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CENTER FOR COMMUNICATION COMPLIANCE LAUNCHES ADVERTISING AND PROMOTIONAL MEDICAL EDUCATION COMPLIANCE TOOLS IN TIME FOR UPDATED PhRMA CODE

Resources help industry, agencies, vendors reduce risk, increase credibility

NEW YORK, November 20, 2008 – The Center for Communication Compliance (CCC) today launches on-line regulatory compliance training and certification tests for healthcare advertising and promotional medical education, just in time for the new PhRMA code, which takes effect in January 2009. CCC introduced training and certification tests customized for healthcare public relations professionals earlier this year.

For the first time, the PhRMA code addresses promotional materials explicitly, stating that the materials should be accurate and not misleading, and consistent with regulatory requirements. Additionally, any person or organization engaged in drug promotion is at risk and accountable, including vendors providing communication services to the industry.

“This call to action by PhRMA underscores the pivotal role that compliance plays in protecting the reputation of pharmaceutical companies. And, it should create a far-reaching sense of urgency for any person or organization engaged in drug promotion, including vendors hired by companies,” says Ilyssa Levins, CCC founder and president. CCC is the first and only centralized resource, training, and certification portal designed to help healthcare communicators navigate the increasingly complex regulatory environment and improve regulatory compliance competency.

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 their products. At the 2008 annual meeting of the Regulatory Affairs Professionals Society (RAPS), 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, says that training and certification are critical for agencies and companies alike. According to Pines, “Compliance officers within drug and device companies need to be sure that all communication agencies working for their company are trained in regulatory compliance. Failure to ensure that their communication agencies are properly trained puts companies at unnecessary risk of noncompliance with federal and state requirements.”

New Jersey-based Integrated Communications Corp (ICC) is the first medical communications agency to invest in regulatory compliance training for its entire team in both advertising and promotional medical education -- from senior management to the most junior staffer.

“Our clients should expect and demand regulatory compliance excellence from every agency partner, given the implications of noncompliance ... for the industry, for healthcare professionals, and for the patients we serve,” says Steve Viviano, ICC president and CEO. Adds Viviano, a former practicing pharmacist: “At ICC, we have always taken seriously our responsibility for the programs and materials recommended and executed by our medical, strategy, and creative teams. Now, with easy, 24/7 access to customized training tools, the entire process is simplified for us.”

Companies, particularly pharmaceutical firms, have paid more than \$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 and FDA. All records, files, and even e-mails of healthcare communication firms are subject to the same scrutiny as that of their clients.

“Regulatory compliance literacy can no longer fall solely on the clients’ shoulders, but must now be shared by the entire team, including vendors,” says Anthony M. Iacono, former Assistant Vice President, Wyeth Pharmaceuticals, where he chaired the company’s Promotional Guidelines Committee. Iacono adds: “Noncompliance is illegal, so I commend every agency that commits to the training and certification of its staff – even before clients require it of their vendors.” Currently president and founder of Access Medical Network, Iacono was a member of the AMA Working Group on Gifts to Physicians from Industry, and education chair and board member of the Healthcare Marketing Council.

Portal, Certification, Standardized Training Catalysts for Change

CCC has developed and administers 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 the 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 tests represent 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.

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.

CCC also provides access to leading regulatory and legal consultants for customized counsel; diagnostic tools for companies to identify gaps in current compliance practices; and reports on the state of regulatory competency in the industry.

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Notes to Editors:

- Visit CCC website: www.CommunicationCompliance.com; view certification test (request pass code)
- See Backgrounder
- See June 2008 press release about the launch of the regulatory compliance training and RCT for public relations.