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STANDING strong

A five-pillared approach for pharmaceutical industry leadership when planning for or handling high-stakes litigation situations

Americans pay a high price for the wrongs, actual and alleged, pursued in court by the men and women who are members of the nation's plaintiffs' bar. This group of lawyers is an effective machine that manufactures costly lawsuits and destroys corporate reputations.

The pharmaceutical industry has, up to now, taken a fragmented and defensive posture in response to these threats. Legal departments are not well-integrated with communications organizations. Decision-making is slow and decentralized. This approach to managing product liability litigation is a strategy for failure, especially in the all important 'court of public opinion', which the plaintiff's bar so effectively uses to pressure its targets.

The industry must develop comprehensive, holistic strategies that harness the power of media relations and communications, legal strategy, and public opinion research (the weapons so successfully utilized by the trial bar and its allies) to protect itself against a coming barrage of reputation- and business-destroying attacks.

The well-oiled machine

Pharmaceutical companies are learning, often the hard way, that certain triggering events in the public domain have the effect of setting in motion a well-oiled tort machine. When the FDA posts an adverse event on MedWatch, announces a label change, or tough questions are

raised at advisory committee meetings, the plaintiff's bar responds.

Plaintiff firms can churn out dozens of suits across the country, mounting sophisticated, multipronged legal, political and mass media attacks. Following closely, in a kind of pincer action, are the media 'horror stories' from allied interest groups, high profile media scrutiny, and promises to investigate from sympathetic political figures.

According to the Manhattan Institute's new book *Trial Lawyers, Inc.*, "...leading plaintiff lawyers run complex multi-million dollar organizations that use sophisticated and expensive marketing to pursue clients through every commercial avenue."

Attorneys incentivize potential lead

plaintiffs by offering a bounty that can sometimes be as high as \$20,000. They also recruit friends and relatives of their firms' employees. The Internet, with its many corporate protest sites, has become a rich hunting ground for potential plaintiffs. For such prospects, the temptations are great. One woman, speaking to a reporter for the Jackson Clarion-Ledger, illustrates the point. When she read that the drug Propulsid might cause harm, she stopped taking it and signed up for a lawsuit. "Actually, I didn't get hurt by Propulsid," she told the newspaper.

But because she had taken the drug, she said she thought she could join a class-action lawsuit "and get a couple of thousand dollars."

The Attorneys' Information Exchange Group (AIEG) is a virtual warehouse storing, among other things, internal corporate documents uncovered by members of the American Trial Lawyers Association – which has just renamed itself 'the American Association for Justice' – the ultimate in 21st century Orwellian Newspeak. Founded in 1980, the AIEG began as an informal network of plaintiffs' attorneys with Ford Pinto cases. In response to the carmaker's hardball litigation tactics, AIEG began sharing internal corporate documents and trading tactical tips. Since then, its scope has grown. It now has specialized units for everything about autos, from tires to airbags to pharmaceuticals.

The AIEG has a Byzantine set of rules 'to ensure that the contents of its library remain secret and protected by attorney-client privilege. Members are forbidden from disclosing what paperwork the AIEG possesses. Nor are the documents posted online. Plaintiffs' attorneys usually have to travel to Birmingham to see them.'

Pharmaceutical companies are not alone in

responding to powerful legal challenges with powerful legal responses, allowing counsel to thoroughly research plaintiffs' claims, refusing to comment on legal issues in question, and lining up support, later, from communicators, experts, and third-party allies. It's a time-tested approach. And it's likely to fail.

A holistic, issues management discipline

The industry can and should learn some important lessons from the comprehensive, issues and crisis management approach utilized by the plaintiff's bar and its allies.

Some definitions

An issue is the point of conflict between an organization's forward progress (new products, for example) and the sensitivities or expectations of key stakeholders.

A crisis is any event or series of events that does, or has the potential to, harm or kill, severely affect operations, damage the environment or surrounding communities, and/or devastate reputation.

Issues management seeks to address concerns of stakeholders and keep these touchy situations from blossoming into crises.

Crisis management, which often deals with life-threatening situations, seeks first and foremost to ensure safety, with a critical focus on keeping crises from getting worse, on communicating with attentive stakeholders hungry for information, and to integrate lessons learned into planning for the inevitable next crisis.

Both issues and crisis management test the values of the organizations involved, putting them under intense scrutiny as stakeholder groups and often the media ask: 'What kind of company would do something like this?' But these types of situations often share another attribute, one that executives skilled in 'manageable' situations often find shocking. Both can and often are instigated by adversaries seeking to embarrass, seek financial gain from, or even destroy the organization.

While litigation isn't the only means by which pharmaceutical companies' adversaries seek to ignite difficult issues into explosive crisis situations, it certainly has some of the highest and most expensive stakes.

There is an urgent need for the industry to further refine its skills in litigation issues management. We suggest a five-pillared approach for pharmaceutical industry leadership, action steps that can be taken immediately to ensure organizations perform effectively when planning for or handling high-stakes litigation situations:

1. Core values – always

At their root, all high-profile litigation issues management situations are about the core values of the company under attack and ask, implicitly or by direct challenge, whether the company has lost its way. No sector asks for, or has historically received, as much trust as healthcare. And no sector has felt such bitter rebuke when this trust is violated.

Every litigation communication management situation must tie back at all levels, from broad objectives to the most precise tactic, to the core values the company wants the world to see. Often, these remind stakeholders that their long-held trust is, of course, warranted, the proof resting in numerous breakthroughs, products and other efforts that have resulted in the amelioration of disease and suffering.

"A crisis is any event that has the potential to harm, severely affect operations, damage the environment or surrounding communities and devastate reputation"

Internally, the use of core values as a touchstone should keep the holistic issues management team focused on the real goal behind winning a tough battle for stakeholder hearts and minds. It's not to make the issue 'go away,' it's to use the spotlight, however unwanted, as a means of discussing core values in action.

2. High-performance organizations

Multi-disciplinary teams must be built on the resources of in-house and outside counsel, but complemented by the skills of communicators, scientists and medical professionals, sales and marketing leaders, risk managers, finance experts, and key opinion leaders. All members must come to the table as equal partners with a common goal – strengthen the position of the company in the real world, not just in a court of law, but in the court of public opinion.

These high-powered experts will offer different opinions, but must act as one and must be led, personally, by the CEO with the authority to make final decisions. In turn, this team is responsible for:

- Long-term objectives. Failure to do so will ensure that the organization plays defense or at a minimum is whipsawed by the objectives of its adversaries

- Trigger points. Litigation communication programs that work well see key triggers in the legal process, such as trial dates and interim rulings, as opportunities to communicate or deploy other resources in the overall issues management arsenal
- Flawless tactical execution. Litigation issues management efforts must embrace the same discipline and accountability as a high-stakes product launch, where the agenda, dissemination of information and tempo of communication is disciplined and accountable. We see far too many campaigns where plaintiffs' representatives and operatives are calling the tune.

3. Eliminating 'gotcha'

Pharmaceutical litigation issues management programs succeed when the element of surprise is heavily mitigated. Emotion, indignation and outrage are important tools for trial attorneys. Even worse are the difficult, embarrassing, discoveries learned during internal discussions, facts that keep oversiloed organizations from getting out of their own way. Rather than stoke these fires, the situation calls for control, for seizing, driving and maintaining the initiative.

"Maintain your initiative by dealing with the media head-on, giving them information that they must use to file a fair and balanced story"

Opposition research. Know your adversaries as well as they know you. More importantly, invest in the kind of research that will uncover every bit of embarrassing, yet publicly available, information. Probe the salience of claims being made against the attitudes of larger audiences

No secrets internally. The issues management team must hold itself to a 'no surprises' standard. This is especially true for in-house and external counsel. Full information sharing is the only way for this team to make broadly informed, holistic decisions that serve the broadest set of needs.

4. Care and connection to communities

Many groups and individuals, such as non-government organizations, advocacy groups and key opinion leaders, have a vested interest in the successful production of medicines and devices to cure or alleviate diseases. They

have the credibility of an objective voice on their topic of interest. They may not want to be seen as 'in bed' with a corporation, but that does not make them any less valuable as allies.

Any corporation, particularly a pharmaceutical company, must take the long view of these relationships. A quick injection of money will not build a relationship, nor would the person or organization who took that money be viewed as a credible source of information. Investing in a relationship involves hard assets, but also time and non-money resources. The most valuable allies are those with whom lasting relationships have been cultivated over time, long before specific attacks by the plaintiff's bar.

5. Responsibility, initiative and the high ground

Maintain the initiative by making the science your most powerful tool, by putting it in the proper perspective. When an Angleton, Texas jury blamed Vioxx for one user's fatal heart attack, it hit Merck for a \$253m award. Media accounts suggest that the company's scientific defense seemed to 'flummox' jurors. "Whenever Merck was up here, it was like wah, wah, wah," said juror John Ostrom in the *Wall Street Journal* last August. "We still didn't know what the heck they were talking about."

Maintain the initiative by pointing the financial conflicts and hypocrisy of so-called 'consumer advocates,' from Public Citizen to the Center for Science in the Public Interest, Friends of the Earth, and the Environmental Working Group.

Maintain the initiative by dealing with the media head-on, giving them information that they must use to file a fair and balanced story, rather than issuing statements that say nothing and only reinforce the presumption of guilt.

Maintain the initiative by understanding how public policy institutes and other relevant thought leaders can be engaged early in the battle for the hearts and minds of elected officials and regulators.

Maintain the initiative by engaging third-party groups and KOLs early and often, not just when you need their help.

Maintain the initiative by building relationships with key elected officials and regulators on big issues rather than only dealing with them when you have a 'pending action.' And make sure these associations are shared within the company. Relationships count in the clutch.

Maintain the initiative by positioning yourself as a leader in healthcare rather than a marketer of products.

Product liability litigation

Legal departments are not well-integrated with communications organizations. Decision-making is slow and decentralized. This approach to managing product liability litigation is a strategy for failure, especially in the all important 'court of public opinion,' which the plaintiff's bar so effectively uses to pressure its targets.

Most importantly, in order to maintain the initiative, you must be able to clearly define and communicate to your team what 'victory' looks like. And that vision must be shared, believed and constantly reinforced. It must drive all your strategies and tactics. It must reinforce corporate integrity.

True justice

Tort law, appropriately applied, helps patients get redress for truly negligent care. When product manufacturers provide fraudulent information to the FDA, or deliberately withhold information about safety problems associated with their products, they should be held accountable. But more and more often, 'mass tort' firms are taking new product-warning labels or withdrawal decisions by the FDA as signals to go forward with aggressive lawsuits. Their activities, unfortunately but not unpredictably, affect multiple innocent victims and injure the American healthcare system.

A more balanced legal system will occur only when elected officials determine the time has come for real tort reform, as it affects pharmaceutical companies. But that day is likely very far off. Healthcare leaders must devote their most aggressive efforts toward reform. In the meantime, the industry can no longer afford to cede best practices in litigation issues management to its adversaries in the trial bar. Traditional corporate responses have placed legal or PR or financial priorities above all others. In the face of sophisticated, multipronged campaigns driven by the trial bar, they are ineffective at best, and a waste of resources at worst. The holistic response provides the industry with a formidable tool to fend off a most formidable challenge.



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