Mass Tort Litigation v. FDA Regulation

Jay P. Mayesh

Drug Safety, Product Liability and Litigation

Track II A

June 7, 2005

FDA Approved Devices

Dalkon Shield IUD

Artificial Heart Valves

Pacemakers

Pedicle Screws

Silicone Breast Implants

Hip Implants

Dalkon Shield IUD and Silicone Breast Implants

Two (A.H. Robbins and Dow Corning) of the 6 manufacturers of FDA approved devices went bankrupt because of mass tort liability.

Artificial Heart Valves, Pacemakers, Pedicle Screws, and Hip Implants

Four of the 6 manufacturers of approved devices incurred $$$$$ liabilities.

The FDA is Your Best Friend

The Courtroom is Your Worst Nightmare

Welcome To My World

Injured Plaintiffs

Judges

Juries

Evidence

Standard of Proof

Judges

FDA	State Courts		Federal
Advisory Committees and FDA Staff	Elected *(partisan or non-partisan)*	Appointed	Appointed for Life

Judicial Selection in the States

Table 1: Helland and Tabarrok

Partisan Elections

Alabama, Arkansas, **Illinois, Mississippi** New York, North Carolina, Pennsylvania, Tennessee, **Texas, West Virginia**

bias against out-of-state residents. Despite the name, Texaco is a New York City corporation whereas Pennzoil is based in Houston where the trial was held. The $11 billion award in favor of Pennzoil immediately bankrupted Texaco. It seems unlikely that a Houston judge and jury would have acted similarly had New York-based Texaco sued Pennzoil for a similar tort. In fact at trial, Pennzoil's lawyers made New York vs. Texas mores a key issue, repeatedly arguing that whatever the case in New York, in Texas a handshake was as good as a signed and sealed contract. Texaco repeatedly tried to move the trial to New York, and whenever they were able to do so (usually for short periods of time) they received rulings in their favor. The Pennzoil case is outstanding because of the size of the award but in other respects it is characteristic. (On the *Pennzoil v. Texaco* trial, see *Oil and Honor* by T. J. Petzinger.)

What about Juries? The theory articulated above focuses on judicial incentives or characteristics. Judges decide only a minority of tort cases directly (i.e., in nonjury trials) and occasionally decide cases by overruling juries. In the *Pennzoil v. Texaco* case, many people thought the judge would overrule the jury's outrageous verdict and were shocked when he let the ruling, and the transfer of resources from the out-of-state defendant to the in-state plaintiff, stand. Our thesis does not require, however, that elected judges make blatantly biased rulings or that they often interfere in jury decisions. Judges have significant control over the trial outcome even without making use of their highest powers. Judges must interpret the law for juries, instruct the juries, allow or disallow objections, rule on motions and countermotions, limit or not limit the lawyers to certain theories of liability and damages, and so forth. Our thesis requires only that, compared with other judges, judges elected in a partisan electoral system make marginal changes in rulings that tend in the direction of supporting larger awards.

Judges have significant control over trials even without using their highest power. Judges interpret the law, instruct juries, rule on objections and motions, and limit lawyers to certain theories.

EVIDENCE

THE ELECTORAL HYPOTHESIS IS INTRIGUING, AND RICHARD Neely's statement provides some support for the hypothesis, but perhaps Neely's actions while on the bench were

judges in nonpartisan elections and in states that elect their judges in partisan elections. (In a nonpartisan electoral system judges are not allowed to run under the affiliation of any political party. In a partisan electoral system judges are identified by political party.) Table 1 summarizes the different types of judicial selection mechanisms for state courts.

Partisan Elections the Key We found few differences between awards in states that appoint their judges and awards in states that elect their judges on nonpartisan ballots. The differences between these states and those that use partisan elections, however, were shocking. Table 2 compares awards

Table 1

Judicial Selection in the United States

Partisan Elections	Alabama, Arkansas, Illinois, Mississippi, New York, North Carolina, Pennsylvania, Tennessee, Texas, West Virginia
Elected on Nonpartisan Ballot	Georgia, Idaho, Kentucky, Louisiana, Michigan, Minnesota, Montana, Nevada, North Dakota, Ohio, Oregon, Washington, Wisconsin
Appointed	Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wyoming

Source: A. Tabarrok and E. Helland, "Court Politics: The Political Economy of Tort Awards," *Journal of Law and Economics* XLII (1999): 157.

Judge Richard Neely

Author, *The Product Liability Mess*

From the Judge's Mouth Elected judges, just like other politicians, have an incentive to shift costs from in- state to out-of-state residents (i.e., from in-state plaintiffs to out-of-state defendants) because only in-state residents are potential voters. Some evidence that judges might act that way is provided by Richard Neely, a retired West Virginia Supreme Court judge, who in his book *The Product Liability Mess* was unusually frank about his judicial incentives and actions:

> As long as I am allowed to redistribute wealth from out-of-state companies to injured in-state plaintiffs, I shall continue to do so. Not only is my sleep enhanced when I give someone's else money away, but so is my job security, because the in-state plaintiffs, their families, and their friends will reelect me. (p. 4)

And, Neely continues, "it should be obvious that the in-state local plaintiff, his witnesses, and his friends, can all vote for the judge, while the out-of-state defendant can't even be relied upon to send a campaign donation" (p. 62).

Neely's second quote provides another reason to expect that tort awards will be exported in states that elect their judges. Elected judges, again just like other politicians, must raise significant amounts of campaign funds. Importantly, the random assignment of judges to cases means that the most consistent contributors to judicial campaigns are trial lawyers. At any given moment some trial lawyers are working for the plaintiff and others for the defense. In general, however, all trial lawyers are interested in larger awards: larger awards mean larger fees, whether one works for the plaintiff or the defense. Consider two judges, both of whom rule in the plaintiff's favor equally often but one of whom tends to be more generous in the granting of awards. Defense and plaintiff's lawyers will both prefer that the more generous judge be elected because generous judges increase the demand for both plaintiff and defense lawyers. Judges who grant large awards will find fund-raising easier than their more "stingy" colleagues will. Thus, even if every judge applies the law with no consideration whatsoever for political factors, we can expect that over time generous judges will be selected for in states with an elected judiciary.

The Money Trail Unlike other participants, trial lawyers engage in repeated interactions with the same judges and so have the most incentive to make campaign contributions. Although business organizations, such as the Chamber of Commerce, can lobby on behalf of large corporations in an effort to elect more restrained judges, their efforts suffer from a free-rider problem. No corporate plaintiff knows for certain where or when he will be sued, let alone which judge will preside over the relevant case. Thus, although contributing to all elections might on average produce more restrained judges, individual defendants have little incentive to contribute and instead free ride on the contributions of others. (Contributions to a judge's reelection chest, which occur after a trial has begun, are heavily monitored and are unlikely to be anywhere near as effective as contributions made much earlier in the process.) Trial lawyers by contrast know that they will have repeated dealings with most judges on the bench. In short, the marginal benefit of a contribution is much higher for a trial lawyer than for an out-of-state corporation.

The evidence on contributions is consistent with the theory that trial lawyers are an elected judge's primary contributors. Trial lawyers are by far the most important contributors to judicial campaigns. One study by the Florida Bar Association, for [illegible] estimated that at least 80 [illegible] contributions [illegible]

[illegible] hyp[illegible] (voters) will discipline judges [illegible] In-state defendants may be able to [illegible] contributions of trial lawyers through [illegible] such counter is available to out-of-state de[illegible]

An Example: Pennzoil v. Texaco In December 1985 a [illegible] jury awarded the Pennzoil Corporation more than $10 bi[illegible]lion dollars in damages ($7.53 billion in compensatory damages and $3 billion in punitive damages)—at the time the largest jury award in history. The Pennzoil case provides an extreme example of the combined effects of campaign contributions, tax exporting, and judicial elections. For example, when Texaco lawyers complained about large campaign contributions from Pennzoil's attorneys to judges ruling in their case, the lead Pennzoil attorney replied that no impropriety was involved because he had contributed money to almost *every* judge. The Texas court of appeals agreed with the reasoning of Pennzoil's attorney, noting: "It is not surprising that attorneys are the principal source of contributions in a judicial election.… A candidate for the bench who relies solely on contributions from nonlawyers must reconcile himself to staging a campaign on something less than a shoestring. If a judge cannot sit on a case in which a contributing lawyer is involved

REGULATION 22 VOLUME 23, NO. 2

"Not only is my sleep enhanced when I give someone else's money away, but so is my job security, because the in-state plaintiffs, their families, and their friends will reelect me." —*Judge Richard Neely*

"Not only is my sleep enhanced when I give someone else's money away, but so is my job security, because the in-state plaintiffs, their families, and their friends will reelect me." —*Judge Richard Neely*

A Jury of Your Peers

FDA

- Scientifically educated
- Chosen by merit
- Make decisions based upon known data and reasonable forecast
- Your colleagues

Courtroom

- Scientifically ignorant
- Chosen by lot
- Decisions infected with retrospective bias
- Injured plaintiff “colleagues”

Juries Do Not Understand Proof of Cause and Effect

Association is not cause.

The plural of anecdote is not data.

"In a world of cause and effect, coincidence is always suspect."

Dr. Marcia Angell, former Editor In Chief of *the New England Journal of Medicine*

Juries will not accept chance.

Human nature wants to find a cause.

Evidence available to Plaintiffs:

Adverse Event Reports

Labeling

Advertising

Marketing

Sales and Profits

Email

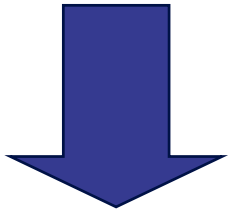
The Pirate and the Hook

Hammers, Ladders, the Garden of Eden

and

Black Box Warnings

A society obsessed with avoidance of risk embraces the fiction that risk and uncertainty can be controlled by WARNINGS.



It should have been in a Black Box.

Jury Charge re FDA
Compliance is the minimum standard

SPECIAL INSTRUCTION NO. 1

COMPLIANCE WITH GOVERNMENT RULES AND REGULATIONS

Request by Plaintiff		Request by Defendant		Request by	
Given as Requested		Given as Modified	√	Given on Court's Motion	√
Refused					
Withdrawn					

Judge

Special 1__

regulations or directives
manufacturer acted reasonably and

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COMPLIANCE WITH GOVERNMENT RULES AND REGULATIONS

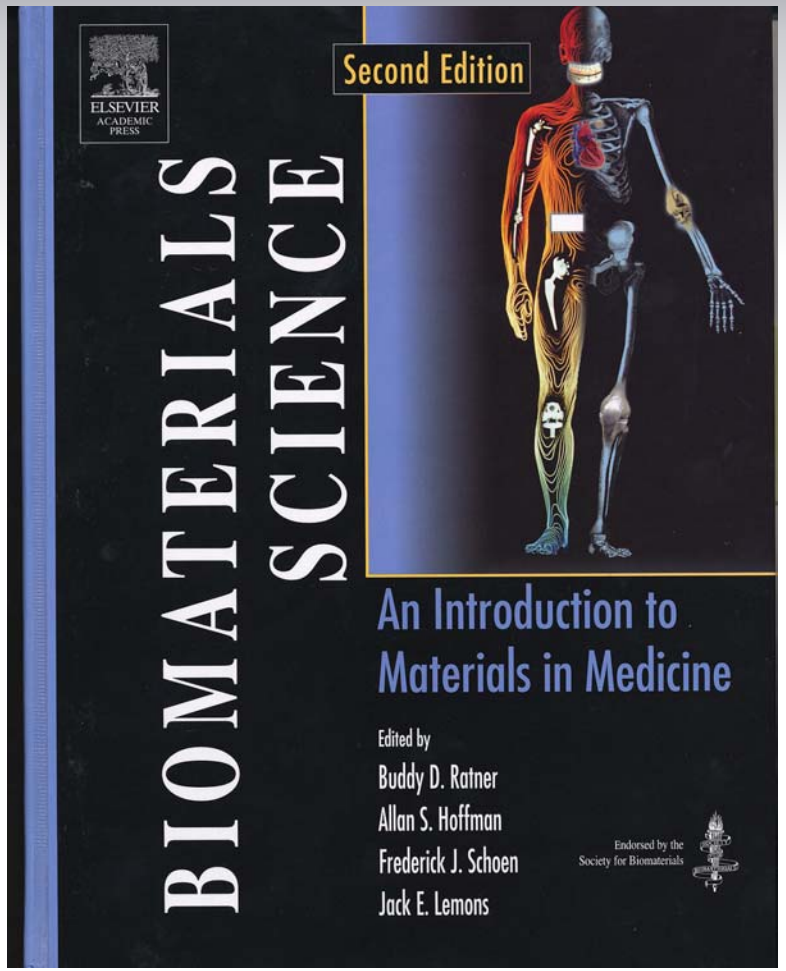
Compliance with rules, regulations, or directives as to warnings, such as those issued by the FDA, is not sufficient to immunize a manufacturer or supplier of a drug from liability. When the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled.

Take home message:

- Compliance with law is minimum standard.
- Juries may overrule FDA and hold you to a higher standard.

Get the picture?

The Courtroom is not friendly.



it some responsibility? Are there overriding moral concerns? While protecting ownership, are we losing sight of a greater duty to public health and welfare? Certainly a system that allows for the suppression of a new and better course of treatment in favor of a more profitable but less effective method of care needs reexamining. A healthy environment where respect for intellectual property can exist along with a sharing of ideas is best facilitated by the professionals who must deal with these issues daily. Openness in discussing these issues will help lead to a consensus among peers. Promotion of values by professional societies fosters the development of an ethically appropriate consensus.

CONCLUSION

We have introduced a few basic issues on the subject of ethics as it relates to biomaterials and medical devices. This is only a start. Change continues to transform our perceptions about what is possible, what we can do but perhaps what we should not do, about limits on research with humans and animals, and about the balance of objectivity and bias. Science and how it is conducted are changing. Medicine and the doctor–patient relationship are changing. The field of ethics has likewise grown. It has matured from what on the surface appeared to be a collection of conflicting principles into a useful basis for finding a resolution of potentially opposing considerations. One author has stated that ethical problems need to be approached in much the same manner as an engineer would approach a difficult problem in design (Whitbeck, 1998). This approach offers fresh insights useful for engineers, scientists, and physicians to address ethical problems.

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10.5 LEGAL ASPECTS OF BIOMATERIALS

Jay P. Mayesh and Mary F. Scranton

INTRODUCTION

Students of biomaterials engineering know that no product lasts forever and that implantable medical devices have unwanted side effects. In today's litigious society, these factors often transform patients and device manufacturers into warring parties in always unwelcome and sometimes financially disastrous products liability litigation over the safety of medical devices. Products liability law imposes legal responsibility on manufacturers of products (ladders, cars, and medical devices, to name a few) as well as other companies involved in the "stream of commerce," such as wholesalers, distributors, and retailers, for injuries incurred by the consumer.

Products liability plaintiffs typically rely on three theories of liability. First, they claim that the manufacturer was negligent, meaning that the manufacturer failed to use reasonable care in designing and manufacturing the product. Second, plaintiffs claim the manufacturer breached legally enforceable promises, called warranties, in that the product did not meet recognized performance expectations or have the expected qualities of products of its type. Finally, plaintiffs sue under strict liability, in which the manufacturer is held responsible for a product that was unreasonably dangerous to the consumer or carried inadequate warnings, regardless of the degree of care exercised, or any promises made, by the manufacturer. Strict liability rests on two assumptions about law and economics. The first of these is that imposing liability on a manufacturer, even without a showing of carelessness on the manufacturer's part, is fair because the manufacturer is best able to discover and correct defects in its products before they cause harm. The second assumption is that, in the event of personal injury attributable to a product, the manufacturer can afford to compensate the injured party, add the cost of the injury to the product, and, if necessary, raise the price to recover the cost. To avoid liability under these legal theories, medical device manufacturers must design, manufacture, and sell products that are reasonably safe, and they must disclose in written warnings to physicians (and sometimes to patients) all risks associated with the products.

Prophylaxis

- Do not resist strong warnings suggested by FDA. Strong warnings are your best friend.
- Do not write e-mails you wouldn't want to see on the front page of the New York Times.
- Prominently include in all DTC advertising the message that all drugs and devices have risks as well as benefits.