

## 7 Steps to Help Companies Reduce Risk of Writing Dangerous Documents

*by Nancy Singer*

When was the last time you cringed after reading an email sent by someone in your organization as you imagined how a prosecutor or plaintiff's lawyer could use it to imply sinister behavior? Maybe it was just last week or last month. It is unlikely that your employees and/or colleagues do not care about this risk; it is that they just do not know that it exists.

Every day thousands of emails are sent, which, because of technology, can be retrieved indefinitely. Employees need to realize that documents are like diamonds – they are very precious and they last forever.



Pharmaceutical and medical device industry leaders like Pfizer, Bayer, CR Bard, Guidant, Siemens and Eli Lilly learned the hard way, when costly lawsuits tarnished their reputations and affected their bottom lines. Recently, the media reported that Wyeth's reserve for litigation for Fen-Phen (fenfluramine and phentermine) is \$21 billion and Merck's exposure to Vioxx (rofecoxib) lawsuits may total as much as \$50 billion. During discovery, these companies were forced to produce documents that contained embarrassing and inflammatory statements that contributed to their expensive settlements. In a particularly noteworthy case, Microsoft was subject to the same fate after it came to light that Bill Gates wrote in an email: "How much do we have to pay you to screw Netscape?"

The vulnerable population of patients who put their faith in drug and medical device companies to manufacture safe and effective products make these companies attractive targets for lawsuits when products do not provide the intended results. Kathleen Touby, a noted trial lawyer in Miami, Florida, explained: "When balancing the benefits that a monetary award can provide to an injured patient compared to the harm it will cause the drug or device firm to provide the compensation, juries, once persuaded of the legitimacy of the claim, try to find ways to make the companies pay."

It is now more important than ever for companies to implement programmes that encourage their employees to take the time to make their written correspondence reflect the depth of the company's commitment to product quality and its culture of compliance with regulatory requirements.

This article relates specifically to companies operating in the US. However, many of the principles outlined and the recommendations proposed are relevant to companies everywhere.

## **Seven steps for reducing risk**

To survive in our litigious society, companies must have in place the right communications culture. Everyone must understand what they should, or should not, write in their emails and other documents. This can be accomplished through the following seven-step programme, for which the details and rationale of each step are discussed.

### **Step 1: Revise the company's core values to include appropriate communication**

The mission statements of most drug and device companies include an affirmation that the company's actions will reflect the company's commitment to manufacturing safe and effective products that comply with regulatory requirements. The problem with these mission statements is that they fail to mandate that the employees' appropriate actions be reflected in all of their written correspondence. Mission statements should be modified to include words such as: "All our actions and written correspondence will reflect our commitment to manufacturing safe and effective products that comply with regulatory requirements." Companies also need to adopt policies that say all documents written on company computers and saved on the company server belong to the company and need to reflect the company's core values.

### **Step 2: Modify goals and job descriptions to reflect the new core values**

As explained by Len Perry, an executive recruiter with Perry-D'Amico and Associates, the role of a position description is to reflect the specific tasks an employee is expected to accomplish to contribute to the mission of the organization. The role of these goals is to motivate employees to achieve specific outcomes.

According to Richard DeRisio, corporate vice president, global policy and regulatory affairs at Advanced Medical Optics: "Employees whose job descriptions and goals articulate the company's expectations to adhere to its values are more likely to do so if they know their performance evaluations will include how well they meet those expectations."

### **Step 3: Present educational experiences where employees discover the information**

If companies are going to evaluate their employees on the extent of their ability to have their actions and written correspondence reflect the firm's commitment to

manufacturing safe and effective products that comply with regulatory requirements, the employees need to be educated on how to do this consistently. "Conventional mandated training classes where employees passively watch a computer screen or listen to a boring lecture will not necessarily change behavior and are often a waste of time," says Dr Shannon Poach, a psychologist in Torrance, California.

For employees to appreciate how their words reflect the firm's values, they need hands-on education where they are actively engaged in the process. The type and amount of training must be geared to the role the person occupies within the organization.

Top management must understand: how often their employees write inappropriate statements; the risks associated with these statements; and the key elements of a preventive action programme.

Middle management must understand: how to recognize inappropriate statements in documents; what to do when they encounter these statements; how to train their staff to prevent them from writing these statements; and ways to evaluate their staff's ability to write documents that reflect the company's core values. Technical staff must be given educational experiences where they can acquire and practice specific skills that directly relate to their roles within the company. For these people, it is helpful for them to be exposed to a lawyer who has prosecuted and defended companies, so they can hear what actually can occur if a prosecutor or plaintiff's lawyer took a hastily written email out of context to infer illicit conduct. A good example would be if a design engineer wrote in a cryptic email: "If we stay late tonight, we can use the shredder and get rid of those documents." Such a document would be a delight for a plaintiff's lawyer, but a nightmare for the design engineer. However, this would not happen if the engineer took a little more time when writing the email by putting it in context.

The engineer might say: "If we stay late tonight, we can use the shredder and implement our document retention policy that tells us every six months we need to go through our files and get rid of draft minutes and memos, irrelevant handwritten notes, and outdated correspondence that are cluttering up the offices and causing a fire hazard."

Other elements of an educational programme could include having employees undertake certain activities. They might, for example:

- take a quiz to see who can be held criminally liable in the US under the Federal Food, Drug, and Cosmetic Act. This is important because employees who work in drug and device companies can be criminally prosecuted for acts that result in the sale of a product that does not comply with regulatory requirements. The test to see if a person can be held liable is whether the individual had a responsibility for the specific task and had authority to do or refrain from performing that task;

- rewrite a memo to assess their writing skills. People need to determine the skills they have and where they need improvement. This serves as a diagnostic tool and a remedial exercise;
- make presentations to show how the company implements risk management. Employees need to be ambassadors for their companies. They need to understand and be able to report on activities that their firm took to manage the risks of their products and to protect public health;
- discuss the “do’s” and “don’ts” for handling customer complaints. Most product liability lawsuits begin when a customer has a problem with a product. Knowing the right way to obtain information from a customer is vital to determining the necessary action to take to correct the problem or mitigate the situation;
- debate whether emails written on company computers should be audited. If companies in the US have a policy that everything written on company computers should be for company business and belong to the company, firms whose employees write inappropriate statements in their emails, such as sexual harassing remarks, can be found liable if they do not audit their employees’ emails for inappropriate statements;
- examine warning letters where the government has cited companies for poor documentation. The US Food and Drug Administration continues to issue warning letters for incomplete documents. When employees get an opportunity to view the warning letters, they are more likely to apply appropriate documentation practices in their official records;
- see how the former New York State Attorney General used carelessly written documents. When people read statements of a prosecutor, they are better able to understand the mentality of a litigator;
- analyse a series of statements to distinguish those containing facts from those containing opinions. Since documents can be retrieved indefinitely, employees need to understand the consequences of writing opinions about issues where they lack the required expertise;
- rewrite sentences that, when taken out of context, appear to be inflammatory. When a company is sued, all “relevant” documents need to be provided to the party bringing the action. Since US courts have interpreted the term relevant broadly, it is important for employees to be able to write documents that reflect the actual events;
- practice substituting less harsh words for inflammatory ones. Studies have uncovered words such as illegal, negligent, story, and excuse that continually appear in litigation. When employees see the effect of these words, they develop the skill necessary to make their point in a less inflammatory way; and/or
- read inappropriate emails from employees of Guidant, Merck, Bayer, Chevron, Arthur Andersen and Microsoft that were reported in the media. People can learn from direct experience or by watching the mistakes of others. By seeing the consequences of inflammatory correspondence from other companies, employees will be less likely to make similar mistakes.

The importance of having employees being engaged actively in the educational process through case studies, workshops, role playing and team quizzes cannot be overemphasized.

To make an impression on someone, you need their attention. If you involve them in an activity where they need to develop a solution, they will more likely be able to process the information and practice it once they leave the training situation and return to their assigned tasks.

Compliance-Alliance, which specializes in the professional development of employees of drug and medical device companies and other manufacturing industries, has presented the educational component of the seven-step programme at device and drug companies such as Medtronic, Allergan, Sepracor, Chattem Pharmaceutical, Varian Medical Systems, Ventana Medical Systems and Intel Digital Health. Key officials in these companies have noticed a difference in how their staff approached their correspondence after attending the presentation.

#### **Step 4: Provide continual reminders**

After attending an educational event, most people find that they will not be able to recall most of the material that was presented after a few days if they do not review the course content. To prevent this from happening, companies can publish phrases like: "Documents are like diamonds, they are very precious and they last forever." These reminders can be distributed as screen savers for computers, posters that are placed strategically around the firm, and on mouse pads that are given to all employees.

#### **Step 5: Hold mandated cleaning days**

Every six months, companies should consider having all employees wear casual clothes, turn off the telephones and mandate that employees go through their files and get rid of documents that are not contributing to their productivity. These include draft minutes and memos, handwritten notes, or any documents where the person wrote an inappropriate comment such as a sarcastic or humorous remark. This assists the company and individuals in knowing what is in their files. Additionally, it helps to improve individual and operational efficiency.

#### **Step 6: Provide refresher education**

To ensure that employees continue to be mindful about writing appropriate documents, companies should consider having luncheons or other occasions where examples of inappropriate documents are collected and employees put the documents in context or rewrite the documents. Some companies have had employees participate in role playing exercises where the people are divided into teams and half the teams are plaintiff's lawyers and the other half are defence attorneys. Both sets of teams use the same documents to argue that the employee acted either appropriately or inappropriately.

#### **Step 7: Measure adherence to new core values in employee evaluations**

At the end of the year, employees and their supervisors should rate the employees on how well they acted as ambassadors for the company by having their

correspondence reflect the company's commitment to manufacturing safe and effective products that comply with regulatory requirements.

### **Conclusion**

Drug and device companies manufacture inherently risky products. They cannot insulate themselves from being sued for products liability. However, if companies implement the seven-step programme described above, their employees should be proud to take responsibility for what they write. They will also be accountable for their actual behaviour, instead of hypothetical actions that could be inferred from incomplete or cryptically written statements.

*[Editor's Note: This article by Nancy Singer was originally published in a 2009 issue of The Regulatory Affairs Journal.]*

\*\*\*\*\*



**Nancy Singer** founded Compliance-Alliance LLC to specialize in the professional development for those employed in drug, device and other manufacturing industries. She created the course on professional communication when she was employed as General Counsel for a drug and device firm.

*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.*