



**William O'Brien
 President's Message**

As 2007 draws to a close, so does my term as president of the Northeast Chapter. It's been quite a ride! When I started in January of 2006, we had about 700 members; today we're over 900! We've increased programming significantly, developed a new Diversity & Inclusion committee, and have a new sponsorship model. Our board is strong and active and will continue with a tradition of excellent leadership.

As president, I have tried to attend almost all of our programs, and am really impressed with the offerings over the past year. The Program Committee has really raised the bar in that regard. I've also met more of our chapter members, and have come to appreciate how important the networking component of our programs is to everyone. Building on this, we are looking into a few "networking only" events for next year so we all can develop and build new relationships.

I am also hoping our pro bono offerings will be greatly expanded next year. In addition to our mediation program, we will afford our members other opportunities to help the communities in which we work and live

In the coming year, we hope that more

members will ask to become involved with the chapter, working on our committees (Pro Bono, Advocacy, Diversity & Inclusion, Local Events, Programs, Membership) and increasing our outreach to in house non-members. The chapter's strength is its members, and we look forward to working with you in the future.

Program Update

We recently developed and offered our first webinar in an effort to reach members who are unable to come to the Boston area to attend programs. The Foley Hoag "Annual Update" program in September was recorded, paired with the powerpoint presentations, and has been posted on our website for our members to view.

We'd like to know what you think about this. While a webinar won't take the place of an actual, interactive program, when schedules or distances don't allow travel, is this a reasonable substitute? Please give us your feedback by emailing acc-northeast@comcast.net.

We are in the final stages of selecting new sponsors and programs for 2008, and will update you on program offerings in December. For upcoming program info, please go to the chapter's website at www.acc.com/chapters/ne.php.

ACC-Northeast Advocacy Update

Two pending bills in the Massachusetts legislature propose to make violations of the Wage Act subject to mandatory treble damages. The Legislature's Joint Committee on Labor and Workforce Development has voted to release the bills with a "favorable report," and the Massachusetts House has approved them. The bills are currently pending in the Senate. Various ACC member companies have submitted comments to the legislature expressing concern about these bills, and as a result, the momentum for their immediate passage has slowed, although these passed both houses of the legislature last year and may pass again without more voices raised in opposition. Our Region's Advocacy Committee, working with an ad hoc group of employment lawyers, has developed a form letter that

continued on page 7

Discover Best Practices from ACC's Annual Meeting2

PEOPLE Skills Help

In-house Counsel Shine4

The Criminalization of Truthful, Non-Misleading Off-Label Promotion: Constitutional, Legal and Policy Concerns5

Discover Best Practices from ACC's Annual Meeting

*Susan Hackett,
Senior Vice President and General Counsel
Association of Corporate Counsel
hackett@acc.com*

I recently attended ACC's annual meeting in Chicago ... heck, who's kidding whom? It's a command performance for ACC staff and we fight over the privilege of attending and spending such high-quality time interacting with members!

There's an adage here at ACC that a former ACC Board Chairman (Bill Lytton, now retired CLO of Tyco, then CLO of International Paper) used to help us define a meeting's success for members: With so much information and so many "opportunities" flying by at light speed in their day jobs, anytime a member can go to a meeting and pick up even one really good, practical idea to take back home and implement, they will feel that the time was spent well. So here's my review of several really good ideas collected from the ACC Annual Meeting that I'd like to share with those of you who weren't there.... Maybe next year (October 19–22, 2008 in Seattle) you'll be able to pick up some gems without a middleman!

In no particular order:

■ **The first thing you do is send everybody home.** A ton of great ideas for responding to government investigations emerged from a wide variety of programs at the meeting, but one that resonated with many attendees is the idea of establishing a policy that if uniformed, government agents invade your premises and begin a sharp edged investigation, you should send the staff home immediately. The govern-

ment often uses the "raid" tactic not so much to collect documents, but to catch employees unaware and to scare them into saying things that damage the company—they don't do this in a formal interview environment, but they will storm an employee's office and begin unpacking their desk drawers. So if they show up, leaders from the law department and other designated staff should surely escort government officials around and cooperate fully, but only after the staff has "evacuated" the premises—the government is not entitled to interview employees without notice and authority, especially without counsel present (either the company's or the individual's personal counsel). They won't be happy with you for killing their fun, but if they're investigating your company in this manner, it's too late to wonder if you'll get extra points for serving coffee and cookies.

■ **On the subject of lawyers as targets in criminal enforcement actions or prosecutions:** There's a whole lot of stuff out there on increasing lawyer liability for client failures, as well as why it is that lawyers are more likely to be targets, along with their clients, when the government comes calling. A number of programs focused on these issues, but one of the most troublesome worries repeatedly raised was whether there was anything that lawyers can do to avoid being called as fact witnesses (especially since many corporate counsel wear multiple hats in their jobs and carry business responsibilities). One idea discussed was for the in-house lawyer to file an appearance as counsel of record for the case. It makes it far more difficult for the government's counsel to call

the defense counsel on a matter as a fact witness, especially, as is almost always the case, when there are non-lawyers in the company who can testify to facts that the government wants to explore and document them. Calling a lawyer to do this endangers the client's ability to assert privilege over anything the lawyer worked on in the past (subject matter waiver) or, for that matter, in the future.

■ **Outside counsel budgets—an oxymoron?** Unfortunately, it seems so. One great idea presented by a large law department that has trouble getting certain high profile firms to follow clearly negotiated and detailed budgets for large matters is to have the board (or a relevant board committee) "approve" the outside counsel's budget for major projects. Then, when the outside counsel suggests that they're going to have to bust the budget or calendar because of "unforeseeable" events, you can ask them: "Would you like to notify the board of this recent development in person, or by report for their next meeting?" Let them know that the in-person presentation is preferred since they'll be able to answer board members' questions directly onsite. Heck, maybe you could sell tickets to your in-house counsel friends and colleagues?

■ **More on outside counsel costs:** Institute a system of shadow bills for outside counsel matters you're most concerned stay within budget or on track. Shadow billing is a law department-driven mechanism for reviewing outside counsel bills as each one comes in, and checking on whether they're on track with cost estimates that the department calculates, usually based on historical experience

but maybe based on other criteria, such as the spending cap for the matter/its value. For each relevant billing period, you compare the actual bill with the shadow bill you've predicted; if you know that monthly costs should be averaging \$35,000, and you start receiving bills for \$3,000 or \$300,000, you know that the matter is not proceeding as planned and is likely to miss budget. You know to ask outside counsel NOW for an explanation of what is causing the variance. You may find their answers completely satisfactory, you may have estimated poorly, or you may decide early out that your outside counsel is not properly managing, supervising, or budgeting the matter and can nip errant behaviors in the bud. After all, it's worse to have this conversation after the matter is irreversibly out of control and over budget.

■ **Think about establishing a more active role for lawyers in government relations.** An increasing number of law department leaders are either leading or supporting their company's "capital" office presence to stay abreast of developments that will affect your company or industry, and to influence emerging regulations when possible. The role of company lawyers is to help ensure that legislation doesn't lead to regulatory nightmares for the company. Involvement of the legal staff does not always entail directly lobbying activities, but usually does include responsibilities that confer new career challenges and personal development for lawyers somewhat trapped within the glass ceilings of their current in-house positions.

■ **Carefully consider the evolving relationship you may have with your company's outside auditors:** while

that primary relationship is "owned" by the CFO, you are likely to be increasingly involved in managing the auditor's requests, and likely also increasingly concerned about what auditors are asking to see in the conduct of their regular reviews of the company's fiscal health. The jewel: focus on a more proactive (rather than waiting to be placed in a reactive) role in anticipating some of these issues and negotiate them with the auditors in advance of retention. A panel addressing this subject and reporting on an ACC initiative to improve the lawyer-auditor relationship offered lots of specific ideas. Catch some of them in the material archived at www.acc.com/php/cms/index.php?id=368.

■ A number of programs touched on the issue of helping counsel prove (as in "quantify") their value to their clients, in spite of their status as a "cost center" within the company. Some counsel discussed their efforts to create what amounts to "dashboards" for their client leadership (a dashboard generally appears on the client's screen when opened and provides a ticker of information). These dashboards provide real-time status and dive-down detail on the costs that the client's area has "incurred," whether charged back to the client or not. This provides a method of linking law department costs more concretely to services and to client actions. Obviously, someone has to feed the dashboard beast, but it's worth thinking about, especially if the information could be entered by non-lawyer staff, outside counsel, or consultants.

* I'm going to let you see all the "substantive law" good ideas by logging onto the ACC website and checking out the course materials posted on the annual meeting's homepages.

One last reminder on picking up pearls at the meeting: If you attend the meeting in Seattle, set aside time to shop the exhibit hall for more good ideas than you can shake a stick at. I mean it. Unless you've been to an ACC annual meeting before, you have no idea what I'm talking about, but ask anyone who's been. The exhibit hall/trade show floor is the busiest place at the meeting. There are almost 200 firms (outside counsel, legal services providers, legal tech experts, staffing and professional consultants, etc.) present and they all bring their tippy top people who understand your business and can fashion solutions designed just for law departments. If you're in the market to interview firms, preview technologies, or discuss consulting services, come to the meeting with your pencil sharpened and your exhibit hall map marked with the most direct routes to visit the folks you need to see. You will have an unparalleled opportunity to meet with the top providers of virtually everything a law department needs: you can talk to them for 30 seconds or 3 hours, with as little or as much specificity as you like; if you're not interested, you walk to the next booth (usually with some nice swag in tow!). This is so much easier than inviting a line of prospects to interminable meetings in your offices and finding out they've sent a local account rep that can't answer your questions.

Comments or ideas for me? Contact me at hackett@acc.com.

PEOPLE Skills Help In-house Counsel Shine

By Maria Drakos

Skilled in-house attorneys spend a great deal of time developing and honing their abilities in researching, analyzing and presenting legal material. But professional ability is only one component of a successful career. Attorneys must also be able to interact effectively with colleagues, support staff, supervisors, executives and outside counsel.

Well-developed “soft skills” are in strong demand in today’s increasingly collaborative workplaces. In a team-based environment, diplomacy, flexibility, persuasiveness and management skills are critical. In a survey of executives at the nation’s 1,000 largest companies conducted by our firm, 79 percent of respondents said self-managed employee work teams will increase productivity for U.S. companies. These productivity gains will be realized, however, only if members of legal project and case teams can work together effectively.

What are PEOPLE Skills?

Soft skills are largely intangible and therefore hard to quantify. To help legal professionals who are typically focused on day-to-day matters determine how they measure up, our firm has identified a composite of key interpersonal traits, represented by the acronym “PEOPLE”:

Problem-solving abilities (organization, judgment, logic, creativity, conflict resolution)

Ethics (diplomacy, courtesy, honesty, professionalism)

Open-mindedness (flexibility, openness to new business ideas, positive outlook)

Persuasiveness (excellent communication and listening skills)

Leadership (accountability, management and motivational skills)

Educational interests (continuous thirst for knowledge and skills development)

A deficiency in these areas can seriously limit career prospects, whether lawyers are looking to change employers or seeking a promotion within their department. Just as individuals at all levels who failed to enhance their techni-

cal skills were left behind by the digital revolution, those who dismiss the significance of PEOPLE skills can jeopardize their career progress.

Assess Strengths and Weaknesses

Since there are no classes on “flexibility” or “positive outlook” at the typical college or law school, how can in-house attorneys acquire and upgrade their interpersonal abilities?

The following steps will help facilitate taking an accurate inventory of strengths and weaknesses:

- **Honestly evaluate aptitude** in each of the PEOPLE skills. Which seem to come naturally? Is there room for improvement in any area?
- **Ask trusted friends, family members and coworkers** for their feedback, observations and opinions.

Commit to Learning

It takes time and experience to fully develop interpersonal skills, so don’t expect to see improvement overnight. Here are some effective strategies to boost progress:

- **Create a list of the major characteristics to develop.** Then brainstorm specific activities that will enhance abilities in those selected areas. For example, an attorney who wants to refine leadership skills could volunteer to work on cases that provide the opportunity to supervise others or manage a project from start to finish.
- **Observe those who demonstrate strong PEOPLE skills in the areas targeted for improvement.** How do they apply their abilities in various situations? What makes their responses ideal in each case?
- **Select a mentor.** Because it’s difficult to see oneself objectively, a mentor’s ongoing support and feedback can be invaluable. The best candidate for a mentor is someone in the legal field who is skilled and willing to share their knowledge. Ask a prospective mentor if he or she is available to help with the PEOPLE skills targeted for enhancement.
- **Enhance listening skills.** Concentrate on paying close attention to what others are saying. In general, avoid

interrupting but ask for clarification when necessary. To prevent misunderstandings, paraphrase information back to the speaker when receiving complex instructions.

- **Become a better writer.** Read books on effective writing to develop a more concise style, or consider taking a journalism or business writing course. Proofread all correspondence, especially e-mail. Because electronic messages are quickly prepared and sent, they can be inadvertently filled with typographical and grammatical errors. In addition, it's important to employ PEOPLE skills when writing to ensure that correspondence is diplomatic and courteous.
- **Refine verbal communication.** Think through the message to be conveyed before speaking or leaving a voice-mail message, and use a tone and style appropriate to the audience. When presenting a report to someone in the legal department or the company, rehearse a few times to ensure that the delivery will be smooth and the message clear.
- **Become a volunteer.** Volunteering helps hone leadership and organizational skills. Whether it's becoming involved in a trade association or a charity, the capabilities developed through volunteer work can be used on the job in a variety of situations.

■ **Seek growth opportunities outside the workplace.**

Hobbies and leisure-time activities are an enjoyable way to enrich PEOPLE skills. Coaching a youth soccer team, for example, helps develop motivational and managerial skills and improves the level of comfort when dealing with diverse personalities. To enhance creativity, consider taking an art or music class.

Devoting time and effort to improving “soft” skills is a worthwhile endeavor for in-house legal professionals. By developing their abilities as leaders, communicators and problem-solvers, attorneys increase the value to the department and the company, and they build a set of skills that will benefit them as their careers progress.

Maria Drakos is the Regional Manager of Robert Half Legal, a leading staffing service specializing in the placement of attorneys, paralegals, legal administrators and other legal professionals with law firms and corporate legal departments. Based in Menlo Park, Calif., Robert Half Legal has offices in major cities throughout the United States and Canada.

The Criminalization of Truthful, Non-Misleading Off-Label Promotion: Constitutional, Legal and Policy Concerns

By Joan McPhee, Ropes & Gray

Over the last several years, the government has pursued an aggressive campaign against pharmaceutical manufacturers to criminalize the dissemination of information regarding off-label uses of FDA-approved products. Not content to limit its prosecutions to false or misleading statements or other inherently wrongful conduct, the government has extended its theory of criminal wrongdoing to reach truthful, non-misleading speech regarding off-label prescribing.

The government's prosecution theory is overbroad and gives rise to substantial legal, constitutional and policy concerns. As a threshold matter, there is no statutory provision in the criminal code that provides, clearly and unequivocally, that truthful, non-misleading off-label promotion is a crime. The government's theory of prosecution is instead predicated upon

two provisions in the federal Food Drug and Cosmetic Act: the misbranding (no “adequate directions for use”) and unapproved new drug provisions. These statutory provisions are exceptionally technical and precise in their terms and do not neatly fit the government's contention that truthful, non-misleading off-label promotion constitutes criminal misconduct. The provisions were enacted decades ago, with other purposes in mind, and long before the government developed its novel off-label prosecution theory. At bottom, the statutory vehicles upon which the Government seeks to predicate a criminal charge do not by their terms proscribe the conduct sought to be criminalized.

There are, moreover, important First Amendment concerns presented by the government's attempted criminalization of truthful speech about a lawful activity—namely, off-label pre-

continued on page 6

continued from page 5

scribing. The Supreme Court has long recognized that consumers' interest in receiving accurate commercial information supports an interpretation of the First Amendment that provides constitutional protection for the dissemination of truthful and non-misleading commercial messages. Because physicians may prescribe FDA-approved drugs off-label, the public – which benefits from the well-informed exercise of medical judgment – has a strong interest in ensuring that physicians have free access to truthful, non-misleading information concerning off-label uses. For this reason, any prohibition on the dissemination of such information is subject to First Amendment scrutiny.

The constitutional issues, and the wisdom of prosecutorial restraint in this arena, are reinforced by a consideration of the patient health and public policy implications of the government's prosecution theory. Specifically, criminal prosecution of free discussion with physicians and dissemination to them of truthful, non-misleading information concerning off-label uses of FDA-approved products raises a serious risk of chilling valuable, protected speech. Drug manufacturers must navigate the FDA's complex regulatory scheme controlling distribution of scientific information concerning off-label uses to physicians. Criminal prosecution of pharmaceutical companies for dissemination of truthful, non-misleading information will likely result in such manufacturers generally avoiding speech on the subject of off-label uses, including speech protected by the First Amendment, and perhaps also speech permitted under the FDA's complex web of regulations.

Criminal prosecution of truthful, non-misleading speech regarding off-label uses could thus have the unintended effect of causing physicians to be less well-informed about the standard of care for the treatment of many diseases. For a disease—cancer, for example—that is in large measure dependent for its treatment on off-label uses, the threat may be of particular significance. The threat is further exacerbated for those types of illness that affect small patient populations, where physicians are less likely to receive information regarding new uses and treatments through the regular mailings and distribution channels of the medical community. Similarly,

physicians treating patients in more remote geographic locations may lack access to many of the sources of information available to doctors in urban centers of medical research. Cutting off the flow of scientific information from pharmaceutical representatives in these settings would increase the risk that physicians would not learn as quickly about potential new treatments.

In short, criminal prosecution of drug manufacturers for distribution and discussion of truthful, non-misleading information concerning off-label uses of FDA-approved drugs could have a significant impact on the distribution of scientific information within the medical community. Any significant curtailment of the free flow of truthful, non-misleading information regarding such uses would in turn likely have an adverse impact on the acknowledged beneficial role of off-label uses in the treatment of many diseases, to the detriment of patients and their families.

For all of these reasons, the Government should exercise restraint in the off-label arena. And yet the government finds itself in a position to proceed—and has in fact proceeded—largely unchecked. While it is difficult to conceive of any jury in America convicting an individual of a crime for “pure” off-label speech-related activities, the corporate entities that have been the focus of the Government's campaign have no meaningful right to a jury trial and thus no practical ability to challenge in a judicial forum the Government's prosecution theory on legal or constitutional grounds. Because in this post-Arthur Andersen era, the corporation cannot risk the potential death knell of a criminal indictment, it cannot afford to test the Government's legal theory or to hold the Government accountable through the traditional safeguards and protections of a criminal trial. At a minimum, and before the Government proceeds further with its efforts to extract substantial settlements from pharmaceutical companies on the basis of such a novel and troubled theory of criminal liability, it should put the strength of its convictions on the line in a court of law.

Joan McPhee is a litigation partner at Ropes & Gray and the co-chair of the firm's Government Enforcement practice group.

Board of Directors

President

William O'Brien
Hewlett-Packard Company
508.467.4016
bill.obrien@hp.com

Vice President

Paul Cushing
Partners HealthCare System, Inc.
617.724.8075
pcushing@partners.org

Secretary

Catherine Mannick
Cole Management, Inc.
617.350.9900
cmannick@colemanagement.com

Treasurer

Alan Glass
CIRCOR International, Inc.
781.270.1255
aglass@circor.com

Immediate Past President

Thomas Farrell
Advance Level Consulting, Inc.
978.462.0688
tfarrell@advancelevelconsulting.com

Board of Directors

Joanne Acford
Susan Alexander
Gregory Allard
Kristin Campbell
Claudia Gilman
Dennis Hart
Winston Henderson
Christopher Mirabile
Barry Nagler
Paul Nightingale
Jane Owens
Susan Permut
Steven Reynolds
Scott Squillace
Danette Wineberg

Chapter Administrator

Louise Rothery
781.631.2246
acc-northeast@comcast.net

continued from page 1

members can use to reach out to members of the legislature on this issue. If anyone is interested in doing so, please contact Paul Nightingale at 617.887.3035 for a copy of the letter.

When You Can't Attend a Program...

Please let us know why. We are concerned that some of you register for programs, and then fail to attend. This is disappointing for our sponsors, who put in a lot of effort developing the content and securing panelists. So if you are unable to attend, please send an email to acc-northeast@comcast.net and let us know why you couldn't attend. With this feedback, we will know whether to schedule programs at another time of day, in a different location, or perhaps to offer it online. Thank you!

Northeast Chapter JobFind: Post Your Positions

Many of you receive our monthly listing of in-house positions in the New England area, but are you aware that member companies can also post their available in-house positions on the JobFind? We will post legal, paralegal, and administrative positions for you—just send a brief description and contact information to acc-northeast@comcast.net before the 12th of each month.

Renewal Time Is Coming Soon!

In January, it will be time to renew your ACC membership! Renewing your membership avoids interruption of services, including these:

- The *ACC Docket*, your best source for cutting-edge practice information. Whether you practice in a department of 1 or 100, the *ACC Docket* covers the issues that you need to know.
- Tap into the Virtual LibrarySM (www.acca.com/resources/vl.php), our databank of best practices in managing your department, working with outside counsel, records retention, billing, and hundreds of other topics specific to in-house practice.
- Gain unparalleled access to the expertise of other in-house counsel through networking opportunities provided by chapter and committee networks and MemberToMemberSM (www.acca.com/membership/search.php), your online network. You can renew online at acc.com/php/cms/index.php?id=12.