

PSA BRIEF:

# Understanding FCPA Risks in the Healthcare Sector



MARCH 2020

## Elevated and Unique FCPA Risks

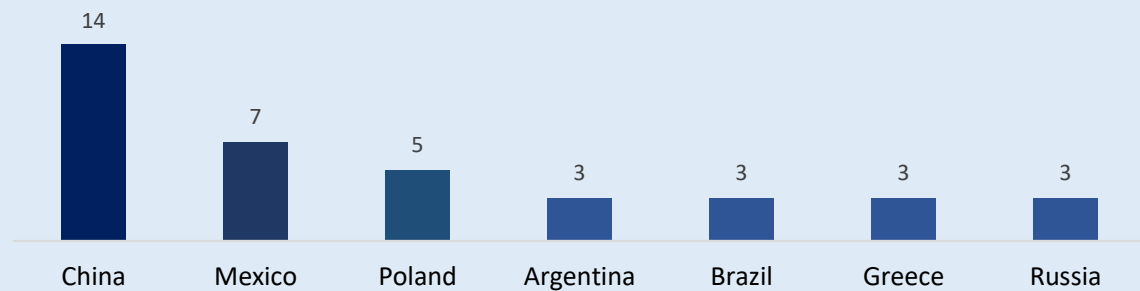
Healthcare is among the most penalized sectors when it comes to FCPA enforcement, with 35 of a total 291 FCPA cases.<sup>1</sup> Pharmaceutical, medical supply, and medical technology companies face extensive exposure to government officials due to high volumes of sales to government end-users and a heightened need for regulatory approvals. Frequent reliance on local distributors also increases risks. In addition to these typical FCPA risk factors, the healthcare sector presents unique risks. The DOJ and SEC pursue FCPA cases on the principle that healthcare practitioners (HCPs) in state-run healthcare systems should be considered “foreign officials” subject to the statute’s restrictions. This extension of the “foreign official” designation creates two related problems. First, the overlap between public and private spheres makes it difficult to determine who such government-connected HCPs are. Second, because HCPs themselves often have multiple affiliations, identifying and mitigating against potential channels for illicit payments can be difficult.

### GEOGRAPHIC DISTRIBUTION OF HEALTHCARE INDUSTRY FCPA CASES

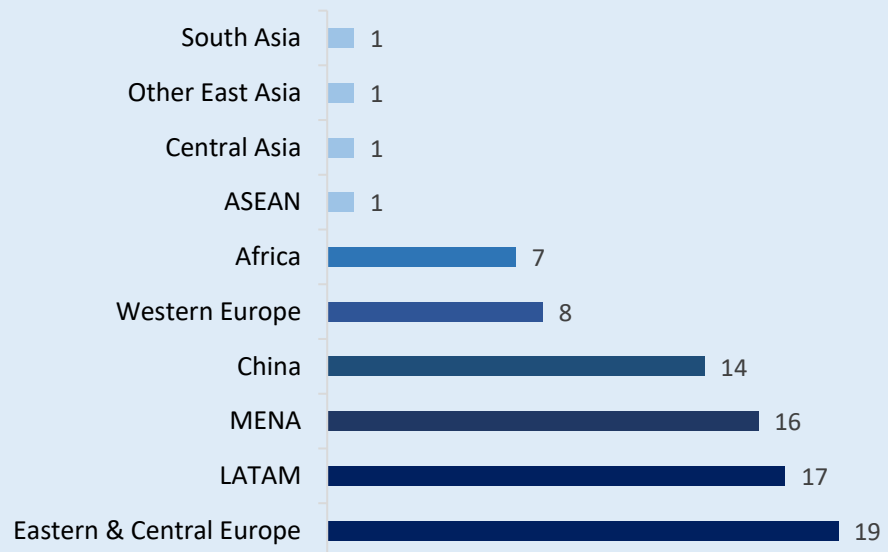
As of March 2020, penalized illicit payments were paid to foreign officials in 50 different countries, several of which appear in multiple cases.

#### FCPA Cases Per Jurisdiction

*Jurisdictions featuring at least 3 cases*



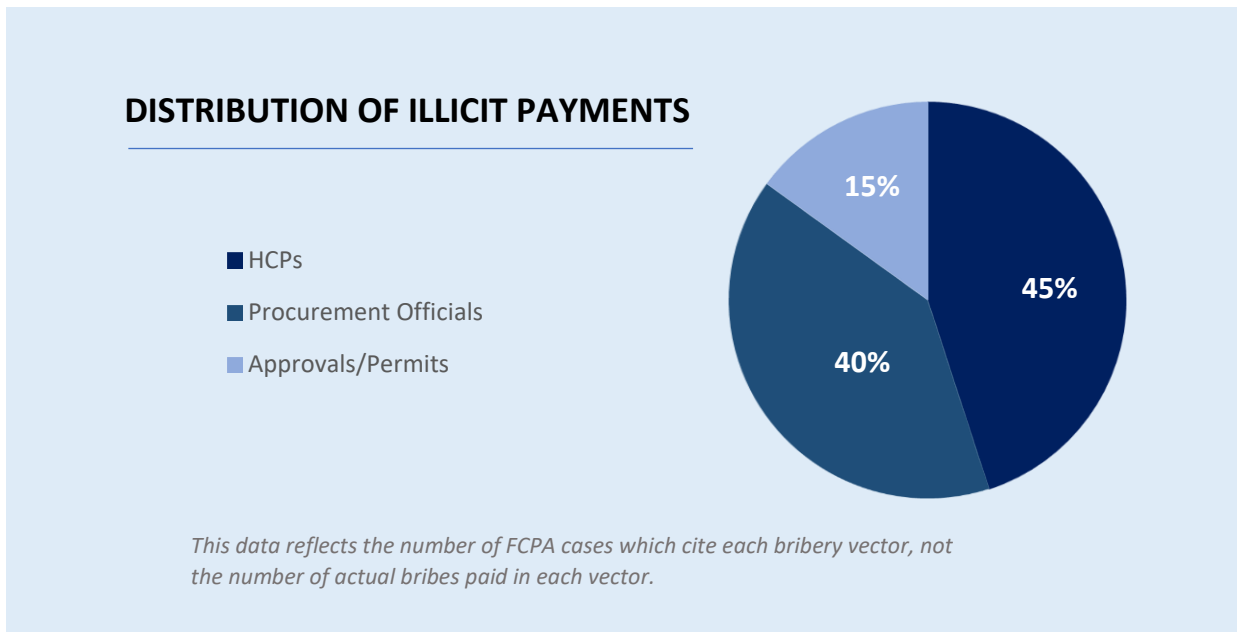
#### FCPA Cases by Region



*This data reflects the number of times each country appears in FCPA cases—not the number of alleged bribes paid in each country, which is typically undisclosed in case details.*

## HCPs as “Foreign Officials”

The healthcare industry presents many FCPA risks similar to those found in other sectors—for example, local subsidiaries or distributors bribing government officials to facilitate sales. However, engagements with HCPs may incur risks due to their potential designation as foreign officials. The key risks here are perks and incentives intended to encourage HCPs to prescribe or purchase the defendants’ products themselves, or to work on the defendants’ behalf to influence procurement decisions made by others. Absent the “foreign official” designation, some incentives might otherwise be considered acceptable in many jurisdictions. SEC and DOJ filings and press releases suggest 45% of FCPA cases involve HCPs in this way, representing the greatest risk within the sector. Alleged bribes to officials engaged in more systemic procurement decisions appeared in 40% of all cases, while approximately 15% of cases included alleged bribes paid to authorities providing various approvals. This last category includes alleged bribes to secure a product’s eligibility for insurance reimbursements, permit the entry of unauthorized products into a country, obtain formulary approvals, and secure approvals for a new therapy.



## Other Potential Foreign Officials

US regulators continue to exercise considerable flexibility in determining who may qualify as a foreign official under the FCPA. This results in a broad category of potential high-risk third parties, many of whom might fall outside common definitions of “politically exposed persons” (PEP). In the 2004 HealthSouth case, prosecutors filed criminal charges over alleged bribes paid to an administrator of a nonprofit hospital funded by members of the Saudi royal family.<sup>2</sup> In the 2017 Alere case a private organization obtained a Colombian government contract to provide health insurance services. Alere’s local subsidiary allegedly made improper payments to this private entity, including during a period when the Colombian Ministry of Health had temporarily seized operational control of it. During this time, the SEC therefore determined that this contractor was a government “instrumentality” and hence its employees were foreign officials subject to FCPA restrictions.<sup>3</sup>

## WHO MIGHT BE CONSIDERED A FOREIGN OFFICIAL?

	Individuals associated with national, regional, or municipal governments
	Administrators of government-run hospitals
	Administrators of government health insurance organizations
	HCPs in government-run healthcare systems
	Employees of government-run labs
	Employees working in public/private healthcare partnerships (under certain conditions)

## Gray Areas between the Public and Private

Complex or opaque interrelations between public and private entities in the healthcare field can make it difficult to draw clear lines between governmental and non-governmental spheres. Some public health nonprofits help implement government initiatives and may accept public grants to do so. In some jurisdictions it is difficult to determine whether a professional association or community healthcare group is government-run or influenced. Some such entities may be connected to a Health Ministry or a public university without overtly describing themselves as such.

Conversely, in some countries, many professional associations might be nominally organized under the auspices of a government ministry without appearing to operate as an instrument of public policy. Due to minimal case law delimiting who is a foreign official under the FCPA, such gray area affiliations should prompt scrutiny.

## HCP Affiliations and Mitigating Risk

It is common for HCPs to have multiple affiliations, often straddling public and private domains. An individual engaged in her capacity as a principal at a healthcare consulting firm may also be a professor at a public medical school. Such cross-affiliation issues should prompt additional efforts to confirm in precisely what role the third party will be acting in the proposed engagement. A second issue of concern is that cross-affiliations frequently appear in FCPA and other bribery cases as conduits for illicit payments. Multiple cases involve ostensibly legitimate donations made to an academic program or nonprofit favored by an HCP in order to influence his decisions in an unrelated entity. Due diligence screening capable of adequately identifying and mapping all of an HCP's affiliations is an important step in assessing the potential scope of prohibited payments to the third party that a local distributor or subsidiary might be tempted to make.

## Due Diligence in Healthcare Transactions

PSA's due diligence program has been presented with numerous examples of these gray areas or HCP cross-affiliations which have prompted us to advise our clients to consider elevated FCPA risks or to consider a wider scope of risk mitigation efforts. While it is ultimately a matter of legal assessment to evaluate if and how FCPA restrictions may apply to a given case, it is critical to begin with a due diligence approach that is capable of identifying and flagging these often obscured potential risks for further review. Limited screenings may fail to spot potential government connections at the institutional level. More problematic is the fact that government-affiliated HCPs are usually not flagged in compliance databases because they are not typically categorized as PEPs. Because an assessment informed by jurisdiction-specific factors may be needed to adequately spot potential issues, human-led desktop research by trained analysts is often the best first step in mitigating third party FCPA risks throughout the sector.

### Endnotes

1. More precisely, "case groups" of related enforcement actions as categorized and quantified by Stanford Law School FCPA Clearinghouse [www.fcpclearinghouse.stanford.edu](http://www.fcpclearinghouse.stanford.edu)
2. <http://fcpclearinghouse.stanford.edu/documents/1000/000325.pdf>
3. <http://fcpclearinghouse.stanford.edu/documents/5000/003574.pdf>



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