PEER REVIEW INSTITUTE

PROFESSIONAL VETTING OF PHARMA MATERIALS

Review Materials Including:

- *Core Claims Documents*
- *Sales Training*
- *Detail Aids*
- *Journal Ads*
- *Publications/Posters*
- *Speaker Slide Sets*

DISCUSSION TOPICS

- Situation Review
- Peer Review Institute (PRI) Overview
- Our Process
- PRI Benefits (& Limitations)
- Summary

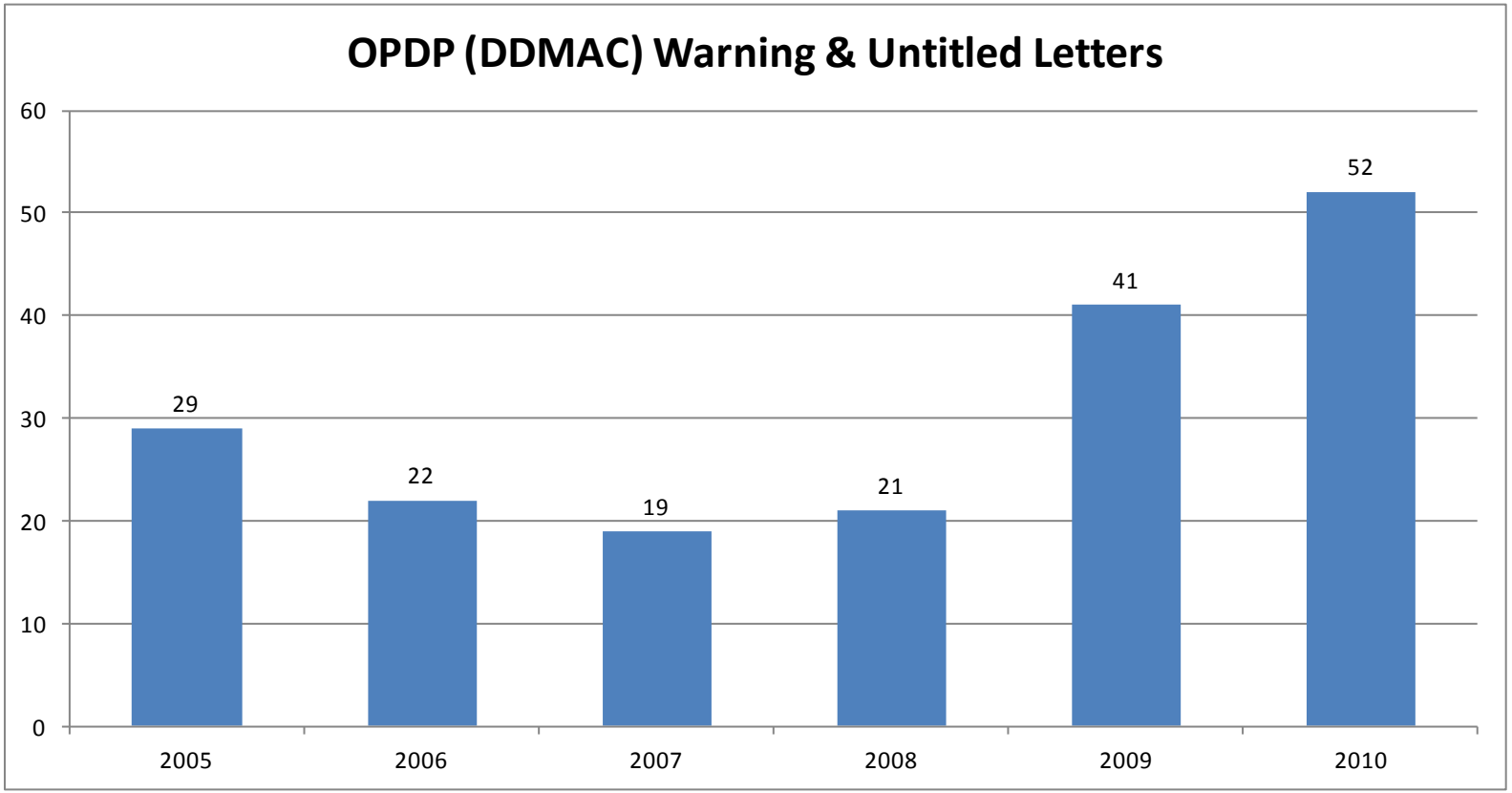
SITUATION REVIEW

OFFICE OF PRESCRIPTION DRUG PROMOTION (FORMERLY DDMAC)

- **Mission**

"To protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers."

SITUATION REVIEW



Source: www.fda.gov (accessed Sept 2011)

SITUATION REVIEW

OPDP (DDMAC) Allegation	2010	2009
Omission & Minimization of Risk Information	85%	86%
Broadening, Omission, or Misleading Indication	40%	56%
Overstatement of Efficacy	63%	37%
Unsubstantiated or Misleading Comparative or Superiority Claim	46%	23%

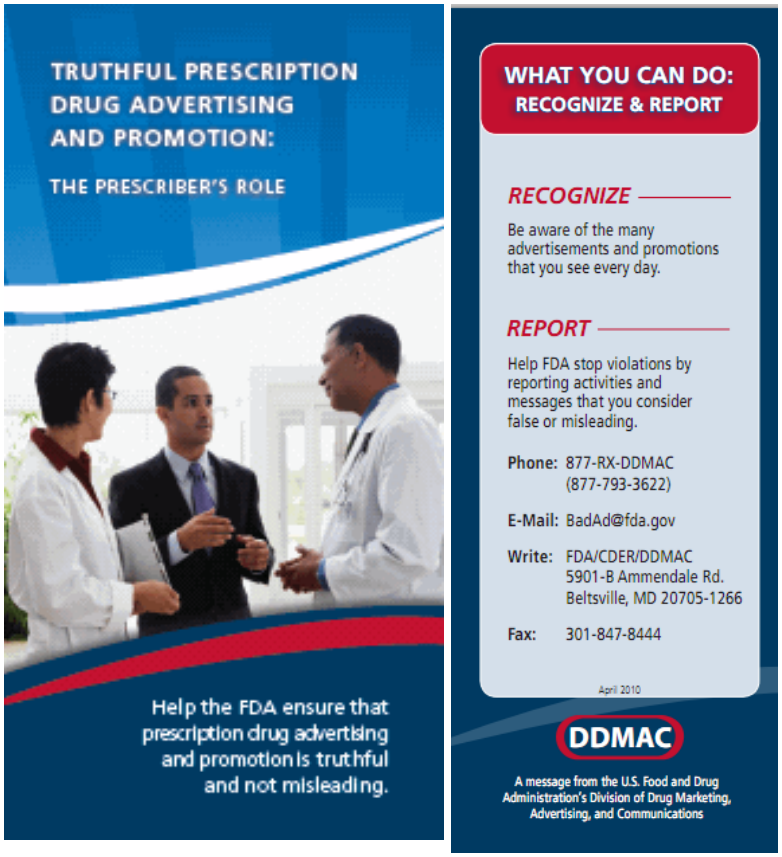
Source: King & Spalding Client Alert, 2010 Year in Review: DDMAC and APLB Warning Letters & Untitled Letters

SITUATION REVIEW

- OPDP (DDMAC) allegations of inadequate presentation of risk information most frequently cited
- Simultaneous issuance of letters to numerous companies
  - Commonly employed promotional practices may not be safe
- Close scrutiny of clinical studies cited in support of claims
  - Type of study (e.g. randomized, head-to-head, etc)
  - Study endpoints – do they adequately support promotional claims?

Source: King & Spalding Client Alert, 2010 Year in Review: DDMAC and APLB Warning Letters & Untitled Letters

SITUATION REVIEW



The "Bad Ad" Program

- FDA outreach program designed to educate HCPs about the role they can play in helping ensure that prescription drug advertising is truthful and not misleading
- Provides HCPs an easy way to report misleading promotion that occurs in field based settings
  - 877- RX- DDMAC
  - BadAd@FDA.gov

SITUATION REVIEW
PROMOTION VIOLATIONS

Company	Fine	Drug(s)	Date
GSK	$3.0 billion	Advair, Avandia, Flovent, Imitrex, Lamictal, Valtrex, Zofran	July 2012
Pfizer	$2.3 billion	Bextra, Celebrex, Geodon, Zyvox, Lyrica	Sept 2009
Eli Lilly	$1.4 billion	Zyprexa	Sept 2009
TAP	$875 million	Lupron	Oct 2001
Serono	$704 million	Serostim	Oct 2005
Astra Zeneca	$520 million	Seroquel	April 2010
Schering-Plough	$435 million	Temodar	Aug 2006
Warner Lambert (Pfizer)	$430 million	Neurontin	May 2004
Cephalon	$425 million	Actiq, Gabitril, Provigil	Sept 2008
Novartis	$422 million	Trileptal, Diovan, Exforge, Sandostatin, Tekturna	Sept 2010

Source: World of DTC Marketing. May 17, 2011

PEER REVIEW INSTITUTE

WHO WE ARE

- PRI's Advisory Board/Reviewers include Thought-Leaders with experience from positions in:

- ***Public Policy***
- ***Food & Drug Administration (FDA)***
- ***World Health Organization (WHO)***
- ***National Institutes of Health (NIH)***
- ***Medical Schools***
- ***Pharmacy Schools***
- ***Pharmaceutical Industry***
- ***Clinical Practice***

PEER REVIEW INSTITUTE
WHO WE ARE—ADVISORS

Advisory Board Member	Key Experiences
Rear Admiral (Ret.) Richard J. Bertin, PhD., RPh	Former Executive Director of Board of Pharmaceutical Specialties, Formerly U.S. Public Health Service, FDA, U.S. Surgeon General's Office
Charles Daniels, PhD, MS	Professor & Assoc Dean Clinical Affairs, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California School of Pharmacy, San Diego Ex-Director Pharmacy, NIH Bethesda, MD
Enrique Fefer, PhD., MS	Director Pharmacy Programs PAHO (WHO) Former Director, International Affairs, U.S. Pharmacopeia
Robert I. Field, PhD, MPH, JD	Professor, Department of Health Management and Policy & Professor of Law Earle Mack School of Law, Drexel University
Albert J. Finestone, MD, MS	Associate Dean of CME, Professor of Medicine Emeritus, Temple University Board Certified: Internal Medicine
Charles Laudadio, MD, MBA	Global Medical Affairs, CSL Behring Director Clinical Development (diverse pharma industry experience)
Bryan Liang, MD, PhD, JD	California Western School of Law, Adjunct Associate Professor of Public Health, College of Health & Human Services, San Diego State University
Eucharia Nnadi, RPh, JD, PhD	Chancellor, Roseman University of Health Sciences, NV Ex-Dean, Howard University School of Pharmacy
Frank Palumbo, PhD, JD, RPh	Professor and Executive Director, University of Maryland School of Pharmacy Center on Drugs & Public Policy
Peter Howard Rheinstein, MD, JD	Former FDA, Director Drug Advertising & Labeling Division

PEER REVIEW INSTITUTE
WHO WE ARE – REVIEWERS

- PRI leverages a team of nearly 300 physicians, pharmacists & other independent specialists
- Reviewers have extensive experience in medical, regulatory & healthcare management
- Reviewers typically affiliated with Academic Medical Centers
  - Dept Chairs – U.S. & International Medical Centers
  - Editorial Board Members – Peer-Reviewed Medical Journals

PEER REVIEW INSTITUTE
WHO WE ARE

PRI's Advisory Board/Reviewers include experts in:

- Adverse Reactions
- Allergy
- Alzheimer's Disease
- Ambulatory Care
- Anticoagulation
- Asthma
- Cardiology
- Clinical Pharmaceutics
- Clinical Pharmacology
- Formulary Management
- Clinical Trials
- Alternative Medicine
- Critical Care
- Dementia
- Dermatology
- Diabetes
- Substance Abuse
- Drug Information
- Drug Interactions
- Dyslipidemia
- Emergency Medicine
- Endocrinology
- Evidence-based Practice
- Family Medicine
- Gastroenterology
- Geriatrics & Long-Term Care
- Health Policy
- Hematology
- Hospice & Palliative Care
- Hypertension
- Immunology
- Infectious Diseases
- Internal Medicine
- Medical Informatics
- Medicine, Law & Ethics
- Medication Safety
- Neonatology
- Nephrology
- Neurology
- Nutrition Support
- Obesity
- Oncology
- Ophthalmology
- OTC Drugs
- Pain Management
- Pediatrics
- Pharmacy Education
- Pharmacoeconomics & Outcomes
- Pharmacoepidemiology
- Pharmacogenetics/genomics
- Pharmacokinetics
- Pharmacometrics
- Pharmacovigilance
- Psychiatry
- Public Health
- Pulmonary
- Quality of Life
- Research Design & Statistics
- Rheumatology
- Risk Management
- STDs & HIV/AIDS
- Toxicology & Poison Control
- Transplantation
- Urology
- Vaccines
- Women's Health

PEER REVIEW INSTITUTE
WHAT WE DO

- Provide unbiased professional vetting of promotional materials developed by pharmaceutical, biotech & medical device companies
  - *Core Claims Documents*
  - *Sales Training*
  - *Promotional & Detailing aids*
  - *Speaker Slide Decks*
  - *Journal Ads*
  - *Publications / Posters*
  - *Agency "Pitch" Decks*

- Ensures objectivity & balance in promotion through rigorous review of scientific literature supporting claims

PEER REVIEW INSTITUTE
WHAT WE DO

- Approve and/or offer specific recommendations to ensure maintenance of scientific rigor in advertising material
  - ✓ *Certification that promotional material was reviewed by independent experts who found it to be compatible with currently available published literature and is presented in an objective and balanced manner*
- Responsive – *typical turnaround within 1 week*
- Minimum of 2 expert reviewers provided per item submitted
- Approved material authorized to display copyrighted Peer Review Institute *Seal of Approval*

PEER REVIEW INSTITUTE
SEAL OF APPROVAL

Peer Review Institute has evaluated the content of this advertisement and deemed it to be objective, fair-balanced, clinically relevant and scientifically accurate.

www.peerreviewinstitute.com

PEER REVIEW INSTITUTE
BENEFITS

- Evaluates claims against peer-reviewed, credible, scientific sources
- Assists in reducing risk of OPDP action via additional level of scrutiny
- Augments trust & integrity of promotional claims through adherence to evidence-based information
- Provides an additional resource to company's Medical reviewers
- Builds a potential competitive advantage
- Enhances credibility of company/brand among HCP customers
- Helps keep promotional review an internal process

PEER REVIEW INSTITUTE
LIMITATIONS

- PRI review is not intended to replace a company's internal Medical, Legal, Regulatory review of promotional items
- PRI does not evaluate material against Legal or Regulatory standards
- Not a guarantee against FDA Regulatory action

PEER REVIEW INSTITUTE
ADVANTAGES

- **Support in the event of regulatory action**
  - *Will provide position paper and counsel in the event of FDA letter, etc*
- **Helps facilitate medical review during busy periods**
  - *Product launches, POA meetings, review of core claims documents*
- **Provides an expert external perspective**
  - *May help identify unconsidered areas of scientifically supported promotional opportunity*
- **Mitigate risk with highly scrutinized promotional tactics**
  - *Journal & DTC advertisements, Web-sites, Speaker slide decks*
- **Good-faith demonstration of commitment to Good Promotional Practices**
  - *Recipients of Warning & Untitled Letters, Corporate Integrity Agreements*

PEER REVIEW INSTITUTE

WHO SHOULD USE PEER REVIEW INSTITUTE?

- Brand Management Teams
- Medical Affairs
- Regulatory / Compliance
- Chief Executive Officers
- Advertising Agencies
  - *"Value add" to the brands it supports*
  - *Fortifies impact of "pitch deck" presentations and provides ideas*
- Publications Planning Personnel
  - *Expert support for clinical studies manuscripts*
- Clinical Research & Development
  - *Expert support in preparation of posters, scientific presentations*

SUMMARY

Peer Review Institute offers additional assurance for pharmaceutical, biotech & medical device companies seeking to provide HCPs with promotional material vetted by independent, therapeutic category experts who will ensure that it is clinically sound, fair-balanced, and compatible with current scientific literature.

CONTACT US

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