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## Ex-FDA Head Says He Didn't Ask NY Docs About Opioid Rx's

By **Emily Field**

Law360 (August 14, 2020, 9:46 PM EDT) -- Former U.S. Food and Drug Administration Commissioner David Kessler on Friday conceded during hearings in the New York attorney general's suit over the opioid crisis that he didn't ask doctors why they wrote opioid prescriptions and he didn't identify inappropriate prescriptions in reaching his opinion that companies' allegedly improper promotions fueled abuse.

Under questioning from Johnson & Johnson lawyer Steve Brody of O'Melveny & Myers LLP, Kessler said he didn't talk to New York doctors nor did he look at individual patients' medical histories or outcomes in determining his opinion. The so-called Frye hearings in the suit, which are used to determine the admissibility of scientific evidence, started on Friday and are scheduled to continue into next week.

"On the subject of doctors, Dr. Kessler, you acknowledge that there are numerous factors that may impact a New York doctor's decision to prescribe a medication?" Brody asked.

"Correct," Kessler replied.

Brody asked if doctors make prescribing decisions based on a "whole host" of factors, such as affordability of a medication, clinical trial results and a drug's adverse event profile, to which Kessler said yes.

Kessler also said it went beyond the scope of his methodology to talk to individual doctors and he considered it inappropriate to review patients' medical histories.

Earlier in the hearing, which was livestreamed, Kessler said he based his opinions on his review of U.S. drug laws and regulations and industry standards in context with his review of the companies' promotional and marketing materials.

"Would it be fair to say that you determined there were departures from the appropriate standards of marketing and promotion?" Hunter Shkolnik of Napoli Shkolnik PLLC, representing Nassau County, asked.

Kessler replied that he had.

"Promotion can, will affect what's said about a drug, promotional efforts will affect prescribing, and the more prescribing, the more use of a drug," Kessler said. "And if its deviations for indications beyond what's on the label ... that could put people at risk."

The highly anticipated trial was set to start on March 20 but was put on hold due to the pandemic. A new trial date has not been

scheduled yet.

The trial is expected to test allegations from New York and Suffolk and Nassau counties against major drug manufacturers and distributors.

Earlier this week, New York Supreme Court Justice Jerry Garguilo said he would allow "meaningful public access" to hearings in the suit after opioid companies protested against livestreaming.

Judge Garguilo said the exceptions against making court proceedings public — which include cases involving divorce, abortion and rape — clearly do not apply here, according to a short order filed on Aug. 10.

Although states and local governments have filed thousands of cases blaming drug companies for the opioid crisis, only one case has gone to trial. That trial saw Oklahoma's attorney general win a \$465 million judgment against Johnson & Johnson, which is appealing.

New York's attorney general had argued that the current suit is exactly the kind of case that should be broadcast, as it's a government suit over a major public health issue.

The case is In re: Opioid Litigation, case number 400000/2017, in the Supreme Court of New York, Suffolk County.

--Additional reporting by Jeff Overley. Editing by Janice Carter Brown.

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