PDUFA and DTC Advertising Reviews Prior to Use

Public Hearing

February 16, 2007

Testimony of the

Coalition for Healthcare Communication

COALITION FOR Healthcare Communication

Coalition for Healthcare Communication

- Companies and trade associations engaged in medical publishing and creating advertising, public relations & CME
- First Amendment protects citizen right to hear and company right to hear about new products and new uses of existing products
- Self-regulation serves citizens, industry & government

PDUFA WORKS

- History supports value of PDUFA to patients, industry and FDA
- CHC support PDUFA since early 90’s
- Program enables new medicines, improved quality of life, prevention of disease & treatment advances

Major Points

- Need for new procedures, staff?
- Reform standards first
- Create clear distinctions for professional & consumer communications
- Limit fee use to DTC prior reviews
- Respect court requirements
- Protect FDA jurisdiction

COALITION FOR Healthcare Communication

DTC Advertising Works

- Patients & caregivers learn of new treatment options
- Stimulates conversations with doctors and other HCPs
- Stimulates diagnosis, treatment
- Advances public health

PhRMA Principles Work

- Clearer risk messages
- Educate prescribers first
- Avoid adult products on Prime Time
- Limit reminder ads
- Pre-clear when possible

PhRMA Principles Work for FDA

- Increased use of Pre-clearance opportunity
- Warning Letters reduced
- Virtually no DTC Warning Letters since PhRMA Announcement in mid-2005
- Fewer consumer complaints

Meanwhile: Clearer Guidance Needed from the FDA

- More objective, predictable standards
- Must respect difference between professional and consumer information needs
- More reliance on social science

COALITION FOR Healthcare Communication

Brief Summary Reform

- Time for FDA to issue final guidance
- Need to avoid complicated messages
- Consider an approved, standard format
- Time to kill “Holy Roman Empire” analogy

COALITION FOR Healthcare Communication

New Standards May Preclude Need for 27 Additional Reviewers

- Avoid calls for mandatory review
  - First Amendment Prevents “Prior Restraint’
  - Mandatory Reviews will clog process
- Clear, consistent standards create significant efficiencies for FDA, companies & ad agencies

Proposed System Requires Safeguards

- Limit revenue use to specified purposes
- Avoid “mission creep,” and “personnel redeployment”
- Develop and adhere to clear deadlines
- Reduce DTC review staff if appropriate

Court Requirements

- Public record for new program
- FDA has “Burden of Proof”
- Must
  - articulate need for new rules, proceedures
  - prove new procedures work
  - consider narrower alternatives
  - use marketing limits only as last resort

COALITION FOR Healthcare Communication

Meanwhile FDA Must Protect Marketing Jurisdiction

- Resist inconsistent state laws, attorney general enforcement
- Participate in state cases
- Resist private actions for “failure to warn” and “false advertising”
- Resist policy expansion by HHS-IG under “false claims” jurisdiction

COALITION FOR Healthcare Communication

Summary

- Start with clear objectives, proceed carefully
- Separate professional & consumer DTC standards
- Follow Court mandates
- Resist attacks on jurisdiction

COALITION FOR Healthcare Communication

For Further Information

- John Kamp
- Coalition for Healthcare Communication
- www.cohealthcom.org
- 212-850-0708
- 202-719-7216
- Jkamp@cohealthcom.org

COALITION FOR Healthcare Communication