Cephalon

MEMORANDUM

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Date: **July 26, 2007**

Subject: **Quarterly Compliance Update**

This interim report summarizes for Cephalon's Board of Directors recent key developments related to the Company's compliance program since the last update which occurred on May 17, 2007.

Key Developments in Cephalon's Compliance Program

Key developments in Cephalon's compliance program include the following:

Policy:

Model Sales Call: In order to provide additional guidance to the sales representatives regarding appropriate promotional techniques, the model sales calls that were previously developed for each of the four sales forces were substantially revised so as to coincide more specifically with the on-label indications for each of Cephalon's products. These model sales calls were rolled out

in a workshop at the Compliance Sales Meeting that took place in Philadelphia on June 25-26, as discussed further below.

Marketing Policy Handbook: Consistent with the policies that have been implemented for the field sales organization, a Marketing Policy Handbook has been finalized and has been rolled out to each of the Marketing teams. Each Marketing team has been trained on the Handbook as have affected employees in Regulatory Affairs and Medical Services. Topics covered by the Handbook include, among others: 1) Advertising and Promotion, 2) Gifts, Meals & Entertainment, 3) Advisory Boards and Consultant Meetings, 4) Grants, 5) Preceptorships, 6) Speaker Bureau and 7) WLF Reprints.

Compliance Field Guide: As part of National Compliance Week, which occurred from May 21-May 25, 2007, Cephalon distributed a new Compliance Field Guide to each member of the field sales force. The Field Guide is a reference tool that sales representatives and area managers can carry in the car with them. The tool provides an overview of the salient points of Cephalon's compliance policies.

Internal Reporting:

Ethics and Compliance HelpLine: The Company continues to operate its Worldwide Ethics and Compliance HelpLine that was first introduced in September, 2004. While ten separate calls were received by the HelpLine since May 17, 2007, only one of these reports raised a specific compliance issue. This issue is discussed below in the *Investigation/Discipline* section.

In order to ensure compliance with the requirements of Sarbanes-Oxley, the HelpLine has been activated in all European countries in which the Company is conducting business. Employees in these European countries have been informed of the availability of the HelpLine through the Code of Conduct.

***Training*:** Face-to-face training continues to be a critical part of Cephalon's Ethics & Compliance Program. Specifically:

- All new sales representatives continue to receive compliance training from a member of the Compliance/Legal team as part of the Initial Sales Training class.
- As noted above, all key employees have received training on the new Marketing Policy Handbook.
- Training on the revised model sales call was provided to all field sales personnel at the Compliance Sales Meeting on June 25-26, 2007. This included videotaping vignettes of Cephalon sales directors and area managers demonstrating appropriate and inappropriate techniques. These videotaped vignettes were then shown in workshops at the sales meeting and discussed in detail. This proved to be a particularly effective tool and appeared to resonate well with the sales representatives.

***Auditing/Monitoring*:**

Sales & Marketing Assessment: As previously reported, the Company retained the law firm of King & Spalding to conduct a compliance assessment. This assessment was comprised of two parts: 1) sales force activities review and 2) medical information review. The sales force activities review consisted of an analysis of field contact reports, sales representative weekly and monthly reports, and sales representative annual evaluations. The medical information review consisted of an assessment of a large sample of requests from physicians to the Medical Services Department (transmitted by the sales representatives) in order to determine if there are any patterns of off-label requests emanating from particular sales areas or regions of the country or for particular products.

This assessment has been completed and the results can be summarized by product as follows:

- Provigil
  - Field Contact Reports and Weekly Reports make repeated references to discussions by representatives of superiority of Provigil to stimulants. This is not supported by clinical trials and was included in the concerns raised by DDMAC in the initial FDA NOV letter for Provigil. Similarly, marketing materials (including hypersomnolence brochure) include images of brain centers affected by Provigil (all based on pre-clinical data) which was objected to by FDA in the past. Thus, some retraining of representatives regarding comparison of Provigil to stimulants appears to be necessary. It is also recommended that marketing materials be reviewed periodically to ensure they do not include material that was previously deemed to be objectionable by the FDA.
  - While overall number of visits to child psychiatrists is low, some representatives have still been making regular calls on this specialty. In order to address this concern, effective July 1, 2007, the Company has directed field sales representatives not to call on child psychiatrists or any other pediatric specialty.

- Trisenox
  - Off-label uses are mentioned very frequently in the weekly reports of representatives. While this does not mean that the representatives are promoting Trisenox for these uses, it does raise the question as to whether representatives have been proactively raising these uses. For example, one representative wrote "My MDS new patient starts are decreasing and my physicians are not indicating an interest in using Trisenox in this diagnosis." Trisenox is not indicated for MDS. Similarly, another representative wrote in a monthly report that "I am getting the impression that people are looking for more options in MM [Multiple Myeloma], and I am looking forward to working … to try to move some of these people to ATO [Trisenox]." Trisenox is not indicated for the treatment of multiple myeloma. The same representative goes on to say that "it would be great to get some clinical trial work going in the Pittsburgh area just so that people get some exposure to the drug and a comfort level with using it." Other representatives made similar comments regarding clinical trials. Giving people exposure to Trisenox obviously is not an appropriate purpose for conducting a clinical trial.

- There were a few references to pediatric use for Trisenox. One manager, in particular, stated in an FCR that Trisenox is indicated for children 5 years of age and older. This is not accurate.
- Reimbursement is also discussed frequently by the oncology representatives, but they need additional training about what is appropriate with regard to reimbursement. For example, one representative wrote, with regard to Fentora, that, she is "asking pharmacy to add Fentora as a line item extension next to Actiq so that we bypass P&T." This is inappropriate, as Fentora is not a line item extension.
- Given these various comments, the Company should consider specific training for Oncology representatives to ensure that they are promoting correctly and to ensure that their documentation accurately reflects their actions in the field.

- Fentora/Actiq
  - Generally, based on representatives' reports, their promotional efforts appear to be on-label.

- Vivitrol
  - Generally, based on representatives' reports, their promotional efforts appear to be on-label. There are, not surprisingly, numerous discussions regarding coverage.

- Review of Medical Information Review Forms (MIRFs)
  - In general, based on the sample of MIRFs reviewed, there did not appear to be any significant misuse of MIRFs by representatives.
  - However, the reviewer did find that the Medical Information letters that are sent out by Medical Services tend to be quite conclusory, rather than factual and objective. It is therefore recommended that all of the Medical Information letters be reviewed to ensure they are appropriately factual and objective.

Ernst & Young Audit

Cephalon's Internal Audit Department and Compliance are working together with Ernst & Young (E&Y) to audit certain elements of the Commercial Organization's routine operations, particularly with regard to Fentora, since that product was recently launched. Specifically, E&Y will review Fentora Marketing Plans and other Fentora marketing materials, projections, promotional strategies and the like to ensure compliance with Cephalon's promotional policies. E&Y will also conduct a retrospective analysis of the Company's sponsored activities for Fentora, such as consultant meetings, advisory boards and speaker training programs in order to ensure these programs comport with Cephalon's compliance policies in these areas. E&Y will also review Cephalon's promotional speaker programs (CSPs). This will include a review of all associated and required paperwork as well as attendance at the CSPs to ensure the content and speakers comply with Cephalon's compliance policies. Finally, E&Y will review certain activities of the Scientific Communications and Medical Services Departments, including interactions of the Medical Science Liaisons with customers and handling of grants.

Audit of Field Sales Representative Calls on Health Care Providers

In light of recent information provided to Cephalon by the US Attorney's Office (See "DOJ Investigation" Section below), Cephalon is beginning a program to audit sales calls of field sales representatives on Health Care Providers. A vendor has been identified—GfK Market Measures—and audits are expected to begin in August. GfK is a market leader in conducting these audits.

Additional Monitoring

In addition to these formal assessments, internal monitoring efforts, as previously outlined for the Board, continue. As a reminder, the Company routinely monitors the following:

- Sales representative expense reports
- Medical Information Request Forms submitted electronically by sales representatives
- Fentora prescriber reports to ensure sales representatives are calling on appropriate physicians
- Cephalon Speaker Programs
- Sales representative weekly/monthly update reports
- Field Contact Reports
- Speaker Utilization
- Field activity through ridealongs (members of the Compliance staff ride with sales representatives and MSLs and evaluate their performance to ensure consistency with the Company's compliance policies)

***Investigation/Discipline*:** Since May 17, 2007, in addition to the HelpLine calls, there have been 24 issues reported directly to Compliance. Investigations of 22 of these issues have been completed. One investigation is ongoing and the other is on hold as the employee is on disability. The matters that have come under investigation primarily include allegations of the following: 1) Sales representative statements that are inconsistent with product label; 2) Falsifying documentation or engaging in other unethical conduct; 3) Violation of the Policy on Promotional Meetings; 4) GMP violation; 5) Violation of Policy on Gifts, Meals & Entertainment; 6) Substance abuse and 7) Copyright infringement. As a result of these investigations, numerous employees received written warning letters and forfeited their quarterly bonuses.

***DOJ Investigation*:** On Thursday, May 17, 2007, I made a presentation to the USAO concerning the Company's compliance efforts over the past several years. While the presentation was well received, the USAO indicated that it did not believe "the culture of the company" had changed despite the compliance program initiatives that had been implemented over the past few years. The USAO indicated that the investigation revealed continued evidence of improper promotion outside of the labeled indications for the Company's products by Cephalon field sales representatives as recently as 2007. As evidence of this assertion, they read excerpts of conversations between Company field sales representatives and physicians, in support of their allegations of off-label promotion. These conversations were taped by physicians who had agreed to assist the government in its investigation. During our meeting, the government went so

far as to say that every sales call they had taped was problematic and included inappropriate promotion by the sales representatives.

This information was of great surprise to the Company as well as to outside counsel who also attended the meeting. As a result, a number of initiatives were immediately undertaken. First, a change was made in the leadership of the sales force. Roy Craig, the former Vice President of Sales, was offered and subsequently accepted a new position within the Company outside of the commercial organization.

The Company has also altered its field sales incentive compensation plan. More specifically, the percentage of "at risk" compensation was decreased to reduce the incentive to promote off-label. The Company is also developing a program whereby field sales representatives, area managers and regional directors will be held financially accountable for specific compliance violations. More specifically, a "compliance score card" is being developed for each representative. This score card can then be used to impact a representative's bonus.

In addition, as discussed above, the Company is implementing a new auditing program which will allow it to gather information about specific sales calls. The Company has selected a vendor to contact physicians after they have been detailed by Cephalon representatives. The physicians will then be asked to respond to certain questions. While this type of survey does not provide perfect information, it will be useful in helping to determine patterns or trends of off-label promotion.

Finally, and perhaps most importantly, the entire U.S. sales force was brought to Philadelphia in late June for a two-day meeting for training and to discuss in very open and honest terms the concerns that had been revealed by the USAO. The purpose of the meeting was to help begin to implement a change in culture that would stress the critical importance of compliance and the clear message that off-label promotion will not be tolerated. The feedback from the meeting has been very positive from all levels of the field sales force.