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Expert Analysis

Opioid Solutions: Insurance, Legislation Or Litigation?

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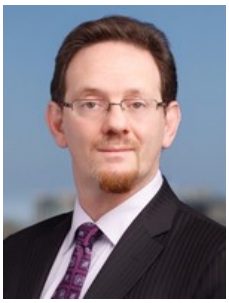
Adam Fleischer

The past month has illustrated that while the opioid epidemic has worsened, solutions to the crisis have begun to emerge. Some solutions are rooted in legislation, while others derive from litigation. All solutions are destined to be very expensive and raise questions as to whether the cost of the opioid battle is more justifiably absorbed by public health legislation, the private pharmaceutical industry or the insurers whose policies were aimed at compensation of discrete injury and of course not wholesale societal repair. These issues are summarized below.

The Epidemic Grows

In 2016, there were 42,249 deaths in the U.S. from opioids, a 28 percent increase from 2015. On March 6, 2018, the Centers for Disease Control and Prevention released new statistics to show where the epidemic is now. It is not good news. From 2016 to 2017, the number of opioid overdoses in hospital emergency rooms jumped by 30 percent. Emergency rooms in the Midwest saw a 69.7 percent increase, with Wisconsin being hardest hit. CDC Director Anne Schuchat commented that the increase may even be worse than the statistics show because many people who overdose do not ever end up at hospital emergency rooms. The CDC believes that while the number of people addicted to opioids may have leveled, the injuries continue to rise because the substances themselves are getting more dangerous. Illegal fentanyl flooding American streets may be 80-100 times stronger than morphine, and one analogue, Carfentaril, is up to 10,000 times stronger than morphine. The opioid epidemic is not slowing.

Legislative Solutions Emerge

Solutions to the epidemic are starting to be delineated, with billions of dollars needed for: 1) addiction treatment; 2) re-education of physician pain management training; 3) sharing of federal and state prescription databases to police proper prescription and distribution; 4) changes to the drug quotas manufacturers are required to produce; 5) changes to the marketing of opioids, and; 6) changes to the health industry's funding of alternative pain management. In 2016, Congress passed the Comprehensive

Addiction and Recovery Act (CARA), which sets forth general goals for battling the opioid epidemic, but with a yearly appropriation process necessary to earmark certain funds for certain prevention efforts.

Within the last month, a bipartisan group of senators has introduced a bill dubbed CARA 2.0 that delineates specific programs to be the recipient of portions of the $6 billion in opioid funding that last month's federal budget has committed over the next two years. The bill proposes $10 million to fund a national education campaign on opioids, $300 million to increase training for first responders, and $200 million for recovery support services. On the House side of the Capitol, the Energy and Commerce Committee is working to pass aggressive opioid legislation by Memorial Day. A key feature of the House plan will require a 3 day limit on the initial prescription of opioids for acute pain. The proposal will also call for funding of a nationwide system of "opioid courts."

Yet another opioid bill was introduced in the Senate on March 12. This bill would allow the U.S. Drug Enforcement Administration to take into account overdose deaths and abuse rates when it sets quotas for how much of a certain drug manufacturers are required to produce each year. Currently, the DEA is required to set quotas on drugs based on the amounts used and sold in the previous year, with an added increase in case of emergency. In other words, under current law, because opioids are being overused and overprescribed, the DEA would be required to order manufacturers to produce the same inflated number of pills next year, with potentially even a higher cap. The application of this illogic led to the DEA approving increases in opioid production quotas each year from 1993 to 2015, with a 39-fold increase for oxycodone during that period.

Solutions Through The MDL?

While Congress has begun to appropriate billions of dollars toward solving the opioid crisis, lawyers bombard local and state governments with marketing materials to race to the courthouse to pursue funds to replace and replenish those spent on the epidemic. Approximately 300 such suits have been consolidated in a national multidistrict litigation in the Northern District of Ohio before Judge Dan A. Polster. Upon receipt of this MDL, Judge Polster set his sights immediately on resolution, commenting at one preliminary hearing "It is [not] in anyone's interests to have this dragging on for five or ten years. ... My objective is to do something meaningful to abate this crisis and to do it in 2018 ... We don't need briefs and we don't need trials. None of those are going to solve [the crisis] we've got."

Therefore with the MDL having emerged as another force pushing for resolutions to the crisis, the last month has seen a potential breakthrough in information sharing that previously did not exist. The most comprehensive database monitoring opioid prescriptions from doctors and pharmacies across the country is the Automated Records and Consolidated Orders Systems database (ARCOS). That database is controlled by the DEA and U.S. Department of Justice and not shared with manufacturers or distributors. In order to understand which defendants had distributed how many opioids and where, the plaintiffs in the MDL subpoenaed information from the ARCOS database. On Feb. 26, 2018, the DOJ filed a notice of compliance in which it agreed to provide the MDL court information to help "identify non-party manufacturers whom (the Court) believes should be part of the settlement process and to identify possible fault by DEA registrants by comparing communities that received the most prescription opiates with CDC statistics." The DOJ agreed to produce "the names of all manufacturers in each state who comprise 95% or more of the market share for certain opioids (and) a spreadsheet of data exported from the ARCOS database for each of the 50 states and Puerto Rico with transaction data for 2012 and 2013." While this production on one hand allows the MDL to continue Judge Polster's push toward settlement, it also highlights the difficulty in accessing important government data that some argue is the necessary foundation for solutions to solve the crisis.

Solutions Through "Opioid Courts"

Last November, a national opioid commission recommended nationwide drug courts to help opioid users break their addiction rather than sending them to prison where the addiction festers and grows. Currently, fewer than one third of federal districts have such drug courts. Buffalo City Court does operate the nation's first opiate crisis intervention court. Opiate offenders appear before a judge who channels nonviolent offenders into recovery rather than jail. Through this system, an addict interested in treatment can get into a program within hours of the court hearing and the criminal process is on hold. The Buffalo program requires addicts to check in nightly with a court staffer, enter counseling, adhere to a curfew and attend a court hearing every weekday for a personal visit with the judge. If a hearing is missed, a warrant is issued for the defendant's arrest. Such courts are thought to be an integral piece of getting help to those most in need, and decreasing the burden on the penal system, as well as decreasing the likelihood of losing an addict back into the chaotic commerce of opioids.

A New Litigation Focus?

On March 12, 2018, CNN and Harvard University released the results of an investigation concluding that physicians who prescribed large amounts of opioids in 2014 and 2015 received large speaking and consulting fees from opioid manufacturers. The study authors cross-checked one government database that tracks payments from drug companies to doctors, and a second database that details which doctors prescribed how many opioids to Medicare patients. The results showed that of those doctors who prescribed opioids, more than 54 percent, or over 200,000 doctors received payments from opioid manufacturers. CNN's study also concluded that those doctors who prescribed more opioids were likely to have received larger payments, with doctors whose opioid prescription volume was in the top 5 percent nationally receiving twice as much money from opioid manufacturers than doctors whose prescription volume was in the median. While it is illegal for doctors to receive "kickbacks" for prescribing certain medications, it is indeed legal for doctors to receive fees from opioid manufacturers for speaking, training, education and consulting.

The link between such payments to doctors and the type and amounts of opioids they prescribe has already been the subject of at least one lawsuit against manufacturer Insys, as well as additional studies by the University of North Carolina and Boston University. As new lawsuits and legislation bring increased pressure to the industry, the manufacturer of OxyContin, Purdue Pharma, announced within the last month that it will stop marketing opioid drugs to doctors, and plans to cut its opioid salesforce by 50 percent. The exploration of the link between doctor payments and opioid prescriptions is sure to become a focus of continuing litigation against the manufacturers, as well as potentially bringing litigation focus to doctors who may need to justify the payments they have received from the manufacturers.

Liability Insurers In The Crosshairs?

The last month's examples of emerging opioid solutions tell of a patchwork of causes and blame for the country's predicament. With such varied causes and solutions, the proposals illuminate the different scope of funding responsibilities as between government gatekeepers versus corporate profiteers versus the liability insurers caught in the middle.

A manufacturer whose widget is defective, which then causes a user to break her leg, may typically seek insurance to fund the manufacturer's liability for the unexpected and unintended harm to that user. In this manner, liability insurance serves an important societal purpose in spreading the risk of such unintended injuries, thereby allowing protection for both widget makers and widget users. However,

insurance policy wording and case law have developed important safeguards and limitations that maintain the benefit of the bargain for the insured, the customer and the insurer. For example, if the manufacturer intentionally mismarkets the product to achieve maximum profit, then insurers typically do not cover the repercussions of such intentional business schemes. Instead, such damages typically are paid from the wrongfully gained profits. Furthermore, if a slip and fall injury results in changes to government flooring requirements or inspection protocol, these costs are not paid by the insurers, but are instead funded by the government agencies responsible for administering such obligations to the public.

Putting these fundamental concepts into the opioid context demonstrates why liability insurers of the pharmaceutical defendants are not the likely source to fund the billions of dollars being appropriated for new pain management training, addiction training or governmental changes in prescription monitoring, reporting or data sharing. Such societal changes have been the subject of government and administrative oversight, proposals and debate for almost a decade, and the costs of societal reforms must fall to those same governments that control the appropriation of such societal funds. Similarly, the costs of harm caused by companies who intentionally monitored and rewarded the doctors prescribing the most opioids are costs that are likely to be borne by the doctors and companies that intentionally profited from such arrangements and not borne by the liability insurers who contracted to compensate liability for unintentional conduct causing specific harm to individuals.

In fact, one piece of legislation best demonstrates that the opioid crisis is a societal problem to be balanced between government policymakers and those companies profiting from the government policies. A pending bill known as the Budgeting for Opioid Addiction Treatment Act (LifeBOAT Act) seeks to establish a 1 cent fee on each milligram of active opioid ingredient in a prescription pain kill. The proceeds of this tax would be used to fund and expand opioid treatment programs across all states.

At the most fundamental level, the opioid epidemic is a societal injury caused by the interplay between for-profit companies who have produced, marketed and profited from a series of pills, and those multiple governmental entities responsible for monitoring, administering and coordinating the programs and procedures to ensure that these drugs are responsibly prescribed and used. While the defendants in the opioid litigation will continue their efforts to pass their financial responsibility to liability insurers, the fundamental nature of the insurance risk and the wording of the insurance contracts are expected to prevent such passing of financial responsibility to an insurance structure that was not created to bear this weight.

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