New report on Big Pharma settlements highlights need for tougher enforcement
BY MICHAEL A. CAROME, M.D. | MARCH 14, 2018

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In honor of Sunshine Week, AHCJ invited organizations devoted to government transparency to write about how their work can help health care reporters. Here is the second of four.

Public Citizen's Health Research Group today released an updated report cataloging all major financial settlements that the pharmaceutical industry has been forced to sign with federal and state governments from 1991 through 2017 for illegal activities.

The report shows a dramatic decrease since 2013 in both the total amount paid and the average penalty. Additionally, it found that state governments have virtually stopped prosecuting pharmaceutical manufacturers on their own initiative and with their own resources.

The companies paid fines for law-breaking such as marketing drugs for unproven uses and paying kickbacks to doctors.

We believe that much larger penalties, as well as successful prosecutions of executives that oversee systemic fraud, are necessary to deter future unlawful behavior.

The Health Research Group is a research-based health advocacy organization that promotes system-wide changes in health care policy and drug safety. For more than four decades, our group has been a leading consumer watchdog over the pharmaceutical industry and the Food and Drug Administration's regulatory oversight of that industry.

Today's report – the fourth edition of one originally published in 2010 – expands the previous March 2016 release with settlement data from 2016 and 2017. From 1991 through 2017, 170 federal settlements with pharmaceutical companies were reached for a total of $34.8 billion, and 242 state settlements were reached for a total of $3.9 billion

The report's most striking finding is a precipitous drop in federal criminal penalties against drug companies. In 2016-2017, federal criminal penalties totaled just $317 million from four settlements. This represents a nearly 90 percent plunge in financial penalties compared with 2012-2013 when criminal penalties totaled $2.7 billion from 10 settlements.

Among all federal penalties – both civil and criminal – the number of settlements fluctuated but their total dollar value dropped steeply after 2013, and the average amount paid fell in each successive two-year period.

In 2012-2013, pharmaceutical companies reached 22 settlements totaling $8.7 billion – an average of $394 million per settlement.

In 2014-2015, they reached 19 settlements valued at $2.4 billion – an average of $128 million.

And in 2016-2017, they reached 29 settlements totaling $2.8 billion – the average payment now down to a mere $97 million.

That represents a 75 percent drop in the average penalty over six years.

This change is primarily due to lower penalties for unlawful promotion of prescription drugs. Such penalties have declined by 94 percent since 2012-2013, reaching the lowest two-year total in 14 years.

At the same time, the states now are doing little to police the industry. In 2016 and 2017, there were just nine state settlements for a total of $82 million, the lowest two-year total for both the number of settlements and the amount of financial penalties since 2004-2005.

Meanwhile, the pharmaceutical industry has been hugely profitable. The 11 largest drug companies took in $711 billion in net profits from 2003 to 2012.

From 1991 through 2017, GlaxoSmithKline and Pfizer paid more in financial penalties – $7.9 billion and $4.7 billion, respectively – and reached more settlements (32 and 34, respectively) with the federal and state governments than any other companies.

In an extremely rare enforcement action targeting drug company officials, several executives and managers of the pharmaceutical company Insys – including its founder and majority owner, John Kapoor – were arrested in 2016 and 2017 for allegedly paying bribes and kickbacks to health care providers in exchange for prescribing the company's fentanyl spray, Subsys. This potent opioid is approved by the Food and Drug Administration only for the treatment of breakthrough pain in cancer patients, but the government alleges that the kickbacks were paid to practitioners in exchange for prescriptions, most of which were not for cancer patients.

Unless federal and state governments put more muscle into enforcing the law, illegal but profitable activities will continue to be part of pharmaceutical companies' business model.