

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

November 21, 2008

Via Facsimile: (301) 951-0739

Roger E. Meyer, MD
Chairman and Chief Executive Officer
Best Practice
7500 Old Georgetown Road
Suite 601
Bethesda, MD 20814

Dear Dr. Meyer:

As the Ranking Member of the United States Senate Committee on Finance (Committee), I have an obligation to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to ensure that taxpayer and beneficiary dollars are appropriately spent on safe and effective drugs and devices. This includes the responsibility to conduct oversight of the medical and pharmaceutical industries that provide products and services to Medicare and Medicaid beneficiaries.

According to publically available information, Best Practice appears to have offered services for pharmaceutical companies to include the “dissemination of new ‘off label’ information.” Specifically, this information can be found on older versions of your company’s Website (www.best-practice.net/). In order to help you understand this issue better, I have attached a page from your Website to the end of this letter.

I am wondering if your company may have engaged in the promotion of off label pharmaceutical information. Accordingly, I would appreciate an explanation of the information found on your company’s Website and whether off label promotion was offered by your company and if such services are currently offered.

Thank you in advance for your assistance. I look forward to hearing from you by no later than December 5, 2008. Any questions or concerns should be directed to Paul Thacker of my Committee Staff at (202) 224-4515. All formal correspondence should be sent via electronic transmission in PDF format to Brian_Downey@finance-rep.senate.gov and original by U.S. mail.

Sincerely,



Charles E. Grassley
Ranking Member

Attachment

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Best Practice, LLC: a network of distinguished clinical investigators and opinion leaders serving as a bridge between drug companies' preclinical scientists, clinical scientists, and marketing specialists

Phase I-III Studies

Providing consultations regarding:

- Basic pharmacology of compounds
- Interactions of compounds with known neurobiology
- Most desirable clinical profile for new drugs
- Current status of treatment for relevant disorders

Providing assistance in design/conduct of Phase I studies as part of concept development

Providing access to Phase I sites in both academic centers and private sector

Phase II-III Studies

Providing assistance in design/conduct of Phase II-III studies including:

- Medical/scientific issues
- Statistical consultation
- Marketing environment
- Regulatory consideration
- Access to research sites in academic and private sector

Post-Marketing Studies

Identifying new uses for marketed products through:

- review of existing research
- review of opinion leader clinical experience

Estimating potential market size

Evaluate regulatory environment:

- new indications
- dissemination of new "off label" information

Relying on strategic relationships with Quintiles and MEDTAP

to assure:

- seamless planning with sponsors
- reduced likelihood of unexpected costs
- "hub and spoke" model