Stresses on Drug Marketing in 2007 & beyond

John Kamp
Executive Director
Coalition for Healthcare Communication
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Macro View

- Public Perception of Pharma
  - Approval Ratings below lawyers, car dealers & President Bush
  - Off Bottom, or "Dead Cat Bounce" ?
- Congressional Action, consumer & prescriber caution on Safety Issues
- FDA's near "freeze" on New Drug Approvals

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Marketing Tactics Under Siege

- Marketing, esp. DTC, attacked by Voters, Doctors, Policy Makers & the Press
- Detailing, sampling & promotional education limited by medical schools, managed care and individual prescribers
- Company funded CME pressured by Congress, ACCME
- Marketing use of prescriber data banned in New Hampshire, Vermont & Maine
- "False Claims" punished by HHS-IG, Whistleblowers
- "Gifts to Physicians" registries growing in states, proposed in Senate and House
- "Failure to Warn" class actions suits follow safety concerns

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What didn't happen Drug Marketing on Capitol Hill in 2007

- Safety Limits on all marketing
  - Symbol on all new drugs
  - REMS "review" of every drug campaign
  - Tax penalty for all marketing
- DTC Ban, new warnings
  - 3 year moratorium on new drug ads
  - Pre-clearance of every ad10 second flash of 1-800 Adverse Events line
  - 10 second flash of 1-800 Adverse Events line
- But, script for Hill and White House in 2008?

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What Did Happen

- Significant new FDA power to review all marketing under REMS program
- Thirty Six new FDA staff to review of DTC
- Congressional "cover" for more aggressive DDMAC enforcement action
- New DTC Advisory Committee

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Broader Safety Provisions FDA Amendments Act of 2007

- Active surveillance system
  - Public private partnerships
- REMS
  - Communication programs
  - Restricted distribution, use
- New Labeling power
- New studies or clinical trials orders

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REMS (the new “Risk Maps”)

- Secretary may require a REMS, if necessary, to ensure that the benefits outweigh the risks
- Secretary may require a REMS if,

  based on a signal of serious risk,

  a REMS is necessary to:
  - Assess signal
  - Mitigate risk
- Perhaps the most significant change in decades

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New DTC Review System

- Payment for Review of television ads
  - Except Required Submissions
  - Raise $6.25 M/ up to 150 ads
    - Workload and cost of living adjusted
- Payment: due Oct 1 of submission FY
  - Late (Nov 1) fee 150%
  - Operating reserve fee, 1st FY you pay
  - Non transferable, carry over max 1
  - Cap $83 K in 08; 150% increase per FY

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Pre-review of TV Ads

- Pre-review of Advertisements (45 day)
  - Information in brief summary relating to a serious risk or a safe use protocol
- Specific Disclosures
  - Serious Risk or Safety Protocol
- Fair Balance, False or Misleading, within label indications

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New FDA DTC Rule

Required Rule-Making on "Major Statement"

- New requirement that the "major statement" in radio and TV ads must be presented in a "clear, conspicuous, and neutral manner"
- FDA must promulgate regulations establishing standards for determining the meaning of "clear, conspicuous and neutral"
- Open Question: Are these regulations subject to the Part 15 Public Hearing procedures?
- If so (and perhaps even if not), any rule-making may be much broader than specifically required and also quite onerous and contentious

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New Civil Money Penalties (CMPs)

- Hill Compromise to avoid DTC Ban
  - Applies to DTC ads that are "false or misleading"
  - $250K for first violation in 3 year period/$500K for subsequent violations
  - FDA may face heavy pressure to make frequent use of new CMP authority
- Major Question: Will CPM authority broaden to all marketing?

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Risks and Opportunities of DTC Reviews

- Unclear if voluntary program will sustain new DDMAC program, reviewers
- Participants will get more timely, predictable reviews
- When is pre-review advisable:
  - Expensive production; long-running, visible ads
  - Ads nearing "edge of envelope"
  - Where required by consent decree/accelerated review
  - Competitive therapeutic classes where complaints likely
  - Insufficient company ad review process; poor compliance history

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What Next ?

- Congressional Report– FDA must report to Congress within 2-years concerning DTC communication with elderly, children, racial and ethnic minorities
- FDA must conduct study by March 2008 to evaluate whether Adverse Events # required in print ads as be in broadcast ads.
- FDA Advisory Committees on Risk Communication & DTC will advise, recommend, raise issues
- New Congress, White House, HHS-FDA leaders
- Candidate Edwards proposes DTC ban

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Certified CME Grants Under Attack

- ACCME increasing oversight
  - 2004 Standards for Commercial Support
  - August 2007 "Commercial Interest" policy
- Congressional Oversight
  - 2007 Senate Finance Committee Report
  - Senate (Grassley & Kohl), House (Waxman) proposals for "national registry of payments and gifts to physicians"

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Continuing Medical Education

- Two types of prescriber education
  - "Promotional detailing, education programs
    - Must stay within labeling
    - Closer review by FDA & under HHS-IG "CIAs"
  - Independent, Certified CME for mandated CE
    - Company grants allowed by 1997 FDA Guidelines
    - Accredited by ACCME, AAFP, others

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NEW RULES FROM ACCME

- Broad definition of "commercial interest"
- New "fire wall" requirements
- Asserts jurisdiction on "joint sponsor" MECCs
- Double Standard for MECCs and favored providers

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Coalition/NAAMECC Response to ACCME

- Coalition letter challenges impossible deadlines on compliance
- Joint Sponsor MECCs deadline now August 2009
- Coalition/NAAMECC request meeting to develop clear guidance
- Coalition to challenge definitions, double standard

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Public/Industry Education

- "Certified CME is Different"
- Development of consistent language, clearer messaging
- Reaching out to broader community
  - SACME, Alliance for CME, AMA Task Force
- Speaking Out at Industry Conferences
  - DIA, FDLI, Med Ed Forum, etc.

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Congressional Education on CME Issues

- Coordinating with Industry Groups, including PhRMA, AMA, AdvaMed
- Reaching out to Hill leaders
- Concern about "Gift to Physician" Registries
- Tom Sullivan, CEO of Rockpointe, coordinating effort

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Prescriber Data

- New Hampshire bans "commercial use" in July 2006
  - Federal trial court invalidates under First Amendment Spring 2006 – appeals pending
- Maine & Vermont pass similar legislation several weeks later
- Congressmen Waxman & Pallone propose federal ban

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Federal & State Prosecutions

- False Claims act
  - Focus on "off-label" information that leads to prescribing, thus "false" reimbursement by Medicare, Medicaid, etc.
  - New interpretation of FDA labeling rules
- Anti-kickback Act
  - Punishes bribes and gifts to physicians
- Over $4.5 Billion in Settlements since 2000

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Failure to Warn

- New private action, negligence tort cases in wake of safety publicity
- High profile actions against Wyeth (phen-phen), Merck (Vioxx) -- GSK ? (Avandia)
- Class actions may be limited, e.g., Merck
- But, new theories every day, e.g., failure to inform

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Kamp Crystal Ball

- Clouded at best, maybe shattered
- Some hope
  - Part D lessens citizen, political pressure
  - PhRMA guidelines on DTC, gifts to physicians
  - Legal, political defense by PhRMA, others
- Some despair
  - Right to free healthcare, drugs
  - Political value in criticizing drug marketing
  - Sicko media

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For More Information

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

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