GSK $3 BILLION SETTLEMENT REFLECTS CONTINUED EXPANSION IN SCOPE OF PHARMA PLEA AGREEMENTS

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To Our Clients and Friends:

On July 2, 2012, the U.S. Justice Department ("DOJ") announced that GlaxoSmithKline LLC ("GSK") had agreed to plead guilty to three misdemeanors under the Food, Drug, and Cosmetic Act and to pay $3 billion to resolve criminal and civil liability relating to allegations concerning the promotion of nine drugs, failure to report safety data for the drug Avandia, and failure to report the "best price" for certain drugs. In addition, GSK entered into an omnibus Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS-OIG"), which incorporates requirements relating to marketing and payer practices, as well as compliance with current Good Manufacturing Practices (a vestige of GSK's settlement in 2010 of allegations relating to conditions at a single manufacturing plant, which included a felony plea and a payment of $750 million).

The GSK settlement features a number of noteworthy aspects, including an evolutionary CIA that that is unprecedented in scope. Among the CIA's more noteworthy provisions is the Executive Financial Recoupment Program, pursuant to which GSK will seek recoupment from a senior executive of an amount equivalent to up to three years of annual performance pay, including bonuses and long-term incentives, in the event of significant misconduct (*i*) by the executive or (*ii*) by employees over whom the executive had responsibility which is not isolated and which the executive knew or should have known was occurring. In another novel provision, the CIA gives HHS-OIG the ability to direct a product recall upon FDA's recommendation, thus filling a perceived gap in FDA enforcement authority and giving HHS-OIG the power to adjudicate disagreements.

Although the CIA is remarkable in many ways, the Company's plea agreement also merits notice in that it appears to reflect a new trend following the May 2012 settlement reached by Abbott Laboratories ("Abbott"). Abbott, which agreed to plead guilty to one misdemeanor and to pay $1.5 billion relating to allegations of off-label promotion, entered into a plea agreement that incorporated a number of compliance-related requirements and which subjects Abbott to an unprecedented five-year term of court-supervised probation. The GSK plea agreement with DOJ does not include a term of probation, but it does incorporate into the plea agreement, and subject to DOJ enforcement, a number of compliance requirements that typically appear in CIAs and which in fact duplicate some of the provisions in GSK's own CIA. The plea agreement also requires GSK to submit regular reports directly to the Health Care Fraud Unit of the U.S. Attorney's Office for the District of Massachusetts ("Boston USAO") and DOJ's Consumer Protection Branch. Inclusion of these measures in the plea agreement signals increased involvement by DOJ in the supervision of

pharmaceutical companies following regulatory settlements, a troubling and potentially important development going forward.

COMPLIANCE PROVISIONS IN PLEA AGREEMENT

The GSK plea agreement requires that the Company maintain policies and procedures designed to prevent violations of FDA regulations for a period of five years, including policies that limit the potential for off-label promotion, promote transparency in research and publications, and emphasize the compliance oversight function and responsibility for compliance of senior executives and directors. Breaches of these provisions can result in stipulated penalties of $20,000 per day (by contrast, CIAs typically provide for penalties of $2,500 per day for most breaches).

Several requirements for these policies reflect now-common industry practices, including: (*i*) removing incentives for off-label promotion from sales representatives' compensation; (*ii*) ensuring independence of Continuing Medical Education, including excluding involvement by commercial business personnel; and (*iii*) requiring that sales personnel refer requests for off-label information to the Company's Medical Affairs group and obtain signatures from physicians requesting off-label information. GSK also must maintain policies and procedures to ensure that its contracting and pricing activities comply with legal and health care program requirements.

In addition:

- The President of GSK's North America Pharma division ("GSK's U.S. President") must conduct an annual Compliance Program effectiveness review relating to the marketing, promotion, and sale of prescription products.
- GSK's Board of Directors also must annually review the Company's Compliance Program, although GSK's CIA adds another layer to Board oversight—requiring that the Board also oversee compliance with current Good Manufacturing Practices.
- GSK must continue its unique performance evaluation system for sales employees, pursuant to which the Company evaluates employees based on business acumen, customer engagement, and scientific knowledge, rather than prescription volume.

A number of provisions of the plea agreement focus on "full, fair, and accurate reporting and transparency in scientific data." Several such provisions reflect best practices in medical publishing and/or have appeared in CIAs for other companies, including: (*i*) registration and posting of study results on ClinicalTrials.gov; (*ii*) disclosure of GSK support and financial interests of researchers; (*iii*) limiting sales, marketing and other commercial participation in the design, conduct or publication of research; and (*iv*) a requirement that authors make substantial contributions in order to receive authorship credit and have final approval of content. In addition:

- GSK must publicly disclose certain types of data depending on study type; for example, for studies involving humans, GSK must disclose protocol summaries before enrollment, full study protocols at the time of publication, and a summary of primary and secondary efficacy endpoints and safety results after study completion.
- GSK must continue seeking to publish results of GSK-sponsored research in peer-reviewed, searchable journals, and continue to implement data dissemination plans that establish protective publication strategies, including appropriateness, accuracy, and balance.
- Employees and contractors who appear as authors must execute a certification that the medical publication provides a fair, accurate, and balanced summary of GSK-sponsored research.
- GSK must continue to require that investigators report study-related information and adverse event data before receiving final payment.

In short, the plea agreement has taken on many of the characteristics of prior CIAs, thus injecting DOJ directly into oversight of the Company going forward.

REGULAR REPORTING TO BOSTON USAO AND DOJ

Whereas Abbott's plea agreement requires submission of reports to a probation officer, GSK is required to submit reports directly to the Boston USAO and DOJ Consumer Protection Branch, including:

- An annual certification by GSK's U.S. President under penalty of perjury that, to the best of his/her knowledge, the Company has satisfied the compliance requirements in the plea agreement, as well as a summary of the annual compliance program review described above.
- An annual resolution adopted by the Board of Directors summarizing its review and oversight of the Company's Compliance Program, and stating that, to the best of its knowledge, the Company has implemented an effective Compliance Program to meet federal health care program requirements, FDA requirements, and the requirements of the plea agreement.
- Quarterly reports of "Reportable Incidents," defined as instances that a reasonable person would consider a probable violation of FDA requirements relating to misbranding or failure to submit adverse event reports.
- Information about the identity and responsibilities of the Company's Compliance Officer and the composition and responsibilities of the Company's Compliance Committee.
- SEC Form 6-Ks.

As noted, reporting directly to DOJ will increase DOJ's awareness of subsequent violations and involve DOJ immediately in any future issues.

RAMIFICATIONS

Although many aspects of the GSK settlement warrant closer examination, among the most noteworthy developments are the following:

Emphasis on Closure and Compliance Requirements. The GSK settlement is comprehensive and contains a number of innovative features, reflecting an effort to obtain closure by incorporating any past issues in order to obtain as broad a release as possible. Viewed together, the GSK and Abbott plea agreements reflect an effort by the government to put additional teeth into compliance requirements typically found in CIAs by incorporating compliance provisions directly into plea agreements, and requiring separate reporting to a probation officer or prosecutor's office.

Parallel DOJ/OIG Compliance Monitoring. Under GSK's plea agreement, DOJ will play an unprecedented role in compliance oversight by receiving periodic reports directly from the Company, representing a further expansion of the government's role in regulating pharmaceutical company activities which began over a decade ago with the watershed Neurontin settlement. The result is a plea agreement and CIA which establish two parallel tracks requiring that the Company report similar information to two regulators monitoring the Company's activities. In addition to increasing the Company's reporting obligations, this development raises questions about how, or if, the two arms of the government will coordinate their compliance oversight activities.

Continued Pressure on Senior Executives and Directors. The GSK resolution continues the government's focus on the compliance responsibilities of senior executives and directors. In addition to the annual compliance program effectiveness reviews and accompanying requirements contained in both the plea agreement and CIA, GSK's CIA includes the Executive Financial Recoupment Program described above. Recoupment of bonus monies adds a new pressure point for senior executives, who in addition face the threat of a *Park* prosecution, program exclusion under Section (b)(15) of the exclusion statute, and, under GSK's plea agreement, the threat of a perjury prosecution for submitting a false certification to the government.

Please contact us if you have any questions or wish to discuss these developments in greater detail.

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