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Medical industry taught legal perils of saying, e-mailing too much

By Kris Hundley, Times Staff Writer

Advice on the legal perils of loose lips, e-mails.

ORLANDO - Outside the Regal Sun Resort, the hotel pools sparkled, the sun shone, the hot tub beckoned.

But mid-level managers from medical device companies were shuttered inside a windowless conference room. Their employers each had ponied up as much as \$995 for a daylong seminar tailored to our times. The topic: "Dangerous Documents: Avoiding land mines in your FDA records and e-mails." Think of it as Evading Lawsuits 101.

The course was full of helpful tips, including: "*4 types of information never to include in documents*" and "*18 words that will attract the attention of prosecutors.*" Nancy Singer, the high-energy lawyer who devised the course, makes no apologies. She was an FDA prosecutor before switching sides and spending most of her career as general counsel for the medical device industry's trade association. In today's litigious times, where potentially incriminating e-mails can be dashed off in seconds but remain on hard drives forever, even good companies can get nailed. "It's a new world," Singer said, as if stating the obvious. "People take things out of context. That's what lawyers are trained to do."

Hard-boiled but still hopeful after 30 years in the medical device business, Singer said her course is intended to prevent legal headaches for what she said are the vast majority of companies doing the right thing. She's confident that bad actors, even those who follow her advice about cleaning up incriminating paper trails, will eventually get caught.

"If there's a bad product out there, the FDA is still going to find out about it," she said. "The plaintiff's lawyer is just going to have to work harder."

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Companies responding to Singer's pitch consider her fees a pittance compared with the possible consequences.

Just last month, Eli Lilly paid \$1.4 billion for off-label marketing of Zyprexa, a drug for schizophrenics that the company pushed for nursing home patients despite evidence that it can kill elderly people. Merck has set aside \$4.85 billion to settle claims that it knew its painkiller Vioxx could cause heart attacks and strokes, allegations supported by embarrassing e-mails uncovered in court.

Such high-profile scandals are the stuff of nightmares for the folks entombed in the Orlando conference room late last month. Their employers ranged from billion-dollar medical device corporations to startups with products still in the testing phase.

Responsible for customer complaints, quality control and FDA affairs, the 16 attendees never want to see themselves or their companies in the news. Asked to comment on the seminar, one woman showed she had paid attention. "Not without my lawyer," she snapped.

The worker bees had been ordered to Orlando, and they know their place. The documents and e-mails passing through their cubicles have the potential to bring down the empire. It is their job to make sure that never happens.

One attendee willing to speak on the record, because he's company president, was Herb Senft, head of Symbios Medical Products. The Indianapolis company makes a disposable pump that delivers painkillers to patients after surgery. Senft, who has been on the job for a year, worries about company-related messages his 25 employees might be shooting into cyberspace.

"I believe 99.9 percent of all companies have the best interest of the individual at heart and want to tell the truth," he said. "But they don't want their words to be twisted against them."

When Senft introduced himself to the group, he said he had previously worked at a nonmedical company that took a big hit in a lawsuit because of "one innocent comment in an e-mail." Nodding heads and murmurs of empathy greeted his story. Singer, now an independent consultant, encouraged role-playing and audience interaction as she zipped around the conference room, bouncing between tables like a pinball. Clicking through her PowerPoint at warp speed, she quizzed attendees. Is an FDA investigator (A) a knowledgeable consultant; (B) an inconsequential bureaucrat; (C) potential adversary? Answer: Don't kid yourself. It's C.

Does sticking the word "confidential" on a document keep it secret? Not for a minute.

Singer spun out the spectre of armies of hungry lawyers rooting through a company's e-mails for inflammatory subject lines or nit-picking FDA inspectors finding white-out on a regulatory report. It's enough to send chills up a CEO's spine.

"There's one lawyer for every 265 people in the U.S.," she reminded the audience, which included several lawyers, all on industry's side." And drug and device companies are perceived as having deep pockets."

When Singer asked how many people had ever received a "CYA" memo from a colleague - employee X writing about inaction on a potentially deadly problem - half of the hands in the audience shot up.

Dissecting a sample "I tried to tell them!!!" memo, Singer showed how, in the world of documentation, less is more. Rather than accuse colleagues of screwing up and predicting catastrophe, the memo's author should have written down a single sentence. "Let's have a meeting" would suffice nicely in a properly sanitized workplace.

And for heaven's sake, Singer stressed, think twice - or even longer - about running to the government if you see a problem. Go to the company president, the board or quit if you must, she said. But nobody likes a snitch.

"You've got to live in this world," she said. "If you're a whistle-blower, potential employers will find you on Google. You're not going to get hired."

Another recommendation from a woman who has been on both sides of the fence: When the feds come snooping, don't start spewing. Answer every question truthfully. Turn over every document requested. But don't start volunteering information like a Girl Scout.

"Think of the FDA as a cop," she said. "When you get stopped for a speeding ticket, you don't tell him you've got an open beer in the back. Nobody is obligated to self-incriminate."

By day's end, Singer's audience seemed dazed at the prospect of what waited back at the office. Embedded on computer hard drives or tucked into file cabinets were a mind-boggling array of potentially deadly documents, ticking time bombs.

What could one person do, even if they *were* armed with a souvenir mouse pad emblazoned with Singer's signature phrase: "Documents are like diamonds. They are very precious. And they last forever."

A couple of women from northern states had the answer. They were headed to the pool.

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Here's what not to say in an e-mail

Real life examples of dangerous e-mails, from Nancy Singer's presentation:

Microsoft

"At Microsoft our mission and values are to *help* people and *businesses* throughout the world realize their full potential."

E-mail of Bill Gates, president of Microsoft: "How much do we have to pay you to screw Netscape?"

Chevron

"We have an inclusive work environment and *actively embrace a diversity of people*, ideas, talents and experiences."

E-mail from Chevron employee: "25 reasons why having beer is better than having women."

Arthur Andersen's Web site

"With more than 60,000 professionals in contact with clients on a daily basis, there is a tremendous opportunity to *create*, share and value knowledge."

Arthur Andersen's e-mail about Enron's financial release: "[We need to] delete some language that might suggest we have concluded the release is misleading."

"Per Dave-No more shredding ..."