

Avoiding Legal Land Mines in Your E-mails and FDA Records

by Nancy Singer

Management must train employees to write concise, factual statements that will not be subject to misinterpretation.

As a device industry executive, imagine this nightmare scenario: A little girl has suffered injuries after being treated with a medical device. As a result, the device manufacturer is sued in a product liability action. During the court case, the plaintiff's lawyer refers to a phrase extracted from an e-mail that was written by an employee. It states: "If we want to stay within budget, we can't implement any changes in 2007." The note fails to describe the changes the writer is referring to, so the meaning of the note is open to interpretation. The plaintiff's lawyer chooses to draw the inference that due to financial constraints, the company failed to make improvements to the device in question.

And now imagine that the jury believes the inference. What would be the result? The jury would want to compensate the little girl's family both for the pain and suffering endured by the child and for her medical expenses. In addition, the jury would want to punish the company with a heavy fine in order to ensure that it bears the consequences of what the jury believes to be highly irresponsible actions.



This e-mail is a "legal land mine." What is a legal land mine? It is a written statement in a company's paper or electronic files that could cause irreparable damage were it to be uncovered during a lawsuit. Most companies are likely to have thousands of these in their files. This article will walk you safely through the minefield and offer recommendations for creating a communications culture that is designed to be land-mine free.

Employees Must Take Care

Every day, device company employees send thousands of e-mails via their companies' networks. These can be retrieved indefinitely. It's not that employees

don't care how their statements might be used by a prosecutor or plaintiff's lawyer to infer inappropriate conduct; it's just that they don't know how to properly word them, and they aren't aware of the potential exposure.

Top managers of medical device and pharmaceutical firms are rapidly becoming aware of the problem caused by dangerous documents, as the number of reported criminal prosecutions and product liability actions continues to increase. The senior executives of firms need to understand their fiduciary duty to train their employees to understand that they are ambassadors for their companies and must express the firm's commitment to quality in their written correspondence.

To find out whether your employees need training in creating safe documents at work, ask yourself if any of them would agree with one or more of the following five statements:

1. I have an expectation of privacy when I write e-mails using the company e-mail system.
2. To be helpful, I send e-mails about my opinion on regulatory issues to the people who are responsible for taking remedial action.
3. Wherever possible, I try to write detailed minutes of meetings including the names of participants and what position they took with regards to each topic discussed.
4. I might write "Confidential" or "For Internal Use Only" on sensitive documents in order to prevent outside parties from gaining access to them.
5. If I notify my boss about a potential public health issue and he ignores me, I would write a memo to place in the file in order to show that I have fulfilled my obligation.

If you have observed any of the attitudes listed above, your company has legal land mines. Now let's examine each one in detail and defuse the mines.

Land Mine One—An Unrealistic Expectation of Privacy. Employees who have an expectation of privacy when they use the company e-mail system harbor an unrealistic belief. They would experience the consequences of this misconception if the company were sued.

When a company is sued, there is a period of pretrial discovery during which the lawyers gather pertinent information they need for the case. During this process, the lawyers have access to all e-mails and other documents that are in any way relevant to the lawsuit. The courts interpret "relevance" broadly, so thousands of e-mails that are saved on a company's servers and backup files will have to be provided.

Industry leaders like Guidant, Bayer Astrazeneca, Merck, and Eli Lilly have all learned this lesson the hard way—through costly lawsuits. The media has reported that these companies during the lawsuits were forced to produce documents that contained embarrassing statements. In a particularly noteworthy antitrust case recently, Microsoft was subject to the same fate after it came to light in a written

document that Bill Gates asked: "How much do we have to pay you to screw Netscape?"

Land Mine Two—E-mailing Opinions. Employees should not send e-mails expressing their regulatory opinions if they are not professionally trained and authorized to take corrective action. If the employee were subpoenaed, a prosecutor or plaintiff's lawyer could argue that the employee who had voiced his opinion had spoken on behalf of the company.

Take for example a staff member in the manufacturing division who states in an e-mail that the company is producing a "misbranded" product that should be "recalled." If the staff member does not have the requisite legal training, he would not be in a position to make these legal judgments. He should restrict his comment to a factual description, such as that the product's package does not contain the manufacturer's street address. Then he would have the lawyers determine whether or not this constitutes misbranding, and what action, if any, the company is obligated to take.

Employees generally should limit their e-mails to factual statements, leaving legal conclusions and corrective action to those who have the requisite knowledge and responsibility for the matter.

Land Mine Three—Detailed Minutes of Meetings. Many employees think they are being conscientious and helpful when they write detailed minutes of meetings explaining who said what. However, these minutes, rather than helping the company, could serve as ammunition in a product liability case.

Here are three examples of potentially incriminating notes:

" John Lester said that we should recall the product."

" Susan James said that the probability of the event occurring was remote and the risk to the patient was minimal, so the cost would not justify the benefit."

" It was decided not to recall the product."

In a product liability lawsuit, the plaintiff's lawyer could focus on John's comment about recalling the product and infer from the e-mail that the firm had acted irresponsibly.

Land Mine Four—The Belief That Headings Such as "Confidential" Prevent Disclosure. Many company employees are under the impression that writing "Confidential" or "For Internal Use Only" on a document protects it against being disclosed to the opposing party in the case of a lawsuit. This is a mistake. Documents marked in this way are not afforded any special protection. As they do with e-mails, a plaintiff's lawyer or a prosecutor has legal access to documents marked "Confidential" or "For Internal Use Only" if those documents are requested during the discovery process.

Land Mine Five—The Exculpatory Memo. Having been ignored in their attempts to draw attention to a product concern, some employees believe that recording their request in a memo will shield them if a public health problem arises. This is a misconception.

If an actionable incident occurs, neither the government nor the public will accept the employee's memo as a sufficient and blameless course of action. When there is a public health issue at stake, employees need to formally meet with the compliance officer, legal counsel, or the head of human resources. Or employees should report the situation through the company hotline rather than merely write a memo stating that they casually spoke to someone concerning the problem.

A Document Is Forever

There is little you can do about the land mines presently in your files. However, your company would be well advised to evaluate your practices and, if necessary, institute a training program on appropriate and professional communication. All levels of personnel need to be involved.

Top management needs to understand:

- How frequently employees write inappropriate documents.
- The risk associated with these documents.
- The key elements of a preventive action program.

Middle management needs to understand:

- How to recognize inappropriate statements in documents.
- What to do when it encounters inappropriate statements.
- How to train staff to prevent employees from writing these statements.
- Methods to evaluate staff members on their ability to write documents that reflect the company's core values.

The technical staff should learn and practice skills that are directly related to its specific responsibilities. The credibility of the training will be increased if a lawyer, who has prosecuted and defended companies, is the instructor. Employing advocacy skills used in the courtroom, the lawyer can demonstrate how a hastily written e-mail can be taken out of context to imply illicit conduct. The training might include asking participants to:

- Rewrite a memo to assess their writing skills.
- Discuss the do's and don'ts for handling customer complaints.
- Debate whether e-mails written on company computers should be audited.
- Rewrite sentences that, when taken out of context, appear to be inflammatory.
- Study how the former New York State attorney general used carelessly written documents.
- Read and learn from news coverage about inappropriate e-mails sent by employees of Guidant, Bayer, Merck, and Eli Lilly.

After participating in the training and focusing on the problem, employees come to understand and embrace the concept that documents are like diamonds. They are

very precious, and they last forever. They learn to appreciate that their written correspondence may some day be scrutinized by an aggressive prosecutor or plaintiff's lawyer who will try to create inferences of inappropriate conduct, negligence, or even incompetence. Understanding that the best defense is to write concise, factual statements that will not be subject to misinterpretation, the employees change what they write and how they write it.

Unfortunately, even the best training cannot guarantee that all your employees will refrain from ever writing an inappropriate statement. However, if you don't provide training, it is likely that every day one or more of your employees will write an incriminating e-mail or other hard-copy document, leaving a legal land mine that could well endanger your company's financial health.

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Nancy's career began as an attorney with the United States Department of Justice where, during a three year period, she successfully prosecuted seven firms for violations of various criminal statutes. Subsequently she was a partner at the law firm of Kleinfeld Kaplan and Becker.

Nancy received her B.S. from Cornell University, and J.D. and LL.M. degrees from New York University Law School. During her career she was an instructor at Catholic University Law School, George Washington University Law School, University of Southern California, and at compliance symposia at Harvard University.