

PHARMA AND HEALTHCARE SECTORS ARE RIPENING FOR WHISTLEBLOWING AT A TIME WHEN EU REGULATIONS MAY COMPLICATE INVESTIGATIONS

There are several factors at play for companies in the pharma and healthcare sectors, which, when combined with the availability of rewards for whistleblowers under several US laws, as well as the EU's forthcoming whistleblowing regime, create an environment that is ripe for whistleblowing. Companies in all sectors need to be prepared, with factors in sectors like pharma and healthcare indicating the possibility of a surge in whistleblowing activity.

WHAT'S CHANGING: EU WHISTLEBLOWER DEVELOPMENTS

While the EU has traditionally been more resistant to the culture of whistleblowing, that is about to change with the union's new Whistleblower Protection Directive ("**EU Directive**"), which Member States must implement by December 17, 2021. Specifically, Member States are required to adopt laws aimed at making whistleblowing more accessible and protecting those who blow the whistle from retaliation. All private companies with more than 50 employees, no matter the sector, will be subject to the requirements of the EU Directive, as well as any additional requirements that the Member States in which they operate decide to impose.

For companies that operate across multiple jurisdictions, the changes mandated by the EU Directive will likely create obstacles to investigating claims made by whistleblowers. Traditionally, companies with formal whistleblower procedures and policies have conducted whistleblower investigations centrally, often with centralized policies, investigation procedures and reporting led by head office. However, under the EU Directive, companies could now be required to establish local whistleblower channels and conduct investigations of whistleblower claims *locally*. In practice, this requirement may limit a company's ability to properly identify, investigate and address serious concerns that arise throughout the group, especially if the right procedures are not in place.

WHY YOU NEED TO PAY ATTENTION NOW: FACTORS INCREASING THE WHISTLEBLOWING ENVIRONMENT

In the pharma sector, the pace with which industry has moved forward with the vaccine development in response to the COVID-19 pandemic and the availability of significant government support have created potentially lasting changes in corporate procedures. The work environment itself has changed, with remote workers potentially feeling isolated or more detached. Change itself can create tension in an organization, where individuals for a variety of reasons might not agree with the changes and might look for ways to challenge them, including taking steps to whistleblow internally or to relevant government agencies if they perceive that something is wrong. Recent high-profile whistleblowing situations both in government and the private sector may serve as examples for these concerned individuals to follow.

Importantly, governments in both the United States and Europe have provided significant funding to pharma companies in both the development of COVID-19 vaccines and therapeutics as well as in purchasing these products in vast quantities. Government funding at this level may result in fraud investigations against pharma (and other) companies who obtained such funding. Pharma companies should be prepared for these investigations, even more so given the risk that the investigation could be prompted by a whistleblower.

Another factor is particular to the fast growth of small pharma disruptors. Technological innovations in the development of medicines and vaccines have made it possible for new companies to grow exponentially, where growth outpaces internal governance and/or the sufficient training of management and other employees. Lack of clear procedures, rapid hiring decisions and other aspects that sometimes come with quick growth are other catalysts that may lead employees to resort to internal or external whistleblowing to correct what they feel may be unlawful lapses in corporate practices.

In the healthcare sector, as in the pharma sector, the pandemic has had a significant impact on several operational aspects. Changes in the operation of facilities, the recording and reporting of data, billing and insurance coverage practices, receipt and spending of government funds and potential disparate treatment with respect to different communities are just a few of the areas in which the stresses of and responses to the pandemic create an environment in which whistleblowing may increase. Corporate actors in this space, large and small, need to recognize the potential for bad actors in their organizations potentially taking illicit advantage of various aspects of the pandemic. A good overview of the types of activities in the healthcare sector on which employees might blow the whistle internally or to a government agency can be found in a recent [advisory](#) to the financial sector from the U.S. Treasury Department's Financial Crimes Enforcement Network.

Finally, the pharma and healthcare sectors are coping with a variety of COVID-related workplace safety complaints to agencies such as the U.S. Department of Labor Occupational Safety and Health Administration, which, as reported [here](#), pushed overall whistleblowing filings at the federal level in the United States up by approximately 15 percent in 2020.

BUT WAIT, THERE'S MORE: LEGAL BASES FOR REWARDS OR COMPENSATION IN THE UNITED STATES

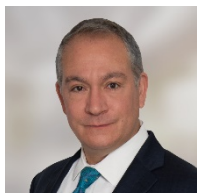
The US has several whistleblowing laws in place, many of which offer rewards to those who provide the government with information leading to successful prosecutions of misconduct. For example, under the False Claims Act ("**FCA**"), whistleblowers can be rewarded for disclosing acts of fraud resulting in a financial loss to the federal government. The FCA is the most commonly invoked whistleblower statute in the pharma space, typically used in cases involving allegations of kickbacks, overbilling and off-label promotion. The SEC also has its own whistleblowing regime under Dodd-Frank which rewards whistleblowers for coming forward with legitimate information about violations of federal securities laws, including the Foreign Corrupt Practices Act ("**FCPA**"). More recently, the Anti-Money Laundering Act of 2020 ("**AMLA**") has beefed up provisions that provide for rewards for tips that lead to the recovery of stolen foreign government assets. None of these laws that invite whistleblowing for a potential reward are limited in application to persons in the United States. Companies with global operations need to understand that persons outside the United States might begin to seek rewards in the United States in this ripening environment.

In addition to offering monetary rewards to government tipsters, Dodd-Frank and the AMLA also provide mechanisms for relief to employees who have suffered retaliation for blowing the whistle. Specifically, a whistleblower who prevails against their employer in a retaliation claim under these laws may be reinstated to their previous position, awarded up to two times backpay with interest and compensated for litigation and attorneys' fees. This scheme is not unique – in fact a number of other US statutes provide for similar damages to injured whistleblowers, including Sarbanes-Oxley ("**SOX**"), the Affordable Care Act ("**ACA**") and the Criminal Antitrust Anti-Retaliation Act ("**CAARA**"). Unlike Dodd-Frank and the AMLA, however, these regimes do not reward external whistleblowers for sharing valuable information with authorities.

How We Can Help

Clifford Chance can discuss with you the impact of the EU Directive on your business, including what changes need to be made to ensure compliance with the new regime while still allowing the company to properly and effectively investigate issues raised by whistleblowers. While companies in all sectors will be subject to and therefore affected by the EU Directive, given all the circumstances described above which make it likely that companies in the pharma and healthcare sectors will see an increasing number of whistleblower complaints, it is especially critical that these companies be prepared for the changes to come.

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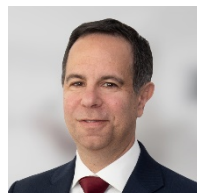
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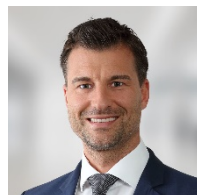
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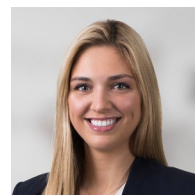
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