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## RISK EVALUATION & MITIGATION STRATEGY (REMS) SERVICES OVERVIEW: THE CONTINUUM

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Throughout a brand's lifecycle, there is a continuum of strategy and executional needs required to satisfy the requirements of Risk Evaluation and Mitigation Strategy (REMS), a provision added to FDA's Amendment Act in 2007.

A REMS must be submitted to the FDA for any drug product deemed to have serious risks – either prior to the product's approval or even after the product is marketed. Further, the FDA can delay approval if it deems the submitted REMS to be insufficient. FDA is also authorized to declare the product misbranded, and thus ineligible for marketing, if the company fails to follow the approved REMS.

**CCC helps to ensure that risk information is communicated effectively and proactively – both internally and externally.**

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CommCore, the leader in message development and speaker training, partners with us on a number of the services below.



Theodolite charts an efficient, effective and profitable path to organizational success, ensures ROI on human capital, and brings organizations and their leaders to the next level.

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### Products and Services

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#### REMS Creation

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##### Assessment

CCC can provide an independent and objective view to help a company determine whether a REMS will be required, or to provide expert guidance on the scope of a REMS. Our experts review product clinical trial data, with particular emphasis on the 1) safety aspects, 2) identified risks in the target patient population, 3) the Integrated Summary of Safety (ISS), and 4) approved ex-US label and risk management plans. If a REMS is necessary, our experts provide an outline for it.

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##### Development

Based on the company-approved outline, a comprehensive write-up of the proposed REMS program is prepared for submission to the FDA.

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##### FDA Interface

Our regulatory and legal experts, many of them former FDA officials, can support a company's interaction with the Agency.

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## Research

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### **Comprehension and Literacy Studies**

Market research is often necessary to gather insights for REMS development and/or to test a REMS program's effectiveness (once it has been completed prior to FDA submission and then at key milestones later on). CCC has a turnkey approach to research, from establishing communications objectives and a discussion guide, to recruitment and strategic analysis.

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## Education

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### **REMS Telecon**

This archived one-hour teleconference, with a supporting slide deck, addresses **REMS in the New ERA of FDA**. The three-part discussion provides an overview of REMS, explores the implications of REMS for communication professionals, and answers a series of questions. (See recent REMS activities below).

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### **REMS Messaging Workshop**

Once a REMS is in place, in-house communication professionals need to work with regulatory, medical, and marketing to nail down internal and external communication needs. This workshop helps to appropriately frame the REMS during the development of marketing communications for a drug – before launch and ongoing, as a part of the overall post-marketing communications campaign. Specific plans for addressing potential FDA announcements of adverse drug effects, or a possible REMS rejection, is part of the preparedness planning.

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### **REMS White Papers**

Our library of benchmarking reports dissects diverse REMS and their communication plans. These were developed based on secondary research and interviews with experts.

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## Preparedness Planning

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### **FDA Advisory Audit**

Often REMS proposals are brought before FDA advisory committees. CCC helps companies prepare a detailed analysis of the advisory committee members who will be reviewing the REMS program. This audit will cover: members' voting history and relationship spheres, positions and opinions. Ultimately, the company creates a focused REMS presentation for the committee, with deep insight into issues that will be of interest and concern to committee members.

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### **Scenario Planning and Message Development**

Through collaboration with CommCore, CCC prepares a scenario-based communication plan to ensure companies are prepared for any advisory committee outcome, as well as for challenges from potential detractors. Crafting solid talking points and key messages increases the likelihood that key stakeholders clearly understand the intent of the proposed and/or approved REMS. We can help build messages that are not only compliant and technically sound, but also memorable. This is particularly important when dealing with scientific data, as only a fraction of the information will be remembered regardless of the audience's scientific knowledge.

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### **Speaker Training**

Presentations by company executives and external stakeholders about a company's REMS program must be engaging, persuasive and build trust and credibility for the speaker(s). Collectively, the team brings 25 years of experience having coached thousands of scientists, executives, researchers,

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investigators and key opinion leaders with proven learning modules.

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### **Mock Advisory Committee Meeting**

CCC and CommCore help companies prepare for FDA advisory committee meetings by simulating the actual event. This mock meeting helps participants better understand the effectiveness of their approach, including the persuasiveness of messaging, whether data are robust enough, and what questions can be anticipated, including strategies to address them.

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### **Organizational Development**

#### **Resource Audit**

CCC helps assess whether a company has allocated sufficient resources to execute against the REMS communication requirements. This would include an analysis of human capital, financial resourcing, and appropriate cross-functional communication.

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#### **Strategic Consulting**

CCC and Theodolite Human Capital provide complete organizational development services, including comprehensive diagnostic and gap analyses. The goal is to align your organization with the most effective communication compliance program to ensure an efficient, effective and profitable path to compliance and organizational success.

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## **Subject Matter Experts**

**WAYNE L. PINES** is an internationally known consultant on FDA-related regulatory issues for the pharmaceutical and medical devices industries. He specializes in regulatory strategy, medical advertising and promotion regulatory issues, crisis communications, and media relations. Pines formerly was Associate Commissioner for Public Affairs at the FDA, where he served for seven years as chief media liaison and spokesperson. He is an author/editor of several books about crisis communications, risk management, and FDA regulatory processes. His publication accomplishments include: the *FDA Advertising and Promotion Manual*, the standard reference in the field; *A Framework for Pharmaceutical Risk Management* and *Pharmaceutical Risk Management: Practical Applications*, both of which deal with risk management for pharmaceuticals; *When Lightning Strikes, A Delicate Balance*, and *Communicating in a Healthcare Crisis*, all of which deal with crisis management; *A Practical Guide to Food and Drug Law and Regulation*, *How to Work with the FDA*, and *FDA: A Century of Consumer Protection*. His latest book, *Marketing Compliance Guide for Drug and Device Manufacturers*, on fraud and abuse issues in the drug industry, was published in October 2008.

**ILYSSA LEVINS** is a healthcare communications and regulatory compliance expert with 30 years in the drug and device industries. Prior to founding CCC, Levins was with Grey Global Group, one of the world's foremost communications firms, for two decades. Her entrepreneurial accomplishments there include launching the BrandEdge marketing consultancy, catapulting Grey's healthcare PR practice to a top 10 global ranking, and leading a PR boutique, GTFH, to be named #1 in healthcare two years in a row. Early in her career, Levins recognized that regulatory compliance was an under-served area in the healthcare communication profession. In 1991, she founded the PR section of the Healthcare Coalition for Communication Professionals, an industry advocacy group focused on FDA regulatory policy making and enforcement. Levins leads workshops and teleconferences with a focus on REMS communication plans. Levins is an industry spokesperson and a published author on regulatory compliance healthcare communication. She was the only healthcare executive to be named a Women Achiever of the Year by the YWCA of New York for the class of 2000, and is a Healthcare Businesswomen's Association (HBA) Rising Star. Levins was also a two-term HBA Global Board member, and holds board positions with *Pharmaceutical Executive* and *Communiqué* magazines. She is a Phi Beta Kappa.

**ANDREW GILMAN** is founder and CEO of CommCore Consulting Group, has been a communications strategist, crisis counselor and keynote speaker for more than twenty-five years. Co-author of the best-selling book *Get To The Point* (Bantam 1990), Andrew is also a lawyer and award-winning journalist. Most recently he was selected as Educator/Trainer of the Year by PR News. He has advised healthcare companies on proactive and reactive communications, including products that have REMS and other Risk Maps. As a crisis communications expert, Andrew's experience includes providing advice to the University of Virginia Medical Center in the baby-switching incident and counsel to Johnson & Johnson during Tylenol I. Andrew is admitted to the Bar in New York State and Federal Courts. He has delivered Grand Rounds at Yale University, and has lectured at Harvard University, Wharton School of Business, American Bar Association, China External Trade Development Council in Taiwan, American Association of Advertising Agencies, New School of Social Research, American Society of Association Executives, Cable Telecommunications Industry Association and D.C. Bar Association. He is a member of the Board of the Food Allergy & Anaphylaxis Network. He holds two degrees from the University of Pennsylvania, a Bachelor of Arts degree in History and a Masters of Science in Education. His law degree is from Fordham University. In addition to *Get to the Point*, he recently contributed two chapters to *When Lightning Strikes*, a Crisis case study book compiled by Wayne Pines, as well as a feature article in the *PR NEWS Media Training Guidebook*. Most recently, *PR News* selected him as Educator/Trainer of the Year.

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**THOMAS SCHOENFELDER, PhD, SPHR** is managing partner of Theodolite Human Capital, applying over 15 years of experience to organizational development in private sector, government, and academic settings. An Industrial/Organizational Psychologist, Schoenfelder manages high impact performance improvement initiatives, including organizational diagnostics, intervention design, project implementation and evaluation for domestic and global companies. Prior to joining Theodolite, he served as Vice President of Organizational Development Services at Caliper Corporation, developing and implementing large-scale human capital management and change initiatives for such companies as SAP, Abbott Laboratories, Caterpillar, Inc., Wal-Mart, and Prudential Insurance. Additionally, he managed national organizational, marketing, and social-based government projects for agencies such as the U.S. Department of Justice, U.S. Office of Personnel Management, the Naturalization and Immigration Service, and the National Science Foundation, on behalf of the Institute of Survey Research. Schoenfelder, who has been honored with numerous academic awards, received his M.A. and Ph.D. in Industrial/Organizational Psychology at Temple University.

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## Recent CCC REMS-Related Activities

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**REMS in the New Era of FDA (July 2009) – one-hour telecon for industry on the communications implications of REMS.** Marketing communication professionals face an increasingly turbulent regulatory terrain with REMS. However, with careful planning, this new era presents invaluable opportunities – whether you are on the client-side or within an advertising, PR, or promotional medical education agency. Attendees learned how to provide more valuable counsel to stakeholders and customers throughout the REMS continuum, from pre-clinical to the 7-year REMS assessment period. Developed, managed, and instructed by Levins; speakers included Pines.

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**REMS Sensitization Event (November 2008) – one-day event for Sanofi-Aventis to prepare the company's global employees for the new era of REMS.** Attendees included R&D, drug development, regulatory, legal, clinical, policy, and senior management. Curriculum included preparation of a REMS for a fictitious product, and the simulation of a mock Advisory Committee meeting to address the challenges associated with the FDA's review of a submitted REMS. Developed, managed, and instructed by Pines and Levins. Leiderman was featured speaker.

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**Best Practices in Risk Management (August 2009) – Article in industry magazine, *PharmaVoice*, authored by Levins.**

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**Pharmaceutical Risk Management: Practical Applications (Published in 2008)** - Book is co-edited by Pines and includes chapters by Pines and by Leiderman. Describes the history and current status of REMS following enactment of the 2007 FDA Amendments Act (FDAAA).

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**Risk Management: A Key Regulatory Theme for 2009 (April 2009) – Article in industry magazine, HBAAdvantage**, authored by Levins.

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