704 - Creating the Best Record Possible

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Faculty Biographies

Diane Biagianti

Diane W. Biagianti, is vice president, deputy general counsel and assistant secretary of Advanced Medical Optics, Inc. where she has, among other duties, responsibility for management of the company's global litigation, employment and regulatory matters, and general commercial matters.

Ms. Biagianti formerly served as vice president, assistant general counsel of Experian Information Solutions, Inc. Prior to Experian, Ms. Biagianti was an associate with the law firm of O'Melveny & Myers LLP, where she practiced as an employment litigator.

Ms. Biagianti received her J.D. from Cornell Law School and graduated from the University of Arizona with a B.A. She is also a certified public accountant.

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Enjoying the Ride on the Track to Success

E-mail Communications

A few things you should keep in mind with using e-mail:

- Remember – there are at least three critical differences between e-mail and other forms of correspondence – e-mail is durable and virtually indestructible; it is never anonymous, and you can not be sure that it is private.
- Be aware that anything you say in an e-mail message could be used against you or your employer in a lawsuit or other dispute.
- Don't say anything in an e-mail message that you would hesitate to say in a letter or other written correspondence, or that would cause any personal embarrassment to you, your employer, or any other person or institution.
- Consider the impact that your e-mail messages may have on your employer.
- Be precise in your use of language. Avoid sloppy, careless, inaccurate, or exaggerated modes of expression.
- Edit your e-mails as carefully as you do your letters or other written correspondence.
- Be sure to address your e-mail properly.
- Protect your password and your computer.
- Always consult with counsel before deleting or destroying any e-mail (or other document) that might be relevant to a pending or potential lawsuit.
- Try to avoid using e-mail to communicate with lawyers representing you or your employer, at least where the communication is intended to be privileged.
- Do not forward any communication with your attorney.
- On communications with your attorney, only copy other persons who have a need to know.

INTERNAL CORPORATE INVESTIGATIONS

RECORD NO.:	2007-________
EMPLOYEE:	
Name:	
Title:	
Department:	
Division / Subsidiary:	
Name of Supervisor:	
Name of HR Manager:	
ALLEGATION:	
Date of Allegation:	
Source of Allegation:	
☐ AlertLine / Anonymous	☐ AlertLine / Name Given
☐ Employee / Co-worker	☐ Competitor
☐ Customer	☐ Other: ______________
Category of Allegation:	
☐ Fraud	☐ Global Guidelines for Interaction with HCPs*
☐ Code of Ethics	☐ Insider Trading Violations**
☐ Regulatory / Clinical	☐ Advertising / Promotion
☐ SOP Violation	☐ Other: ______________
Description of Allegation:	
INVESTIGATION:	
Name of Investigator:	
Date(s) of Investigation:	
Description of Investigation (interviews, verifications, etc.):	
INVESTIGATION RESULT:	
☐ Inconclusive finding	☐ Nonsubstantiated claim
☐ Written reprimand	☐ Counseling review / verbal warning
☐ Termination	☐ Other: ______________
Disposition Date:	
FOLLOW-UP ACTIONS:	

* Includes AdvaMed and EucoMed
** Does not include pre-approvals or routine questions under Insider Trading Policy, only alleged violations.

[CONFIDENTIAL, ATTORNEY-CLIENT PRIVILEGED COMMUNICATION]

INTERNAL INVESTIGATIONS REPORT

RECORD NO.	DATE OPENED	NAME OF EMPLOYEE OR INVESTIGATION	INVESTIGATOR	STATUS OF INVESTIGATION	DATE CLOSED
2007-					

17 August 2007

[CONFIDENTIAL, ATTORNEY-CLIENT PRIVILEGED COMMUNICATION]

1

[redacted] (Legal)

From: [redacted] (Legal)
Sent:
To:

Cc:
Subject: Email Communication Do's and Don'ts

Importance: High

Attachments: Document.pdf

Document.pdf (56 KB)

ATTORNEY-CLIENT PRIVILEGED COMMUNICATION

To the [redacted] team,
As a follow up to my earlier voice mail and my statements in our daily conference calls today, attached is a list of Do's and Don'ts in communicating internally and externally by e-mail. Please forward to your team members as appropriate. It should not be forwarded outside AMO.

It is very important to evaluate whether you need to send or reply to an e-mail regarding the [redacted] situation or whether it is better to pick up the phone or call a meeting to discuss a topic. As a general rule, please avoid e-mail communications if at all possible. If necessary to send an e-mail, the e-mail you send should be short, concise, factual and without speculation, commentary or opinion. Any e-mail should be sent only to necessary persons.

For instance, do not speculate in any e-mail communication on possible reasons for the results [redacted] against AK, do not discuss R&D or outside test results, do not engage in hindsight evaluation or discussion of prior decisions, etc.

Most importantly, review any e-mail before you send and ask yourself these questions: "Would I say this in a letter to a third party? Is this something I and AMO would be uncomfortable seeing in the newspapers or hearing in a court of law? Could the e-mail be taken out of context by an adverse party?"

Lastly, please retain all documents (including e-mail) in accordance with the litigation hold notice you should have received earlier today.

If you have any questions, please don't hesitate to call me.

[redacted]

1

[redacted] (Legal)

From: [redacted] (Legal)
Sent: Friday, August 17, 2007 7:47 AM
To: Biagianti, Diane (Legal)
Subject: FW: Email Communication Do's and Don'ts

We've received a number of questions this week about the attorney-client privilege and thought it might be useful to provide you with some additional information. Please remember that a communication does not automatically become "privileged" simply because an attorney is copied.

For example, communications about business issues (as opposed to legal issues) are among those that might not necessarily be privileged simply because an attorney is among the recipients. Similarly, forwarding an email to Legal that was received from elsewhere does not make the underlying communication privileged.

On the other hand, a communication about a legal question or concern may fall within the privilege, as would a response to a question from the Legal Department.

Please keep these considerations, as well as those described below, in mind when preparing email and other written communications. Thank you, and please call us if you have any questions.

DOCUMENT RETENTION NOTICE

From: [redacted] **Corporate Counsel**

Subject: **Litigation Hold Notice and Instructions re** [redacted]

LITIGATION HOLD NOTICE AND INSTRUCTIONS
ATTORNEY - CLIENT PRIVILEGED COMMUNICATION
ATTORNEY WORK PRODUCT
DO NOT FORWARD

You are receiving this email because the Legal Department has concluded that you have potentially relevant documents relating to this litigation. This means that you must follow the instructions in this notice regarding the retention of documents. Should you have any questions about this notice, please contact [redacted]

In the course of our investigation and defense of the lawsuit, we will need to gather and maintain relevant documents and information. We have identified you as a potential source of documents (as that term is described below). This pending litigation creates a continuing obligation to preserve documents concerning the following ISSUES (broadly interpreted):

ISSUES

1. All documents related to [redacted], including the Device History Record; applicable specifications and design documents; records of installations, upgrades and service; call histories relating to the [redacted]; records of the sale of this [redacted] system and any upgrades; [redacted] and reports of examinations of [redacted] from [redacted];

2. All documents related to physician and operator training, including all documents relating to training and certification of [redacted]; Physician Training Manuals and updates provided to [redacted]; Operator Manual and updates;

3. All documents regarding any communications with [redacted] regarding this incident or the treatment of [redacted].

4. All documents related to sales and marketing of this [redacted] system to [redacted] including advertising or promotional material provided to [redacted]; any notes of any visits to [redacted] by applicable sales personnel;

5. All documents related to special risks associated with [redacted], with [redacted], or with the [redacted], including any literature, posters, study materials or the like regarding said issues; communications with physicians regarding said issues;

6. All documents which constitute "labeling" of the [redacted] System.

7. All documents regarding any regulatory investigations of this incident.

8. All documents reflecting regulatory approval for the [redacted] System as of [redacted], including applications for approval and all documents and data supporting such applications, all communications with FDA regarding such applications, and all actions by FDA on such applications.

Please do not discuss this mail, the litigation, the merits or lack of merits of any claim, or any other issue outlined above with anyone not in the Legal Department. The Legal Department will notify you if you should expect to be contacted by one of [redacted] outside counsel to discuss any of these issues. If you are contacted by someone about these issues, do not speak with them unless the Legal Department authorizes it.

If you have any doubt about whether a document fits within these areas or is relevant to the subject of the litigation - retain it.

"Document(s)" means any thought or communication preserved in a tangible medium relating to the issues described above. This includes any hard copy material, such as memos, reports, correspondence, specs, marketing materials, presentation materials, meeting minutes, and handwritten notes; any electronically preserved material regardless of the medium in which it is saved, including e-mail, calendars, saved instant messages, videotapes, and audiotapes. It includes working drafts as well as final copies of any relevant document. It also includes any documents that you may create in the future regarding these issues.

AS ONE OF THE POTENTIAL CUSTODIANS OF DOCUMENTS, YOU MAY NOT FOLLOW YOUR NORMAL DOCUMENT RETENTION PRACTICES UNTIL FURTHER NOTICE. FOR EXAMPLE, YOU CANNOT AUTOMATICALLY DELETE E-MAIL OR RECYCLE DOCUMENTS RELATING TO THE ISSUES LISTED ABOVE AS YOU MIGHT OTHERWISE DO IN THE ORDINARY COURSE OF YOUR EMPLOYMENT.

At this time, you do not need to send documents on the above issues to the Legal Department. You do need to preserve any such documents, and suspend your normal document retention practices with respect to such documents.

This instruction remains in effect until further notice. **In the event you transfer to another group or leave [redacted] it is your responsibility to notify [redacted] as soon as possible before you transfer or leave in order for us to capture your soft copy documents, email and hard copy.**

During the pendency of this matter, if you have concerns about your current storage capacity, please contact [redacted], who will arrange for someone to come and copy your electronic and hard copy documents.

If you have any questions, please contact [redacted].

If you are aware of additional personnel who may have documents regarding these issues, please notify [redacted].

Please refrain from sending any e-mail commentary regarding this case, even if you copy an attorney. Please do not forward e-mails from attorneys to anyone.

ATTORNEY WORK PRODUCT

ACC Annual Meeting
Session 704 – Creating the Best Record Possible
Tuesday, October 30, 2007

Panelists: Diane Biagianti, Alison Brotman, John Hueston, Michael Ray

I. Definition of the "Record."

The record is the evidence created by individuals which, taken as a whole, proves or suggests what transpired in a given situation.

Elements of a record could include the following:

- Verbal statements by individuals.
- Written communications from individuals, such as letters, memos, and email.
- Written documents, such as contracts, policies and procedures.
- Decisions or actions taken by individuals, such a decision to investigate alleged misconduct or a decision to terminate an employee.
- The absence of any of the above.

II. What is the goal of your record?

Your record should serve your ultimate goal, which might include some or all of the following:

- Avoiding or reducing the risk of litigation.
- Resolving a dispute on favorable terms prior to the start of the litigation process or before the parties have invested significant resources in the litigation process.
- Creating a favorable set of facts for a test case in order to set legal precedent or send a message to third parties, such as competitors or the plaintiffs' bar.
- Gaining regulatory approval.
- Avoiding or mitigating government intervention and/or sanctions.

III. What is the purpose of your record?

After you determine your goal(s), you will craft the narrative you will present to your ultimate audience, whether a judge, jury, opposing counsel or government agency.

You want to be able to support your arguments or narrative with the evidence you create or assemble as part of your record.

You then continuously assess record building in the context of does it advance the narrative or fix a problem in the narrative.

Absent an overarching narrative, record building can meander and become inefficient and/or expensive.

IV. Creating a record proactively.

Clients are always creating a record since every document they write, every conversation they have, and every action they take or fail to take will comprise your record.

In-house counsel can help shape a record by taking the following steps:

- Educating clients on the laws, regulations and policies particularly relevant to their function within a company.
- Encouraging a culture of compliance with those laws, regulations and policies, and providing regular opportunities to train employees.
- Setting up processes to regularly certify that employees understand their obligations and are complying with them.
- Training clients to look ahead and always be thinking, "How will what I say or do be perceived in the future by someone outside the company, by the public or by someone adverse to the company?"

In-house counsel can also work with their clients to prepare favorable elements of a record in preparation for a future dispute, as the following examples illustrate.

If your purchasing team wants to prepare a favorable record in the event of a dispute with a supplier, in-house counsel can assist with the following:

- Drafting a written contract between your client and a supplier.
- Drafting communications from your client to the supplier consistent with the contract's terms.
- Drafting purchase order terms and conditions consistent with the contract's terms.
- Training and emphasizing the importance of your client's adhering to the terms of the contract in its course of dealing.
- Emphasizing the importance of only modifying the contract's terms in a writing signed by an authorized representative, and drafting any such modification.

If your engineering team wants to prepare a favorable record in the event of an allegation that they improperly handled third party confidential information that they received from a development partner, in-house counsel can assist with the following:

- Drafting a nondisclosure agreement between your client and the development partner identifying appropriate uses of the confidential information received and restrictions on the use of the confidential information.
- Drafting protocols on how confidential information is to be received, who can have access to it, and how the information is labeled and stored while in your client's custody and control.
- Drafting affidavits to be signed by your client's employees or representatives who handled the information in which they verify that they understand and have complied with their obligations to not improperly use or disclose the information.

If a manager wants to minimize the likelihood that her decision to terminate an employee for poor performance will be contested, in-house counsel can assist with the following:

- Reviewing and helping draft performance reviews and performance improvement plans.
- Reviewing and helping draft precise, measurable performance objectives against which an employee's performance can be evaluated.
- Scripting talking points for a manager to use when counseling an employee on performance problems.

V. Making an initial assessment when a problem arises.

When a problem arises, in-house counsel should make an initial assessment about the nature of the problem and the kind of record that may or will result. Among the questions you will want to answer are:

- What is the nature of the problem or dispute?
- Is there an allegation of misconduct?
- What laws and/or regulations will most likely govern?
- Which clients group or groups will be affected by this problem or dispute?
- What information do I need to know immediately?
- Who do I need to talk to in order to get that information?
- Should I involve outside counsel?
- Who else at the client needs to know or should be consulted?
- How time-sensitive is the problem – what, if anything, has to be done or addressed immediately?

IV. Elements of the Record – Written Communications and Work Product.

- Documents, memoranda and correspondence
  - Once a problem arises, all written communications or written work product which will comprise portions of the record should be reviewed by counsel.
  - Advise clients to consider whether written communication is necessary or helpful, or whether a meeting, phone call or direct communication with another party is more productive.
  - Advise clients to use precise language, and avoid sloppy, careless, inaccurate or exaggerated modes of expression.
  - Emphasize to your clients that any written communications or written work product can be produced in litigation, and marking a document "confidential" will not prevent that document from being discovered in litigation.
- Email
  - Clients often are less attuned to what they write in email because it is a less formal method of communication. They should be reminded that email is durable and never anonymous.
  - Advise clients to always consider the impact an email message will have before the message is sent.
  - Advise clients to draft and edit their emails as carefully as they do letters or other written documents.
  - Advise clients that emails between a client and his/her attorney (i) should always be marked "Attorney-Client Communication/Confidential and Privileged," (ii) should not be forwarded to anyone else, and (iii) should only copy other persons who have a need to know.
- Test results and analyses
  - Clients should consider undertaking tests or evaluations of products at the direction of their counsel so that the results are shielded by the work product privilege.
- Third party service providers
  - Counsel may require the assistance of third party service providers, such as IT specialists, forensic accountants, and environmental, health and safety experts.
    - ❖ Counsel should typically retain such service providers and outline the scope of services they will provide.

VII. Elements of the Record - Verbal Communications.

- Witnesses
  - When determining who should conduct a conversation or attend and speak at a meeting as part of your record, consider who will present well as a witness.
    - ❖ Is the potential witness credible and articulate?

- ❖ Is the potential witness knowledgeable about the subject at issue in the dispute or problem?
- ❖ Does the potential witness have any conflict of interest or anything in his/her history that would detract from his/her testimony?

- o Counsel should prepare the witness and provide the witness with a script for the witness' communication, if appropriate.
- o Sometimes counsel does not get to choose witnesses and must work with individuals whose demeanor, conduct or presentation skills make them less attractive.
  - ❖ With these witnesses, extensive preparation – including conducting mock depositions, sample Q & A, or dress rehearsals of the conversations/presentations the witness will conduct – is especially important.
- o Counsel should decide to involve/not involve members of senior management based on additional factors, such as their availability, potential disruption to the business, and their suitability as witnesses.

VIII. Avoiding the Negative Record.

When creating the best record possible, counsel should focus on both creating affirmatively helpful evidence and avoiding, whenever possible, the creation of unhelpful evidence.

- Review attorney-client and work product privileges with clients – emphasize that conversations they have without an attorney present are discoverable.
- Encourage clients to include counsel in conversations and to allow counsel to review all relevant communications before they are sent.
- Issue a notice of litigation hold, if appropriate, and communicate periodically thereafter.
- Correct the written record contemporaneously, especially when a client's communication conveys the wrong impression or an incorrect conclusion.
- Emphasize to clients that every action they take and decision they make will be viewed in the context of the dispute or problem that has arisen.

XI. Conducting an Investigation.

If in-house counsel determines that the client should conduct an investigation as part of its record, the following issues will need to be addressed:

- Who should conduct the investigation?
  - o Internal resources or an outside law firm?
  - o If an outside law firm, should you use a firm familiar to the client or will there be an actual or perceived conflict?
- Who should be notified immediately or later? Notification triggers should include an assessment of the credibility of the source as well as the breadth of the allegations.
  - o The board or a committee of the board?
  - o Senior management?
  - o External auditors?
- Scope and Process
  - o What is the appropriate scope of review?
    - ❖ Too narrow a review can be criticized as not reasonably calculated to discover misconduct.
    - ❖ Too broad a review can be unnecessarily disruptive and costly.
  - o Consider whether the actions you are about to take can possibly be construed, with the benefit of hindsight, to have predetermined the outcome of the investigation.
  - o Which employees should be interviewed?
  - o Who should take notes of the interview and should those notes be retained?
  - o Should they be provided with separate counsel?

- What process do you need in place to make witnesses available and retrieve relevant documents without causing unnecessary disruption to the workplace?
- Consider how your actions and inactions during the course of the internal investigation might later be viewed as either facilitating or obstructing the investigation.

- Assessing collateral consequences of your actions during the internal investigation.
  - Consider the possibility of regulatory or criminal actions.
  - Avoid a record that may assist plaintiffs' counsel.

X. Protecting and utilizing your record in dealings with the government.

- The McNulty Memo, though deficient in its purported effort to broaden protections of the attorney-client privilege, presents new opportunities to negotiate with the government in order to protect your record.
- Because the government must demonstrate "legitimate need" for each "Category I" item requested, consider negotiating the withholding of attorney fact compilations such as chronologies in favor of prompt production of documents and witnesses.
- Carefully review all documents intended for disclosure to ensure that "Category II" information is not inadvertently disclosed.
- For negotiating purposes, consider "Category II" information as beyond the reach of regulators.
- Negotiate withholding any report of an internal investigation and witness interview memoranda (if any) in lieu of prompt witness interviews carefully monitored by counsel.
- Negotiate with the SEC to produce information in compliance with the McNulty standards rather than the broader Seaboard standards.
  - Though the SEC currently has broader authority, it may waive its broader powers for reasons related to joint investigative protocols with the Office of the US Attorney.
- If faced with parallel SEC and criminal investigations, secure "double credit" with the same package of information by producing "grand jury" material first to the criminal authorities so that the SEC must obtain this same information from you.