What DOJ Enforcement Shift Means For Life Sciences Cos.

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In recent years, the U.S. Department of Justice has announced a number of criminal resolutions with life sciences companies based upon quality and manufacturing deficiencies that include novel, forward-looking compliance provisions that vest the DOJ with ongoing oversight of the company's compliance program.

These resolutions require the settling companies to take affirmative steps to monitor their compliance programs, including with respect to certain requirements arising under the Federal Food, Drug and Cosmetic Act, and to make reports to the DOJ on an ongoing basis regarding those efforts.

In this regard, these new resolutions bear striking similarities to corporate integrity agreements historically imposed on life sciences companies by the U.S. Department of Health and Human Services' Office of Inspector General as well as consent decrees of permanent injunction imposed by the U.S. Food and Drug Administration through the DOJ, to monitor compliance with the FDCA.

As the DOJ has begun to impose these new compliance provisions in certain criminal resolutions, enforcement data published by the FDA suggests that the FDA is making less frequent use of consent decrees — the FDA's tool for imposing proactive monitoring in circumstances where a company has had significant FDCA compliance deficiencies.

It is unclear whether there is any causal connection between the decline in FDA consent decrees and the increase in compliance reporting obligations in DOJ resolutions. Nevertheless, the confluence of these trends suggests that the DOJ may be assuming a primary role in monitoring life science company compliance, both with the FDCA and with respect to compliance program design — historically the domain of the HHS OIG through the imposition of corporate integrity agreements.

This development leads to a host of interesting questions regarding the impact of such DOJ oversight, particularly for companies who may find themselves subject to such oversight in the years ahead.

Forward-Looking Compliance Obligations in Recent DOJ Settlements

Since late 2018, the DOJ's Consumer Protection Branch, which has responsibility for criminal and civil enforcement of the FDCA, has entered multiple criminal resolutions with life sciences companies that include significant forward-looking compliance obligations that extend beyond the specific scope of conduct at issue in the resolution.

Olympus

In December 2018, Olympus Medical Systems Corp. and one of its former senior executives pleaded guilty to distributing misbranded duodenoscopes in interstate commerce in violation of the FDCA.

The DOJ charged that Olympus' duodenoscopes were misbranded because Olympus did not timely file medical device reports. To resolve these charges, Olympus agreed to pay $80 million in fines and $5 million in criminal forfeiture. In addition, in its plea agreement with the DOJ, Olympus agreed to:

- Retain an independent medical device reporting expert to inspect and review Olympus' policies and procedures and, for a period of three years, report to the DOJ and FDA on the status of the company's compliance with FDA medical device reporting requirements;

- Conduct a self-review and audit of the device classification and market pathway for certain endoscope device types manufactured by Olympus; and

- Have Olympus' president and board of directors periodically conduct a review of Olympus' medical device reporting compliance measures and classification and marketing pathway review, and make certifications to the FDA and DOJ relating to those reviews.

Fresenius

In February 2021, Fresenius Kabi Oncology Ltd. pleaded guilty to violating the FDCA by failing to permit access to records as a result of its efforts to conceal and destroy records prior to a 2013 FDA plant inspection.

The DOJ charged that Fresenius engaged in unofficial testing and blending of active pharmaceutical ingredients in violation of good manufacturing practices requirements, maintained separate manufacturing records documenting these activities and removed computers, equipment and records from its manufacturing facility in advance of an FDA inspection in order to avoid detection of its good manufacturing practice deficiencies.

Fresenius was sentenced to pay $50 million in fines and forfeiture and, as part of its plea agreement, agreed to:

- Implement and maintain a compliance and ethics program;

- Direct reporting to the board by the chief compliance officer, who would sit on the CEO's staff;

- Annual CEO and CCO certifications and board resolution regarding the compliance and ethics program, including for the CEO certification, that it was effective in preventing intentional violations of the FDCA:

- Maintain a compliance committee comprised of senior executives that meets at least quarterly;

- Quarterly compliance reports to the board by the CCO;

- A training program designed and used to educate employees on compliance policies and procedures;

- A hotline to allow reporting of violations of law or compliance policies and procedures;

- An auditing and monitoring program designed to deter and detect compliance issues;

- Maintenance of a log of all reports received by the compliance and ethics program regarding an FDCA violation believed to be a potential violation of criminal law, production of that log to the DOJ upon request, and annual certifications to the DOJ regarding the log; and

- Quarterly reports to the DOJ regarding any intentional violation of good manufacturing practices, systemic or repeated intentional failure to maintain manufacturing records, or intentional failure to disclose material information regarding manufacturing practices that would warrant enforcement.

Avanos

In July 2021, Avanos Medical Inc. entered into a deferred prosecution agreement to resolve criminal charges that it introduced misbranded surgical gowns into interstate commerce with the intent to defraud and mislead.

In the agreed statement of facts included in the deferred prosecution agreement, Avanos admitted that it labeled its gowns as offering the highest level of protection against fluid and virus penetration despite not actually meeting those standards, and that an Avanos employee and agent impeded an FDA inspection by making numerous false entries into stability testing records requested by FDA investigators.

Avanos agreed to pay $22 million to resolve the matter, and to the following compliance measures:

- Implementation of a compliance program, including all standard elements of a compliance program, including, among other provisions, policies and procedures, training, mechanisms for reporting potential misconduct, and auditing and monitoring processes;

- Development and annual update of compliance policies and procedures based on periodic risk assessments;

- Assignment of compliance oversight responsibilities to a senior corporate executive with direct reporting to independent monitoring bodies, the board or a board committee;

- Policies and procedures for conducting due diligence in connection with mergers and acquisitions, and ensuring that its compliance policies apply to new business entities as quickly as possible; and

- Submission of reports to the DOJ regarding annual compliance reviews and work plans undertaken to enhance self-reporting and ensure compliance with the FDCA and U.S. fraud and obstruction of justice laws.

Historical Parallels of Compliance Obligations in DOJ Resolutions

The compliance obligations contained in these various resolutions may sound familiar to those in the life sciences industry, as they are quite similar to those generally imposed by the FDA in consent decrees and by the HHS OIG in corporate integrity agreements.

In particular, FDA consent decrees — which are often implemented to address persistent quality system failures and good manufacturing practice failures at manufacturing facilities — generally require a company to do the following:

- Retain an independent expert to assess the state of the company's compliance system;
- Develop a work plan to address any identified deficiencies and undertake steps to remediate those deficiencies as specified in the work plan; and
- Have an independent expert audit the effectiveness of the remedial actions.

Each of these steps must be reported to the FDA, and the FDA has authority to enforce failures to comply with the consent decree.

Similarly, corporate integrity agreements — which are implemented to ensure ongoing compliance where a company's conduct provides a basis for permissive exclusion from federal health care programs — generally require a company to:

- Implement and maintain a compliance program, including the traditional elements of an effective compliance program as well as policies and procedures specifically directed at areas of focus in the matter that gave rise to the corporate integrity agreement;
- Engage an independent review organization to conduct periodic reviews of the company's compliance systems and specified transactions, and report to the HHS OIG on the results of those reviews; and
- Self-audit and monitor various activities. In addition, companies subject to a corporate integrity agreement are required to make periodic self-reports to the HHS OIG, and to report potential violations of law.

What Inclusion of Compliance Provisions in DOJ Resolutions Could Mean for Companies

While the types of compliance obligations imposed in the DOJ's recent criminal resolutions are not necessarily novel in and of themselves, the fact of their inclusion in DOJ resolutions is notable as it makes the DOJ — rather than the FDA or HHS OIG — responsible for monitoring and enforcing these obligations.

Having the DOJ as the overseer of these obligations, in turn, creates a number of potential questions and risks for companies that may find themselves subject to this oversight.

First, the DOJ's primary role in overseeing compliance with these agreements may raise the stakes on any identified noncompliance.

For example, in the ordinary course, failures in medical device reporting would likely be identified through an FDA inspection, which a company would have an opportunity to address, and perhaps via a warning letter, which again a company could respond to, before judicial enforcement was considered.

The Olympus and Pentax agreements, however, provide the DOJ with direct access to information regarding those companies' medical device reporting compliance, raising the specter that issues that might otherwise have been viewed as regulatory in nature could instead be seen as a potential enforcement issue from the outset.

This possibility is particularly fraught in light of the strict liability misdemeanor provisions of the FDCA, which allow for the possibility that a company or individual may be found to have violated the statute without evidence of intentional conduct.

Along the same lines, these new provisions create the risk that a DOJ resolution, which often takes a long and heavily negotiated path, may not be the end of the road for a settling company's exposure.

Instead, the compliance provisions require settling companies to sign on to a prolonged period of continued involvement with the DOJ, at a time when most companies are looking to put that behind them. And, because these obligations are included in deferred prosecution agreements and plea agreements, failure to comply with their terms come with stiff consequences — such as prosecution of a company under a deferred prosecution agreement or stipulated penalties.

This substantially raises the stakes for the underlying FDCA and health care compliance requirements incorporated in the compliance obligations. Further, by requiring ongoing management and board certifications regarding compliance program effectiveness, these agreements create a new risk of liability for impacted officers and directors.

Finally, giving the DOJ oversight over companies' compliance programs, and over certain aspects of their FDCA compliance, raises a question of whether the DOJ possesses — or will partner with other agencies to obtain — the expertise and perspective necessary to evaluate the information it will receive.

It is clear that the Consumer Protection Branch is devoting substantial efforts to its oversight of the compliance obligations in its agreements. In April, the branch's first-ever recent highlights report explained that the attorneys in the corporate compliance and policy unit "assess compliance programs and help craft resolution terms, including evaluating whether to impose an independent monitor [and] have primary responsibility for ensuring that defendants follow the compliance and reporting provisions of resolutions."

The report states that "[i]n handling this work, CCP attorneys collaborate closely with ... FDA agency counsel," but it is unclear whether DOJ attorneys also have access to other subject matter experts within the FDA — such as Office of Regulatory Affairs personnel for good manufacturing practice matters — who would ordinarily be involved in assessing whether regulatory violations have occurred.

For its part, the HHS OIG has a cadre of monitors who oversee companies subject to corporate integrity agreements and have an extensive understanding of common life science industry compliance practices.

It is unclear how, if at all, theDOJ will consider prior corporate integrity agreements in assessing the compliance programs covered by the recent resolutions or developing health care compliance program requirements in future resolutions.

For the heavily regulated life sciences industry, in which companies often view FDA and HHS OIG guidance and CIAs as the benchmark for their compliance with regulatory requirements, the advent of DOJ oversight in these areas could substantially complicate what it means to be in compliance.

Conclusion

It remains to be seen how the DOJ will exercise the compliance oversight authority vested in it by the agreements discussed above, and to what degree it will take into consideration the views of the client agencies that historically have played the primary role in monitoring company compliance.

In the interim, it is clear that the compliance provisions included in the DOJ's recent resolutions will

substantially increase the downstream costs of the resolutions — both in the pure economic costs of implementing systems and processes to meet the requirements in the resolutions and in the potential for further follow-on enforcement of the resolution requirements.

These new developments thus highlight the importance of life sciences companies establishing, monitoring and continuously improving their quality and health care compliance programs.

In the best case, such programs may prevent the types of issues that can lead to DOJ resolutions. However, even where such monitoring does not prevent lapses altogether, close coordination between quality and compliance personnel may help to ensure that quality issues are promptly elevated to management decision makers.

This allows responsible personnel to affirm necessary investigative steps and to ensure that remedial actions are carefully considered and well documented in the ways that generally have become expected in response to reports of potential lapses in health care compliance.

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