



J O I N T C E N T E R
AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

The Adverse Side Effects of Pharmaceutical Litigation

Judyth Pendell

Related Publication 03-22
September 2003

Judyth Pendell is a senior fellow at the AEI-Brookings Joint Center for Regulatory Studies. She thanks Robert Hahn and Adam Sloane for their helpful comments, and the U.S. Chamber of Commerce for its support. The views expressed in this paper reflect those of the author and do not necessarily reflect those of the AEI-Brookings Joint Center for Regulatory Studies or the U.S. Chamber of Commerce.

Executive Summary

Prior research has demonstrated that a fear of unwarranted medical malpractice liability causes doctors and other healthcare practitioners to engage in self-protective activities, such as ordering unnecessary tests or treatments. This paper examines the impact that the liability system could have on prescription drug use. It reports on a Harris poll of doctors, pharmacists and patients. Situations where patients fail to receive appropriate medications as a direct result of the liability system are revealed. It recommends reforms that allow healthcare professionals to know with greater certainty which actions are likely to result in liability.

The Adverse Side Effects of Pharmaceutical Litigation

Judyth Pendell

Introduction

Healthcare is a public policy issue in which everyone has a very personal stake. Individual concerns about whether or not quality care will be available when it is needed commonly focus on whether good doctors and hospitals, and the best technology, will be accessible and affordable. It probably rarely occurs to anyone that even when the best care is within reach it might not be forthcoming because doctors or nurses or pharmacists may have concerns about themselves that trump their concerns about their patients.

Fear of unwarranted malpractice liability claims can create just such a conflict. In 2002, Common Good, an organization headed by lawyer and author Philip Howard, produced new, compelling evidence that doctors and other healthcare professionals are so concerned about unfounded lawsuits that they order unnecessary tests and procedures, and sometimes feel constrained from providing the candor and openness that would serve the patient's best interest.

Building on that work, this paper provides a window into how fear of liability could be getting in the way of patients not receiving medications they should have. The paper discusses first the dominance of non-meritorious suits and how the liability system creates undesirable incentives in the delivery of healthcare generally. It then discusses the findings of a Harris poll in which doctors, pharmacists, and patients are interviewed about how liability over pharmaceuticals is affecting their behaviors relative to prescribing, warning, and compliance with prescriptions.¹ It concludes that the randomness and uncertainty of the liability system is creating perverse incentives, including deterring pharmaceutical companies from research and development in some areas.

Healthcare professionals and pharmaceutical companies should be able to anticipate with some reliability which actions will result in liability being imposed, and which actions will provide protection from liability. Healthcare liability should be

¹ The U.S. Chamber Institute for Legal Reform commissioned Harris Interactive to conduct a study on the issue of pharmaceutical product liability litigation. The study was conducted among three target populations: physicians, pharmacists, and patients. A PowerPoint presentation on "Pharmaceutical Liability Study Report on Findings" prepared for the U.S. Chamber Institute for Legal Reform can be viewed at <http://www.acei-brookings.org/admin/pdffiles/phpgm.pdf>.

reformed to allow for that predictability. Freedom from fear of liability will restore patient well-being as the dominant priority.

Background

The tort system was always meant to affect the conduct of professionals, businesses, and organizations. The rationale has been that if those who provide goods and services are required to pay for the harm they cause they will be deterred from causing harm. The deterrence theory of tort litigation has recently come under intense scrutiny and criticism, however, among legal scholars. Priest² and Viscusi³ have conducted research that concludes that the tort system does not appear to be making products or the environment safer. Sunstein, Schkade, and Kahneman⁴ have questioned whether people really want optimal deterrence. Garber,⁵ Schwartz,⁶ Green,⁷ and Burk⁸ have focused on whether the tort system over-deters, whether efforts to protect against liability actually create socially undesirable behavior. For example, Garber's research shows how the tort system may be encouraging undesirable behaviors such as avoidance of R&D in product areas at risk of attracting litigation.⁹

Nowhere is this debate more focused than in the healthcare area. According to Alex Azar, the general counsel of the U.S. Department of Health and Human Services, defensive medicine, or the practice of ordering tests or other procedures solely as a protection against litigation, raises healthcare costs by as much as 70 to 126 billion

² See George L. Priest, "Understanding the Liability Crisis," *Liability: Perspective and Policy* (1988).

³ See W. Kip Viscusi, "The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts," *Geo. L. J.* 285 (1998). P. 87.

⁴ See Cass R. Sunstein, David a. Schkade, Daniel Kahneman, "Do People Want Optimal Deterrence?" *Punitive Damages: How Juries Decide* (2002) The concept of optimal deterrence applied here is that which is accepted in the field of law and economics. "People appear to reject the view, widespread within economic analysis, that punishment should be increased beyond compensation where the probability of detection is low, and that compensation is adequate where the probability of detection is 100%."

⁵ See Steven Garber, "Product Liability, Punitive Damages, Business Decisions and Economic Outcomes," *Wis. L. Rev.* (1998). P 237.

⁶ See Victor E. Schwartz, Mark A. Behrens, Joseph P. Mastro Simone, "Reining in Punitive Damages "Run Wild": Proposals for Reform by Courts and Legislatures," *Brook. L. Rev.* 1003 (1999). P 65.

⁷ See Michael D. Green, William B. Schultz, "Tort Law Deference to FDA Regulation of Medical Devices," *Geo. L. J.* 2119 (2000). P 88

⁸ See Dan L. Burk, Barbara A. Boczar, "Biotechnology and Tort Liability: A Strategic Industry at Risk," *U. Pitt. L. Rev.* (1994). P. 55.

⁹ See Steven Garber, "Liability and Patient Health," Transcript of Conference Sponsored by AEI-Brookings Joint Center and Common Good, March 4, 2003.

dollars a year.¹⁰ Unfortunately, the financial costs are not the entire story. Unnecessary interventions can be invasive, risky, and sometimes painful.

To explore further the importance of the problem of defensive medicine, a recent Harris poll commissioned by Common Good (a healthcare poll hereafter referred to as Harris HC) interviewed physicians, nurses, and hospital administrators to explore how the fear of litigation affects the practice of medicine and the delivery of medical care. It revealed that nearly all physicians and hospital administrators feel that unnecessary or excessive care is very often or sometimes provided because of fear about litigation. Physicians indicated in the poll that fear of malpractice claims causes them (or other physicians) to:

- Order more tests than they would based only on professional judgment of what is medically needed. (91% have noticed other physicians, and 79% report they themselves do this due to concerns about malpractice liability.)
- Refer patients to specialists more often than they would, based only on their professional judgment of what is medically needed. (85% have noticed other physicians, and 74% report they themselves do this due to concerns about malpractice liability).
- Suggest invasive procedures such as biopsies to confirm diagnoses more often than they would, based only on their professional judgment of what is medically needed. (73% have noticed other physicians, and 51% report they themselves do this due to concerns about malpractice liability.)
- Avoid candid discussions of medical mistakes when they are made. (Fear of liability is cited by physicians and hospital administrators as the leading factor that discourages medical professionals from openly discussing and thinking of ways to reduce medical errors.)¹¹

Most of the literature on the impact of the liability system on healthcare has focused on defensive medicine in the context of the delivery of care, particularly in relation to diagnostic and treatment procedures. There has been little attention paid to the impact on pharmaceuticals--prescribing, the warnings about side effects, and patient compliance with recommended medications. The Harris HC poll did ask about doctors prescribing more medications than necessary, and it found that doctors prescribe more medications, such as antibiotics, than they would based only on their professional

¹⁰ See Alex Azar, id. at 4.

¹¹ See *Fear of Litigation*, Harris Interactive, April 2002.

judgment of what is medically needed. (Some 73% have noticed other physicians, and 41% report they themselves do this due to concerns about malpractice liability.) However, the poll did not ask whether doctors sometimes avoid prescribing certain medications that they deem appropriate for their patients because the medications have or could become targets of litigation. Similarly, although the literature on defensive medicine has focused primarily on the delivery of healthcare in doctors' offices and in hospitals, little is known about the impact of liability on pharmacies and pharmacists' practices.¹²

To fill this void and expand what is known about the impact of liability on healthcare, and on patient well being, the U.S. Chamber of Commerce commissioned a Harris poll of physicians, pharmacists, and patients with the objective of better understanding how the behaviors of individuals within these groups are affected by litigation involving pharmaceuticals (hereafter referred to as Harris PHRM).¹³ The survey is based upon 250 interviews with physicians, 251 interviews with pharmacists, and 301 interviews with patients. (The sampling error for this poll is +/- 6.9% for physicians, +/- 6.2% for pharmacists and +/- 5.6% for patients.) To target patients who are likely to be currently taking medications (or needing to take medications in the future) patients qualified for the poll if they had been diagnosed with at least one of eight specified medical conditions: high cholesterol, hypertension, arthritis, depression, obesity, diabetes, heart disease, or stomach ulcers. The findings of that poll are discussed in this paper, and the entire poll, including detail about the methodology, appears as an attachment.¹⁴

The Impact of the Fear of Pharmaceutical Litigation on Physician Practices

In most jurisdictions doctors have a duty to warn patients of side effects associated with a drug, and the pharmaceutical companies are relieved of this duty, when

¹² The Harris poll commissioned by Common Good expanded the prior, almost exclusive, focus of the impact of fear of liability on physician practices to include hospital administrators and nurses. For example, nearly half or 43% of all nurses also feel prohibited or discouraged from doing what they think is right for the patient because of rules or protocols set up for liability protection.

¹³ See *Pharmaceutical Liability Study Report on Findings*, Harris Interactive, July 2003.

¹⁴ See <http://www.aei-brookings.org/admin/pdffiles/phpgm.pdf>.

the pharmaceutical company has provided an adequate warning to the doctor¹⁵. This “learned intermediary doctrine” first emerged in the 1960s, and is premised on several assumptions:

- physicians can evaluate best an individual patient’s medical needs and possible drug sensitivities,
- patients may wish to participate in the decision as to whether or not to take on the risks of a particular drug,
- a physician can provide ongoing supervision of the patient’s use of the drug, and
- physicians are best positioned to manage any possible side effects that do occur.

The learned intermediary doctrine does not relieve the manufacturer of the duty to provide adequate warnings of risks associated with specific drugs it merely requires that an adequate warning be given to physicians who might prescribe the drug. The assumption is that physicians will pass on an appropriate warning to their patients.¹⁶

The communication of warnings, however, has been distorted and complicated by fears of tort liability. According to FDA Commissioner Dr. Mark McClellan, “So long as the product developers we work with are facing an environment in which any adverse outcome can result in a major lawsuit, we may get labels written for lawyers, not doctors and patients. Because risk management often means reducing liability risks not reducing patient risks, there’s pressure to make labels read like liability avoidance tools. Instead they should be efficient documents for conveying risk--tools for helping doctors help patients. To protect the health of the public product labels should be written with the patient in mind, not a jury.”¹⁷ Three in four (74%) doctors interviewed for the Harris PHRM poll feel that the information contained in the patient packet insert is more complicated than it needs to be--and that product liability litigation plays a critical role in making it complicated. In fact, nine in ten (91%) physicians who think the information is too complicated believe that product liability is the problem.

¹⁵ See Bernard J. Garbutt III, Melinda e. Hofmann, “Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium,” *Food & Drug L.J.* 269 (2003). P. 58 (Pharmaceutical companies can be sued under negligence or strict liability theories for product defects.)

¹⁶ See Laurie K. Marshall, “Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physicians,” *U. Dayton L. Rev.* 95 (2000). P. 26

¹⁷ Mark B McClellan, MD, PhD, Commissioner, Food and Drug Administration. Speech before the Physician Insurers Association of America, May 24, 2003, Chicago, IL.

Since many patients want to participate in making critical medical decisions it is imperative that patients receive accurate and understandable information about the risks and benefits of medical options. This is particularly true for medications where it is almost always true that there are potential adverse side effects. The specter of liability practically assures that warnings will not be clearly worded in a patient-friendly way.

Unfortunately, the malpractice litigation environment in which doctors take on potential liability for the drugs they prescribe and the warnings they issue is far from rational and predictable. The Harris PHRM poll reveals that doctors unanimously (100%) agree that groundless malpractice litigation, or the threat of it, is a major concern to doctors. Nearly all physicians (99%) are personally concerned that they may be the target of groundless litigation or threat of litigation. Two-thirds of doctors (67%) say that they are personally *very* concerned about groundless litigation. Empirical research gives legitimacy to this fear. A study of general medical malpractice claims in the state of New York conducted by Harvard University revealed that for every claim that is filed by a meritorious plaintiff there are five or six other claims that don't involve either a negligence or an injury or both.¹⁸

Doctors believe that malpractice lawsuits against them that result from prescriptions they have made occur with some frequency. Two in five (40%) doctors are aware of other physicians who have been sued by patients who have experienced side effects from a prescribed drug, even though the drug was indicated and properly prescribed, leading them to think this type of litigation is common practice. In fact, most (57%) doctors are concerned that they may be sued by a patient who experiences side-effects from a drug they properly prescribe.

Doctors are handicapped in their efforts to provide adequate warnings to patients by the failure of the courts to defer appropriately to the expertise of the Food and Drug Administration (FDA). Doctors are dependent upon the patient package inserts provided by the pharmaceutical companies and approved by the FDA. The FDA provides an expert and careful review of all drug labeling, and requires that all warnings must be supported by solid scientific evidence. As Daniel E. Troy, general counsel of the Food and Drug Administration, has noted: "The agency [FDA] demands scientific substantiation not only

¹⁸ See Michele Mello, "Liability and Patient Health," conference sponsored by AEI-Brookings Joint Center, March 4, 2003. The study focused on medical malpractice claims generally, not just on claims involving pharmaceuticals.

for statements concerning the drug's clinical utility, but also for statements of precaution, contraindication, and warning. A statement in the labeling of a prescription drug has been found by FDA to represent the most current and complete scientific information. If a statement has been omitted, it is generally because FDA has not found it scientifically substantiated or necessary to assure safe use of the drug."¹⁹ Yet, taken together, doctors don't get clear and consistent messages from the FDA and from the courts.

The dominance of lawsuits without negligence creates a situation of great uncertainty for doctors. They realize the liability system does not have clearly defined rules, where violating the rules means liability is incurred and compliance with the rules means protection from liability will be granted. Professor George Priest of Yale Law School has often referred to this as the "gotcha" system of liability.

How does this fear affect physicians' choices regarding prescribing medications? A sizable number of physicians (43%) have avoided prescribing a particular drug that was appropriate for a patient because they were aware that it might be involved in product liability litigation. Although most physicians do not observe this as a common occurrence, 28% of surveyed physicians did indicate it happened frequently or very frequently. This is less than one third, but the results occur in a situation where the number of physicians responding affirmatively should be zero. Clearly, all patients want their doctors to base their care on medical considerations, not legal considerations.

Doctors also are aware that patient behavior may be influenced more by information coming from the liability system than by information about risks coming from their own doctors. Two in five (38%) doctors reported in the survey that they know of patients who have stopped taking a medication that was properly prescribed for them because the patient discovered the drug was involved in product liability litigation. About three in ten (29%) doctors have had patients refuse to take a drug properly prescribed for them because they were aware that the drug was involved in product liability litigation. Despite the fact that the liability system does a poor job of keeping out unfounded lawsuits, some patients seem to treat the mere existence of a lawsuit as an indication that a drug is harmful.

¹⁹ See Dan Troy, *FDLI Update*, Jan/Feb 2003.

The Impact of the Fear of Pharmaceutical Liability on Pharmacists' Behaviors

Historically, pharmacists have been on the liability hook almost solely through errors made in filling prescriptions: mistakes involving failure to provide the correct medication, the proper dose, or accurate directions for use.²⁰ Three theories have generally been relied on to relieve pharmacists of a duty to warn:

- 1) it would interfere with the doctor-patient relationship,
- 2) it would violate the learned intermediary doctrine, and/or
- 3) it would contradict public policy.²¹

Recently pharmacists as a professional group have been expanding their role well beyond that of prescription fulfillment to play a more active role in the healthcare delivery system. This new vision of “pharmaceutical care” transforms the pharmacist into a caregiver who provides patient education, monitoring, and adverse event reporting²². Through these changes in the professional paradigm, pharmacists are creating a new standard of care, one that incorporates a responsibility to warn patients. As noted by Myhra, of Texas Tech University School of Law:

Today’s pharmacy education, in contrast, is patient oriented. Pharmacists receive five or more years of education and training, during which they learn, among other things, how to interact with patients and physicians and how to provide information and warnings to patients. In short, pharmacy schools emphasize the necessity for pharmacists to take active roles in the provision of patient health care and, importantly, in the counseling of patients about prescription medications and potential problems such as adverse interactions and side effects.²³

Most courts addressing the pharmacists’ potential duty to warn have not addressed this shift in the profession. However, courts in several jurisdictions have noted this change and in so doing have found a duty to warn. These courts have acknowledged the expertise of the pharmacist and the potential for improved therapeutic outcomes if

²⁰ See R. Paul Asbury, “Pharmacist Liability: The Doors of Litigation Are Opening,” *Santa Clara L. Rev.* 907 (2000). P. 40

²¹ See Jennifer L. Smith, “Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists’ Expanding Liability and Duty to Warn,” *Hous. J. Health L. & Pol’y* 187 (2002). P. 2

²² See Alison G. Myhra, “The Pharmacist’s Duty to Warn in Texas,” *Rev. litig.* 27 (1999). P. 18

²³ See *id.* at 60.

this duty is imposed.²⁴ To some extent the courts may also be reacting to Congressional requirements that pharmacists expand their role and deliver more direct care.²⁵

When patients face the task of deciding whether or not to take a medication that has been prescribed for them, they need to balance the potential benefits of the drug against the risk of side effects and the seriousness of the side effects. To do this they need information that does not exaggerate either side of that equation. One would expect that this environment of expanding liability would inhibit candor by pharmacists in that it likely would cause them to overemphasize the risks and seriousness of the side effects. In fact, two in five (39%) pharmacists surveyed in the Harris PHRM poll indicated that they often over-emphasize the possible side effects of prescription drugs to patients. One in ten (10%) does this very often. Half of pharmacists (51%) believe the information given to patients in the patient packet insert is too complicated and that product liability is central to making it complex. So, patients appear to be getting overly complicated information in the package inserts, and then too often they get information from pharmacists who overemphasize the risks.

As is the case with physicians, pharmacists reported instances when patients have stopped taking medication or refused medication that was properly prescribed because of awareness the medication was the subject of litigation. Over two in five (44%) pharmacists report that some of their patients have stopped taking medication that was properly prescribed for them because they found out the drug might be involved in product liability litigation. Two in five (40%) pharmacists also report that patients have refused to take a properly prescribed drug because the patient knew the medication was involved in product liability litigation.

The Impact of Pharmaceutical Liability on Patients

It has already been noted that the fear of liability may have an adverse effect on patients in several respects:

²⁴ See *id.* at 71.

²⁵ The Omnibus Budget Reconciliation Act of 1990 (OBRA) requires states to implement “drug use review” programs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse events. It requires, among other things, that pharmacists offer to discuss with patients, in detail,

- The financial costs of defensive medicine are high and passed through to patients.
- Unnecessary tests or procedures that are not medically necessary but are ordered as a protection against liability impose risks and discomfort on patients.
- Doctors prescribe more medications than are needed, putting patients unnecessarily at risk of side effects.²⁶
- Patient packet inserts are more complicated than they need to be due to the influence of liability, interfering with the ability of patients to get meaningful information about risks and possible side effects.
- Physicians sometimes avoid prescribing appropriate medications because of litigation fears.
- Pharmacists sometimes over-emphasize the risks and seriousness of side effects because of liability fears.
- Both physicians and pharmacists report that they are aware of patients who refused to take a medication, or discontinued taking a medication, because of litigation involving the drug.

Harris also went to the patients themselves to supplement this information. In the interest of interviewing people who were currently under medical care, the interviewees were randomly selected from lists of patients with at least one of eight medical problems: high cholesterol, hypertension, arthritis, depression, obesity, diabetes, heart disease, or stomach ulcers. The patients were asked about their awareness of product liability litigation involving specific drugs. As testament to the ubiquity of trial lawyer advertising to solicit clients for pharmaceutical product liability actions, most patients (86%) are aware of advertisements run by law firms about product liability suits over a specific drug. One in five (21%) have seen an advertisement for litigation over a drug they were taking.

Patients react to such advertisements with concern. Nearly nine in ten (86%) of the patients would be concerned if they saw an advertisement regarding litigation over a drug they were taking. Half (50%) would be very concerned. The patients were asked what actions they would take as a result of seeing such litigation ads. The results were as follows:

- Would call their doctor: 90% yes, 6% no, 4% not sure;
- Would stop taking the drug immediately: 25% yes, 44% no, 31% not sure;
- Would call the law firm mentioned in the ad: 19% yes, 47% no, 34% not sure.

facts about the use of medications, including “side effects, adverse effects, adverse interactions, or contraindications.”

²⁶ In addition, the excessive prescribing of antibiotics has contributed to a reduction in their efficacy.

Less than one in ten (8%) have ever had to do any of these. This is inconsistent with the findings discussed above: one in five has seen a litigation-related ad for a drug he/she was actually taking, nine in ten would react to such an ad with concern, and nine in ten would call their doctors. Since the people who were interviewed were in the continuing care of their doctors, it is possible that the need to call their doctors was obviated by regular visits at which time the medication could be discussed.

The majority of patients (69%) also express concern if a packet insert warns of possible serious side effects, with one in five (20%) patients not taking a drug prescribed by his/her doctor as a result of reading information about possible serious side effects provided by the patient packet insert. This information about patient noncompliance underscores the need to have packet inserts communicate side effects and risks in a way that is clear and meaningful to patients, not in complicated legalese as is often the case.

Although patients would be alarmed by news that a drug they were taking was the object of litigation, patient responses to questions about whether or not such litigation is likely to be meritorious reveal a cynicism about the litigation. Most patients (72%) believe that it is common for law firms to file product liability lawsuits against drug companies when only a small number of people have experienced side effects from a drug. Two in five (41%) think it is *very* common for law firms to do this. Although few patients (27%) say they would join a lawsuit over a drug if they had not experienced side effects, the majority (86%) thinks that it is common for other people to join these lawsuits. Two in five (43%) believe it is very common for people to join a lawsuit over a drug they were taking, even if they had not experienced any side effects from the drug.

Patients have a striking awareness of the possible overdeterrence effect of product liability litigation. The majority of patients (71%) feel that product liability litigation, or the fear of litigation, has likely caused pharmaceutical companies to avoid research in certain product areas. Over a third (35%) say it is very likely that companies have avoided research because they fear groundless product liability litigation. Four in five (80%) patients are concerned that groundless product liability litigation prevents pharmaceutical companies from developing new and beneficial drugs. Nearly half (44%) say they are very concerned this may be occurring.

There is independent evidence that their concerns are founded in fact. Below are some examples:

A Conference Board survey of corporate CEOs, across many industries including pharmaceuticals, revealed that 36% had been prompted to discontinue products because of litigation, and 30% had decided against introducing a new product because of litigation concerns.²⁷

In the early 1990s liability against vaccine manufacturers drove many from the market. For some vaccines, only a single supplier existed in 1994. For one manufacturer a single punitive damage claim totaled more than 200 times the annual revenue generated by the vaccine.²⁸

Steven Garber of RAND has developed a simulation model based on how R&D decisions get made in pharmaceutical companies. It's based on an investment model that looks at future profit flows and discounts them to present value, factoring in product liability risks above and beyond typical risks for a typical product. Garber uses the model to illustrate how incremental increases in the discount rate caused by projected increases in product liability risks can significantly affect a company's R&D decisions such as whether to initiate clinical trials. He notes that "product liability risks can have a very real, a very very large effect on incentives to innovate."²⁹

Finally, the likely impact of significant tort liability in the biotechnology industry is particularly poignant, in light of the role that industry plays in pharmaceutical innovation. To quote Burk, George Mason Law School, and Boczar, McCutchen, Doyle, Brown, and Enersen:

The possibility of overdeterrence in the biotechnology industry is heightened by additional factors related to the structure of the industry. Dedicated biotechnology companies tend to be small, entrepreneurial, and focused on a single product. Any shadow on a small company's single product is likely to portend the end of that company. This is what occurred, for example, in the case of Cetus Corporation. Although Cetus was considered a large and relatively strong DBC, postponement of FDA approval for its flagship product,

²⁷ See Schwartz, *supra* note 5, at 1010.

²⁸ See Gregory C. Jackson, M.D. "Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation," *Am. U. L. Rev.* 199 (1992). P. 42. In response to this crisis the Congress passed into law a federally administered compensation system for vaccine claimants.

²⁹ See Garber *supra* note 8 at 14.

Interleukin-2, contributed to the company's dissolution. A court injunction or major damage award could lead to the same result for many biotech companies, and even a single such incident could well discourage the capital investments that have been required either to start new DBCs or to sustain those already in existence.³⁰

Conclusion

Using a Harris poll of doctors, pharmacists, and patients to inquire about the impact of liability on pharmaceutical prescribing, warning, and compliance adds force to the existing evidence that the tort liability system creates overdeterrent effects. The impact on patients may be significant: doctors may avoid the best prescription because of liability fears; pharmacists may overemphasize the risks and frighten patients into not taking it; patients may learn of litigation involving the drug and not begin the medication or stop taking medication they are currently on; and pharmaceutical companies may fail to develop or to bring to market new medications out of fear that they will become targets of unfounded litigation. More research is needed to clarify how frequently this occurs and to what effect. It is likely that much of this overdeterrence is fueled by the unpredictability of the tort system, which fails to set up clear rules or standards *ex ante* so that doctors and pharmacists can assess which behaviors will expose them to liability and which will protect them from liability. Personal injury litigation involving a specific drug also frequently sends inaccurate signals to patients that a drug may have risks that go beyond what they were told by their physician or pharmacist. Reforms that reduce the unpredictability in the pharmaceutical liability system would go a long way toward protecting the well being of patients.

³⁰ See Burk and Goczar *supra* note 7 at 830.