Continuing Medical Education

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PhRMA Code

- PhRMA Code on Interactions with Healthcare Professionals was adopted in July 2002
- Focuses on interactions with healthcare professionals related to the marketing of products
- Interactions should
  - Inform healthcare professionals about products
  - Provide scientific and educational information
  - Support medical research and education
  - Obtain feedback and advice about products through consultation with medical experts

FDA Guidance

FDA Guidance on Medical Education

- **Factors considered in evaluating activities and determining independence, (factors are considered as part of overall evaluation of an activity no individual factor is likely by itself to stimulate an action)**
  - Control of content, selection of presenters
  - Disclosures
  - Focus of program – educational content free from commercial influence or bias; representative title; provides discussion of treatment options
  - Relationship between provider and supporting company
  - Provider involvement in Sales and Marketing
  - Provider's demonstrated failure to meet standards of independence, balance objectivity, and scientific rigor
  - Multiple presentations
  - Audience selection
  - Opportunities for discussion
  - Dissemination
  - Ancillary promotional activities
  - Complaints
  - Additional considerations: documentation

ACCME Guidelines

- Independence
- Resolution of Personal Interest
- Appropriate Use of Commercial Support
- Appropriate Management of Associated Commercial Promotion
- Content and Format without Commercial Bias
- Disclosure Relevant to Potential Commercial Bias

Franklin v. Parke-Davis – 2002

Ad Agency Helped Push Neurontin, Documents Show
Posted: 11/08/2002

THE WALL STREET JOURNAL, 11/8/2002

By Rachel Zimmerman

A drug company now owned by Pfizer Inc., in an alleged effort to promote epilepsy drug Neurontin for unapproved uses, went so far as to hire a New York advertising agency to wage an all out marketing "war," according to documents that are part of a lawsuit.

***

The campaign by Cline Davis & Mann Inc., the Manhattan advertising firm, lays out a "tactical plan" with detailed strategies to increase prescriptions and sales of Neurontin for uses such as pain management, psychiatric disorders, migraine headaches and a condition related to diabetes.

***

The newly released documents, including a 1996 report written by the Cline Davis agency for Parke Davis called "Neurontin War Games," show "an advertising company creating illegal marketing strategies to promote off-label uses of Neurontin under the guise of medical-education seminars, advisory-board and consultants meetings," said Thomas Greene, Mr. Franklin's lawyer.

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Legal Background

- Medicaid generally covers drugs for uses approved by FDA or uses listed in certain official compendia.
- Neurontin was not approved by FDA for the off-label uses at issue listed in those compendia.
- Approximately 50% of Neurontin off-label sales thought to be reimbursed by Medicaid (25% of total sales) or VA.
- Allegations that Warner-Lambert/Pfizer* caused submission of false claims. Foreseeable that company's conduct would result in false Medicaid claims (off-label promotion and kickbacks).

* - Parke-Davis was purchased by Warner-Lambert which was subsequently purchased by Pfizer.

CME Allegations**

- Pfizer had control of virtually every aspect of the events and paid all expenses including seminar companies' fees.
- Although the seminar companies acted as conduit for payments and gratuities given to the physician attendees, Pfizer controlled every aspect of the CME programs.

** - See amended complaint, Franklin v. Parke-Davis, filed under seal in D. Massachusetts.

CME Allegations (cont'd)

- Pfizer
  - Designed and approved the programs.
  - Hand-picked the speakers for the seminars.
  - Approved the seminar presentations.
  - Previewed, in most cases, the contents of the seminars prior to delivery.
  - Selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin.
  - Evaluated the presentations to make sure their "message" was appropriately delivered.
  - Black-listed presenters whose presentations were not sufficiently pro-Neurontin.
  - Monitored the prescribing patterns of the physicians who attended to insure the purpose of the conference – increased writing of Neurontin prescriptions – was achieved.
- Follow-up reports to marketing executives highlighted that attendees received presentations regarding off-label marketing and recommendations for doses larger than those labeled effective by FDA.

Schering-Plough Settlement

- Allegation
  - Schering knowingly and willfully made material false statements to the Health Care Financing Administration regarding best price of Claritin RediTabs by concealing that Schering was providing free drug to an HMO contingent on purchases of drug from Schering
    - Blended price of samples and drug purchased was $1.10 per RediTab
    - HMO did not allow physicians to receive samples except in small quantities
    - Full trade packs shipped and distributed via pharmacies no differently from purchased drug

Schering-Plough Settlement (cont'd)

- Schering knowingly and willfully made material false statements to the FDA in order to avoid scrutiny by the FDA of Schering's off-label promotional activities regarding Temodar and Intron A
  - Untitled letter from FDA re: promotional activities at ASCO meeting
  - Sales force trained to seek off-label sales through training classes, ride-alongs and sales meetings
  - Marketing department provided sales force with plan of action that targeted off-label sales
  - Clean copies of "for your information only" articles for use with physicians
  - Goals/compensation for off-label sales as well as budget for advisory boards, speakers, entertainment and preceptorships to assist in sales

Schering-Plough Settlement (cont'd)

- Settlement
  - $435,000,000 ($180,000,000 – criminal and $255,000,000 – civil)
  - Addendum to Corporate Integrity Program
    - Five years from effective date
- Corporate Integrity Agreement
  - Compliance Program
  - Notification of communications regarding off-label uses issues
  - Specialty Field Sales Force Promotion Monitoring Program
    - Inspection of messages and materials delivered to HCPs
  - Monitoring and review of requests for off-label information
    - Policies and procedures, document and record inquiries
  - Message recall monitoring program

Schering-Plough Settlement (cont'd)

- **Independent Review Organization**
  - Promotional and Product Services Engagement
    - Review of systems
    - Transaction review
  - Systems Review
    - Field sales force handling of requests for off-label information
    - Medical liaisons
    - Medical information
    - Criteria to hire HCPs
      - Role of field
      - Written agreements
      - Fair market value
      - Tracking of services
    - Grants and sponsorships
    - Research agreements/grants
    - Compensation of field sales force
  - **Transaction Review**
    - Speaker programs, advisory boards, consulting, promotional support

How Have CME Providers Responded?

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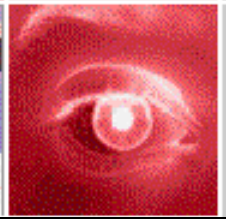
The Mission



The Goal is Customer Delight

is a proactive, knowledge-based, oriented communications and marketing organization dedicated to the creation, analysis, and delivery of ...t to management of health care and ...sion of related services in support of this goal, and the building of high-value relationships with all our customers.

The future of ... is dependent ...
not on the services and products we wish to sell ...
but on the products and services
our potential customers wish to purchase!

Our staff and their accumulated knowledge and talents are our single most important and valuable asset. The ability to leverage the knowledge, dedication, and talents of our staff to provide products and services for our customers is the core competence of the company.

April 2004

"The Goal is Customer Delight"

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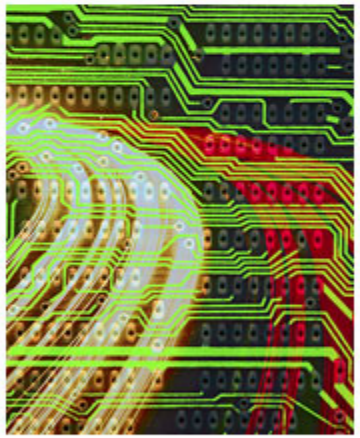

The Institute is a leader in the development execution of **independent**, appropriately **accredited**, **educational initiatives** for health-care professionals and their patients. We plan for the contextual **visibility** of new knowledge targeted to specific audiences.

We are obsessive about compliance with standards set by accrediting, regulatory, and other authorities with regard to the funding, management, and execution of such initiatives.

Please visit the Institute's separate Web site for more information.

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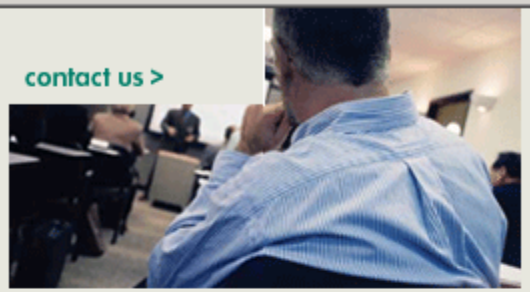

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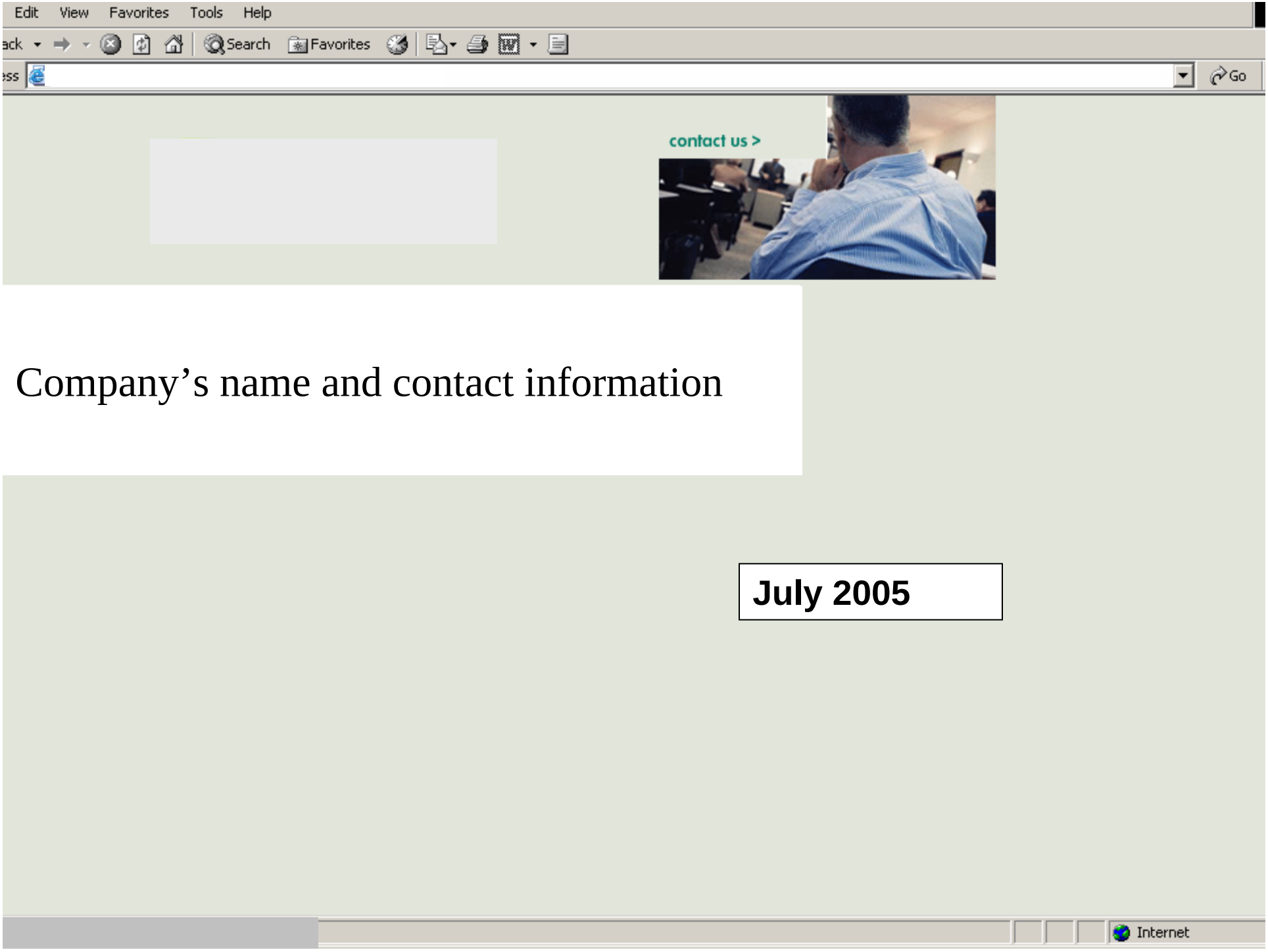
STRATEGIC THINKING

Successful marketing plans embody several strategic, tactical and innovative elements for proper market and competitive positioning. Medical education is an essential part of that approach.

believes that medical education is complementary to promotional plans. brings critical and strategic thinking to education planning in partnership with the product team. Knowledge of products and clinical data, disease states, marketing focus, and relationships with key opinion leaders and faculty are main components of the process. Targeted marketing of education is key.

CME company believes that medical education is complementary to promotional plans

April 2004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Potholes in the Road of Appropriate CME...

Pothole #1: The Vendor and the Contract

- "We've hired a vendor to do the program. The vendor is going to have an accredited organization provide the CME accreditation. The vendor's proposal states that the program will "build brand awareness and will be essential to the success of our business plan."
- This should be a great program for us! We've worked with this vendor before with no problems. They've done lots of programs just like this for other pharmaceutical companies.
- Why do we need a contract anyway? It only slows things down."

The Vendor/Contract (cont'd)

- The objective of "building brand awareness"
  - FDA/ACCME
    - Activities must be free of commercial bias...present objective information about products based on accepted scientific methods
    - Materials shall not advance the specific proprietary interests of the sponsor

The Vendor/Contract (cont'd)

- FDA Guidance
  - One factor: Is the central theme of the program based on a single product marketed by the sponsor?
  - One factor: Is the [vendor] also involved in advising/assisting the sponsor in the sales or marketing of the sponsor's product?

Avoiding the Vendor Pothole

- Work with accredited CME providers
  - Institutional or commercial
- Use only vendors who have a reputation for developing rigorous, objective scientific & educational programs

Avoiding the Vendor Pothole (cont'd)

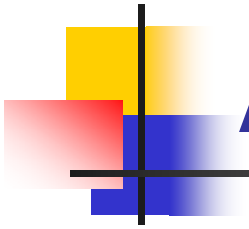
- First rule: GET IT IN WRITING
- ACCME Standards require that accrediting provider has a signed contract with supporter/sponsor
  - FDA Guidance: Contract is optional, but provides evidence of independence; should contain FDA Guidance factors

Pothole #2: The Roadshow...or "That was so good let's do it again!"

- "If the program turns out really good for our product, we'll go back to the vendor who says they can get the speaker to give this program 15-20 more times over the next year...all with CME accreditation!"

The Roadshow (cont'd)

- ACCME Standards: CME providers must demonstrate that repeated activities all meet the requirements of the Standards
- FDA Guidance: Multiple presentations of the same program are a factor FDA will consider in determining the independence of the program



Avoiding this Pothole

- The contract with the accrediting organization should provide for a specified number of programs