

PEER REVIEW INSTITUTE

EXPERT, OUTSOURCED PROMOTIONAL REVIEW

***Contract Promotional Review Committee
support for the Pharmaceutical Industry***

- ***Medical Affairs***
- ***Regulatory***
- ***Legal***



DISCUSSION TOPICS

- Situation Review
- Peer Review Institute
- Our Services
- Client Advantages
- Summary



SITUATION



Promotional Review Committee (PRC)

Copy Clearance Committee (CCC)

Medical Legal Regulatory Review (MLR)

Review Committee (RC)

Marketing Advertising Review Committee (MARC)



SITUATION – INDUSTRY TRENDS

- A heavy and increasing workload is industry norm for many key functional areas
 - Medical Affairs, Regulatory, Legal

- Vacancies often exacerbate this existing personnel challenge
 - Promotions, Resignations, FMLA absences, RIFs

- High volume periods may complicate the timely approval of promotional materials
 - Product launches, POA meetings, new indications



SITUATION – INDUSTRY TRENDS

- **Limited talent pool**
 - Identifying and acquiring experienced Regulatory and Medical Affairs candidates with highly specialized expertise is challenging
- **Cost savings and efficiency initiatives on-going**
 - Unpredictable “spacing” of new NDAs and launches creates staffing inefficiencies with very heavy and very light workload periods
- **Outsourcing of critical functions has become commonplace**
 - Contract Sales Organizations (CSOs), Contract Research Organizations (CROs)



PEER REVIEW INSTITUTE – MISSION

A new concept in outsourcing...

The first and only company specialized to provide expert, outsourced Medical Affairs, Regulatory & Legal talent to facilitate the internal review of promotional materials for the pharmaceutical, biologicals, medical device and diagnostics industries.



PEER REVIEW INSTITUTE – OVERVIEW

- **Established 2011**
 - First and only company specializing in Contract Promotional Review Committee (C-PRC) support
- **Advisory team comprised of accomplished, senior-level, high profile experts in healthcare industry**
 - FDA, WHO, NIH, industry and academia
- **PRI has an affiliation with approximately 300 reviewers**
 - Medical Affairs: HCPs representing a wide array of medical specialization
 - Regulatory: Personnel with both industry and regulatory (OPDP) experience
 - Legal: Numerous legal reviewers with clinical and industry background



PEER REVIEW INSTITUTE – OVERVIEW

PRI's Advisory Board and 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 – ADVISORY BOARD

Advisory Board Member	Key Experiences
Rear Admiral (Retired) 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
Eucharía 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 H. Rheinstein, MD, JD	Former FDA, Director Drug Advertising & Labeling Division



PEER REVIEW INSTITUTE – CATEGORIES

*PRI's Advisory Board and Reviewers include experts in:**

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



* Chart represents only a partial list of therapeutic categories. Please contact us if there is a specialty of interest that does not appear above.

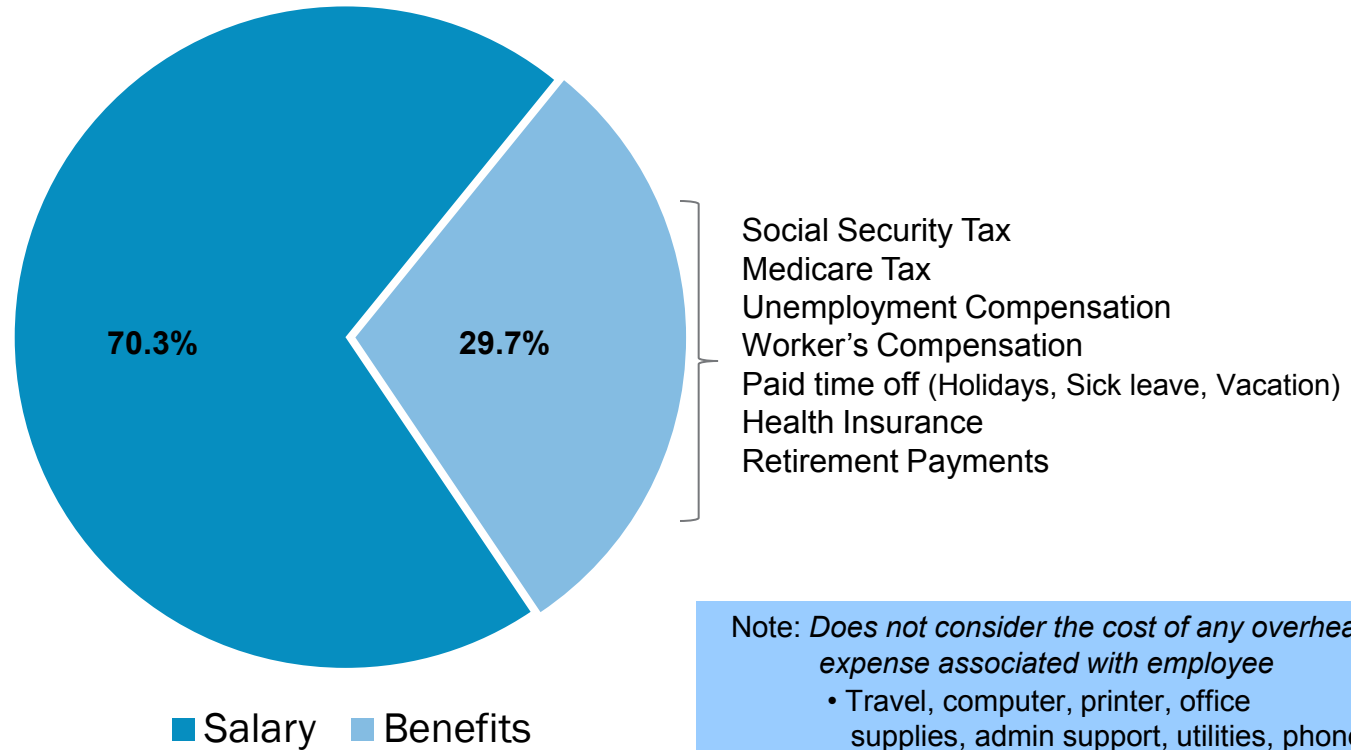
PEER REVIEW INSTITUTE – OUR SERVICES

- Effectively handle any or all aspects of a company’s promotional review needs
 - Medical Affairs, Legal, Regulatory reviewers
- Highly Flexible
 - Short notice
 - Available for temporary or long-term assignments
 - Entire team or specific roles (individual reviewers)
- Economical when compared to hiring employees
 - Compare PRI to paying Recruiter fees, employee “Sign On” Bonus + Salary + Year-end Bonus + Benefits + Overhead
 - Same employee expense incurred with light or heavy workload periods
 - No separation/severance payments to consider



PEER REVIEW INSTITUTE – OUR SERVICES

Benefits as a % of Total Employee Compensation



Note: *Does not consider the cost of any overhead expense associated with employee*

- Travel, computer, printer, office supplies, admin support, utilities, phone, etc



PEER REVIEW INSTITUTE – OUR SERVICES

- **Expert support in the event of regulatory action**
 - PRI will provide position paper and counsel in the event of FDA letter, etc

- **Provides an expert external perspective**
 - May help Marketing team identify unconsidered areas of scientifically supported promotional opportunity
 - PRI medical experts can help an organization accelerate through the “learning curve” if launching product in new, unfamiliar category



PEER REVIEW INSTITUTE – OUR SERVICES

- All control and management over process is retained by company
 - Reporting and communication performed at client direction
- PRI Reviewers are subject to all client SOPs, guidelines and policies
 - Compliance training and certification
 - Non-disclosure
- Seal of approval may be used on any promotional materials approved by PRI reviewers
 - Good-faith demonstration of commitment to Good Promotional Practices



CLIENT ADVANTAGES

- **Small or start-up companies**
 - Stay “virtual” - hire fewer permanent employees, take on little overhead, run lean, economical organizations
- **Mid-to-large organizations**
 - Provides quick solution to filling any coverage gaps – short or long term
 - ❖ Promotions, disability/maternity leave, resignation, retirement, reductions
- **Big Pharma**
 - Augment permanent staff during periods of heavy review volume
 - ❖ Launches, POA, new indications, adverse information communications



PEER REVIEW INSTITUTE – CONTACT US

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