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The Vioxx Litigation

Part I

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Abstract

Part I of this AEI Working Paper looks at the history of Vioxx and asks questions about potential over-deterrence from having manufacturers bear the full measure of the social cost of drugs through strict products liability or failure-to-warn claims.

Robert Ernst was fifty-nine, with two partially blocked arteries, when he suddenly died in his sleep from an arrhythmia. He had been taking the painkiller Vioxx for eight months. On August 19, 2005, a Brazoria County jury in Angleton, Texas, held Merck, the pharmaceutical company that sold Vioxx, liable for his death. The jury assessed damages at a staggering \$253 million: \$24 million “compensatory” damages and \$229 million in punitive damages.

Frederick Humeston suffered a heart attack after taking Vioxx for two months. On November 3, 2005, a New Jersey jury, presented with the same evidence that led the *Ernst* jury to assess punitive damages for outrageous conduct, found that Merck had done nothing wrong in its marketing or sale of Vioxx, and exonerated Merck, without even having to evaluate Mr. Humeston’s shaky evidence of causation or questionable claims of substantial injury. Still, Merck spent millions of dollars defending itself in the seven-week trial.

Fifty-three-year-old Richard “Dicky” Irvin weighed 230 pounds, had blood pressure of 149/90, a family history of heart trouble, and significant heart disease (with one coronary artery being 60–70 percent blocked). Nevertheless, plaintiffs’ attorneys seek to blame his fatal heart attack on the twenty-three days that he was taking Vioxx, and a federal judge will allow a jury to hear his claims in late November 2005.

The production of Vioxx, as with any innovative drug, was a risky venture at the start. It costs millions to develop a new drug, and there is no guarantee of success in obtaining regulatory approval or market acceptance. The revenues from a drug must fund not only the original cost of development, but the *ex ante* risk that development will fail. A famous study showed that, on average, it costs \$802 million to bring a successful drug to market.¹ Even this is an underestimate, however, if manufacturers are held liable to the tune of billions of dollars if the drug is perceived or discovered to have been more dangerous than originally anticipated.

The Vioxx cases, and *Ernst v. Merck* in particular, present several problems and issues.

Part I of this AEI Working Paper looks at the history of Vioxx and asks questions about potential over-deterrence from having manufacturers bear the full measure of the social cost of drugs through strict products liability or failure-to-warn claims.

First, to what extent should pharmaceuticals that have passed the extensive and expensive regulatory gauntlet be subject to tort liability? With the cost-benefit scrutiny given to new drugs, what is the net marginal benefit of adding additional regulation through litigation?

Second, even if liability is appropriate in some circumstances, Merck is being held liable here for failure to have perfect foresight. Cherry-picking evidence in hindsight paints a false picture of the cost-benefit decision to produce a drug and creates poor incentives for corporate behavior.

¹ Joseph DiMasi, Ronald Hansen, and Henry Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22 (2003): 151–185.

Part II of this paper, to be released next month, goes further into specific problems presented by the Vioxx cases for the litigation system as a whole.

First, Ernst, Humeston, and the first federal case, Irvin Plunkett, are cases where evidence of causation was entirely speculative. If post hoc, ergo propter hoc becomes the standard by which pharmaceutical companies are to be adjudged liable, there will be over-deterrence. This effect is magnified by the recent New Jersey state-court certification of a class of insurers seeking reimbursement on grounds of consumer fraud for Vioxx that they purchased for their insureds.

Second, the Ernst jury's damages award was excessive in both its compensatory and punitive components. Previous liability reform implemented in Texas law will cap the punitive damages at less than \$2 million and thus reduce the total award to about \$26 million. But even this presents excessive and unmoored non-economic damages that over-compensate the plaintiff's family and, like the causation problem above, present a problem of over-deterrence.

Third, many have suggested that the arguments above could have been presented to the Ernst jury, and that, therefore, the failure of Merck's attorneys to persuade the jury justifies the verdict beyond criticism. Whether the tactical decisions of Merck's attorneys can be second-guessed is beyond the scope of this essay, but if Merck was "outlawyered" by one of the most successful trial attorneys in America (and then in turn outlawyered plaintiffs' attorneys in New Jersey), it is a non sequitur to suggest that the verdict is therefore an appropriate result. Public policy decisions should not be resolved by the results of a game show: while lawyers on both sides may hate to hear it, there is a great social cost in a mechanism that makes millionaires out of the most successful players of the game.

Fourth, even if one disagrees with the above propositions, the Ernst case was infected by unfairly prejudicial trial-court decisions that contradicted Texas law and sound public policy. While these problems may eventually be corrected on appeal, Merck will suffer and Ernst's attorney, Mark Lanier, will benefit from the publicity in the interim.

Finally, Lanier was able to bring his action in a favorable forum, a Brazoria County courtroom, through manipulation of a loophole in federal jurisdictional law that creates an almost impossible-to-meet-standard for proving "fraudulent joinder"—the act of suing in-state defendants for the purpose of keeping a case in state court rather than seeking recovery against them—and forbids removal more than a year after a case was filed. He was thus able to take advantage of procedures like a non-unanimous jury, a voir dire procedure that allowed him to target jurors through their favorite television shows, and the trial court's unwillingness to act as a gatekeeper to exclude unfairly prejudicial evidence that most federal court judges would not have countenanced. Simply closing this loophole is a minor reform that would have tremendous power to prevent rogue state court judges from exercising disproportionate influence on the nationwide economy. The power of plaintiffs to have their choice of three potential forums—a plaintiff's home state, a federal court, or New Jersey—means that many plaintiffs' attorneys are waiting

until the absolute last moment to file their cases to see where they are most likely to get favorable rulings.

The combination of all these factors takes a system that would over-deter the research and development of new drugs in the best of circumstances, and adds even more distortions. The Vioxx litigation demonstrates precisely why the judicial system is poorly equipped to make dispositive judgments on American drug safety policy.

Background

Merck launched Vioxx (the brand name for rofecoxib, a COX-2 inhibitor NSAID²) commercially in 1999 after receiving approval from the Food and Drug Administration (FDA). In the Phase III studies that were the basis for FDA approval, Vioxx showed no increased risk of cardiovascular events compared to other NSAID pain relievers, including popular over-the-counter drugs such as Advil, or to placebos.³

Merck continued to study Vioxx, both to explore issues of side effects and to determine whether the drug had additional uses that could increase sales. Merck's VIGOR study—released to the FDA in March 2000 and published in November 2000⁴—showed that Vioxx had less gastrointestinal toxicity than another pain reliever, naproxen. However, study participants did have a statistically significant difference in some types of cardiovascular events, particularly myocardial infarctions—heart attacks. But mortality rates (as well as mortality rates from cardiovascular causes) were statistically indistinguishable between the two groups in VIGOR, and other studies continued to show no significant difference between Vioxx and other NSAIDs or placebos.⁵ Merck debated the issue internally and decided that the difference in cardiovascular events was attributable to a combination of the probable cardioprotective effects of naproxen and random chance from the small sample size. Starting in June 2000, Merck negotiated with the FDA about the labeling that would appropriately reflect the VIGOR results, and the FDA approved a new label that included a cardiovascular-incident-warning detailing those results in April 2002.

A 1998 small-sample study, Study 090, showed a statistically insignificant increase in cardiovascular events, but a raw number differential of 6:1—out of a set of 390 Vioxx

² “NSAIDs” is the standard term for nonsteroidal antiinflammatory drugs.

³ A. S. Reicin et al., “Comparison of Cardiovascular Thrombotic Events in Patients with Osteoarthritis Treated with Rofecoxib versus Nonselective Nonsteroidal Antiinflammatory Drugs (Ibuprofen, Diclofenac, and Nabumetone),” *American Journal of Cardiology* 89 (2002): 204–209.

⁴ C Bombardier, et al. “Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid arthritis.” *N Engl J Med* 343 (21): 1520-8.

⁵ M. A. Konstam et al., “Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib,” *Circulation* 104 (2001): 2280–2288; M. Mamdani et al., “Effect of Selective Cyclooxygenase 2 Inhibitors and Naproxen on Short-Term Risk of Acute Myocardial Infarction in the Elderly,” *Archives of Internal Medicine* 163 (2003): 481–486; F. T. Shaya et al., “Cardiovascular Risk of Selective Cyclooxygenase-2 Inhibitors Compared to Other Nonsteroidal Anti-Inflammatory Agents: An Observational Study of a Medicaid Population,” *Pharmacoepidemiology and Drug Safety* 13 (2004): S234–S234.

patients and 196 placebo users.⁶ The plaintiffs' bar complains that Merck never "published" Study 090, but it was made available to the FDA, was summarized on the FDA website, and was mentioned in a 2001 *Journal of the American Medicine Association* article by Dr. Eric Topol and two other authors.⁷ Dr. Topol has been an especially prominent critic of Merck, appearing on *Sixty Minutes* second-guessing the failure to withdraw Vioxx in the wake of VIGOR and Study 090. In 2001, though, his article dismissed Study 090 as failing to demonstrate "the significant increase in cardiovascular event rate noted in VIGOR," and concluded that, "because of the evidence for an antiplatelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR was due to a benefit from naproxen or to a prothrombotic effect from rofecoxib," and called for additional study.

Merck already had such a study underway. In September 2004, the ongoing APPROVe study confirmed previously ambiguous study results, and demonstrated statistically significant results that Vioxx elevates the risk of a heart attack or stroke after eighteen months of usage, with a relative risk⁸ of 1.92—though overall and cardiovascular mortality was similar between the Vioxx and placebo populations.⁹ Merck immediately shut down the study and voluntarily withdrew Vioxx from the market. Merck had expected \$700-\$750 million in worldwide sales in just the fourth quarter of 2004, and had realized \$2.5 billion in worldwide sales for all of 2003.

A recent retrospective study of 113,000 elderly Canadians suggested a barely statistically significant increased relative risk of heart attacks of 1.24 from Vioxx usage, with a higher (but also barely statistically significant) increased relative risk of 1.73 for higher-dose Vioxx usage.¹⁰ A Canadian expert advisory panel voted 12 to 1 this summer to recommend that Canada permit the prescription of Vioxx because the benefits outweigh the cardiovascular risks—which the panel characterized as no worse than that from ibuprofen, sold over the counter in the United States, or even of other COX-2 drugs such as Celebrex.¹¹

⁶ FDA Advisory Committee, *Cardiovascular Safety Review of Rofecoxib* (Rockville, MD: Food and Drug Administration, 2001).

⁷ D. M. Mukherjee, S. E. Nissen, and E. J. Topol, "Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors," *Journal of the American Medical Association* 186 (2001): 954–959.

⁸ Relative risk is the ratio of risk between two populations. Thus, a relative risk of mortality of 2 would reflect a death rate twice as high, and a relative risk of 3 would be three times as high. If the relative risk is not statistically significantly different from 1, then that would indicate that any difference in relative risk is statistically insignificant.

⁹ R. S. Bresalier et al., "Cardiovascular Events Associated with Rofecoxib in a Colorectal Adenoma Chemoprevention Trial," *New England Journal of Medicine* 352, no. 11 (2005): 1092–1102.

¹⁰ L. E. Levesque et al., "The Risk for Myocardial Infarction with Cyclooxygenase-2 Inhibitors: A Population Study of Elderly Adults," *Annals of Internal Medicine* 142 (2005): 481–489.

¹¹ Health Canada, *Report of the Expert Advisory Panel on the Safety of COX-2 Selective Non-steroidal Anti-Inflammatory Drugs (NSAIDs)*, July 6, 2005, p. 6, available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/sap_report_gcs_rapport_cox2_e.pdf (last accessed November 14, 2005). See also S. P. Johnson et al., "Risk of Hospitalization for Myocardial Infarction among Users of Rofecoxib, Celecoxib, and Other NSAIDs," *Archives of Internal Medicine* 165 (2005): 978–984, which shows the risk differential insignificant relative to other non-aspirin NSAIDs.

In the February 2005 issue of *The Lancet*, internal FDA critic David Graham published a study from Kaiser Permanente data suggesting a 1.47 relative risk for low-dose Vioxx, and 3.58 for high-dose Vioxx compared to current use of celecoxib.¹² The smaller number was not statistically significant (though barely so). The use of celecoxib as a baseline was selectively chosen from the data to make the comparison to the dataset for the drug that had the lowest observations of cardiovascular events; the use of any of the other available baselines from the Kaiser data for relative risk would have produced statistically insignificant results. Graham then cherry-picked two outside studies showing the highest relative risk to conclude that there were as many as 140,000 excess cases of serious coronary heart disease in the United States from Vioxx usage—though his own data in a September 30, 2004, memo to the FDA (on which *The Lancet* article was based) produced a number a fifth that size.¹³ And even that figure would not have been statistically significantly different than zero when compared to a general population that had stopped using NSAIDs at least sixty days earlier.

Over-deterrence through the Misweighing of Costs and Benefits

Pharmaceutical companies face two hurdles in introducing drugs to the U.S. market. First, they must obtain FDA approval, a lengthy process that prospectively measures the costs and benefits of a drug. Though patents last for twenty years upon issuance, the regulatory approval process takes a substantial percentage of that. The average *effective* patent lifetime is only twelve years.¹⁴ Others have noted that, if anything, the FDA is biased towards product safety and is too hesitant to approve new drugs, which has cost thousands of lives.¹⁵

With such an overprotective regulatory scheme already in place, it behooves us to ask whether there should also be a private regulatory scheme that reevaluates the costs and benefits of a drug in hindsight, and then assesses the ostensible costs of the drug against the manufacturer. Even if one believes juries well-suited to make these judgments, the results will over-deter pharmaceutical manufacturers. In fact, this is true even if one believes that the jury system does a perfect job of evaluating drugs.

¹² David J. Graham et al., “Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-Oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Nested Case-Control Study,” *Lancet* 365, no. 9458 (2005): 475–481.

¹³ David J. Graham, “Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with COX-2 Selective and Non-Selective NSAIDs,” memorandum to Paul Seligman, September 30, 2004, available at <http://www.fda.gov/cder/drug/infopage/vioxx/vioxxgraham.pdf> (last accessed November 13, 2005). A Dr. Michael Jacobson blog post pointed out this discrepancy, at <http://www.journalclub.org/2005/01/25/n50>, January 25, 2005 (last accessed November 13, 2005).

¹⁴ Henry Grabowski, “Patents, Innovations, and Access to New Pharmaceuticals,” *Journal of International Economic Law* 5 (4): 849-860 (December 2002).

¹⁵ Sam Peltzman, “The Benefits and Costs of New Drug Regulation,” in *Regulating New Drugs*, ed. Richard L. Landau, pp. 114–211 (Chicago: University of Chicago Press, 1973); John E. Calfee, “Is the FDA Broken?” Tech Central Station (March 30, 2005); Paul H. Rubin, “FDA Advertising Restrictions,” in *Hazardous to Our Health? FDA Regulation of Health Care Products*, ed. Robert Higgs, pp. 29–53 (Oakland, CA: The Independent Institute, 1995); S. N. Wiggins, “Product Quality Regulation and New Drug Introductions: Some New Evidence from the 1970s,” *Review of Economics and Statistics* 63 (1981): 615–619; S. Kazman, “Deadly Overcaution,” *Journal of Regulation and Social Costs* 1, no. 1 (1990): 35–54.

It is suggested that the products liability system is needed to deter the production of unsafe drugs. But efficacy and safety must be proved to the FDA before a drug can even be placed on the market. In the case of pharmaceuticals, products liability can only be brought to bear on this subset of products that have already received approval.

Many argue that the jury system is meant to compensate—i.e. make whole—those who have suffered damages from taking a drug. If it is working perfectly, the manufacturer will thus bear the social costs created by its drug. The problem is that, on the other side of the equation, a pharmaceutical manufacturer—despite its patent-granted monopoly—has no way to extract the full consumer surplus from those who value the benefits of the drug.

The result? A manufacturer only collects a fraction of the benefits that are attributable to a drug (a fraction already subject to political pressures over alleged “gouging”), while the tort system attempts to assess the full measure of damages for the costs attributable to the drug. The resulting cost-benefit analysis becomes distorted such that the manufacturer may find it unprofitable to produce drugs that would have a net positive social benefit. The distortion is magnified by the huge transaction costs. Merck has already set aside \$675 million simply to cover the legal expenses of trying the thousands of Vioxx cases. If, as some analysts are predicting, Merck’s ultimate liability will total \$10 to \$50 billion, some \$4 to \$20 billion of that will go towards paying attorneys on both sides. Perhaps more: in the mass-tort asbestos cases, litigation and administrative costs have totaled 58 percent of the total costs.¹⁶ Simply put, one can expect that *Ernst*, by itself, will deter at least some research and development of life-saving drugs.

Vioxx was one such life-saving drug. The painkillers that it replaced (and is now replaced by) cause their own health problems. Current medical thinking is that, for at least some people, Vioxx would be a safer as well as a more effective painkiller than aspirin is—because of aspirin’s gastrointestinal side effects—despite what we now know to be the latter’s better cardioprotective profile.¹⁷

Merck cannot collect millions from each person whose life it saves, even if it were possible to identify after the fact a particular individual who did not die from gastrointestinal complications because he or she was taking Vioxx. A legal system can impose a \$2 million cost on Merck for every life their drug takes, but Merck has no means to obtain \$2 million for each life saved. The problem is even worse once the damages multiply. One can easily devise a hypothetical scenario where a drug saves the lives of a hundred people for every person killed by a side effect, but the cost-benefit analysis that the plaintiffs’ bar wishes to impose on the pharmaceutical industry forces the manufacturer to pull the drug from the market.

¹⁶ Stephen J. Carroll et al., *Asbestos Litigation* (Santa Monica, CA: Rand Institute for Civil Justice, 2005).

¹⁷ While the economic distortions in the American medical system suggest that doctors over-prescribed Vioxx for many patients for whom cheaper unpatented painkillers would have been sufficient, it seems perverse to selectively penalize Merck for these flaws not entirely of their own making, and to do so in the forum of products liability law.

The economic incentive to invest in research and development depends on the likelihood of recovering a return from that investment. Increased costs at the back end will reduce investment at the front end. One study suggests that a 1 percent decrease in the revenue from drugs reduces the growth rate of new drugs by 4 percent.¹⁸

It would be bad enough if the political fallout from Vioxx causes ripple effects in the regulatory regime that delay approval of drugs; this appears to be happening in the case of approvals for a multiple sclerosis drug and a new form of insulin that does not require injection.¹⁹ But more important still will be the research and development projects that never even begin but would have resulted in successful new drugs, the consequences of which are unmeasurable.

All this is the case even if we assume that the judicial system is performing its job perfectly; that juries are not acting out of sympathy to award money to plaintiffs who have not suffered consequences from the drug in question; that plaintiffs (with meritorious cases or otherwise) are not recovering overcompensating windfalls; and that judges are applying rules equitably. Unfortunately, none of these assumptions is true, and the problem is even worse than the problematic best-case scenario described above.

Over-Deterrence through Cherry-Picking Hindsight

In a large organization, there are often mechanisms that produce warnings for hundreds of improbable events. It is not uncommon for lawyers to find those warnings in the process of litigation discovery, show a jury and leak to the press the ones that might have prevented a disaster, and then accuse the defendant of having failed to heed its own internal warnings.²⁰ At the same time, the plaintiffs and the press will completely disregard the hundreds or thousands of warnings the defendant legitimately disregarded as false alarms. Demanding that a corporation's decisions be evaluated by 20/20 hindsight would require it to behave with excessive and inefficient caution.

In the case of Vioxx, some studies showed no adverse cardiovascular effect from usage; one study, the 2000 VIGOR study, comparing Vioxx users to naproxen users, showed a marginally statistically significant difference for some types of cardiovascular events, but no statistically significant difference for sudden cardiac death, fatal heart attacks, unstable angina, or cerebrovascular thrombotic events. Merck attributed the statistically significant element of the difference to what it believed to be the cardioprotective effects of naproxen. Plaintiffs' attorneys and the FDA have criticized Merck for suggesting naproxen had cardioprotective effects, but later studies appear to corroborate this.²¹

¹⁸ Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *Quarterly Journal of Economics* (April 2004).

¹⁹ See, e.g., Scott Hensley, Paul Davies, and Barbara Martinez, "Vioxx Verdict Stokes Backlash that Hit FDA, Manufacturers," *Wall Street Journal*, August 22, 2005.

²⁰ This problem is not unique to litigation. See, e.g., Judge Richard A. Posner's criticisms of the 9/11 Commission's second-guessing in "The 9/11 Report: A Dissent," *New York Times*, August 29, 2004.

²¹ D. J. Watson et al., "Lower Risk of Thromboembolic Cardiovascular Events with Naproxen among Patients with Rheumatoid Arthritis," *Archives of Internal Medicine* 162 (2002): 1105–1110; D. H. Solomon et al., "Nonsteroidal Anti-Inflammatory Drug Use and Acute Myocardial Infarction," *Archives of*

The scientific method requires the proposal of hypotheses. Brainstorming of and debate over possible problems is precisely what we want pharmaceutical companies to be doing because it is the investigation into those problems that permits the scientist to accept or reject the hypothesis. But if the mere fact of the debate is used to demonstrate the proposition “the defendant should have known,” the corporation is faced with one of two choices: either squelch the debate before it happens or paralyze the company until absolute certainty is reached on every question. The first option increases the danger to consumers; the second so increases the cost of producing drugs (or, indeed, any other innovation) that none gets produced.

Precisely this sort of hindsight is central to the Vioxx debate. Plaintiffs’ attorneys provided numerous documents to the press and successfully persuaded the media to portray them as smoking guns.²² It is fascinating to read these documents because it is only through the after-the-fact characterization of them that they become “smoking guns.” In a marvelous example of cherry-picking, trial lawyers point to a March 2000 e-mail discussing the concerns of an Italian doctor, Carlo Petrono, who suggested to Merck scientists that naproxen’s cardioprotective effects could not account for the difference observed in the VIGOR study. Thus, they argue, Merck should not have been telling doctors that VIGOR’s results were because naproxen was used in the control group. But the very same e-mail states Dr. Petrono’s conclusion: “what we saw in VIGOR is to be attributed to a large extent to chance.”²³

More than just scientific documents are subject to litigators’ cherry-picking. One document that captured the popular imagination, and played a prominent role in Mark Lanier’s opening statement, is “Dodgeball Vioxx”—a colorful set of pages that has been characterized as instructing sales representatives to “dodge” questions about Vioxx. Except the document does no such thing.

The “Dodgeball” game was part of a day-long training session for representatives on how to intelligently answer questions and concerns doctors might have. The session also had role-playing and other educational games, including one that had sales representatives throwing a koosh-ball to one another, and another that was a game-show team competition similar to *Jeopardy!* Dodgeball was a card game that consisted of two-sided cards; some cards had questions that doctors might pose to sales representatives, other cards said “Dodge” and allowed the representative to advance without answering a question.

Internal Medicine 162 (2002): 1099–1104; E. Rahme, L. Pilote, and J. LeLorier, “Association between Naproxen Use and Protection against Acute Myocardial Infarction,” *Archives of Internal Medicine* 162, no. 10 (2002): 1111–1115.

²² See, e.g., A. W. Matthew and B. Martinez, “E-mails Suggest Merck Knew Vioxx’s Dangers at Early Stage” *Wall Street Journal*, November 1, 2004.

²³ Martino Laurenzi, e-mail message to Brian F. Daniels, Eliot W. Ehrlich, and Alise S. Reicin, March 28, 2000, available on the pro-litigation website “Safer Drugs Now” at <http://www.saferdrugsnow.org/documents/vio/E-mailreCarloPatronoVIGOR.pdf> (last accessed November 14, 2005).

One might question the pedagogical effectiveness of this exercise, which could easily be satirized in a *Dilbert* cartoon. But it hardly amounts to the sinister conspiracy that the plaintiffs' bar has sold to the media, which apparently took attorneys' representations at face value without actually trying to understand the underlying document. It says something about the litigation system's creative cherry-picking of documents that a camaraderie-building educational exercise can be characterized as one that "taught representatives to play 'Dodgeball' when doctors voiced concerns."²⁴ If lawyers need to vet the most trivial activities to anticipate the possibility that they'll be used against the company in future product liability litigation, the costs of doing business will rise astronomically.

The exact same documents were viewed differently by the two different juries. The *Ernst* jurors—including several homemakers, a child-care provider, a twenty-year-old electrician, a technician, and a human-resources worker—claimed to be shocked by the e-mails and the other company documents. In contrast, the generally older, more educated, and more business-savvy *Humeston* jury was unimpressed by the supposed "smoking guns," recognizing that inflammatory comments were being taken out of context. "If someone peeked through all my e-mails, forget about it," said juror Patricia Healey.²⁵

On the other hand, some observers have suggested that the real issue with Vioxx was that Merck failed to warn consumers of its potential risks. Again, however, this is second-guessing. There aren't allegations that Merck hid the results of studies. Rather, Merck released studies and then came to a reasonable conclusion about the implication of the studies that proved to be false in hindsight. To punish a manufacturer for such a result is to steer manufacturers to the only alternative: turning every drug disclosure form into the equivalent of the modern investors' prospectus that, by warning about every possibility, ends up providing no warning whatsoever.²⁶ Studies on Vioxx presented dozens of statistically insignificant and contradictory findings; is each to merit a warning on the off-chance that one of them turns out to be statistically significant upon greater study?

Consider yourself: Do you scrutinize the inserts in your prescription drugs? Do you read every line? Have you ever, after purchasing a prescribed drug, told your doctor to prescribe you a different drug because of information you saw for the first time in the insert? Would you be more or less inclined to read inserts if they were twice or twenty times as long, listing additional warnings for every potential risk, including those that have not shown statistical significance yet?

It seems that the *Ernst* jury would not have exonerated Merck even if it had complied with this irrational standard. The *New York Times* quotes one juror insisting on the impossible: "In the first label, it didn't jump out at you that [cardiovascular] events were

²⁴ Alex Berenson, "For Merck, Vioxx Paper Trail Won't Go Away," *New York Times*, Aug. 30, 2005. The Dodgeball document is available at http://www.saferdrugsnow.org/documents/vio/jeopardy_game.pdf (last accessed November 14, 2005).

²⁵ Heather Won Tesoriero et al., "Merck Scores Major Victory in the Second Vioxx Trial," *Wall Street Journal*, Nov. 4, 2005.

²⁶ See, e.g., *Todd v. Societe BIC, S.A.*, 9 F.3d 1216, 1218-19 (7th Cir. 1993) (*en banc*).

happening,” the juror said. “You had to dig three levels to see it.”²⁷ The label listed the results of the VIGOR study, as well as warnings from other studies and introductory scientific data about clinical pharmacology required or requested by the FDA. In other words, providing warnings for every contingency isn’t enough: the manufacturer is expected to have perfect foresight and emphasize (and perhaps personalize) the warning of the problem that might have affected a particular plaintiff.

If only the surest, safest drugs shield companies from the risk of being bankrupted by product liability suits, then it becomes increasingly likely that investors will decide that research projects into new drugs are not worth the candle.

Ted Frank is a resident fellow and the director of the Liability Project at AEI. Prior to his position at AEI, Mr. Frank was an attorney at O’Melveny & Myers LLP, where he did legal work for Merck in several Vioxx cases. The opinions in this piece are entirely his and not the responsibility of his former client or his former employer, and rely solely on publicly available information. Some portions of this piece appeared in a different form on the websites Overlawyered.com, Point of Law, National Review Online, and Medical Progress Today. Mr. Frank would like to thank Karlyn H. Bowman, John E. Calfee, Christopher DeMuth, Richard Epstein, Michael S. Greve, Walter Olson, Sally Satel, Philip Wallach, and Will Wilson for helpful comments and suggestions, but claims any errors as his own.

²⁷ Bill Dawson and Alex Berenson, “Working through a Decision Cut in Shades of Deep Gray,” *New York Times*, August 20, 2005.