

Course shows companies what NOT to put in writing



Thu, Jan 8 2009

By [Bill Berkrot](#)

NEW YORK (Reuters) - Want to avoid those embarrassing internal emails containing concerns that an important product may be harmful, or documents that could attract the attention of an ambitious prosecutor?

The Medical Technology Learning Institute and Compliance-Alliance is offering: "Dangerous Documents: Avoiding Land Mines in Your FDA Records and Emails" -- a course tailor-made for the drug industry and medical device company executive anxious to cut down on pesky multimillion-dollar legal settlements. Dangerous Documents offers such helpful tips as: Instead of writing, "We'll meet on Thursday to destroy the documents," it's better to say, "We'll meet on Thursday to implement our document retention policy."

The course is the brain child of Compliance-Alliance founder Nancy Singer, a former U.S. prosecutor who did litigation for the Food and Drug Administration. Singer is using her expertise to educate company officials on how to write internal and external communications that do not contain potential "landmines," which she describes as anything that "if it's uncovered, it explodes."

"Documents are like diamonds," she is fond of saying. "They are very precious and they last forever."

The Compliance-Alliance mission statement says the course will present "the latest thinking on what it takes to achieve and maintain compliance with FDA and CMS requirements."

However, there appears to be more here than instruction on how to be an upstanding corporate citizen and keep government agencies happy. The course agenda reads more like a primer on how to avoid raising red flags with the regulatory police or the suspicion of prosecutors and product liability lawyers. Some of the more eye catching topics listed in the program for the \$995 course include:

- * Who can be held criminally liable under the Federal Food, Drug and Cosmetic Act
- * 18 words that will attract the attention of prosecutors or plaintiffs' lawyers
- * 8 common practices that are sure to get you in trouble
- * The dangers in not monitoring employee emails

Singer insists this is not about how to bury negative data or avoid getting caught for nefarious practices.

"I want to educate all employees on the ramifications of how inappropriate statements can be used," Singer said.

Indeed, in every personal injury trial in which Merck & Co defended its handling of the withdrawn pain drug Vioxx, plaintiffs' lawyers dredged up internal Merck memos that questioned company interpretations of clinical safety data. Despite winning most of those trials, Merck finally agreed to a \$4.85 billion settlement.

"To survive in our litigious society, organizations need to have the right communications culture. Everyone needs to understand what they should, or should not, write in their emails," Singer writes in a pitch for the course.

Never use words like illegal or negligent when you can instead say, "It could be argued that that doesn't comply with requirements" or "perhaps we haven't been as careful as we should be," Singer said.

She teaches that all written communication should be constructed with the idea that it will be viewed by a third party who may try to use it against the company. Medtronic Inc, Allergan Inc, Sepracor Inc, Varian Medical Systems Inc and Siemens AG, which last month agreed to pay \$800 million to settle a U.S. bribery probe, are among the health care companies with employees who have taken the course. "I'm a big proponent of the course," said Michael Morton, Medtronic's director of regulatory affairs. "It's heightened the awareness of everyone who participated." Among the pitfalls Singer discusses is what she calls the CYA (Cover Your Ass) memo, in which an employee puts concerns in writing for the files to show he or she raised the issue.

If the employee gets subpoenaed in a product liability case the CYA memo will be used against the company, Singer says, "and it's not going to protect you from the government."

Another common misconception, Singer says, is the belief that putting "confidential" or "internal use only" on a memo will keep it out of the hands of investigators or government agencies.

"Writing 'confidential' doesn't mean anything."