told Duchesnay that Kim Kardashian West's promotion of Diclegis violated FDA rules because she had omitted information about the drug's risks. Kardashian later issued correctives on Twitter, Instagram and Facebook.

The regulator issued 37 untitled letters and 6 warning letters to pharmaceutical companies from 2013 to 2015, according to Sheetal Patel, J&J's director of regulatory advertising and promotion, and John Riehl, a regulatory advertising and promotion fellow at the company.

The FDA issues fewer warning letters, which require corrective action by the company, than untitled letters, which are for less serious violations and usually request, rather than require, a company response.

Pharma has argued for years that the FDA's regulations for social media limit the industry's use of new channels for drug promotion and education. The FDA has since issued guidance for Twitter and paid search. Still, Jack Scannelli, head of regulatory advertising and promotion at Novartis, said he doesn't expect the FDA to issue guidance for each social-media channel.

"By the time they come out with a guidance on a certain platform, it may be totally useless," he said. *—Jaimy Lee*

Sanders against Califf nod for FDA

THE OBAMA administration's nomination of Dr. Robert Califf as FDA commissioner is under scrutiny. Califf currently serves as the agency's deputy commissioner, overseeing medical products and tobacco. A cardiologist, he held various roles at Duke University Medical Center.

Sen. Bernie Sanders (I-VT), a presidential candidate, said he will oppose the nomination in part because of Califf's ties to the pharmaceutical industry. As a long-time researcher, Califf received $29,000 in non-research payments and other transfers of value made by manufacturers in 2014, according to the Open Payments database.

The Boston Globe reported on Oct. 7 that Califf had asked that his name be removed from a series of scientific papers he co-authored that questioned FDA oversight of clinical trials prior to publication. A spokeswoman for Califf declined to provide comment to the *Globe*. *—JL*

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