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America's Legal System Is Dangerous To Its Health

by Larry Kamer and Peter Pitts¹

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, which commentator Jim Cramer has called "the single most insulated, most lucrative endeavor in America," is an effective machine that manufactures costly lawsuits and destroys corporate reputations.

Estimates peg the American "tort tax" at \$40 billion, an economic behemoth roughly twice the size of Coca-Cola and almost precisely the same amount, \$39.4 billion, invested in 2005 by the pharmaceutical industry for the research and development of new, life-saving therapies. Litigation costs have also helped drive up the price of health insurance, which has risen 11-14% each year since 2001.

These should be troubling facts for any executive, researcher or employee in America's pharmaceutical industry, which is a ripe target for the sort of political, legal and economic attacks from the plaintiff's bar that have crippled once thriving industries and saddled others, like automotive manufacturers, with burdensome costs.

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.

In MS&L's view, the pharmaceutical 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.

This white paper captures the problem succinctly, provides facts about the interlocking influence of the trial bar and its political allies, and discusses effective and workable strategies for the pharmaceutical industry to convey its messages more effectively.

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How the Plaintiff's Bar Tries to Punish Scientific Success

Since 1990, scientists have discovered and developed over 300 completely new medicines, vaccines and biologics approved by FDA to treat over 150 conditions. These medicines treat a variety of illnesses: Infectious and chronic diseases, common diseases afflicting millions of patients, and rare disorders affecting fewer than 200,000. They prevent illness and cure or alleviate previously fatal or debilitating conditions.

Innovative new medicines make it possible to prevent or slow the progress of many conditions and avoid costly hospitalization and invasive surgery. Between 1980 and 2000, the number of hospital days fell by 56%. The pharmaceutical industry's investment in health care helped Americans avoid 206 million days of hospital care in 2000 alone.² They play a significant role in life expectancy gains made in the U.S. and around the world. Recent research published in the journal *Health Affairs* concludes that new medicines generated 40% of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000.

Consider these breakthroughs:

Ulcer surgery has become a relic of the past.

Pharmaceutical research company scientists developed new medicines to treat a number of gastrointestinal disorders over the past two decades. Since these medicines became available to patients, surgical procedures to correct ulcers have fallen, and today ulcer surgery is rare.³

Medicines have reduced hospitalization and surgery for heart disease.

Several studies have found that use of statin therapy to treat people with high cholesterol reduces hospital admissions and invasive cardiac surgeries. For example, a study of one statin showed that it reduced hospital admissions by a third during five years of treatment. It also reduced the number of days patients had to spend in the hospital when they were admitted and reduced the need for bypass surgery and angioplasty.⁴

New drug treatments now delay nursing home care for Alzheimer's patients.

A new Alzheimer's drug slows the progression of cognitive decline, allowing patients to maintain their independence longer. As a result of higher functioning, they are able to delay entering a nursing home by an average of 30 months. Nursing home care is more costly than in-home care, so this delay can significantly reduce expenditures. By reducing the symptoms of this devastating disease, this medicine reduces the economic and emotional burden on both patient and care-giver.⁵

The death rate has fallen for HIV/AIDS with the advent of new medicines.

New medicines have made a major contribution to the decline in the death rate from HIV/AIDS in the U.S. over the last 10 years. Since the mid-1990s, when researchers developed a new wave of medicines to treat HIV/AIDS, the U.S. death rate from AIDS dropped about 70 percent.⁶

² MEDTAP International, Inc. The Value of Investment in Health Care. Bethesda, MD: 2004. Available at: <http://www.medtap.com/Products/policy.cfm>.

³ M. McClellan, "Speech Before the First International Colloquium on Generic Medicine," September 25, 2003.

⁴ Cholesterol Pill Linked to Lower Hospital Costs," The New York Times, March 27, 1995.

⁵ G Provenzano, et al., "Delays in nursing home placement for patients with Alzheimer's".

⁶ CASCADE Collaboration, "Determinants of Survival Following HIV-1 seroconversion after introduction of HAART," The Lancet, 362 (2003): 1267-1274.

New cancer drugs are increasing survival.

Since 1971, when the U.S. declared war on cancer, our arsenal of cancer medicines has tripled. These new drugs account for 50-60% of the increase in six-year cancer survival rates since 1975, Frank Lichtenberg of the Columbia University Graduate School of Business recently reported. Today, there are three million more cancer survivors than there were a decade ago.⁷

Use of medicines prevents strokes.

A study sponsored by the Agency for Health Care Policy and Research concluded that increased use of a blood-thinning drug would prevent 40,000 strokes a year, saving \$600 million annually.⁸

The response to these and scores of lesser-known success stories? Ever-increasing amounts of media scrutiny, political focus and, most disruptive of all, litigation.

Pharmaceutical companies have felt the sharpness of the plaintiff bar's bite. Several recent examples illustrate the affect of litigation on research, clinical trials and other investments:

- Lyme disease remains an often-misdiagnosed disease that causes severe arthritis-like symptoms and can impair brain function. Less than a year after GSK introduced LYMERix in 1999, attorneys claimed the adult Lyme Disease vaccine caused arthritis. In 2002, GSK withdrew the drug. Lyme disease infections grew by 40 percent.
- A quarter of pregnant women once used Bendectin for morning sickness. Facing more than 2,000 lawsuits claiming birth defects and \$18 million in claims, against \$20 million in sales, Merrell Dow Pharmaceuticals pulled the drug from the market in 1983. No evidence ever linked the drug with birth defects, and the drug is still sold abroad. Thankfully, birth defects in the U.S. have remained flat in that period, but morning sickness hospitalizations have doubled.

Plaintiffs in one vaccine lawsuit sought \$30 billion in damages. *The entire vaccine industry's annual revenues total \$6 billion.*

As Dr. Marc K. Siegel, an internist at NYU Medical Center and associate professor at the NYU School of Medicine, writes: "Unfortunately, when the media and the lawyers target a drug, they overlook the fact that the side effects are rare, and/or alternative treatments more problematic. Sober statistics-based analysis gets tossed aside. The drug-maker's stock price and the number of prescriptions written plummet.

"Decisions on drug safety should be based on real facts, a weighing of the real risks and benefits. Hysteria doesn't belong in the drug-safety equation."

According to the Manhattan Institute: "Countless other potentially useful drugs sit in Petri dishes because companies hesitate to spend hundreds of millions of dollars on products that could land them in court, costing hundreds of millions more."

⁷ Frank R. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper No. 10328 (Cambridge, MA: NBER, February 2004).

⁸ D.B. Matchar, G.P. Samsa, Secondary and Tertiary Prevention of Stroke, Patient Outcomes Research Team (PORT) Final Report - Phase 1, AHRQ Pub. No. 00-N001, Rockville, MD: Agency for Healthcare Research and Quality, June 2000.

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, multi-pronged 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." As one lawsuit industry-sponsored website declares: "Seek justice NOW by submitting your class action information online to be considered for a FREE case evaluation!"

Such tactics are designed, according to Trial Lawyers, Inc, "to launch numerous mass tort cases of the sort that have all but replaced the principle of fair and impartial justice with a new governing principle: Winning through intimidation."

Investigative journalist Mike France writes: "As the money has escalated, tort lawyers have succeeded in turning litigation into an all-but-automated process ... Empowered by the Internet and enriched by a never-ending stream of lottery-size verdicts and settlements, tort lawyers have built an ingeniously organized industry that operates, for the most part, well out of the public eye."⁹

Attorneys incentivize potential lead plaintiffs by offering a bounty, which 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.¹⁰

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 I might 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

⁹ "The Litigation Machine," BusinessWeek, January 29, 2001.

¹⁰ Ibid

has specialized units for everything about autos, from tires to airbags. Other groups are devoted to school buses, motorcycles, boats, and, now, pharmaceuticals.¹¹

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 of the group 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.”¹²

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.

Our Point of View: A Holistic, Issues Management Discipline

According to *Pharmaceutical Executive*, the number of articles on legal and ethical issues relating to the pharmaceutical industry more than doubled in top newspapers in 2005. Examples:

- *USA Today*: 22 front-page stories and 37 editorials. A 247% increase from 2004.
- *Wall Street Journal*: 20 front-page stories and 17 editorials. A 118% increase from 2004
- *New York Times*: 33 front-page stories and 16 editorials. A 145% increase from 2004
- *Los Angeles Times*: 27 front-page stories and 26 editorials. A 141% increase from 2004
- *Washington Post*: 36 front-page stories and 37 editorials. A 152% increase from 2004
- Total cumulative increase: 158%.

Not surprisingly, the public's confidence in the industry has fallen. According to recent polls, consumers assign considerable responsibility to the industry when drug safety is called into question.

- Four in five believe pharmaceutical companies should be held responsible for any problems with their products, regardless of the FDA's approval. This number is on the rise.
- Four in ten, the plurality, say that when new risks are uncovered, it is the fault of the company, rather than the FDA
- Just one in three agrees that when new risks are uncovered, it may not be anyone's fault, as all medicines have risks

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. First, 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.

¹¹ Ibid

¹² Ibid

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. In our view, 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 health care. 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 improved health and the amelioration of disease and suffering.

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 (KOLs). 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, even embarrassing, discoveries learned during internal discussions, facts that keep overly-siloed organizations from getting out of their own way.

Rather than stoke these fires our point of view calls for control, for seizing, driving and maintaining the initiative.

- 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 (NGOs), 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, at the same time, not want to be seen as “in bed” with a corporation, but that does not make them any less valuable as allies.

These third parties will only be true allies through carefully cultivated relationships, relationships that have been built over time and have been of benefit to both parties. 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.

Targeted companies must identify the individuals and groups who share a mutual interest. 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. 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 \$253 million 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. Because such statements 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 health care rather than a marketer of products.

Most importantly, the MS&L point of view is that, 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.

Conclusion

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. When patients are hurt, the justice system should provide redress.

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 stakes for patient communities, researchers, employees and shareholders remain extremely high, and 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, multi-pronged 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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