



Recent Developments on the Opioid Front

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The “Opioid Crisis” continues to drive measures that will significantly affect the pharmaceutical industry in general, the relationship between prescribers and their patients, and the role of regulators – and law enforcement – in medical decisions. As the White House is reportedly preparing to declare the opioid epidemic a national emergency,¹ which could lead to a wide range of agency actions,² and as the number of government-backed lawsuits against the pharmaceutical companies continues to grow, with reports almost daily of new cases filed across the country,³ federal and state legislators, too, are taking up the cause. Within the last couple of weeks, proposed or announced legislative initiatives have included the following:

On October 16, 2017, following a joint Washington Post/*60 Minutes* investigation that found that a provision in the *Ensuring Patient Access and Effective Drug Enforcement Act of 2016* had “dramatically restricted the ability of the Drug Enforcement Administration (DEA) to crack down on opioid distributors suspected of wrongdoing,” Senator Claire McCaskill announced plans to repeal the legislation.⁴ The provision weakened the standard for freezing suspicious and suspiciously large pharmaceutical shipments, and limited the DEA’s authority to go after companies that failed to report such suspicious shipments. On October 17, Representative Tom Marino, who had been a primary sponsor of the legislation and was the nominee to lead the White House Office of National Drug Control Policy, announced that he was withdrawing from consideration for the post.⁵

On October 13, 2017, a Florida state Representative introduced legislation that would place a three-day limit on prescriptions involving opioids and establish a database for medical providers to better track patient records.⁶ While the proposed three-day limit is stricter than the seven-day limit common in most states that impose such limits, doctors still may provide seven-day prescriptions in some cases. However, physicians must first prove it is “medically necessary to treat the patient’s pain as an acute medical condition,” and document the “lack of alternative treatment options to justify” the seven-day script.⁷

The State of Iowa, which ranks near the bottom in the rate of opioid deaths, is also considering measures to combat the epidemic. These measures reportedly include: limits on the length of opioid prescriptions; a requirement that prescribers consult the state’s Prescription Monitoring Program, which can help identify individuals who attempt to obtain opioid painkillers from multiple sources; a needle exchange program; and a “Good Samaritan” law, which provides immunity for an

1 <http://www.cnn.com/2017/10/16/politics/donald-trump-opioids-national-emergency/index.html> (last visited Oct. 24, 2017).

2 <http://nymag.com/daily/intelligencer/2017/10/report-trump-administration-doesnt-have-an-opioid-strategy.html> (last visited Oct. 24, 2017).

3 See, e.g., <http://www.jsonline.com/story/news/local/milwaukee/2017/10/19/milwaukee-county-panel-endorses-hiring-legal-experts-lawsuits-against-opioid-drug-makers-distributor/778100001/> (last visited Oct. 24, 2017); <http://www.post-gazette.com/news/overdosed/2017/10/16/Beaver-County-suing-opioid-painkiller-firms-doctors/stories/201710160126> (last visited Oct. 24, 2017); <http://www.freep.com/story/news/local/michigan/2017/10/12/wayne-oakland-sue-drugs-opioid/757822001/> (last visited Oct. 24, 2017); <http://www.washingtontimes.com/news/2017/oct/6/newark-sues-opioid-makers-alleging-deceptive-adver/> (last visited Oct. 24, 2017).

4 https://www.mccaskill.senate.gov/media-center/news-releases/mccaskill-announces-legislation-repealing-2016-law-after-reports-that-it-prevented-aggressive-dea-enforcement-of-opioid-distributors_-- (last visited Oct. 24, 2017).

5 <https://www.nytimes.com/2017/10/17/us/politics/trump-says-drug-czar-nominee-tom-marino-withdraws-from-consideration.html> (last visited Oct. 24, 2017).

6 <http://dailycaller.com/2017/10/14/florida-politicians-go-full-throttle-on-containing-opioid-epidemic/> (last visited Oct. 24, 2017).

7 *Id.*

individual who contacts authorities or emergency personnel to notify them of another individual who has overdosed.⁸

While these recent examples of legislative efforts to combat the opioid crisis represent only the immediate visible tip of what is likely to prove a significant iceberg, they are indicative of a sea change in the tone and tenor of enforcement within the pharmaceutical industry. The central characteristic of these efforts is the expansion of the *responsibility* for causing the crisis beyond the users to the manufacturers, distributors, sellers, and prescribers of opioids.

In a possible sign of things to come, last week STAT's Pharmalot reported that the State of California wants to revoke the pharmacy wholesaler license for a Valencia facility operated by Cardinal Health, one of the three largest pharmaceutical distributors in the country. The report states that California's interest in revoking the license stems from the company's apparent failure to notice unusual and increasingly large sales of opioids and other highly regulated drugs to a single pharmacy. The drugs noted include Norco and Xanax, and the sales occurred between 2013 and 2015. According to the report, these sales constituted "red flags," that were not noted by the distributor.⁹ If California is successful in this effort, the concept of responsibility, itself, will expand beyond allegations of industry complicity in the crisis to specific allegations of failure to act or to prevent cases of illegal opioid use and distribution.

⁸ <http://www.thegazette.com/subject/news/government/iowa-lawmakers-scrutinize-opioid-law-options-20171021> (last visited Oct. 24, 2017).

⁹ <https://www.statnews.com/pharmalot/2017/10/18/california-cardinal-health-opioids/> (last visited Oct. 24, 2017).

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