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Contact: Susan Sikora, 919-889-1411
SSikora@communicationcompliance.com

**CENTER FOR COMMUNICATION COMPLIANCE LAUNCHES FIRST REGULATORY RESOURCE,
TRAINING AND CERTIFICATION PORTAL FOR HEALTHCARE COMMUNICATORS**

***GOVERNMENT FINES OF \$6 BILLION IMPOSED ON PHARMACEUTICAL INDUSTRY FOR NONCOMPLIANCE
Standardized, centralized, expert-reviewed site helps reduce risk, increase credibility, save time***

NEW YORK, June 25, 2008 – The first and only centralized, resource, training and certification portal for healthcare communication professionals launches today, to help improve regulatory compliance. Called the Center for Communication Compliance (CCC), this on-demand, on-line Web site helps pharmaceutical, medical device, and biotech companies, and their public relations, advertising, and medical education agencies, navigate the increasingly complex regulatory environment.

“We brought together the tools and expertise the industry needs to set a new standard for regulatory compliance before one is set for us,” says Ilyssa Levins, CCC’s founder and president. “Every violation is another blow to the industry’s reputation, so we must move fast.”

Government Questions Industry Efforts

Compliance is a top priority for the healthcare industry, yet government officials like Michael Loucks, Esq., Chief of the Health Care Fraud Unit and Assistant U.S. Attorney for the District of Massachusetts, continue to express concern about how companies are promoting products. At the May 13 meeting of the Regulatory Affairs Professionals Society, Loucks questioned whether the industry is doing all that it can to ensure compliance with government regulations.

Wayne Pines, former FDA Associate Commissioner for Public Affairs and chair of the CCC Advisory Board, said training and certification are critical for agencies and companies alike. “The application of regulatory policy is constantly evolving. Every new FDA enforcement letter or settlement by the Department of Justice has the potential for generating a new policy. Keeping up with regulatory changes around drug and device promotion is every professional’s responsibility to reduce risk.” Pines is an expert on compliance with healthcare advertising and promotion rules.

Regulatory expert and CCC Advisory Board member Michael Misocky, former FDA official and Industry Compliance Officer, concurs: “Government enforcement of off-label promotion has not yet reached its apex. With SEC and FDA now collaborating on press materials enforcement, companies are continually looking for ways to mitigate risk in these areas. Expansion of a current compliance training program to include competency tests for employees and external partners would be yet another step toward the ultimate goal of instilling and maintaining a culture of compliance throughout an organization.” Misocky currently runs his own regulatory consulting firm.

Companies, particularly pharmaceutical firms, have paid about \$6 billion in fines this decade for off-label promotion under the False Claims Act alone. Pharmaceutical executives and even a physician have

been personally indicted for noncompliance, and whistleblowers continue to bring cases to the Department of Justice. All records, files, and even e-mails of healthcare communication firms are subject to the same scrutiny as their clients.

Portal, Certification, Standardized Training Catalysts for Change

CCC has developed and will administer the only expert-reviewed test available for healthcare communication professionals that certifies regulatory compliance competency. Called the Regulatory Compliance Test (RCT), CCC's certification covers knowledge of regulations and voluntary policies, development and execution of materials, and application of regulatory guidelines to complex healthcare communication scenarios. RCTs for each communication discipline are reviewed by the CCC Advisory Board, which includes former FDA officials, regulatory lawyers, and regulatory affairs experts from industry and professional consulting firms.

"The test represents the core level of competency that is required in healthcare communication," said Levins, who has practiced healthcare marketing for more than three decades. CCC also offers a series of standardized Web-based training courses, "Regulatory Compliance 101," taught by nationally recognized regulatory experts. The company's first training course and RCT certification credential are directed to the PR professional, both within companies and their communication agencies.

According to Laura Schoen, president of the global healthcare practice at public relations firm, Weber Shandwick: "Centralized tools make it easy to gain basic regulatory knowledge, which will have a profound effect on the current state of regulatory compliance competency industry wide." Weber Shandwick, which has one of the largest healthcare PR practices in the industry, will train and certify its U.S. healthcare staff, to further the agency's investment in a culture of compliance. Schoen believes that the advantages of regulatory literacy are wide reaching. She added: "Submitting compliant materials the first time around streamlines the review process and increases productivity so that corporate PR, regulatory, and legal staffs are free to focus on other priorities."

CCC saves time with its free one-stop library offering links to more than 50 resources. Current information critical for regulatory compliance, including regulations, policies, guidelines, books, articles, presentations, and other original content is organized and annotated for easy look up. Levins likes to refer to this approach as a combination of Google and Wikipedia for healthcare regulatory compliance.

"Easy access to key regulatory information and tools will enhance our staff's expertise to effectively dialogue with clients on regulatory matters," says Lisa Davidson, Partner at Porter Novelli. "Commitment to regulatory compliance must be supported at all levels for sustainable change to take hold," emphasized Davidson, who will train and certify the New York healthcare practice, in addition to health care staff in other offices.

CCC will expand its offerings this fall to include global public relations, advertising, medical education, and a beginner's orientation, with other disciplines to follow. Additionally, the company provides access to leading regulatory and legal consultants for customized counsel; diagnostic tools for companies to identify gaps in current practices; and reports on the state of regulatory competency in the industry. CCC will also provide annual grants earmarked for education to universities and non-profit associations. One goal is to create a core curriculum on public relations for regulatory affairs students, and one on regulatory compliance for public relations and journalism students.

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- See CCC Backgrounder
 - Visit CCC website: www.CommunicationCompliance.com; view certification test (request pass code)