

VOL. VIII, ISSUE 8/MAY 21, 2009

R COMPLIANCE
X REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL
SALES AND MARKETING COMPLIANCE

SEC disclosures show that off-label, antikickback, Best Price cases continue to dominate enforcement landscape, reports Saul Ewing

More than 50 active drug and device cases are reported at both the state and federal level, says veteran attorney

According to former federal prosecutor **Christopher Hall**, a comprehensive examination of recent disclosures by drug and device companies to the Securities and Exchange Commission (SEC) shows that off-label, antikickback and Best Price cases continue to dominate the enforcement landscape

In all, the data shows more than 50 active investigations in these sectors underway at U.S. Attorneys' Offices around the country, along with approximately two dozen similar investigations at Main Justice. The increased level of activity among state Attorneys General Offices is also reflected in the SEC disclosures. In fact, says Hall, the number of active cases in state agencies now rivals the number of active investigations in U.S. Attorney Offices (*see table, this page*).

In short, says Hall, drug and device companies have to fight on two and sometimes three fronts. "On the government side, its not always a happy marriage, though many times it is," he says.

The bottom-line, he says, is that companies have to anticipate multiple scenarios to protect their respective interests.

These findings were derived from the latest quarterly review conducted by Hall's firm, Saul Ewing, of over 2,000 securities filings made by publicly-traded drug and device manufacturers. While closely held companies do not file these disclosures, says Hall, the information serves as a useful proxy and a valuable guidepost to smaller companies as well. The survey reports all disclosed pre-indictment investigations. Saul Ewing then sorts the information to reveal the most active enforcement agencies and their most current focus.

This data, along with supporting information collected by his firm, are used by drug and device companies to develop annual risk assessments. Companies also use it as background prior to responding to government subpoenas. In addition, securities attorneys use the information to inform their disclosure judgments.

Here is a rundown of the aggregate data compiled by Saul Ewing for the first quarter of 2009:

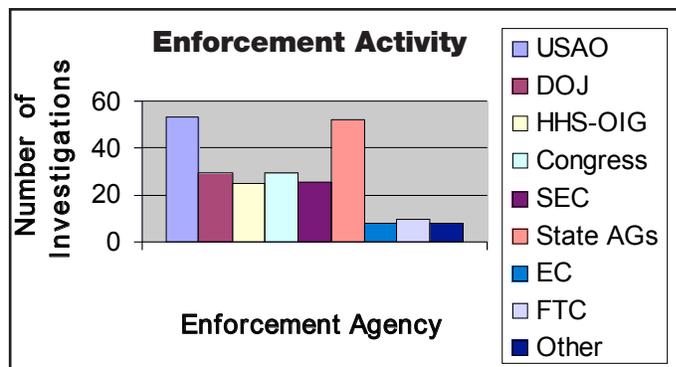
Enforcement activity: The agencies

As noted above, the data show more than 50 disclosures regarding active drug and device investigations in U.S. Attorney's Offices, as well as a similar number of investigations by state

Attorneys General. In addition, Main Justice has roughly two dozen investigations underway. The HHS Office of Inspector General works "hand-in-hand" with the U.S. Attorney's Offices and Main Justice, notes Hall. Several Congressional inquiries are also underway, he adds.

In addition to the increased level of activity in the states, says Hall, the data reflects an uptick in European Community (EC) investigations, as drug and device companies become more global in their reach.

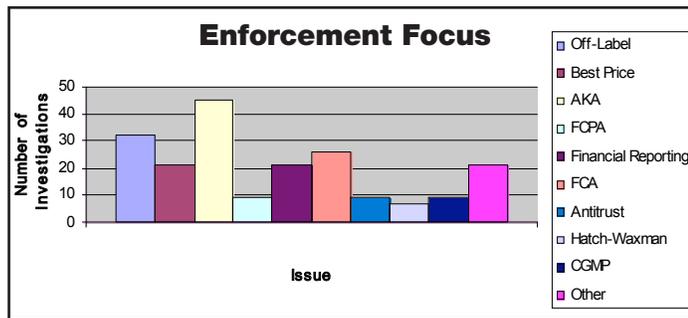
The increased level of activity among state Attorneys General Offices is reflected in the SEC disclosures.



The focus of investigations

The next area examined by Saul Ewing is the focus of these investigations. To nobody's surprise, says Hall, the two areas receiving the most government scrutiny are off-label promotion and kickback violations, roughly 32 and 46, respectively. The data also confirm a continued focus on Best Price cases, he adds, with more than 20 such cases reported.

The number of Foreign Corrupt Practice Act (FCPA) cases does not figure as prominently in terms of the *number* of investigations, says Hall. "But the number of investigations does not necessarily reflect the potential dollar volume of those investigations," he points out.



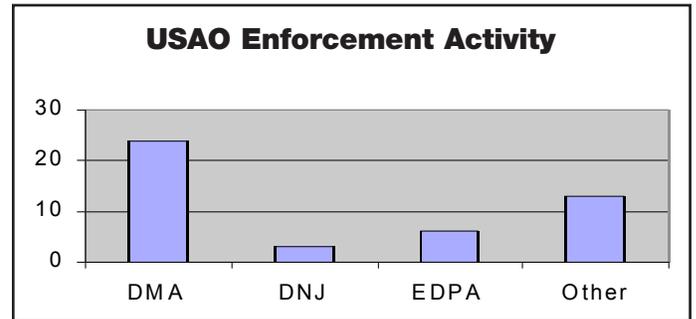
USAO Enforcement activity

In terms of the U.S. Attorneys' Offices conducting these investigations, the District of Massachusetts remains "far and away" the most active, Hall reports, with roughly two dozen open investigations. The Eastern District of Pennsylvania placed second, with approximately half that number. "That is largely a function of the reputation of those offices for investigating cases in these areas by *qui tam* relators," he explains.

In addition to the increased level of activity in the states, the data reflect an uptick in European Community investigations.

The raw number of cases does not necessarily reflect the dollar volume of those cases, Hall points out. For example, he says, there are some very sizable cases coming out of the Eastern District of Pennsylvania that may speak louder than the raw number of cases alone.

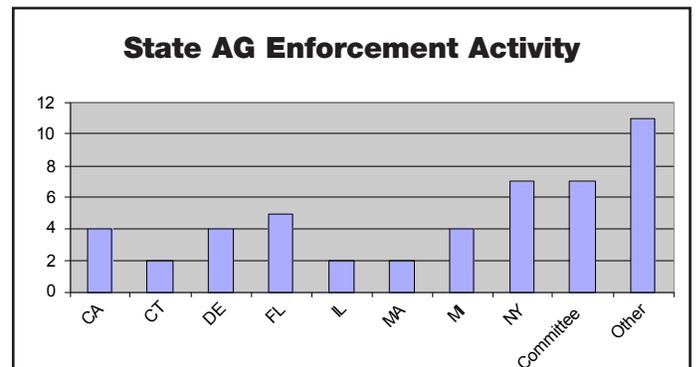
Several cases were reported in the District of New Jersey, he says, along with several cases scattered in various offices around the country.



State AG Enforcement activity

The New York Attorney General is the most active state agency, Hall reports, with seven drug and device investigations underway, followed by Florida with five.

According to Hall, the Illinois Attorney General is another very active office, which collaborates with the U.S. Attorney's Office in the Northern District of Illinois. The Massachusetts and Delaware Attorneys General are also very active, he adds.



■ **Christopher Hall**, Partner, Saul Ewing, Philadelphia, PA, chall@saul.com