

Health Care Enforcement Update: What Is in Store for the Next Five Years

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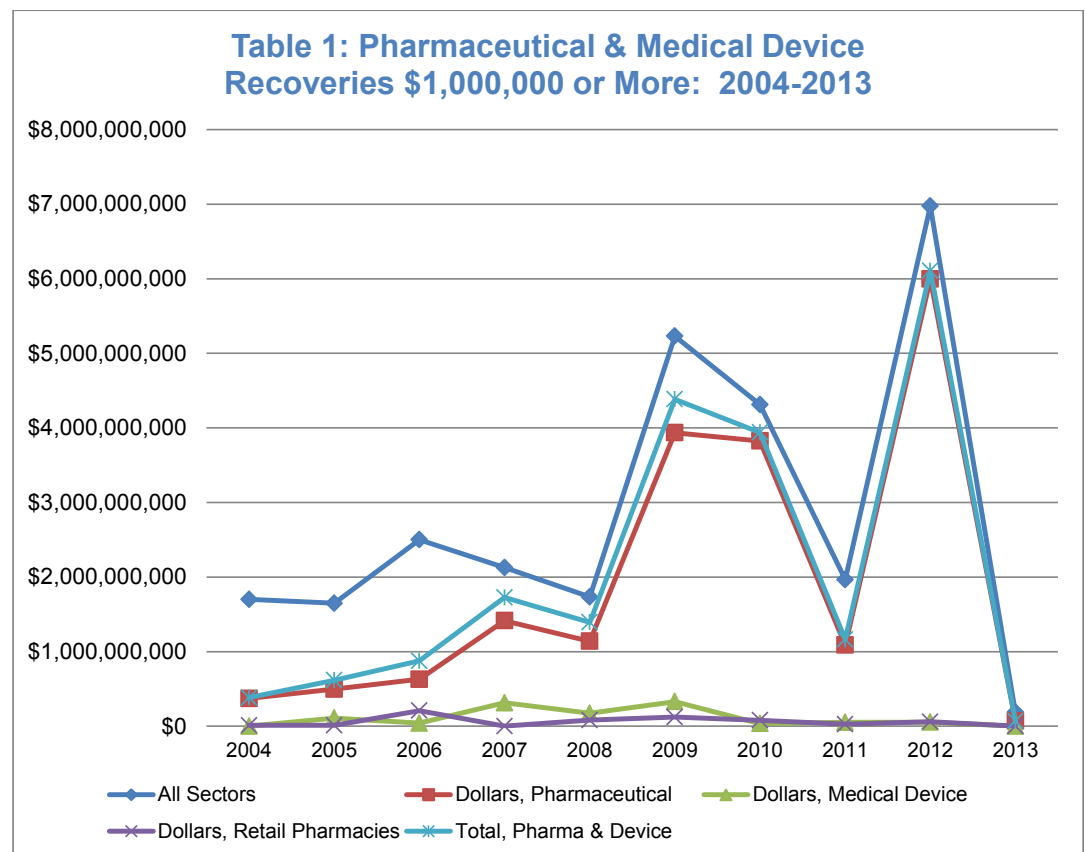
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While predicting enforcement trends over the next five years is not without uncertainty, the best marker for future activity may be to look to the past. We believe that industry members and counsel can expect the Department of Justice and its enforcement partners, the Office of Inspector General for the Department of Health and Human Services, the Food and Drug Administration, and the Federal Bureau of Investigation, to essentially remain on their current course, subject to certain trending modifications.

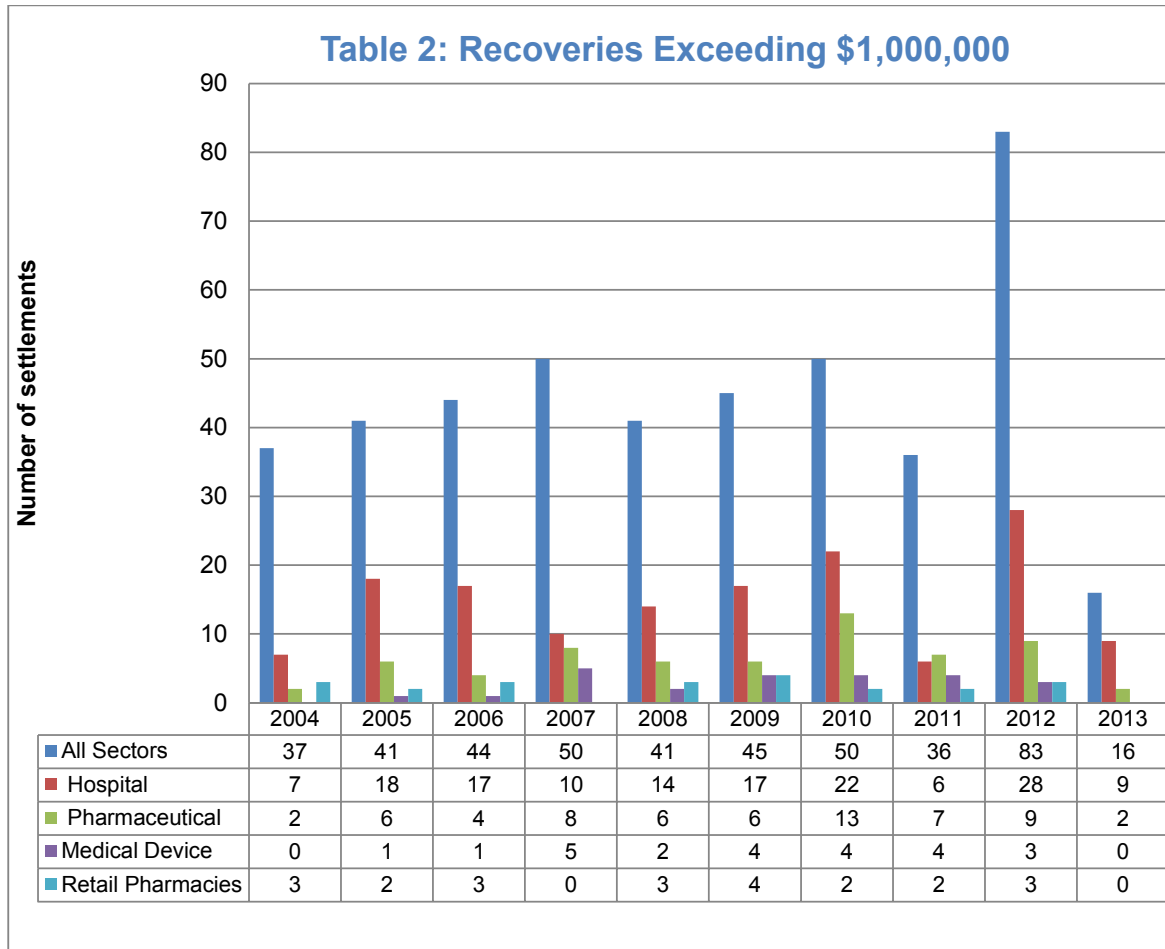
The following tables reflect criminal and civil resolutions by the federal government over the past 10 years where the resolution was \$1 million or higher. Table One reflects all health care settlements and settlements in three specific industry sectors: pharmaceutical, medical devices and retail pharmacies.

Table 1: Pharmaceutical & Medical Device Recoveries \$1,000,000 or More: 2004-2013



In seven of the past 10 years, government recoveries have fluctuated consistently between \$1.6 billion and \$2.5 billion. However, in three of the past four years, recoveries substantially exceeded that range, including a recovery of nearly \$7 billion in 2012. Recoveries in 2013 are dramatically lower and have not exceeded \$200 million through May. Whether this is a harbinger of a dramatic drop in settlements remains to be seen, as one or two cases later this year with recoveries in excess of \$1 billion will push the year’s total into the “normal” range. The sector breakdown demonstrates that outside pharmaceuticals, government settlements have been relatively small in each of the past 10 years. See our [appendix](#) on page five for a table detailing the settlements.

Table Two below reflects the number of settlements by certain sectors and overall.



As seen above, there is a small number of settlements in each sector in each year. The government has publicly announced a focus on the drug and device industries; nevertheless, the total number of settlements in any one year in those two sectors combined has never exceeded 17. Despite the apparent government focus on the medical device industry, there have been three or more \$1 million-plus settlements in only four of the past 10 years. In addition, the numbers of settlements has remained remarkably consistent from one year to another, ranging between 36 and 50. The 2012 election year had the highest number of settlements (83) and highest dollar recoveries (almost \$7 billion). As seen in Table 1, there is a similar sharp drop in the numbers of settlements to date in 2013.

Important Questions Our Clients Are Asking

Will there be more prosecutions of corporate executives and officers? While there has been substantial talk over the past four years by the Department of Justice and its partner agencies regarding the prosecution of corporate executives and officers, in fact there have been only a handful of such prosecutions that have involved major companies. Moreover, there have been few so-called “*Park Doctrine*” or responsible corporate officer prosecutions, where individuals are prosecuted under the Food Drug and Cosmetic Act based not upon their individual criminal intent, but predicated upon their corporate positions relative to the criminal activity engaged in by other employees in the corporation. The government’s success rate in prosecuting corporate executives has been mixed, and in the past year we have seen the affirmance of the prosecution of a former CEO of Intermune and the

reversal of the conviction of a drug company sales representative (*Caronia*). Whether this will change is in part dependent on context: In our view, these prosecutions will most likely occur when the executives have substantial knowledge of or actual involvement in wrongdoing, particularly where there are aggravating circumstances such as allegations of risks to patient health and safety or where a manager has certified lawful behavior knowing that illegal activities occurred under his or her supervision. We believe true *Park*-style strict liability prosecution will (and should) remain rare.

Will there be a prosecution of a major corporation that results in exclusion from federal health care programs? While we have seen many companies enter into corporate integrity agreements following criminal and civil and civil-only settlements with the government, we have not seen a prosecution of a corporation for conduct committed while under a corporate integrity agreement. It is impossible to predict whether the DOJ will have the fortitude and political will to push a prosecution knowing that the result will mean automatic exclusion of a major corporation. The DOJ knows that it can expect certain and lengthy litigation if it pursues exclusion and potential backlash for the harm done to innocent third parties (such as the company's employees) who were not involved in the wrongdoing. More likely in the near term will be agreements to divest a business unit or product line rather than exclude an entire operating company. Just as counsel representing corporations look for an avenue out from a prosecution that could trigger an exclusion, so too do government counsel.

Will the Department's appetite for off-label promotion prosecutions wane as a result of the *Caronia* decision? Notwithstanding its public statements to the contrary, we think the DOJ will take a more careful approach in this arena and only pursue criminally those matters where the off-label promotion involved false and/or misleading statements about the drug or device. The DOJ's decision not to appeal the U.S. Court of Appeals for the Second Circuit's panel opinion in *Caronia* was telling and reflects concern within the DOJ that the opinion would have been affirmed either *en banc* by the Second Circuit, the Supreme Court or both.

Can smaller companies expect to see greater prosecution scrutiny? We believe the government will pursue more investigations in the medical device marketplace and that some of these will likely result in prosecutions — and exclusions — of businesses and individuals. There is a tendency on the part of the government to treat business decision-making in the device arena just like it has treated decision-making in the pharmaceutical marketplaces. There are of course substantial differences between the two marketplaces, which complicate any attempt to treat the two similarly. Indeed, a basic difference is that a drug rarely undergoes any ingredient variation once approved by the FDA, whereas devices can go through many iterations of design and component changes post-initial approval. In the black-and-white world of the government prosecution team, this difference is often overlooked or ignored. Businesses with products subject to rapid design evolution can expect to see an increase in government scrutiny.

Are major pharmaceutical company investigations over? Unfortunately, we think the answer to this question is no in the short term. A drop in the number of settlements does not necessarily signal a drop in the number of pending investigations. While there may be a recent dip in negotiated resolutions — and the first five months of 2013 support such a conclusion — companies should not expect to see a drop in investigations. By all reports, the filing of False Claims Act cases is up, and there is no indication that the whistleblower attorney bar has concluded that pursuing major companies does not remain a fertile ground to plow. Moreover, as discussed above, the number of major cases in the drug and device arenas remains relatively small when measured against the number of drugs and devices sold and the number of companies operating in both sectors. In many respects, the government has become dependent upon financial recoveries and will feel pressure, even if that pressure is self-generated, to try to maintain the current level of recoveries.

Will more False Claims Act cases get litigated with positive outcome for members of industry?

We believe the answer to this question is a resounding yes. Over the past four years, we have seen growth in government (and whistleblower bar) theories that push the envelope beyond normal boundaries. The *Caronia* prosecution is but one example, reflecting pursuit of an off-label prosecution predicated on truthful nonmisleading statements. Additionally, we have seen repeated instances of spoliation by government agencies in the False Claims Act arena. In many cases, government agencies have not discharged routine litigation obligations, including the preservation of documents. Those failures create a powerful litigation vulnerability. These two factors, favorable developing case law in various circuits concerning the first to file and public disclosure bars, and a shortage of prosecutorial resources will result in more litigation successes for the industry in False Claims Act cases.

Will implementation of the Affordable Care Act result in an uptick in government investigations? There is no reason to associate the two at present. That said, the government and the relator bar will feel the financial pinch if recoveries from conventional False Claims Act cases drops. Given the growth in that bar over the past decade, as the more routine and typical theories run dry, businesses and counsel should expect an increase in so-called “novelty” or new government and plaintiff theories over the next several years.

Appendix: Pharmaceutical & Medical Device Recoveries of \$1 Million or More: 2004-2013

	All Sectors	Dollars, Pharmaceutical	Dollars, Medical Device	Dollars, Retail Pharmacies	Total, Pharma & Device
2004	\$1,700,908,110	\$372,469,482	\$0	\$10,880,000	\$383,349,482
2005	\$1,648,674,869	\$496,700,000	\$109,000,000	\$11,725,000	\$617,425,000
2006	\$2,500,851,969	\$629,400,000	\$40,000,000	\$207,500,000	\$876,900,000
2007	\$2,127,192,469	\$1,414,515,475	\$312,293,451	\$0	\$1,726,808,926
2008	\$1,733,566,356	\$1,139,243,590	\$172,500,000	\$81,600,000	\$1,393,343,590
2009	\$5,229,960,737	\$3,934,500,000	\$329,098,337	\$121,300,000	\$4,384,898,337
2010	\$4,312,009,913	\$3,824,682,921	\$35,828,100	\$78,715,000	\$3,939,226,021
2011	\$1,965,131,235	\$1,086,700,000	\$51,140,000	\$25,500,000	\$1,163,340,000
2012	\$6,973,670,091	\$5,995,470,743	\$52,884,263	\$59,150,000	\$6,107,505,006
2013	\$186,279,258	\$69,900,000	\$0	\$0	\$69,900,000
Totals	\$28,378,245,007	\$18,963,582,211	\$1,102,744,151	\$596,370,000	\$20,279,346,880