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It's Back—True to the Promise of Continued Scrutiny of Life Sciences, the SEC Enters a $25M FCPA Resolution with Novartis

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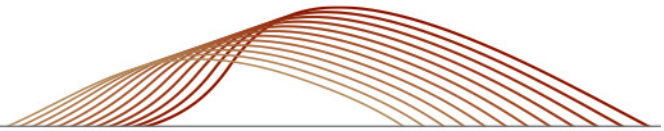
In yet another resolution in life sciences, the Securities and Exchange Commission ("SEC") announced its settlement with Novartis AG ("Novartis"), resolving allegations that two China-based Novartis subsidiaries violated the Foreign Corrupt Practices Act ("FCPA") by providing gifts, cash payments, and entertainment to healthcare professionals ("HCPs") and engaging in "pay-to-prescribe schemes to increase sales"—conduct Novartis neither admits nor denies in the March 23, 2016 cease-and-desist order.[1] Under the resolution, available here, Novartis will pay $25 million and engage in a two-year self-monitorship to resolve the alleged improper activity and related books and records violations.

Enforcement's Continued Focus on Life Sciences

Following an initial wave of resolutions in the industry in the early 2000s, in November 2009, the then Assistant Attorney General of the Criminal Division of the Department of Justice ("DOJ") advised a gathering of pharmaceutical industry compliance and legal professionals that the DOJ "will continue to work closely with our partners at the SEC to ensure that the full range of the federal government's enforcement tools and remedies are utilized. . . . Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in your industry."[2] This sentiment was expressly shared by the SEC, which issued its own warnings to the industry, such as that from Andrew Ceresney, Director of the Commission's Enforcement Division, who cautioned that "the pharma industry is one on which we have been particularly focused."[3]

True to these warnings—and substantiating them as imminent and credible enforcement threats—the past six years have seen tremendous enforcement activity within the life sciences industry. Indeed, since 2009, the DOJ and SEC have investigated and resolved allegations of FCPA violations with more than a dozen pharmaceutical companies, resulting both in monitorships and billions of dollars in disgorgement and penalties. For example, following the commencement of the industry sweep, in 2012 alone, 50% of FCPA corporate settlements involved the life sciences industry. And even in matters the DOJ has declined to prosecute—such as those involving Bristol-Myers Squibb and SciClone Pharmaceuticals—the SEC has charged forward, ultimately leading to resolutions.

On the heels of this activity, it came as no surprise when in February, Kara Brockmeyer, the SEC's FCPA Unit Chief, warned that the agency "is going back to the pharma industry after a break for a period of years." Once again true to its word, the SEC entered its resolution with Novartis.



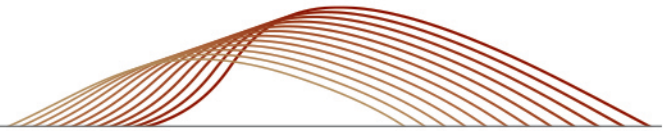
The Novartis Resolution

The Novartis resolution focuses on conduct purportedly occurring from 2009 to 2013 at two Chinese Novartis subsidiaries: Shanghai Novartis Trading Ltd ("Sandoz China") and Beijing Novartis Pharma Co, Ltd ("Novartis China"). As to Sandoz China, the resolution asserts that from 2009 to 2011, employees who provide sales and marketing activities for Novartis generics in China, "improperly provided things of value to HCPs in China in connection with pharmaceutical sales." These "things of value" included "gifts, travel, improper sightseeing or vacations, entertainment, and favors for families of HCPs," as well as "cash and gifts" funded via falsified expense reports. Per the SEC, the payments were "improperly recorded on the general ledger as legitimate employee expenses, sponsorships, conferences, medical studies, and marketing costs." These practices purportedly were deliberately tracked—with high prescribing HCPs designated as "key" customers and "money worshippers," cash payments identified as "investments," and reports provided to "senior management" at the subsidiary. The resolution expressly cites approximately $9,000 in falsified expense reimbursement requests, noting that the funds were utilized to provide entertainment and gifts to HCPs, including holiday gifts and spa and sauna sessions—expenses allegedly approved by a regional sales manager. As previously seen in cases out of China, third-party travel agencies were also utilized for the stated purpose of organizing educational events, though here "the scientific/educational components were minimal in comparison to the sightseeing or recreational activities," and "related expenses were approved and paid with little or no supporting documentation." In one instance, for example, a group of 20 Chinese HCPs were sponsored to attend the American College of Surgeons 95th Annual Clinical Congress in Chicago. Though the Congress was educational, the trip included a sightseeing excursion to Niagara Falls, travel expenses for the spouses to accompany the HCPs, "$150 in 'pocket' or 'walking around' money," and payment of cover charges at a strip club. Several Sandoz China employees—including a senior manager—accompanied the HCPs on the Chicago trip.

Additionally, Sandoz China utilized "patient studies," so-called form phase IV or epi-dermatologic studies that companies undertake to collect and analyze patient medical data. Here, Sandoz China allegedly paid HCPs approximately $522,000 from 2009 to 2010 to undertake these programs for the "stated purpose of better understanding" particular Novartis products. According to the SEC, however, senior sales and marketing colleagues were involved in the design and execution of the programs, which violated Novartis policy, and the studies "did not provide any legitimate medical data," operating instead as another vehicle for "financially reward[ing] HCPs" for prescriptions.

For its part, from 2011 to 2013, Novartis China purportedly utilized numerous third parties, including travel agents, "ostensibly" to arrange transportation, accommodations, venues, and meals for HCPs in connection with "educational conferences and other business activities." In reality, these "complicit vendors" were merely a front to provide payments and "improper inducements" to HCPs to boost prescription sales or recommendations of Novartis products. These third-party expenses were then recorded as "legitimate selling and marketing costs" by Novartis China. Speaking to the potential volume of the alleged fraud, the resolution states that Novartis China hosted "thousands" of events over the last several years and characterizes its use of third-party travel and event planning vendors as "widespread."

Though silent on the topic of voluntary disclosure, the resolution expressly notes that these issues were identified in the course of an internal review by Novartis in the wake of "the SEC Staff's investigation . . . and media reports concerning a competitor in August 2013." As a result of its internal review, Novartis "identified weaknesses in its internal controls over third-party relationships" and "promptly took remedial steps to improve its internal controls . . . including overhauling its anti-



corruption policies and procedures, terminating and/or imposing other disciplinary sanctions against culpable employees, suspending vendor relationships and payments, doubling its training initiatives, re-organiz[ing] its compliance function . . . , and eliminat[ing] the use of vendors to support external meetings." Via its self-monitorship obligations, Novartis is required to report to the SEC the "status of its remediation and implementation of compliance measures" periodically for the next two years.

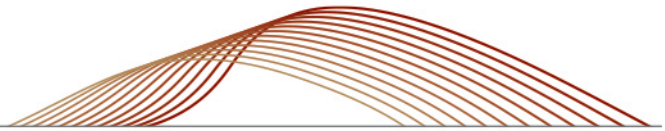
Reflections on the Resolution

Though it certainly pales in comparison to recent resolutions reaching into the hundreds of millions (*e.g.*, the March 1 resolution with Olympus Corporation of the Americas, analyzed here), the SEC's resolution with Novartis both underscores current enforcement trends and reiterates points those in the industry—and particularly those operating in China—do well to heed:

1. **The SEC as a Pharma Enforcer**—True to Brockmeyer's promise, the SEC remains squarely focused on the life sciences sector and the pharmaceutical industry, in particular—even when its DOJ counterpart is absent. Continuing the trend observed in 2015, an increasing number of resolutions appear to be led by or involve only the SEC. This trend is most recently reflected by the resolutions with Bristol-Meyers Squibb (October 2015) and SciClone Pharmaceuticals (February 2016)—both of which received DOJ declinations on the heels of the SEC resolutions. Perhaps this trend is explained by the respective jurisdictional hooks faced by these enforcement bodies—the SEC able to pursue any U.S. issuers, while the DOJ must establish a sufficient U.S. nexus with the players or activity at issue. Regardless—and particularly in view of the SEC pronouncement of renewed focus on the industry—life sciences companies should expect continued attention from the SEC, even independent of other regulators.

2. **Administrative Proceedings**—Consistent with other areas of white-collar enforcement that the SEC has deemed "high priority," the SEC appears increasingly to favor administrative proceedings—as utilized with Novartis—to resolve alleged FCPA violations. Whereas in 2012 only one of 10 FCPA resolutions by the SEC came in the form of an administrative proceeding, and just three of eight in 2013, all but four of the agency's 25+ enforcement actions since the beginning of 2014 have been resolved as administrative proceedings. The first quarter of 2016 has continued this trend with only one of eight FCPA enforcement actions brought by the agency—VimpelCom, the third largest FCPA settlement in history—initiated in federal court. Though interesting on a number of levels, two points related to this seeming shift are particularly notable. First, administrative proceedings circumvent the need for judicial approval of the resolution. Second, the showing required to establish the requisite "likelihood of future violation" for the purpose of a cease-and-desist order has been interpreted as less stringent than that required to support a resolution in federal court. These distinctions may well explain the apparent popularity of administrative proceedings with regulators.

3. **Self-Monitorships Continue**—Once again, the SEC has allowed an alleged transgressor to monitor itself, rather than appoint the more onerous and costly independent monitor. The SEC emphasized the "cooperation and remediation" undertaken by Novartis, including an "expansive review of its relationships in China with travel and event planning vendors," which enabled the identification of internal control weaknesses. Consistent with prior resolutions, particular attention was paid to the prompt remedial action undertaken by the Company to improve the internal controls at Novartis China, including an "overhaul[]" of its anti-corruption policies and procedures, disciplinary sanctions against culpable employees, suspension of problematic relationships, increased training initiatives, a reorganized and enhanced compliance function, and the elimination of vendor



involvement to support external meetings. The Novartis resolution once again highlights the value in conducting a thorough investigation and implementing a carefully considered remediation plan.

4. China-Only Resolutions—Now Possible to Resolve Without Global Scrutiny?—Of the 10 largest FCPA resolutions in the life sciences industry, only two (Bristol-Meyers Squibb and Novartis) bear exclusively on China, reflecting the historic risk of landing before the government based on allegations in one market and leaving with a resolution encompassing concerns around the globe. Although the 10 largest resolutions stretch across five years (from 2011 to present), the resolutions with Bristol-Meyers Squibb and Novartis, together with the SciClone Pharmaceuticals resolution (another China-only outcome), have all come in the last six months. Time will tell whether the exclusive focus on China in these resolutions reflects only the particular circumstances of these matters and companies, or represents a more meaningful shift, *i.e.*, a willingness of enforcement authorities to focus investigations and reach resolutions on one market without forcing a broader review of global operations.

5. "Things of Value" Without So Much Value—As the focus on pharma continues, the Novartis resolution acts as a reminder that lesser "things of value" may draw significant regulatory scrutiny, even in China—a market where, in view of its challenges, companies may believe regulators will tolerate some level of fraud. For example, the Novartis resolution cites (alongside more egregious allegations) "favors for families of HCPs," incidents involving less than $2,000 in fraud, and holiday gifts amounting to less than $50 per HCP. The inclusion of matters of all sizes bolsters the regulators' position—as has been consistently reiterated—that they will not accept "it's China" as a defense. Instead, the enforcement expectation continues to be that companies implement creative compliance programs evolving to meet and mitigate the risks of this ever-important market.

6. Case History Programs—The Novartis resolution reflects the SEC's enhanced scrutiny of "case history programs," differentiating legitimate programs from programs intended primarily (or exclusively) to facilitate payments to HCPs and induce product sales. The resolution identifies numerous indicia associated with the Novartis program that undermined its stated purpose—"to collect and analyze patient data . . . [to] better understand[] the use and reaction" of the drug among patients—including the involvement of senior sales and marketing colleagues in the studies' design and implementation, lack of approval by the required quality assurance group, and failure to collect or analyze substantive patient data regarding the drug. In view of the SEC's willingness to examine the operation of these programs, companies should ensure that any case history programs are consistent with company policy, operate with sufficient independence from the sales and marketing function, and accomplish their intended research / scientific purpose.

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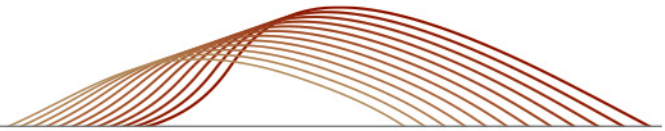

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[1] Just days after its resolution with the SEC—and in the context of the Company's ongoing review of concerns in South Korea, where local officials visited Novartis facilities in connection with suspected bribery—the media reported corruption concerns related to Novartis in Turkey (allegations the Turkish authorities are now reportedly investigating), where a whistleblower has alleged the Company paid bribes via a consulting firm.

[2] Lanny A. Breuer, Assistant Attorney Gen., Criminal Div., Dep't of Justice, Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009), *available at* http://www.ehcca.com/presentations/pharmacongress10/breuer_2.pdf.

[3] Andrew Ceresney, Dir., Div. of Enforcement, Sec. & Exch. Comm'n, Remarks at CBI's Pharmaceutical Compliance Congress in Washington D.C. (Mar. 3, 2015), *available at* https://www.sec.gov/news/speech/2015-spch030315ajc.html.