

## [의료기기 - 5] 제약, 의료기기 분야 미국 FCPA 처벌 사례 – 외국에서의 Compliance Issue



외국에서 벌어진 불법 리베이트, 향응제공 등 부패사건을 이유로 미국 **Foreign Corrupt Practices Act ("FCPA")**를 적용하여 거액의 과징금을 부과한 최근 사례를 소개합니다.

모두 언론에 보도된 공개된 사례들입니다.

### **GlaxoSmithKline**

- 2016 settlement for alleged payments to doctors by Chinese subsidiary in pay-to-prescribe schemes to boost sales.
- Between 2010 and 2013, allegedly spent nearly \$225M on planning and travel services. Payments also allegedly included gifts, improper entertainment with little or no educational value, shopping excursions, family and home visits, and cash.
- These costs were allegedly falsely recorded as legitimate expenses.
- In related Chinese action, GlaxoSmithKline was fined \$490M and its former head of China Operations was given a three-year suspended prison sentence and deported.
- GlaxoSmithKline had hired a private investigator in China to investigate possible whistleblowers, including a clandestinely-filmed sex tape involving a member of company management. The investigator was arrested and jailed in China.
- \$20M disgorgement to SEC.

중국에서 의사들에게 처방대가를 지급하는 전형적인 리베이트 건이 적발된 사례입니다.

중국자회사에서 리베이트 적발을 덮기 위해 내부고발자에 대한 몰카촬영, 협박 등 그 후속처리가 더 엽기적이라서 화제가 되었던 사건입니다.

2016년에 중국 자회사의 리베이트 행위에 대해 미국에서 \$20 million (약 2 백 2 십억원)의 과징금이 부과되었습니다.

#### **Bristol-Myers Squibb**

- 2015 settlement for charges of alleged improper payments to doctors in exchange for increased prescribing.
- Between 2009 and 2014, Bristol-Myers' China sales representatives allegedly tried to win and increase business by giving healthcare providers cash, jewelry, gifts, meals, travel, entertainment and sponsorships for conferences and meetings.
- Expenses were allegedly falsely recorded as legitimate business expenses.
- \$14M disgorgement and penalty to SEC.

BMS 자회사도 아니고 독립된 중국회사 distributor 판매회사에서 의사들에게 처방대가로 리베이트 지급, 향응제공 등 불법행위가 적발되었습니다. 2015 년 BMS 는 미국에서 \$14 million (약 150 억원)의 과징금 제재를 받았습니다.

### **Smith & Nephew**

- 2012 settlement over alleged charges of bribery of government-employed doctors in Greece to win business.
- Beginning in 1997, Smith & Nephew's subsidiaries allegedly made payments to three shell entities in the UK controlled by a distributor. Smith & Nephew allegedly sold its products to the distributor at full list price, but then paid the amount of the distributor discount to an off-shore shell company controlled by the distributor.
- The distributor allegedly used roughly \$9.4M of these off-the-book funds to pay cash bribes to Greek doctors to buy Smith & Nephew products.
- \$16.8M criminal fine to DOJ.
- \$5.4M disgorgement to SEC.

유명한 의료기기회사의 영국 자회사가 페이퍼 컴퍼니를 설립하여 그 명목으로 의사들에게 사용대가로 불법 리베이트 지급, 향응제공 등 불법행위를 한 사안입니다. 2012 년 미국 본사 Smith & Nephew 는 미국에서 총 \$22 million (약 240 억원)의 과징금을 받았습니다.

## Biomet

- 2012 settlement over alleged charges of bribery of government doctors in Argentina, Brazil, and China from 2000 to 2008. China sales were allegedly made through a distributor known to provide travel and money to government doctors.
- Biomet allegedly paid more than \$1.5M and falsely disguised the payments as commissions, royalties, consulting fees and scientific incentives.
- Biomet allegedly sent 20 Chinese surgeons to Spain where a substantial part of the trip was devoted to sightseeing and other entertainment.
- \$17.3M penalty to DOJ.
- \$5.5M disgorgement to SEC.

브라질, 아르헨티나, 중국 등 복수의 국가에서 의사들에게 제공한 불법 리베이트, 해외여행, 향응제공 등 불법행위가 적발되었습니다. 2012 년 Biomet 는 미국 당국에 총 \$23 million (약 250 억원) 상당의 벌금 및 과징금으로 처벌 받았습니다.

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