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The Law and Economics of Public Health

Frank A. Sloan and Lindsey M. Chepke

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The Law and Economics of Public Health

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Abstract

The fundamental question addressed by this paper is whether or not and the extent to which imposing tort liability on potential injurers improves the public's health. Conceptually, imposing the threat of litigation on potential injurers gives them an incentive to exercise more care than they would absent the threat. While the conclusion might seem to be obvious at first glance, in reality, the conclusion is far from obvious. For one, insurance coverage may blunt incentives to take care. Also, the tort system may operate far less perfectly than the theory would have it. In the end, the question must be answered on the basis of empirical evidence.

Keywords: Medical malpractice; tort liability; product liability; workers compensation; public health.

Contents

1

Introduction

The allocation of most goods and services in market-oriented economies is left to market forces. For some goods and services, however, there is a collective decision that some form of government intervention in resource allocation is appropriate. There are other reasons for government intervention, such as pursuit of fairness and justice, but the goal on which we will focus in this review is pursuit of economic efficiency — that is, the goal of attaining the highest level of wellbeing of members of society from a given level of resource endowments.

One rationale for promoting economic efficiency through public intervention is the presence of externalities in production and/or consumption of a good or service. Another concerns situations in which consumers are not well-positioned to make rational decisions about resource allocation because they lack the requisite information, e.g., such as inability to make rational choices due to youth or lack of cognitive ability, or a product's characteristics include risk inherent in consuming the good.

Government intervention may take one or more forms, including tax-subsidy arrangements, various forms of regulation ranging from mandates to outright bans on a particular activity, and implementation

of legal rules that are enforced by the state or by litigation brought by private parties (see, e.g., Breyer, 1982). Laws may be efficiency-enhancing if they reduce costs of market transactions.

In principle, regulation is designed to serve the public interest. Yet as several scholars have noted (Stigler, 1971; Peltzman, 1976; Becker, 1983; Laffont and Tirole, 1994), the regulatory apparatus is often subject to control or substantial influence by the stakeholders it is established to regulate (for a somewhat more favorable view, see Breyer, 1993). While individual citizens have a vested interest in market outcomes, their interest is often distributed among many different outcomes. By contrast, the stakeholders' self-interest is often highly concentrated. It is often worthwhile for stakeholders to invest in influencing regulatory decisions in pursuit of private gain rather than the public interest (Wilson, 1980). Even if stakeholders were ineffective in promoting their self-interest, public employees may lack adequate resources to make timely decisions. For tobacco, a strong case can be made that tort litigation radically changed the political balance between tobacco manufacturers and interests supporting tobacco control (Trogdon and Sloan, 2006).

Much research in the law and economics literature, at least narrowly defined, has been theoretical. By contrast, there are large pertinent empirical literatures, particularly pertaining to findings relating legal practices to the public health that are not in publication outlets typically read by specialists in law and economics but which offer important implications for the field. Empirical research findings on the relationship between law and the public's health are scattered in different literature ranging from economic journals to medical journals, journals on addictive behaviors, law reviews, and books. No study to date has assembled the empirical evidence from various areas, ranging from motor vehicle liability and dram shop liability, to medical malpractice, to products liability as it applies to pharmaceutical products and medical devices. This is the task of this paper.

The fundamental question addressed by this paper is whether or not and the extent to which imposing tort liability on potential injurers improves the public's health. Conceptually, imposing the threat of litigation on potential injurers gives them an incentive to exercise more

care than they would absent the threat. While the conclusion might seem to be obvious at first glance, in reality, the conclusion is far from obvious. For one, insurance coverage may blunt incentives to take care. Also, the tort system may operate far less perfectly than the theory would have it. In the end, the question must be answered on the basis of empirical evidence.

The following sections discuss theory and empirical evidence in several areas of personal injury to which tort liability has been applied. Section 2 describes the general law and economics framework used to assess both positive and normative issues as they apply to tort liability. Sections 3–8 present the rationale for, and empirical evidence, on particular applications of tort liability as it applies to personal injury.

Section 3 describes motor vehicle torts. Judged in terms of the sheer number of legal claims, this is the most active area among those we discuss. Compared to several others, motor vehicle liability is widely accepted as socially beneficial. State legislatures have passed legislation on an ongoing basis, but such legislation tends to be below the public radar screen.

Section 4 is about dram shop liability, statutory or common law, which reaches the alcohol seller legally responsible for loss from injuries directly caused by a minor or an obviously intoxicated adult who, after leaving the establishment, injures or kills a person or persons in a roadway accident. Less frequently, common law imposes liability on social hosts that serve minors or obviously intoxicated adults. There is less empirical evidence on social host than on dram shop liability.

Section 5 is about medical malpractice. This topic commands considerable public attention particularly during times of crisis, which follow substantial increases in medical malpractice insurance premiums and sometimes withdrawal of insurers from this line of business. Only a small part of the literature on medical malpractice focuses specifically on injury deterrence. In contrast to dram shop liability and to a lesser extent motor vehicle liability for which there is evidence that tort law deters accidents and injuries, based on what we know, there is little evidence that the threat of medical liability leads to improvements in the public's health. Reforms that have been enacted do not address structural flaws in the medical malpractice system as it exists today.

Section 6 discusses tobacco litigation. Tobacco is distinct in that the alleged misconduct generally occurred several decades before the lawsuits against the tobacco manufacturers were filed, in particular, the litigation that resulted in payment to plaintiffs. This type of litigation is controversial since it would seem that smokers would have known about the health harms of tobacco consumption, and they decided to smoke anyway. Tobacco litigation has improved the public health mainly by its effect on the price of cigarettes and the political fallout that has facilitated passage of legislation raising cigarette excise taxes.

Section 7 focuses on products liability for pharmaceuticals, medical devices, and vaccines. The case for imposing liability on the manufacturers of these products is namely that patients are not sufficiently informed about the underlying risks of consuming these products. But, as we discuss, empirical evidence on this point is scanty at best. Products liability has had a major impact on availability of some products. Whether the public's health has been measurably improved by having pharmaceutical products liability remains to be demonstrated.

In Section 8, we describe the rationale for and empirical evidence on workers compensation. From an historical viewpoint, workers compensation should be discussed as the first application of the role of tort liability in the public's health. However, litigation brought by injured employees against their employers has been virtually eliminated in the United States and in other countries for about a century, having been replaced by employer-provided insurance coverage for work-related injuries and illnesses. An exception is that products liability remains in force. Employees can file products liability suits against manufacturers of products, alleging that these products caused work-related injuries or illnesses, but the employer is not named as a co-defendant. There are advocates for introducing workers compensation type insurance in other contexts, such as for injuries sustained in the process of receiving medical services. However, no other field has gone as far in substituting insurance for tort as has workers compensation.

In Section 9, we evaluate the evidence from the various applications and present our conclusions and suggestions for future research.

2

Government Intervention in Markets: Alternative Approaches

2.1 Tort Law in an Economic Framework

In contrast to criminal law, which is enforced by public agencies, civil law relies on enforcement by private parties under rules promulgated by the public sector. One branch of the civil law is tort law. A tort occurs when someone deliberately or through carelessness causes harm to another person or property. In common law, a tort is a civil or private wrong for which the law provides a remedy in the form of monetary payments and equitable remedies for the party or parties, which are victims of wrong-doing. Under tort law, enforcement is performed by injury victims rather than by public officials, thus possibly overcoming the reluctance, or the lack of resources, of public officials to observe and act upon observed departures from regulatory rules.

Tort law applies to civil wrongs arising from extra-contractual liability, i.e., other than wrongs arising from a breach of contractual obligations. Contract law is an alternative to tort law, and substitution of contract law for tort law has been advocated under some circumstances, e.g., for situations involving medical injuries. In other circumstances, contracts are clearly impractical, such as among strangers and

operators of motor vehicles, or when the contingencies that would be regulated by contract are very small, e.g., death or personal injury from using a product (Landes and Posner, 1987, p. 280).

Tort law has several goals, among the most important of which are (1) to deter misconduct and hence injury and (2) to compensate injury victims. There are also other objectives, such as meting out justice and providing a safety valve for airing victims' grievances. These latter objectives are important to maintaining a civil society. However, the deterrence is most directly pertinent for promoting the public's health.

An insight of economics is that optimal deterrence does not require that the injury rate be zero. Rather the socially optimal rate of injuries would only be zero if the cost of averting injuries were zero. Conceptually, the goal of injury prevention is to minimize the total cost of injuries which consists of (1) the costs resulting from the injury and (2) the costs of averting it. Costs resulting from an injury include but are not limited to expenditures on medical care and rehabilitative services, costs associated with reduced longevity, increased disability, pain and suffering as well as losses to property. Costs of averting injuries range from investments in the goods or services themselves and in redundancy (back-up systems to be used in the event of failure) to the time and effort involved in monitoring.

More specifically, let e be a potential injurer's expenditure on accident prevention during a specific time period, $\mathrm{p}(e)$ be the probability of an accident occurring, like e defined for a specific time period, and $D(e)$ be the total loss incurred by the accident victim(s) should an accident occur.

Then the social objective is to find the e that minimizes

$$e + \mathrm{p}(e)D(e)x. \tag{2.1}$$

In Figure 2.1, e is a 45° line from the origin. The expected loss $\mathrm{p}(e)D(e)$ declines monotonically as e is increased but at a decreasing rate of decline. The sum $e + \mathrm{p}(e)D(e)$ declines up to the socially optimal investment in prevention e^* and increases with further units of e. For this reason, e^* is considered to be the socially optimal investment in prevention.

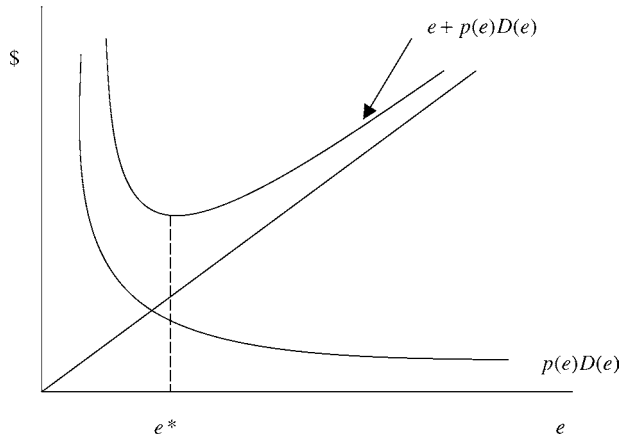

Fig. 2.1 Social costs and optimal care.

In other words, the total cost of injuries is minimized by investing in injury prevention up to the point at which the marginal cost of injury prevention equals the marginal benefit of such investments, which is the value of reductions in injury cost (Calabresi, 1970). Investing an infinite amount in injury prevention would only be optimal if the costs resulting from the injury were infinite, which is surely not so. In addition, allocating infinite amounts on injury prevention would leave no resources to satisfy other wants. In promoting socially appropriate deterrence levels, the task of tort is to provide signals to private decisionmakers about how much they should invest in injury-prevention activities.

Now suppose potential injurers faced no potential loss from the injuries that they cause. Then from a private standpoint and assuming that accidents cause no damage to oneself, the optimal level of e would be at zero. Potential injurers would allocate much less than the socially optimal amounts to injury prevention.

2.2 Alternative Liability Rules

Tort law operates under specified liability rules. Under a no liability rule, the victim bears all of the injury cost him or herself. Such rules apply in situations in which victims are thought to be well

positioned to make decisions about the market transactions in which they engage, and there are no externalities in consumption or production. If, for example, consumers are well informed about both the positive attributes and the risks of a good they consider purchasing in advance of the purchase and there are no externalities in consumption, then society is likely to be willing to decide (implicitly) to let the injury victim bear the full injury cost. Or, under no-fault insurance, the injury victim is responsible for covering his or her own loss although, as explained more fully below, such loss is often covered by insurance.

Under a rule of strict liability, the injurer bears the loss if it is determined that the injurer caused the loss. Finally, under a negligence liability rule, the injurer, not the injury victim, bears the loss if it can be determined (1) that the injurer in fact caused the loss and (2) the loss occurred because of the injurer's failure to exercise due care, where the ideal is that due care is set at the socially optimal level of care defined in the conceptual terms above. These rules are applicable under different circumstances to be described.

Alternatively, returning to Figure 2.1, if the potential injurer faced a strict liability rule, s/he would be responsible for any losses that s/he causes. Under this rule, the potential injurer would select the optimal amount of care e^* since investment minimizes his or her expected loss.

Still another alternative is that potential injurers operate under a negligence rule. Under these circumstances, there is an additional condition to causation for payment, namely that the injurer did not adhere to a due care standard when the accident occurred. Under these circumstances, if the due care standard is set at e^* or higher, the injurer pays nothing. If, however, e is less than e^*, the injury pays the accident victim's loss. Thus, for e equal to or greater than e^*, the injurer's cost equals e. For e less than e^*, the injurer's cost is $e + \mathrm{p}(e)$. The potential injurer's cost is thus lowest at e^* (Figure 2.2).

Thus, under a negligence rule as well as under strict liability, socially optimal amounts are allocated to prevention. There is likely to be more litigation under strict liability, however. The legal cost of proving both causation and failure to set injury precaution at e^* or higher is likely to be higher under negligence because proving that the injurer failed to exercise due care can be very costly.

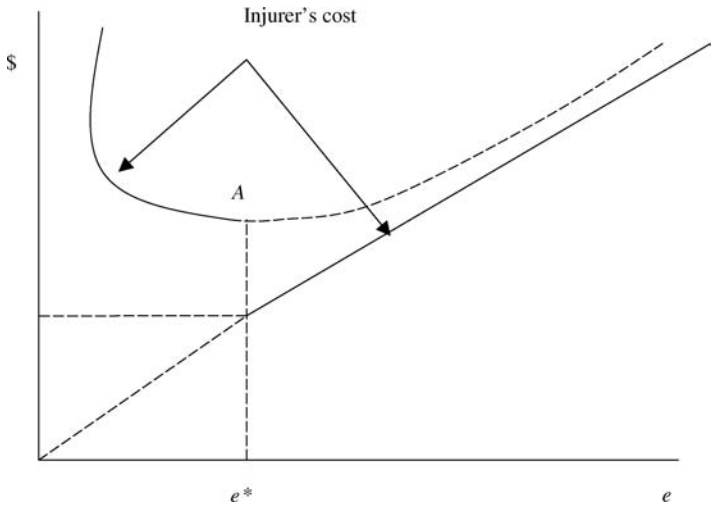

Fig. 2.2 Potential injurer's choice of care under a negligence rule.

2.3 Contracts versus Torts

One might argue that having a well-functioning liability system is not a prerequisite for injury prevention or quality assurance. One alternative to liability would be to achieve injury prevention by contract. This is not feasible in some contexts. For example, it is not feasible for drivers to contract to establish mechanisms for accident prevention. Nor is it likely that bartenders would contract with patrons to provide services to prevent injuries due to drunk driving. Nor would it be reasonable to expect tobacco manufacturers to contract with consumers of their product to, e.g., provide compensation in the event that the smoker were to develop lung cancer. It would be inefficient for the purchaser of a product with an associated mortality rate of one in 10 million to contract terms of compensation with the manufacturer conditional on death.

Contracting might work as an alternative to medical liability. With this scheme, individuals would purchase insurance from an enterprise, such as a managed care organization (MCO). The enterprise would then contract with specific hospitals and physicians to supply care at

a particular level of quality. To assure quality, these hospitals and physicians could implement specific patient safety programs agreed upon with the MCO in advance. The insurance contract could also provide a schedule of indemnity payments to compensate insureds in the event of an iatrogenic injury.

Contracts between employers and employees for payment following work-related injuries or illnesses existed during the 19th century in the United States (Witt, 2001). However, courts denied a legal basis for such contracts on grounds that employees are often ill-positioned to negotiate contracts with employers given the dominance of employers over employees.

In a very well-known paper that eventually led to a Nobel Laureate in Economics, Ronald Coase (1963) states that if all parties are fully informed about risk, and contracting is costless, then the allocation of resources to loss prevention, which is what exercising due care is about, will be the same, whether or not losses reside with the injury victim or with the injurer. There is an incentive for potential injurers to take safety precautions no matter if the injurer or the injury victim bears the loss.

However, an essential part of Coase's theorem is if consumers or patients misperceive risks and/or contracting is costly, then loss prevention may be insufficient (Spence, 1977; Shavell, 1980). Indeed, risks of adverse outcomes may be misperceived (i.e., perceived to be less than they really are) and/or consumers or their agents (e.g., health maintenance organizations) may not be well-positioned to monitor the quality of care received. If so, absent some type of intervention in the market, such as imposing liability, fines, surcharges or some other penalty on potential injurers, the rate of risky procedures will be too high, and the amount of care undertaken per procedure may be too low compared to a level desirable from a societal standpoint (see, e.g., Danzon, 1994).

At first glance, it may seem obvious that consumers misperceive risks and are not well positioned to monitor quality. However, the issue is more complex than this. For example, health care consumers may be knowledgeable about some risks, such as the risk of adverse outcomes in the case of routine pregnancies, but highly uninformed about care

for a very rare condition (Pauly, 2002). Markets may often be adequate in conveying differences in quality, though perhaps not as frequently as one would like. But, even when markets fail, there are quality assurance mechanisms in addition to tort.

2.4 Unilateral versus Bilateral Precautions to Avoid Accidents

Another important conceptual distinction is between unilateral and bilateral precautions. Up to now, we have only considered unilateral accidents in which the roles of potential injurers and potential injury victims are well defined. In some situations, an agent is either a potential injurer or a potential injury victim. For example, in the case of medical malpractice, the health professional or consumer of the product is the injury victim if personal injury occurs. Then, in this unilateral precautions case, it is largely, but perhaps not entirely, up to the potential injurer to take care. Once the decision has been made to purchase the good or service, the potential injury victim is often passive. For example, a patient can decide whether or not to have surgery and can select a surgeon but once under anesthesia, the patient can do nothing to avoid a mishap. By contrast, suppose a patient suffers an adverse reaction from a drug, although the drug caused the reaction and not the reverse, the aware patient may stop taking the drug immediately and hence mitigate the loss.

In the bilateral precautions case, such as with drivers of motor vehicles, an agent can be both an injurer and injury victim. By taking additional precaution, the injury victim can help avoid an accident even if others fail to exercise due care.

In a bilateral care model, each party actively takes precautions to avoid accidents, assuming the precaution levels of others is fixed. Now let e_1 be the expenditure on injury precaution in preventing injury by the potential injurer and e_2 be the expenditure on injury precaution in preventing injury by the potential injury victim. Then the probability of an accident occurring is $\mathrm{p}(e_1, e_2)$ and loss sustained by the victim conditional on an accident occurring is $D(e_1, e_2)$. Here the socially optimal levels of care from both types of prevention correspond to levels of

e_1 and e_2 that minimize the following expression:

$$e_1 + e_2 + \mathrm{p}(e_1, e_2)D(e_1, e_2). \tag{2.2}$$

The graphical counterpart to (2.2) is a three-dimensional version of Figure 2.1.

In a no liability regime, each party to an accident bears his or her own loss. Potential injurers have nothing to lose in the event of an accident as injurers but they bear the full loss in their roles as injury victims. Thus, potential injury victims invest in precaution up to the point at which the marginal cost of precaution equals the marginal benefit measured in terms of averted losses, which is at the socially optimal care level. However, the potential victim has no incentive to invest in care since s/he bears none of the loss. No liability in the bilateral case is equivalent to imposing strict liability on accident victims (Miceli, 2004, p. 47). Strict liability in the bilateral case involves transferring the loss from the victim to the injurer. This too leads to optimal care, but this time on the part of injurers. Injury victims have no incentive to invest in precautions. Under the negligence rule by contrast, the injurer only compensates the victim if s/he fails to exercise due care, which by assumption is set at the socially optimal precaution level. At the same time, potential injury victims expect that others (potential injurers) will exercise due care and thus not have to pay the victim in the event an accident occurs. Given this assumption, the optimal care level for injury victims is at the due care standard. Under the negligence rule, accidents would occur (at the socially optimal level), but no one would ever be negligent. This theoretical prediction, of course, runs counter to the facts.

2.5 When Will Applying the Negligence Rule Lead Private Parties to Select a Socially Optimal Precaution Level?

The above theoretical results about effects of the negligence rule only apply under very restrictive assumptions. Among the most important assumptions are: (1) that due care standards, when applicable, and damages are set appropriately — the former to reflect the socially optimal care level and the latter as an accurate measure of losses incurred;

and (2) that claims for damages are filed whenever, but only when accidents are truly caused by an action or an inaction of an injurer under strict liability and whenever there is causation and the due care standard is breeched under the negligence rule.

In reality, fewer than the appropriate rates of claims will be filed given the transaction costs of obtaining payment for losses incurred. Moreover, given that under the negligence rule it is necessary to demonstrate both causation and negligence, one expects to observe more claims under strict liability than under the negligence rule. A factor operating to reduce the number of claims under which strict liability is asserted is the defendant, a large manufacturer, may have more resources to expand on litigation than does an individual plaintiff. Sufficient conditions for negligence to occur exist when courts make errors in determining causation and/or the due care standard. Theoretical predictions are also made more difficult in that potential injury victims often carry first party insurance to cover their losses from accidents in part and in full and potential injurers often carry third party insurance which covers loss incurred by others in an accident. Both first and third party insurance may lead to moral hazard — in this context, a lower level of precaution than the agent would undertake if the individual were insured.

2.6 Four Markets

2.6.1 Overview

Although useful for analyzing outcomes under alternative liability rules and under circumstances in which injurers and injury victims coincide or differ, the real world of litigation and decision-making is much more complex than tractable theoretical framework permits. Depending on the type of injury to which tort law is applied, there are up to four markets that operate in concert.

The first "market," the injury precaution market, involves actions of parties that affect the probability of an injury occurring; depending on the nature of the market, the injury victims and injurers may be distinct, e.g., a patient and physician, or coincide, e.g., motor vehicle operators. Second, there is the legal market, where both injury victims

and parties who are alleged of causing an injury and associated loss, supported by lawyers and the courts, participate.

Third is the market for third-party and first-party insurance. In third-party insurance markets, suppliers are property-casualty insurers and consumers in this context are motor vehicle operators, professionals, such as physicians, and organizations, such as hospitals and other businesses. Such insurance offers coverage for financial obligations incurred by insureds to pay for losses occurring to others as a consequence of an accident. Under first-party insurance, the insured covers his or her own loss. Some organizations, in particular larger organizations, may chose to self insure against the possibility of a loss. Examples of first party coverage are collision insurance for motor vehicles and various forms of no-fault coverage.

Fourth, there is the market for government activity in which the law-as-market view asserts legislation and government activity is a good or service demanded and supplied much like other goods (see, e.g., Persson and Tabillini, 2002).

2.6.2 Injury Precaution Market

In this market, individuals and other parties make decisions about how much precaution they will undertake and given the optimal level of precaution, conditional on the level of precaution, what the level of activity is in which they engage. For example, a motor vehicle operator may decide to eschew driving on New Year's Eve given the high level of precaution need to avoid an accident. Similarly, an obstetrician–gynecologist may decide to give up delivering babies because of the high probability of an adverse outcome leading to a lawsuit. The higher premium paid by physicians who deliver babies and the added cost of avoiding injuries and hence lawsuits may be too high for physicians to earn a competitive rate of return. Thus, physicians may reduce output of deliveries, the activity level, to zero. Or a manufacturer may decide not to invest in R&D in a line of products that is likely to lead to adverse outcomes resulting in costly litigation. Yet as seen above, under a no liability rule, parties may invest insufficient amounts in precaution.

2.6.3 Legal Market

In the most basic but still widely used law and economics framework, injury victims sue when they are entitled to recover compensation for losses they incur and the expected returns are greater than or equal to the cost of obtaining payment. In fact, in the vast majority of legal claims, plaintiffs are represented by attorneys, and in personal injury litigation the attorneys bear the litigation cost. Most frequently in personal injury litigation, lawyers are compensated on a contingent fee basis. Although contingent fees may be advantageous to the risk-averse client in that the client does not incur an out-of-pocket fee in the event that s/he loses, paying lawyers on a contingent fee or hourly basis may make a difference in an attorney's choice to represent a client, their effort on behalf of their clients, and on what terms the dispute is resolved. Courts too face problems. Concerns have been expressed that jury decisions are unduly swayed by the severity and circumstances of the plaintiff's injury (Sunstein et al., 2002), but this is disputed by other studies (Vidmar, 1998; 2004).

Although some evidence suggests a well-functioning legal market (Sunstein et al., 2002), more recent evidence suggests otherwise. For example, courts located in areas with high proportions of minorities and low-income households award higher amounts than in other areas (Heland and Taborrok, 2003). Medical malpractice suits appear to yield higher compensation to injury victims than in other contexts, e.g., auto liability (Bovbjerg et al., 1991). Furthermore, jury awards are highly variable even among automobile and medical malpractice cases, raising questions of horizontal equity (Bovbjerg et al., 1989). Whether or not a negligence rule results in potential injurers providing optimal care critically depends on the standard of due care being set at socially-optimal levels. In practice, courts are likely to set the standard incorrectly, leading to deviations in either direction depending on where the standard is set, either under- or over-deterrence of injuries. Market failures can occur when claimants consistently file non-meritorious claims and obtain settlements, and payments to claimants systematically exceed injury cost.

On the other hand, under the negligence rule, a plaintiff must demonstrate that the defendant owed a duty of care, that s/he failed to

conform to the required standard of care, and that this failure was the proximate cause of the plaintiff's injury. Thus, in principle, tort does not compensate plaintiffs who can just show that they were injured, or injured but only as consequence of the receipt of a service, such as medical care. Importantly, the defendant must also be shown to have been negligent in performing or not performing some act that led to the injury. Plaintiffs must present evidence which is convincing to a jury on all three criteria: an injury occurred; an action or inaction of the defendant caused the injury; and the action or inaction represents a failure to exercise due care. This is not an easy hurdle for plaintiffs to surmount.

Plaintiffs who suffered a minor injury should not expect much compensation. And those who cannot demonstrate causation or failure to exercise due care should receive no compensation.

The legal market is also criticized for unjustly enriching attorneys (Brickman, 2003). Controls over attorneys' fees have been suggested because current fees are excessive, arguably providing too much financial incentive to file a tort claim. Aside from the lack of empirical support for arguments supporting the regulation of attorneys' fees, it seems inequitable to impose constraints on fees for attorneys who represent claimants without imposing like constraints on other professions in which individuals tend to be highly compensated.

Also, compensation under tort is very expensive, measured in terms of the legal fees incurred by plaintiffs and defendants, court costs, and insurer overhead (Sturgis, 1995, p. 8). For tort liability as a whole, between 40 and 50 cents on the medical malpractice premium dollar is returned to plaintiffs as compensation for their injuries, which is a much lower than the share returned to insured individuals in other contexts, such as by health insurance or various forms of social insurance provided by governments (Kakalik and Pace, 1986). However, the overhead for automobile liability insurance is appreciably lower than this (Schwartz, 2000).

In spite of some limitations, the American jury gives ordinary citizens, other than injury victims and their legal representatives, a role in the dispute resolution process. Regulatory agencies and even judges may not be equally sensitive to consumer interests.

Being able to sue in combination with the contingent fee method for paying for plaintiffs' attorneys gives patients, who are unsatisfied with outcomes of medical care or the performance of a product, a mechanism for addressing their grievances that may not be possible through other channels. Because of political pressures from well-organized stakeholders (e.g., professional societies, business groups, and/or inadequate resources), regulatory agencies may be unresponsive to patients' complaints. Ironically, one reason that liability is so aggravating to parties subject to being named as defendants is that tort empowers consumers to obtain justice and compensation when other systems, more under provider or corporate control, fail. Not all patients' complaints prove to be meritorious in the end, but many do.

2.6.4 Insurance Market

Even though insurance may enhance well-being of insureds by reducing expenditure risk, insurance coverage raises the risk of moral hazard. In this context, potential injurers with insurance may exercise less precaution than they otherwise would, especially if insurance premiums are not experience-rated. Under experience rating, following a payment by the insurer for a traffic violation, insurance premiums increase as the violation may be a signal to the insurer that the insured's probability of being involved in an accident has increased. Motor vehicle operators are most often covered by third-party (liability) and first-party (collision and health) insurance. Retailers, e.g., alcohol sellers, often have third-party coverage for injuries to patrons that occur on their premises (Sloan et al., 2000a). Physicians obtain medical malpractice insurance, a form of third-party insurance, which is most often not experience-rated (Sloan, 1990). Hospitals, by contrast, typically self-insure, as do large corporations, for their liability risk (Sloan et al., 1991). Workers compensation premiums are more highly experience rated for larger than for smaller employers (Ruser, 1985; 1991).

2.6.5 Government Market

The government market consists of legislative and executive branches of government. Except in rare events in which proposed constitutional

changes sometimes subject to vote in an election, statutory changes tend to be most influenced by special interests since they bear the direct benefit of the change. By contrast, the cost reflected, e.g., in higher taxes and/or higher product prices, is dispersed among a large number of taxpayers and/or product purchasers. Legislative protection flows to groups obtaining the greatest value from public sector decisions, irrespective of their impact on social welfare.

Liability rules are often determined by legislatures with the consent of the executive branch. Alternatively, rules are altered by judicial decisions. Statutory changes reflect pressures from stakeholders with a variety of self-interests. Legislatures enact laws affecting claims resolution; they regulate insurers, their solvency, premiums, and marketing practices. They create special organizational forms, e.g., mutual insurers; in some states, the state is a medical malpractice insurer, providing no-fault coverage and public reinsurance.

2.7 Tort Liability Under Attack

During the last three decades or so, tort liability has been under attack from critics who emphasize the costly and capricious nature of tort liability and its negative effects on prices and availability of specific goods and services. Criticisms have not been applied equally to all areas of tort.

In ascending order of the amount of criticism, tort liability can be divided into three categories (see Hensler et al. (1987) and Haltom and McCann (2004). Haltom and McCann refer to the three categories as the first, second, and third worlds). First, there are routine personal injury torts. These cases experience gradual changes in costs and outcomes and are of high volume. In this category, there is little emphasis on deterrence, there are small stakes, and the law is stable (Hensler et al., 1987). Slip and fall and auto accidents are examples of routine personal injury torts. The second category, in contrast, has a lower volume of cases and a still evolving but somewhat stable body of law. These types of cases have a larger presence in the media and in the public consciousness. The stakes are considerably larger, and there is a greater emphasis on deterrence. Products liability, medical malpractice,

and business torts fall into the second category. The last category, mass latent injury cases, tends to be more public than the first two.

Latent injury cases have several characteristics: deterrence is important; there are stupendous monetary stakes; there is procedural innovation; and the law is unsettled and sometimes problematic. Because of the complexity and uncertainty of the law, as well as the high monetary stakes, there is a small highly specialized bar for this area of tort. The number of these suits, their outcome, and costs are highly uncertain. Examples of mass latent injury cases include asbestos, tobacco, and pharmaceuticals such as silicone implants and the Dalkon Shield.

Much of the criticism is emotionally charged and is largely devoid of analytic content and replete with factual errors (see, e.g., Baker (2005) and Haltom and McCann (2004) which describe the generally low level of public discourse about tort liability). Concerns are raised more frequently during times of rising insurance premiums but a standing concern among scholars of tort law is the actual performance of tort in attaining the above objectives. Whether or not the process or outcomes of tort law are just involves subjective judgments. Unfortunately, much of the public discourse is based on anecdotes, which may be valid as isolated cases, but do not generalize.

However, some fundamental issues have been raised by critics, including scholars, which merit careful scrutiny. There is now a large body of empirical evidence on the performance of tort liability as it has been applied in several contexts. Most pertinent to this paper are concerns about deterrence.

There is no evidence that the threat of tort deters medical injuries, although such evidence exists for other applications of tort law, such as for dram shop liability, which makes alcohol servers liable for injuries caused by persons who drank in their establishments or were under the legal drinking age (Sloan et al., 2000b). For automobile liability, empirical evidence shows that tort offers some, albeit weak, incentives for deterring injuries (White, 2004).

Why the threat of a civil lawsuit is effective under some circumstances and not under others is not entirely clear. One reason, but not the only, may be that the underlying technology of injury prevention is easier in some areas than others. Having a bartender order a taxicab

for a patron who has consumed too many beers seems to be a simpler technology than preventing a mishap in transplanting an organ or even in preventing a mix-up in distributing medications in a hospital since so many hands are involved in these activities.

The above-stated rationale for tort assumes that the legal system is efficient and accurate in adjudicating claims. At some point, inefficiencies and inaccuracies would tip the balance against use of tort liability. Inefficiencies and inaccuracies have often been cited by critics of tort liability in general and of medical malpractice liability in particular. Some legal disputes can take years to resolve, requiring substantial use of legal resources on both sides of the dispute. Jury verdicts are seen as subject to error. Plaintiffs are said to be overcompensated for their injuries. Judging from the commentary of the critics, this hardly seems like an efficient and accurate system. However, advocates for tort see this as an effective private mechanism for meting out justice, especially when other systems, such as self-regulation by business and professional organizations, and public regulation fail to achieve their stated purposes. Defenders of the current system, however, argue that individualized justice is expensive to achieve and hence is inherently expensive.

3

Motor Vehicle Accidents, Insurance, and Tort Liability

3.1 Context

Injury from motor vehicle accidents is the leading cause of death in the United States among persons aged 1 to 34 (Quinlan et al., 2005). Overall, in 2005, 37,594 persons in the United States died from motor vehicle crashes and a far greater number were injured (National Center for Statistics and Analysis, 2007a,b). Given the substantial externalities from reckless driving, governments have enacted and enforced laws to promote safe driving, investing in roadways, promulgating regulations to promote vehicle safety, and to control entry of alcohol sellers. Yet tort liability in various forms plays a major role in promoting safety on roadways as well.

3.2 Four Markets

3.2.1 Injury Precaution Market

Individuals as motor vehicle operators make decisions about how much, where (e.g., congested versus rural areas), and what they drive (e.g., heavy versus light vehicle, amount of safety equipment in vehicle). The

level of precaution depends in part on the liability rules and insurance coverage, which in this "market" are fixed, as well as the precaution levels of other motor vehicle operators.

As indicated above, in the bilateral case, in which operators are uninsured and the negligence threshold is set at the socially optimal level of precaution, each operator would, in theory, comply with this standard. This conclusion requires socially appropriate standards. Setting the standard too high has ambiguous effects on the precaution level (Cummins et al., 2001). On the one hand, a higher negligence standard should make operators more careful to immunize them against tort claims from other vehicle operators involved in an accident. However, when the negligence standard is higher, the probability that a successful suit will be brought declines and, operators tend to be less careful as a result. The accident precaution level also depends on how responsive the probability of being declared negligent is. If the relationship is practically zero and the standard enforced by the courts is random, this will tend to reduce the precaution level.

Switching from a negligence rule to no liability coupled with first-party insurance, which occurs under a no-fault system, is likely to reduce the care level, although ambiguously so. In complex but more realistic models, predictions about the effect of switching liability regimes on the amount of deterrence depends on how the switch is implemented, e.g., when no liability applies for relatively minor losses and the negligence rule applies for larger losses or which dollar level of loss the switch occurs.

Liao and White's (2002) theoretical analysis is a case in point. Their game-theoretic model is for two periods. In the first period, drivers exercise different degrees of precaution and an accident occurs or does not occur. Care is described as a discrete variable, high or low. Due care is set between high and low levels of care. In the second period, each party decides whether or not to sue the other party.

Their main theoretical result pertains to the dollar threshold of loss at which injury victims can sue for negligence and below which a no liability rule applies. As the threshold is increased, drivers may exercise less care, given that they are less likely to be sued under tort in the event of an accident. On the other hand, when injury victims have

the choice of whether to sue over a certain dollar threshold of loss, they may be more careful. If they are more careful under comparative negligence, the driver of the other vehicle has a lesser amount of money to recover under tort if s/he can be shown to have been more careful.

Allowing for moral hazard when there is insurance coverage, which in this context refers to the amount of care exercised when operating a motor vehicle, if operators are insured for their losses, they may be expected to be less cautious. However, if third-party or first-party insurance is experience-rated based on violations and accidents, care should increase in proportion to the extent that premiums are sensitive to the driving record, especially if having insurance is compulsory (Cummins et al., 2001; Cohen and Dehejia, 2004).

3.2.2 Legal Market

Motor vehicle torts are the most common liability claim (Kakalik and Pace, 1986). As with other tort claims, dispute resolution starts with a pool of injuries. There is some evidence that a relatively high fraction of injury victims from motor vehicle accidents eventually obtain tort recovery. Three quarters of such victims obtain tort recovery in some amount; the share of accident victims pursuing a tort claim of some sort is far higher than in other areas, such as medical malpractice (Bovbjerg et al., 1991; Schwartz, 2000). The vast majority of tort claims of all types are settled before reaching a jury. For those claims reaching verdict, plaintiffs alleging negligence from a motor vehicle accident receive much less compensation than do plaintiffs in medical malpractice cases. Presumably, litigation cost is much lower as well, in part because causation and negligence are often more easily established.

The most important distinction, and certainly the most studied one, is between jurisdictions with a negligence rule, no-fault coverage, or a combination of the two. Several countries, including Canada, Australia, and New Zealand, have substituted no-fault systems with the negligence rule. (The concept was first developed by Jeffrey O'Connell, University of Virginia Law School. See, e.g., O'Connell (1985),

O'Connell and Joost (1986), O'Connell et al. (1995). In the United States however, those states with no fault systems for personal injuries from motor vehicle accidents have adopted a hybrid approach in which no fault generally applies to losses up to a dollar threshold of loss, allowing the injury victim to sue for losses exceeding this amount.[1] Further, whereas no fault compensation is limited to pecuniary loss, for pecuniary losses above the dollar threshold, plaintiffs can recover compensation for non-pecuniary loss (e.g., for "pain and suffering") as well as for pecuniary loss.

Contributory negligence is the traditionally used common law rule. Contributory negligence makes an injurer liable for the full amount of the victim's loss, but only when the injurer is found to have been negligent for the victim's injury and the victim's actions did not contribute to their injury. Under this doctrine, even if a plaintiff was only one percent negligent for the accident, they are precluded from recovering from a defendant who was 99 percent negligent. Many juries have ignored this rule in their deliberations and as a result, most U.S. states have either modified their contributory negligence rule or replaced it with variants of the comparative negligence rule. Modified contributory negligence, as discussed earlier, makes a defendant liable for the victim's damages so long as s/he is 50 percent negligent. Comparative negligence, on the other hand, specifies an injury victim's recovery is reduced by the amount s/he is negligent: the loss is shared between the alleged injurer or defendant and the victim or plaintiff when both are found to have been negligent. Under the pure comparative negligence rule, the victim's loss is allocated among all negligent parties involved in the accident (plaintiff and all, if there are multiple, defendants) according to the share of the blame assignable to each party. A plaintiff fails to receive compensation only if s/he is 100 percent to blame.

The switch to comparative negligence has made it easier for plaintiffs to obtain some compensation through tort. Holding other factors constant, an increase in the probability of plaintiff winning should

[1] One state allows injury victims to sue for losses attributable to personal injuries but not for loss to property.

increase the frequency of legal claims. However, the decreased award under comparative negligence should decrease claims frequency. In the end, the effect of the switch from contributory to comparative negligence is an issue to be settled empirically.

3.2.3 Insurance Market

Insurance for personal and property loss from motor vehicle accidents is third-party and first-party. Liability coverage is third-party insurance. In many U.S. states, such coverage is compulsory. Whether or not liability coverage is mandatory or voluntary, such insurance may blunt the potential deterrent effect of tort liability, especially if premiums are not set appropriately to reflect insureds' expected losses (Shavell, 1982; Abraham, 1986; Boyer and Dionne, 1989). Precautions taken before accidents occur are costly to observe, and therefore can be only observed after an accident or violation is documented.

Experience rating, a method used to update risk classifications based on violations and accidents as they occur, may not be as widely used for several reasons (Sloan and Githens, 1994). First, even *ex post* observations of driving records are inaccurate. In particular, errors have been documented in driving records maintained by states. Second, some types of adverse events are rare, and basing premiums on such adverse events may unfairly place a good driver in a bad driver category. Third, surcharging drivers may lead some drivers to drop coverage, leading to a higher number of uninsured motorists (Smith and Wright, 1992; Cohen and Dehejia, 2004). Fourth, being able to drive is often considered to be a right, and experience rating is discouraged as a matter of law or regulation. Conceptually, one expects that requiring motor vehicle operators to be covered by highly experience-rated third-party insurance would substantially offset the moral hazard that would otherwise result from being covered for such loss. There is a limit on the deterrent effect of even compulsory highly experience-rated third-party insurance in states with low mandatory liability limits; in states with low amounts of required coverage, premiums are correspondingly low. Thus a percentage increase in premiums following a chargeable accident or violation does not result in a premium increase

sufficient to encourage policyholders to exercise care. In such states, defendants who are unable to pay losses in excess of the liability limits are "judgment proof," meaning they are unable to compensate injury victims who file a tort claim. Being judgment proof blunts much of the deterrent effect such insurance might have if the liability limits were set at a higher value.

While no-fault plans vary among U.S. states, all contain the same basic features. Drivers purchase liability insurance to cover medical payments and income losses resulting from an accident. The policyholder's insurance company makes payments to the policyholder, regardless of who may be at fault. Most plans do not compensate for pain and suffering. No-fault coverage is experience rated to varying degrees.

The moral hazard of insurance can be offset, at least in large part, if insurance coverage is both compulsory and highly-experience rated. In spite of the hurdles of experience rating, in several states insurance is highly experience rated (Sloan and Githens, 1994). Moreover, persons with bad driving records can purchase motor vehicle insurance from surplus line companies which take all comers, albeit at a higher premium and may offer more limited coverage, i.e., closer to the compulsory liability limits. Several European countries and most U.S. states have instituted point systems for drivers, which are applied to insurance premiums as well as fines and license revocation (Lemaire, 1985; Vandebroek, 1993; Bourgeon and Picard, 2007).

Compulsory liability insurance is often required by law. There are several justifications for requiring such insurance. The most important are to reduce adverse selection in such insurance markets and to assure minimum levels of compensation in the event that injurers are "judgment proof." Combining compulsory liability insurance with point systems based on traffic-related convictions and chargeable accidents reduces (depending on enforcement) the probability that levying a premium surcharge on persons with an adverse driving record will drop coverage. This potentially makes surcharging much more effective as an accident deterrent. On the other hand, if insurance is compulsory and insurance is not experience rated, requiring insurance may increase the accident rate (Cohen and Dehejia, 2004).

First-party coverage includes health and disability insurance, coverage on the loss to the owner's own vehicle ("collision insurance") and no-fault insurance in jurisdictions with no-fault laws. Health and disability insurance coverage is generally provided on a group basis and hence not experience rated at the individual level. Collision insurance is most often provided on an individual basis with experience rating practices varying among jurisdictions. The rationale for the no-fault concept is the saving from determination of fault. Experience rated premiums can be set on the basis of the number of previous claims an insured has filed.

3.2.4 Government Market

Insurance is subject to substantial government regulation and markets for motor vehicle insurance are no exception (see, e.g., Grabowski et al., 1989). Each U.S. state has a Department of Insurance where most regulatory oversight of the industry is housed. The rationale for such regulation is that (1) there is insufficient consumer information without intervention by government, (2) insurers may possess market power which premium regulation may offset, (3) without oversight, companies may go bankrupt, which would leave policyholders without coverage, as well as (4) redistributional objectives (Meier, 1988).

There is tension between making insurance widely available at a reasonable price and promoting efficiency in insurance and injury prevention markets which require that insurance premiums be based on the underlying risk of insureds. States weigh these objectives differently.

The most in-depth study of regulation of insurance is a book by Kenneth Meier (1988). Professor Meier emphasizes the heterogeneity of circumstances under which regulation takes place, even within the insurance industry. A number of lines of insurance, such as motor vehicle and homeowners insurance are important to a large number of persons. Other lines of insurance, e.g., commercial liability insurance, are far less relevant to the general public. Bureaucracies tend to have greater influence on public policies when policies are complex and not particularly salient to the public. In relative terms, the public has a high degree of interest in decisions as they relate to motor vehicle insurance,

and there is considerable interest among constituents in having motor vehicle insurance available at "affordable" prices, to a much greater extent than whether or not economic efficiency is promoted by public policymakers.

A concern in empirical analysis of effects of insurance on motor vehicle safety is that state policies and practices may be endogenous to measures of roadway safety. In other words, causation may run in both directions, from insurer policies and practices to the level of safety and the reverse. Reverse causation occurs because state legislatures may react to a poor safety record by enacting legislation designed to improve it. Tables 3.1 and 3.2 present brief descriptions of empirical studies on this topic.

3.3 Empirical Evidence

3.3.1 Public Insurance Policies and Practices of Insurers

Sloan and Githens (1994) report results of national surveys of standard, surplus line, and involuntary plans that they conducted in 1991. Involuntary plans are assigned risk plans that states run to assure availability of liability coverage to persons who have difficulty in obtaining coverage at standard rates, but generally for a higher premium than charged by insurance companies issuing standard policies. The surveys elicited information on insurer characteristics, underwriting practices, and premiums charged to insured with various characteristics. The mean surcharge for one driving under the influence (DUI) conviction for males over age 25 was 163 percent. For male drivers under age 25, the surcharge was even higher. There was a tenfold variation in surcharges for DUI. Surcharges for chargeable accidents were lower but also substantial. Surplus line insurers imposed about the same surcharges for DUIs and chargeable accidents. These insurers charged much higher premiums overall than did the standard insurers. More importantly, they limited the amount of liability insurance that a customer could obtain. The involuntary insurance plans charged premiums in the range of the nonstandard insurers and also imposed substantial surcharges but there was appreciable variation in surcharging practice.

Table 3.1 Effect of no-fault motor vehicle insurance on fatalities.

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/Significance
Cohen and Dehejia (2004)	Panel/1970–1998/ 50 states and DC/$n = 1450$	(1) Fatalities per 10,000 persons; (2) Fatalities per 10,000 persons (4-year window); (3) Fatalities per vehicle-mile; (4) Fatalities per 10,000 persons	(1–3) No-fault binary; (4) No-fault "level": 0 = add-on states (threshold = 0); 1 = no-fault threshold < 200; 2 = no-fault threshold > 500	OLS	(1) Positive (no-fault increases fatalities) (1%); (2) Positive (not significant; attributes non-significance (compared to row above) to reduced sample size); (3) Positive (5%); (4) Positive (1%)
Cummins et al. (2001)	Pooled cross-section, time series/1968–1994/50 states/ $n = 1350$	(1–6) Fatal accidents per 10 million vehicle miles	(1) No-fault binary (2) Instrument of no-fault: probability that a state is under no-fault; (3) No-fault binary; (4) Proportion of automobile bodily injury claims ineligible for tort because of thresholds in no-fault states (=0 in tort states); (5) Instrument of proportion of claims ineligible for tort: the predicted value from a reduced-form Torbit model with the dependant variable consisting of the proportion of ineligible claims for no-fault states; (6) Proportion of claims ineligible for tort	(1) OLS; (2) Instrumental variable to account for endogeneity (in adoption of no-fault); (3) Inverse Mills to account for endogeneity; (4) OLS; (5) Instrumental variables; (6) Inverse Mills	(1) Positive (1% or 5% depending on specification); (2) Positive (1%); (3) Positive (1%); (4) Positive (1%); (5) Positive (1%); (6) Positive (1%)

Table 3.1 (*Continued*).

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/Significance
Lemstra and Olszynski (2005)	Number of motor vehicle injury claims by year and province/ 1990–1999/ Saskatchewan and Manitoba, British Columbia, Quebec/$n = 40$ (4 provinces × 10 years)	(1–2) Motor vehicle injury claims per 100,000 residents	(1) Changes in claims after implementation of no-fault for Saskatchewan and Manitoba (one year before and after change); (2) Changes in claims after implementation of no-fault for Saskatchewan and Manitoba (five years before and after change)	(1) Rate ratios of Saskatchewan and Manitoba compared to British Columbia; z statistic used (z[Saskatchewan and BC] = 21.85; z[Manitoba and BC] = 28.83); (2) Rate ratios of Saskatchewan and Manitoba compared to British Columbia; z statistic used (z[Saskatchewan and BC] = 39.09; z[Manitoba and BC] = 97.06)	(1–2) Negative (adopting no-fault decreases claims rate) (1%)

Table 3.1 (*Continued*).

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/Significance
Loughran (2001)	Panel data/1975–1998/48 states and Hawaii/$n = 1176$	(1) Log (Fatal accidents per 100 million vehicle miles); (2) Proxy for number of accidents: ratio of auto property damage claims to exposure (= [number of property damage claims]/[number of property damage policies in effect]); (3) Proxy for driver care: proportion of drivers involved in fatal accidents cited with negligent behavior	(1) Post-implementation no-fault binary and within-state dollar threshold; (2) No-fault binary; (3) Within-state dollar; (4) No-fault binary and within-state dollar threshold	(1) Difference-in-differences; (2) OLS; (3) OLS; (4) Direct comparison	(1) Positive: fatal accident rates fell equivalently in percentage terms in tort and no-fault states between pre- and post-implementation (not significant); (2) Negative: increase in dollar threshold decreases fatal accident rates (not significant); (3) Negative: no-fault decreases accident rate (not significant); (4) Negative: drivers in no-fault states less negligent and increase in threshold decreases (significance n/a)

Table 3.1 (*Continued*).

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/Significance
Brown (1985)	Year-on-year data/ 1964–1980/New Zealand/$n = 15$ years	Accidents, casualties, and fatalities per 100 million vehicle kilometers	Comparison of tort (1964–1973) to no-fault (1974–1980)	Year-on-year comparison	No evidence that no-fault increases accident, injury, or fatality rates
Devlin (1990)	Yearly counts/ Quebec 1971–1984, Ontario 1967–1984/ Quebec and Ontario/$n = 32$	(1) Number of fatal accidents; (2) Number of bodily injury accidents; (3) Number of property-damage-only accidents	(1–3) No-fault binary	(1–3) Multivariate regression	(1) Positive: no-fault increases fatalities (t-statistic = 2.63); (2) Positive: no-fault increases bodily injury accidents (t-statistic = 8.98); (3) Positive: no-fault increases property-damage-only accidents (t-statistics = 4.22)
Kochanowski and Young (1985)	Cross sectional state data/1975–1977/ 50 states and DC/$n = 153$	(1–3) Fatalities per 100 million vehicle miles	(1) No-fault binary; (2) True no-fault binary, add-on binary; (3) Percentage of claims barred from tort by no-fault	(1–3) Multivariate regression	(1–3) Negative (not significant)
Landes (1982)	fatal accidents by state and year/ 1967–1976/ 50 states and DC/ $n = 510$	(1–2) Annual fatal accidents	(1) Threshold value; (2) Real value of medical expense (threshold deflated by medical price index)		(1) Positive (significant for high threshold values ($t \geq 2.09$ for levels of \$1000 and above)); (2) positive (significant for high threshold values ($t \geq 2.03$ for levels of \$750 and above))

Table 3.2 Effect of no-fault motor vehicle insurance on other outcomes.

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/Significance
Sloan et al. (1995)	Behavioral Risk Factor Survey/ 1984–1990/ 18 states in 1984, increased to 45 states by 1990/ $n = 49{,}199$	(1–2) Probability of binge drinking at least once during the prior month; (3–4) Number of binge episodes in the prior month for those who said they binge drank; (5–6) Fraction of binge episodes in which the individual drove	(1) No-fault binary interacted with fraction of claims in which a tort action was barred because claim did not exceed threshold; (2) Binary for states in which tort action is not barred but compels drivers to purchase first-party insurance for losses due to bodily injury; (3) No-fault binary interacted with fraction of claims in which a tort action was barred because claim did not exceed threshold; (4) Binary for states in which tort action is not barred but compels drivers to purchase first-party insurance for losses due to bodily injury; (5) No-fault binary interacted with fraction of claims in which a tort action was barred because claim did not exceed threshold; (6) Binary for states in which tort action is not barred but compels drivers to purchase first-party insurance for losses due to bodily injury	(1) Probit; (2) Probit; (3) OLS; (4) Tobit; (5) OLS; (6) Tobit	(1) Positive: increases probability of having binge drank during the prior month (not significant); (2) Negative (1%); (3) Negative (not significant); (4) Positive (10%); (5) Positive (5%); (6) Negative (not significant

Table 3.2 (*Continued*).

Study	Data type/time period/location/n	Dependent variable	No-fault measure	Statistical method	Effect/ Significance
Sloan et al. (1994b)	Fatal Accidents by state and year/1982–1990/48 lower states/ $n = 391$	(1–2) Motor vehicle fatalities per 1000 population of 18–20 age group; (2–3) Motor vehicle fatalities per 1000 population of 25–64 age group; (5–6) Motor vehicle fatalities per 1000 population of 25–64 age group	(1) Fraction of accidents involving bodily injury for which a tort claim could not be filed; (2) Binary for states that did not bar tort claims but require drivers to purchase minimum amounts of first party insurance; (3) Fraction of accidents involving bodily injury for which a tort claim could not be filed; (4) Binary for states that did not bar tort claims but require drivers to purchase minimum amounts of first party insurance; (5) Fraction of accidents involving bodily injury for which a tort claim could not be filed; (6) Binary for states that did not bar tort claims but require drivers to purchase minimum amounts of first party insurance	Weighted least squares	(1) Positive (not significant); (2) Positive (not significant); (3) Positive (5% or 10% depending on specification); (4) Positive (5% or 10% depending on specification); (5) Positive (1% with year fixed effect); (6) Positive (1% or 5% depending on specification)
Zador and Lund (1986)	Fatal accidents by state and year/1967–1980/50 states and DC	Number of fatal accidents	Threshold, real threshold, percentage of claims barred from tort, no-fault stringency "ranking"	Multiple (14) regressions	Some are positive, others are negative (all but one are not significant)

Sloan and Githens' most important finding comes from their analysis of the relationship between premium surcharges for DUIs and chargeable accidents and driving behavior. Using data at the individual level on self-reported drinking and driving from the 1989 Behavioral Risk Factor Survey, the authors find that the sensitivity of the premiums to DUI had a statistically significant effect on the amount of self-reported drinking and driving that the respondents reported. An increased surcharge for DUI decreased drinking and driving.

Cohen and Dehejia (2004), using a pooled time series cross-section of U.S. state data, find that compulsory liability insurance reduced the rate of uninsured motorists and reduced motor vehicle fatality rates. Although being insured would decrease driver precaution, requiring insurance which is subject to experience rating may make drivers more careful. The authors do not explicitly investigate whether combining compulsory insurance with experience rating of premiums affects the rate of traffic fatalities. Also, uninsured motorists may reason that they will declare themselves judgment proof if required to compensate all injury victims. To the extent this is so, uninsured drivers may be less cautious.

An earlier study by Sloan et al. (1995) of self-reported binge drinking and driving under the influence of alcohol assesses these effects. First, they find that compulsory third-party insurance does reduce the probability that the person reported a binge drinking episode in the period preceding the survey as well as the number of binge drinking episodes, but not the fraction of episodes in which the survey respondent binge drank and drove. Second, compulsory liability insurance with high premium surcharges reduced the probability of binge drinking and the number of binge drinking episodes more than did compulsory insurance with low premium surcharges for chargeable accidents and conditions.

When liability insurance is not required, adverse selection could lead to successive rounds of premium increase with even larger numbers of drivers uncovered. Overall, the empirical evidence on whether or not adverse selection and moral hazard are important phenomena in markets for motor vehicle insurance is unsettled. Empirical evidence on motor vehicle insurance from French data in Chiappori and Salanié

(2000), Quebec Canada in Dionne et al. (2001), and Japan in Saito (2006) find no evidence for adverse selection in these countries; however Cohen (2005) finds evidence of adverse selection in the motor vehicle insurance market in Israel. Saito (2006) also reports no moral hazard in the Japanese market in spite of government policies to make such insurance affordable and available, which would lead to flatter premiums than actuarially fair.

3.3.2 Deterrent Effects of Contributory versus Comparative Negligence

Sloan et al. (1995) also analyze the effect of pure and modified (e.g., the 50 and 49 percent rules) on the propensity to binge drink and drive under the influence of alcohol. Binge drinking is more likely under both forms of comparative negligence, but conditional on binge drinking, binge drinking and driving is less likely. However, the former overwhelms the effect of the latter in terms of magnitude, implying that the switch to comparative negligence in the United States has made roadways less safe.

3.3.3 No-Fault Programs

Empirical research into the effects of no-fault on road safety usually focuses on the motor vehicle fatality rate as the data are consistent and comprehensive across states. However, other measures, such as self-reported drinking and driving behavior, property damage claims, and injury claims are also used to measure the impact of no-fault on levels of care and road safety. In the earliest study, Landes (1982) reports that implementing no-fault in the United States increased the motor vehicle fatality rate. On the other hand, Kochanowski and Young (1985) and Zador and Lund (1986) find no such effects working with the same dependent variable. Using data from New Zealand, Brown (1985) reports that no-fault does not increase the amount of driving or accident rate; however, his investigation does not account for other determinants of driving behavior. Gaudry (1987) finds that implementing no-fault increased the total number of accidents and accident victims in Quebec. Devlin's (1990) research concurs, and additionally finds that

no-fault resulted in an increase in the number of drivers. This is because the adoption of no-fault caused premiums to fall, decreasing the price of driving. Furthermore, no-fault often did not require experience-rated premiums, which decreased the relative price of driving for careless drivers.

Sloan et al. (1994b) report that motor vehicle fatality rates increased with the fraction of accidents for which a tort claim is barred, and report a smaller increase for states that did not bar tort claims but required drivers to purchase minimum first-party insurance. Sloan et al. (1994a) find that no-fault decreased self-reported binge drinking, although the magnitude is small and the finding is only significant at a ten percent level.

More recent studies have also yielded mixed results. Lemstra and Olszynski (2005) compare number of injury claims in the periods prior- and post-implementation of no-fault in Saskatchewan and Manitoba, which switched from tort to no-fault, with those of British Columbia and Quebec, which maintained tort and no-fault respectively. They report that the adoption of no-fault is accompanied by a significant decrease in injury claims. However, the authors admit that this should not be interpreted as causation as other determinants and endogeneity are not accounted for and that injury claims might not be representative of total injuries or fatalities.

Loughran (2001) concludes that no-fault does not affect overall road safety, working with several different dependent variables and equation specifications. He uses a difference-in-differences approach, comparing states that switched to no-fault from tort with those that maintained tort, to measure the impact of no-fault on fatality rates, and finds the change due to no-fault insignificant at the three percent level. Next, he uses the ratio of property damage claims to property damage exposure as a proxy for accident rate, and, with a difference-in-differences approach, finds that no-fault does not affect fatality or accident rates. Finally, by analyzing the causes of fatal accidents, he finds that no-fault does not significantly affect negligence as a cause of fatal accidents. Thus, by examining measures of the fatality rate, accident rate, and driver negligence, Loughran (2001) concludes that no-fault does not affect a driver's level of care.

Cummins et al. (2001) argue that adoption of no-fault is endogenous and report results consistent with this hypothesis. To account for endogeneity, they calculate the probability that a state is under no-fault and use this probability as an instrumental variable to gauge the no-fault laws on motor vehicle fatalities. They also use the inverse Mills ratios approach to account for the selection process in no-fault program adoption.

Using both approaches, they find that implementing no-fault and increasing the number of claims barred from tort action raises fatality rates. However, they also find that strong experience rating (drivers are assessed points even if they are less than 50 percent at fault) can mitigate the adverse effects of no-fault.

Cohen and Dehejia (2004) observe that much of the prior work does not separate the effects of no-fault from the effect of compulsory insurance, as both are sometimes adopted simultaneously. They separate the effects by limiting the data to states that had either compulsory insurance or no-fault, comparing no-fault to the base case of compulsory insurance. They find a significant one-year increase in fatality rates but also find the four-year impact is not significant, which the authors attribute to decreased sample size. They also report that an increase in the threshold beyond which one can bring tort claims also increases fatalities.

It is not certain that switching from tort to no-fault increases accident and fatality rates. Weighing results of the more recent and more econometrically sophisticated studies (but not all, notably Loughran (2001), who finds no weakening of deterrence under no-fault), it seems that switching to no-fault has reduced the deterrent effect that tort would otherwise have. Although not all studies investigate the effects of experience rating, those that do generally agree that experience rating is likely to enhance road safety. However, it might not be feasible if one of the main purposes of no-fault was to eliminate costly determinations of fault.

4

Dram Shop and Social Host Liability

4.1 Rationale

A substantial share of motor vehicle accidents are attributable to driving under the influence of alcohol (Levitt and Porter, 2001; Shults et al., 2001; Room et al., 2005; Quinlan et al., 2005). In 2005, an estimated 40 percent of the 39,000 reported fatal motor vehicle crashes in the United States were alcohol-related (National Center for Statistics and Analysis, 2007a,b). Of these crashes, establishments that serve alcohol for consumption on the premises, such as bars and restaurants, are often identified as the source of alcohol for the drunk driver. O'Donnell (1985) conducted a review of 11 studies and found bars and restaurants were the preferred drinking place for 40–63 percent of drivers arrested for DUI, 43–64 percent of drivers with blood alcohol content (BAC) exceeding 0.10 who participated in roadside surveys, and 26 percent of drivers involved in alcohol-related crashes.

This indicates that imposition of liability on alcohol venders can potentially have a large impact on the frequency of alcohol related motor vehicle crashes. In fact, motivated by the magnitude of the drunk

driving problem, many courts and legislatures have chosen to create liability for servers, called dram shop liability. Dram shop liability gets its name from the English word dram, which refers to a unit of measure in which alcoholic beverages are served. Stores that sold alcohol in these measurements were called dram shops. Such liability imposes on alcohol servers, both on-site (bars, restaurants, etc.) and off-site (liquor stores, convenience stores, etc.) the obligation (1) not to sell alcohol products to minors and (2) to control the behavior of obviously intoxicated adult patrons of alcohol sellers so as to prevent accidents from occurring on the roadways. The seller who fails to exercise due care, as well as the drunk driver, are the potential injurers, while the injury victim has standing to sue.

Preventing minors from purchasing alcohol may take the form of examining patron identification cards before the patron can purchase alcohol. Controlling drinking behavior of adults may involve not continuing to serve an obviously intoxicated patron or finding a ride home for a patron who has had too much to drink. The intent is that with imposition of civil liability, alcohol dispensers will be forced to more closely monitor their customers' drinking. The presumption is that alcohol servers may be more efficient in monitoring drinker behavior than the drinker him or herself. Referring to imposing civil liability for alcohol servers in general and in the United Kingdom in particular, Room et al. (2005) argue that the "general rule in such situations is that it is easier and more effective for the state to influence licensed occupational behavior than it is to influence the behavior of private customers" (p. 527).

The majority of U.S. states have imposed dram shop liability and a few states have imposed liability on social hosts. Examples of social hosts are a sponsor of a party at a college or a family that entertains guests at home. Social host liability is much less widespread than dram shop liability.

Dram shop and social host liability are controversial in the following sense. In general, the doctrine of consumer sovereignty has adults weighing the benefits and costs of particular decisions with such individuals being responsible for the consequences of their actions or inactions. In this context, however, the presumption is that someone else,

the alcohol seller or the social host, is relatively efficient in preventing harm, and the law imposes an obligation for these parties to intercede when there is reason to believe that a third party on their premises is in a position to do harm to others. This does not absolve this third party from the obligation to exercise care, but the responsibility for exercising such care is shared.

Historically, most of the effort to control traffic accidents has been concentrated on changing drivers' behavior through police surveillance and prosecution (see, e.g., Dewees et al., 1996). At least comparatively speaking, imposing tort liability on unsafe drivers has been largely viewed a secondary line of defense.

However, there are reasons to believe that the potential of civil liability as a deterrent for motor vehicle accidents may have been underestimated. For one, under other types of regulatory regimes, such as administrative law (e.g., regulation by Alcohol Beverage Commissions) and criminal law, the victim has no incentive to supply information about the injury or the circumstances under which it occurred. Of course, there may be non-financial reasons for reporting an injury in any regulatory regime. Uniquely under tort, however, the victim stands to recover his or her loss from an injury. The incentive to file a tort claim is directly proportionate to the magnitude of the loss.

Shavell (1984) has developed a framework for deciding when tort liability or government regulation is the more appropriate mechanism for reducing rates of injury. He argues that tort is more appropriate when (1) private parties are knowledgeable about the probability of an accident occurring and the associated cost, (2) harm is concentrated in a few injury victims, which increases their incentive to file tort claims, and (3) causation is easily proved. Conversely, regulation is preferred when (1) the optimal amount of precaution is not individualized to particular circumstances, (2) when the regulatory agency has better information than do private individuals, and (3) when lawsuits are rare because losses are highly dispersed and causation is difficult to prove.

Dram shop liability falls into the first category. Monitoring alcohol consumption of patrons is feasible. Losses caused by drunk drivers are

borne by a few victims who often experience substantial loss. Fault is relatively easy to ascertain. By contrast, regulatory agencies cannot possibly oversee the myriad situations in which alcohol is consumed. Police and alcohol law enforcement agencies monitor drinking, but cannot possibly oversee all situations in which excessive drinking occurs. Not only may resources be lacking, but also the public may view such monitoring as oppressive.

4.2 Four Markets

4.2.1 Injury Prevention Market

In contrast to the motor vehicle liability, for dram shop liability and the other applications in this study, the unilateral care model is the more relevant one. In Liang et al.'s (2004) framework, the owner of an alcohol establishment seeks to maximize profit by selling units of alcohol net of wages and non-wage expense and losses from citations and lawsuits. The establishment's employers execute the owner's policy. To achieve the establishment's objective, the owner sets the compensation rule and level of training in safe alcohol serving practices and levels of monitoring of employee behavior. Employees maximize utility, which depends on earnings and effort subject to the compensation rule and monitoring activity of the employer. Employees earn more if they can sell more drinks. Yet if they sell too many, they may be subject to dismissal and/or exposure to citations and lawsuits. Thus, employees face conflicting incentives.

4.2.2 Legal Market

Dram shop liability has a long history in the United States. Traditionally, vendors were not liable for the actions of their intoxicated patrons. Statutes creating liability emerged in the mid-1800s while common law negligence cases continued to be unsuccessful because they lacked an essential element, causation. While it may be proven that a server had a duty to those injured by the intoxicated person and breached that duty, proving the server is the proximate cause of the injury has been much more difficult. Many courts viewed the resulting injury as sufficiently

remote in time to have been unforeseeable by the vendor; or, the chain of causation was severed when the customer voluntarily drank alcohol. The consumption of the alcohol, not the sale, was the proximate cause of the injury. As a result of this view, servers and suppliers of alcohol were not held liable under common law for the injuries resulting from their patron's intoxication.[1]

Vendor liability changed during the 19th century when, with pressure from the temperance movement, many states began to move away from the common law tradition and enacted laws placing civil liability on suppliers for the injuries caused by their intoxicated patrons. The first of these statutes was enacted in Wisconsin in 1849; the statute required tavern owners to post a bond for the support of widows and orphans injured by a patron's drinking. The bond was also used to pay the expenses from civil and criminal prosecutions resulting from the sale of alcohol. Four years later Indiana passed a statute creating a cause of action against any person retailing alcohol when the intoxicated patron produced an injury to a person, property or means of support. The class of plaintiffs was broad; any wife, child, parent, guardian, employer or other person injured by an intoxicated person could bring suit against the vendor of alcohol. The temperance movement encouraged the enactment of dram shop legislation in other states and by the late 19th century, 11 states had enacted such laws (Sloan et al., 2000b).

The popularity of dram shop statutes was short lived; the end of Prohibition also brought the cessation of dram shop legislation. States would not begin enacting dram shop legislation again until the late 1970s. After World War II, bars and other liquor retailers successfully lobbied state legislatures and dram shop laws were repealed. Until new legislation was enacted, suits were brought under common law negligence claims. In 1978, California was the first state to enact a dram shop statute since the Prohibition. Within 10 years of enactment of

[1] There have been departures from this rule. Some victims who were injured by an intoxicated person brought dram shop suits under common law that had begun to develop in some states. For example, a South Carolina case in 1847 held a shopkeeper liable for the death of a slave to whom he had sold alcohol; the court determined the sale of alcohol was the proximate cause of the slave's death.

California's dram shop statute, 37 other state legislatures had followed suit and enacted legislation regulating commercial vendor liability (Sipes, 1988). Of these statutes, 19 states allowed a cause of action against a vendor; the remaining 18 states place restrictions on or completely prohibit a cause of action against alcohol retailers (Sipes, 1988). But even before the resurgence of dram shop legislation in the 1970s, the judiciary began to re-examine the original purpose of the non-liability rules.

Over time, 26 states have come to acknowledge a common law cause of action for dram shop liability (Sloan et al., 2000b). New Jersey is often credited as instituting modern common-law liability for commercial servers. In 1959, the New Jersey Supreme Court issued an opinion, *Rappaport v. Nichols*, wherein the Court extended liability to vendors.[2] The court reasoned that holding vendors liable would give innocent third parties a better opportunity for justice and at the same time give greater force to the statutory and regulatory precautions against alcohol sales. The court acknowledged they did not want to place any unjustifiable burdens upon defendants, and decided a defendant can discharge their civil responsibilities through the exercise of due care.

Courts have employed several different methods for finding liability in the absence of a statute. Many courts have re-evaluated the traditional common law rule and determined it must be adjusted to fit the needs of modern society. The Supreme Court of New Mexico in *Lopez v. Maez* held intervening acts would not relieve the vendor from liability if the intervening acts were reasonably foreseeable.[3] Further, given the high frequency of accidents involving drunk drivers, it is reasonably foreseeable that there could be injuries when a vendor serves an intoxicated person who they knew or should have known intended to drive. In *Nehring v. LaCounte*, the Montana Supreme Court recognized drunk drivers create a more unreasonable risk of harm under today's conditions due to the regularity of automobile travel to and from taverns, than when the issue was last before the court.[4] For those reasons,

[2] *Rappaport v. Nichols*. 31 N.J. 188 (1959).
[3] *Lopez v. Maez*. 98 N.M. 625 (1982).
[4] *Nehring v. La Counte*. 219 Mont. 462 (1986).

they abrogated the former common law approach and created a cause of action for negligence based on violations of the alcohol control statutes. The court described the proximate cause approach as a "Neanderthal approach to causation" and instead used foreseeability as grounds for liability.[5]

4.2.3 Insurance Market

Vendors of alcohol can purchase insurance coverage for losses they incur from dram shop liability by carrying commercial liability insurance. While insurance does not completely shield a vendor from liability, it does cover the damages deemed the legal responsibility of the policyholder. The goals of liability insurance, risk spreading and loss prevention, are frustrated by several factors. Liability insurance is mandatory in only a few states; as a result, many establishments run their business without insurance.

In a national survey by Mathematica Policy Research of on-site alcohol establishments and their employees conducted in late 1996 and early 1997, respondents mentioned several reasons why they did not purchase liability insurance (Mathematica Policy Research, Sloan et al., 2000b). The most frequently mentioned reason pertained to the price of such insurance. Surely, price is a consideration, but one likely reason that the firms without insurance did not want to pay the price is that they would be judgment proof in the event of a large lawsuit (Sloan et al., 2000b).[6] But another reason is that some firms faced experience rated premiums, which the firms may have believed were unjustified based on their expected future losses from lawsuit (Sloan et al., 2000b). In some cases, insurers added a surcharge of up to 25 percent. In some others, insurers would not insure the alcohol seller at any price. According to the survey respondents, insurers offered few incentives to implement safety measures. Some granted premium discounts for safe drinking

[5] *Nehring v. La Counte*. 219 Mont. 462 (1986).

[6] Other responses included: business was too small to bother, they were in between two companies, they monitor themselves, there was no need for insurance, business is incorporated, and there was not enough business.

practices, while others provided no discount for the same safety procedures (Sloan et al., 2000b).

4.2.4 Government Market

In contrast to other lines of insurance, in any given year, dram shop liability and insurance are minor public policy issues. Groups with a major stake in dram shop liability are those representing bars and restaurants and other alcohol sellers. For insurers, this is a very small line. The stakes in other areas are far greater. Driving under the influence of alcohol in general is a highly salient issue. Newspaper accounts frequently describe fatal motor vehicle accidents and premature deaths of innocent persons or youths with inexperience in many domains, including in operating a motor vehicle. Such tragedies do translate into legislation, but often into criminal rather than civil penalties and into public demands for greater law enforcement.

4.3 Empirical Evidence

Tables 4.1 and 4.2 present brief descriptions of studies discussed in more detail in the text.

4.3.1 Perceptions of the Threat of Tort Liability

The Mathematica Survey provides a unique opportunity to look inside what is normally the black box of decision making of potential tortfeasors. Sloan et al. (2000b) investigate relationships between commercial server's self-reported perceptions, precautions, and firm characteristics such as net worth as reported by owner/manager respondents to the Mathematica survey and risk perceptions of the respondents. They find that strict (as rated by the authors based on characteristics of the laws) dram shop laws increased a bar owner's perceived probability of being sued, and both strict and less strict laws increased the probability of having been sued, the former more than the latter. Overall, there were strong relationships between risk perceptions and the objective risk of a civil or criminal sanction.

Table 4.1 Effects of imposing dram shop liability on motor vehicle and other fatalities.

Study	Data type time period location n	Dependent variable	Dram shop measure	Statistical method	Effect (Significance)
Benson et al. (1999)	State year, 1984–1992, 48 states, $n = 432$	(1) Driver involvement rates in alcohol related traffic fatalities (BAC $\geq$ 0.01) (= [number of involved drivers]/[total number of drivers]); (2) Driver involvement rates in alcohol related traffic fatalities (BAC $\geq$ 0.10); (3) Driver involvement rates in alcohol related traffic fatalities (BAC $\geq$ 0.01) (= [number of involved drivers]/[total number of drivers]); (4) Driver involvement rates in alcohol related traffic fatalities (BAC $\geq$ 0.10)	Dram shop binary	Weighted least squares with logistic transformation	(1) Negative (dram shop laws decrease alcohol related fatalities) (5%); (2) Negative (dram shop laws decrease alcohol related fatalities) (10%); (3) F = 4.72 or 5.36, depending on equation specification (1%); (4) F = 4.81 or 5.86, depending on equation specification (1%)
Chaloupka et al. (1993)	State year, 1982–1988, 48 states, $n = 336$	(1) Total motor vehicle fatality rate; (2) Night-driver fatality rate; (3) Alcohol involved driver fatality rate (BAC $\geq$ 0.05); (4) 18–20-year old motor vehicle fatality rate; (5) 18–20-year old night-driver fatality rate; (6) 18–20-year old alcohol involved driver fatality rate (BAC $\geq$ 0.05).	Dram shop binary	Weighted least squares with logistic transformation	(1) Negative (1%); (2) Negative (1%); (3) Negative (1%); (4) Negative (10%); (5) Negative (10%); (6) Negative (10%)

Table 4.1 (*Continued*).

Study	Data type time period location n	Dependent variable	Dram shop measure	Statistical method	Effect (Significance)
(Eisenberg, 2001)	State Year, 1980–2000, 50 states and DC, $n = 1050$	(1) Total fatal crash rate: number of crashes per 10,000 licensed drivers; (2) High BAC fatal crash rate: estimated number of high BAC (≥ 0.10) crashers per 10,000 licensed drivers; (3) Any BAC fatal crash rate: estimated number of any BAC (≥ 0.01) crashes per 10,000 licensed drivers; (4) Weekend night time fatal crash rate: number of fatal crashes occurring between 7 pm and 5 am on Friday or Saturday night, per 10,000 licensed drivers; (5) Weekend night time single vehicle fatal crash rate	Dram shop binary	Weighted least squares	(1) Negative (5%); (2) Negative (5%); (3) Negative (5%); (4) Negative (5%); (5) Negative (not significant)
Ruhm (1996)	State year, 1982–2000, 48 states, $n = 336$	(1) Total vehicle fatality rates per 10,000 persons; (2) Total vehicle fatality rate per 100 million vehicle miles; (3) Total night time (12 am to 3:59 am) vehicle fatality rate	Dram shop binary	Equation estimated as grouped data logit models, by weighted least squares	(1) Negative (10%); (2) Negative and significant for all but one specification (10%); (3) Negative (5%)
Sloan et al. (1994b)	State year, 1982–1990, 48 states, $n = 391$	(1) Motor vehicle fatalities per 1000 population of 18–20 age group; (2) Motor vehicle fatalities per 1000 population of 21–24 age group; (3) Motor vehicle fatalities per 1000 population of 25–64 age group	Dram shop binary	Weighted least squares	(1) Negative (5%); (2) Negative (5%); (3) Negative (1%)

Table 4.1 (*Continued*).

Study	Data type time period location n	Dependent variable	Dram shop measure	Statistical method	Effect (Significance)
Sloan et al. (1994a)	All US deaths, 1982–1988, 48 states, $n = 304$	(1) Death rates per 1000 for 25–64-year old with alcohol as the primary cause of death; (2) Death rates per 1000 for 25–64-year-olds with traffic accidents as cause of death; (3) Death rates per 1000 for 25–64-year-olds with homicide as cause of death	Dram shop binary	OLS	(1) Negative and statistically significant with state variables but without time variables (1%); (2) Negative (5%); (3) Negative (1%)
Sloan et al. (1995)	Behavioral Risk Factor Survey, 1984–1990, 18 states in 1984, increased to 45 states by 1990, $n = 49,199$	(1) Probability of binge drinking at least once during the prior month; (2) Number of binge episodes in the prior month for those who said they binge drank; (3) Fraction of binge episodes in which the individual drove	Dram shop binary	(1) Probit; (2) OLS and Tobit; (3) Tobit	(1) Negative (not significant); (2) Negative (not significant); (3) Negative (not significant)
Young and Likens (2000)	State year, 1982–1990, 48 states and DC, $n = 432$	(1) Motor vehicle fatalities per 1000 population; (2) Number of alcohol-involved (BAC ≥ 0.05) driver deaths per 1000 population; (3) Number of motor-vehicle fatalities for drivers 18–20 per 1000 population of 18–20-year-olds; (4) Number of alcohol-involved (BAC ≥ 0.05) 18–20-year old driver deaths per 1000 population of 18–20-year-olds	Dram shop binary	Logistic transformation and Linear	(1) Negative (not significant); (2) Negative (1%); (3) Negative (not significant); (4) Negative (not significant for logistic transformation, 1% for linear)

Table 4.2 Effects of imposing dram shop liability on other outcomes.

Study	Data type time period location n	Dependent variable	Dram shop measure	Statistical method	Effect (Significance)
Sloan et al. (2000a)	1996 Survey of Commercial Servers, 1990–1996, 48 states, $n = 778$	(1) Bar owner's perceived probability of being sued for serving an intoxicated adult; (2) Bar owner's perceived probability of being sued for serving a minor; (3) Bar's probability of having been sued	Strict dram shop binary; not strict dram shop binary	(1) Ordered logit; (2) Ordered logit; (3) Logit	(1) Positive for strict (1%), positive for not strict (not significant; (2) Positive (not significant; (3) Positive (1%); not strict has higher magnitude (1.19) than strict (0.73)
Stout et al. (2000)	Behavioral risk factor survey; random 25% sample of observation of people over age 21, 1984–1996, 50 states and DC, $n = 199{,}358$	(1) Probability that one drank heavily at all; (2) Probability that one engaged in drinking and driving at least once, given that one consumed alcohol; (3) Probability that one engaged in drinking and driving at least once, given that one drank heavily; (4) Probability that one drank heavily at all; (5) Probability that one engaged in drinking and driving at least once, given that one consumed alcohol; (6) Probability that one engaged in drinking and driving at least once, given that one drank heavily	(1–3) Dram shop binary; (4–6) Binary for dram shop laws that allow drinker to sue	Logit	(1) Negative (not significant); (2) Negative (5%); (3) Negative (almost significant, $p = 0.056$); (4) Positive (laws that allow drinkers to sue increases probability that a person drank heavily) (1%); (5) Positive (5%); (6) Positive (not significant)

4.3.2 Effects of Owner/Managers' Risk Perceptions on Actions Taken to Avoid Lawsuits

The authors further analyze the effects of risk perception of being sued on behaviors undertaken to avoid litigation. The behaviors analyzed are: rules regarding server drinking on the job; an index of services provided to intoxicated patrons (e.g., providing or arranging rides home); checking references of potential employees; content of the establishment's server training program; and provision of written procedures to employees regarding server training. Holding many other factors constant, a higher perceived probability of a dram shop suit was positively and significantly related to a policy of (1) not allowing servers to drink on the job, (2) checking references of potential employees, (3) having a more comprehensive server training program, and (4) having a higher likelihood of providing written procedures to employees regarding the establishment's server practices.

4.3.3 Alcohol Establishment Employees' Precautions to Avoid Accidents of Patrons and Resulting Lawsuits

Using data from the interviews of employees of alcohol establishments conducted by Mathematica, Liang et al. (2004) analyze bar employee behavior. This study addresses these issues: To what extent does the imposition of dram shop liability affect employees' incentive to take care? Do various liability rules affect employees' serving practices? Does how the employee is paid make a difference? The authors find that employees received higher compensation in the form of salary and tips when they engaged in serving practices that may lead to patrons' driving under the influence. Since their pay in the form of tips is derived from selling more drinks, employees face a clear financial incentive to sell drinks. On the other hand, when they engaged in behaviors that may decrease rates of patron driving under the influence, their pay did not increase. Thus, the threat imposed by tort liability and financial incentives that employees faced were often not aligned. While imposing a threat of tort liability on alcohol sellers did increase employees' precaution levels, when employees derived most of their compensation from tips, the deterrent effect of tort liability was reduced.

4.3.4 Evidence on the Effects of Dram Shop and Social Host Liability on Roadway Safety

Whether or not there are important theoretical reasons to expect that dram shop liability deters careless behavior and losses due to accidents and even whether potential tortfeasors perceive the threat that liability imposes, in the end, the proof of the pudding is in the empirical evidence on outcomes. That is, does the empirical evidence show that imposing dram shop liability deters injuries? The answer from most studies is "yes." Dram shop liability has been shown to consistently and significantly decrease alcohol-related motor vehicle fatalities and increase levels of precaution. Such studies use a variety of outcomes as dependant variables, such as motor vehicle fatality rates, self-reported drinking behavior, and self-reported commercial seller perceived risks and precaution levels. Not only does empirical evidence support the view that dram shop liability deters, but also it tends to be effective relative to criminal penalties. In contrast to dram shop liability, there is relatively little empirical evidence on the deterrent effect of social host liability.

Chaloupka et al. (1993) find that dram shop liability had a statistically significant effect on total motor vehicle fatalities occurring at night (which are more likely to be caused by intoxicated drivers), and those involving intoxicated drivers. These results are confirmed by Sloan et al.'s (1994b) analysis of motor vehicle mortality rates and by Ruhm's (1996) study of vehicle fatality rates. Ruhm (1996) uses various specifications and finds that one of the most impressive findings was the effectiveness of dram shop liability laws. Sloan et al. (1994a) find that implementing dram shop liability lowered death rates not only from traffic accidents but also from those primarily caused by alcohol including homicides.

Young and Likens (2000) report that dram shop liability does not influence total motor vehicle accident fatality rates, but does reduce alcohol-related fatality rates. Benson et al. (1999) divide alcohol-related fatalities into two categories; those with low BAC (BAC ≥ 0.01) and high BAC (BAC ≥ 0.10). They find that dram shop liability laws have a negative and statistically significant relationship to fatalities of both

types. Eisenberg's (2003) findings concur, and additionally find that dram shop liability decreases weekend night accident fatality rates, and fatality rates for those under 21 years of age. In contrast, Whetten-Goldstein et al. (2000) introduce a binary variable indicating whether or not the drinker could sue their server. They find that dram shop statutes decrease accident fatalities, alcohol-related accident fatalities, and nighttime fatalities.

In contrast to these findings, one study does not find that dram shop laws were effective. Using data from Behavioral Risk Factor Surveys, Sloan et al. (1995) find no statistically significant effects for dram shop liability.

Based on data from Behavioral Risk Factor Surveys, Stout et al. (2000) report that although dram shop statutes does not affect the probability that a person engages in heavy drinking, it does significantly reduce a drinker's probability of drinking and driving. Conversely, allowing a drinker to bring suit significantly increases both the probability of heavy drinking and drinking and driving. This suggests that such statutes encourage drinking and driving behavior.

4.3.5 Effects of Dram Shop Liability on Mortality from Other Causes

In addition to assessing the impact of dram shop liability and other laws and alcohol prices on motor vehicle fatality rates, Sloan et al. (1994a) also examine the impact of these laws on mortality rates from other causes. Statistical significance was somewhat sensitive to equation specification. However, significant findings are often obtained for dram shop liability in analysis of primary (alcohol) cause of death (chronic liver disease, alcoholic cirrhosis of the liver, alcohol liver damage, other mortality with alcohol listed as the primary cause) and homicides. The evidence that imposing dram shop liability reduces fatality rates from falls, fires, and other (other than traffic) accidents, however, is ambiguous.

4.3.6 Effects of Social Host Liability

Whetten-Goldstein et al. (2000) provide empirical evidence on the effects of social host liability motor vehicle fatality rates by state for the

period 1984–1995. Determinants of total motor vehicle fatality rates, alcohol-related motor vehicle death rates, and single car nighttime driving deaths are analyzed separately. They present regression results for minors separately from adults. An explanatory variable for whether or not a bar can be sued for serving minors is negative and statistically significant at conventional levels in five out of six regressions. In the sixth regression, the coefficient is negative but not statistically significant. By contrast, for social host liability, coefficients are positive in the analysis of minor motor vehicle death rates. In the corresponding analysis for adults, the coefficient on social host laws is negative, but statistically significant in only one out of three regressions and much smaller in magnitude than the one for dram shop liability. Thus, the results confirm previous findings that dram shop liability is an effective deterrent, but the results for social host liability are equivocal at best. The authors explain the difference by noting that a much higher proportion of drunk drivers obtain their alcohol in a bar rather than at a private social gathering. They entertain an alternative explanation, however, that perhaps breeches of social host liability are much less likely to be enforced.

5

Medical Malpractice

5.1 Background and Context

Medical malpractice litigation in the United States, in the form it exists today, was in place by the mid 19th century (DeVille, 1990; Olsen, 1996). On the other hand, the development of malpractice insurance as a distinct type of insurance did not occur until over a century later. Public discussions of medical malpractice as a major public policy issue began when medical malpractice insurance became a separate line of property-casualty insurance in the mid-1970s. Since this time, there have been three major medical malpractice crises in the United States: the mid 1970s; the mid-1980s; and the early-2000s (Mello et al., 2003b). Throughout the crises, which have been characterized as periods of substantially rising premiums and in some crises, lack of availability of medical malpractice insurance coverage, much attention has been devoted to medical malpractice, diagnosing deficiencies, and proposing short-term policy solutions (Baker, 2005; Sloan and Chepke, 2008). While crises have characterized products liability, they have not attracted as much media and legislative interest as has medical liability. The reason is perhaps that no group is as well organized politically as physicians.

There are many quality assurance mechanisms in the medical field, including licensure, certification, accreditation, peer review by hospitals' medical staffs, and by organizations external to suppliers of care such as Peer Review Organizations, which are authorized by federal legislation. There has been some use of "report cards," which have the ability to inform consumers about quality differences among providers (Dranove et al., 2003; Weinstein et al., 2005). Then we have medical malpractice. A cynical view is that medical liability continues to exist because of the political influence of the plaintiffs' attorneys. An alternative view, however, is that medical liability is justified because the other regulatory mechanisms are also subject to political influence, e.g., by physicians and hospitals.

5.2 Four Markets

As in the previous two sections, we provide a framework for explaining the controversies of medical malpractice by dividing the determinants of medical malpractice outcomes into four conceptually distinct markets. The first market is for medical care where consumers are patients, and physicians are suppliers, analogous to the injury precaution market in the applications of tort law previously discussed. Second, there is the legal market, where both injury victims and physicians as defendants demand legal services, supplied by lawyers and the courts. Third is the market for medical malpractice insurance (Sloan et al., 1991). In this market, the consumers are physicians and other health professionals, and the suppliers are medical malpractice insurers. Finally, there is the market for government activity in which the law-as-market view asserts legislation and government activity is a good demanded and supplied much like other goods (see, e.g., Persson and Tabillini, 2002).

5.2.1 Medical Care Market

Individuals may select physicians, hospital, and other health care providers based on perceived quality and other factors. Furthermore, following a medical encounter, patients may follow or not follow medical advice. Patient compliance with medical recommendations is sometimes an issue in litigation. In general, the unilateral care rather than

the bilateral care model is the more appropriate one in the medical field. That is, the health care provider is the potential injurer and the patient in the potential victim.

Conceptually, providers take account of downstream liability cost in deciding on their professional care standards. Ideally, providers could be sure that they could escape liability by exercising the due standard of care set at the socially optimal care level. At least three impediments stand in the way.

First, courts are likely not to set the care standard at socially optimal levels and/or they may be inconsistent in the standards they set. Realistically, medical care is so multifaceted that there is no way that courts could set standards for every medical situation.

Second, as explained below, the number of lawsuits against health care providers falls far short of the number of medical errors that are committed by these individuals and organizations. This is not unique to medical malpractice. Citations of drivers who exceed the speed limit are far rarer than is the number of drivers who exceed statutory speed limits. Underclaiming or too few citations can lead to excessively careless behavior.

Third, the vast majority of physicians have complete insurance for their medical malpractice losses (Danzon, 1985). Consequently, physicians do not bear a financial cost for the negligent injuries that they cause. Nor, in contrast to motor vehicle liability insurance, are medical malpractice premiums experience-rated (Sloan, 1990). Although complete non-experience rated insurance may be expected to blunt any deterrent effect that imposing medical liability might otherwise have, being sued does exact a price in terms of psychological distress and possibly loss of reputation as well. Furthermore, the time and earnings loss associated with being involved as a defendant in a lawsuit are not covered by medical malpractice insurance.

A distinction is often made between "positive" and "negative defensive medicine" in discussions of medical malpractice. Positive defensive medicine refers to increases in the cost of personal health care services attributable to the threat of being sued. Confronted with the threat of suits, physicians may order more tests, perform more surgical

procedures, and undertake other medical interventions than they might in absence of this type of threat.

Negative defensive medicine applies to a physician's withdrawal of care due to retirements, location changes, and the dropping of procedures that often lead to lawsuits, such as those associated with obstetrical care. That the threat of liability may affect the activity level that potentially exposes an agent to litigation is not unique to medical malpractice. For example, the cost of dram shop liability might cause some bars to close.

For an economist, a test or procedure or other intervention becomes "defensive" when, in the view of an informed decision maker, the marginal benefit is less than its marginal cost. Using this definition, to the extent that the threat of medical malpractice litigation increases provision of care for which marginal benefit exceeds marginal cost, then such litigation serves its desired purpose, and conversely.

Several other definitions have been used in the literature. For example, the U.S. Congress Office of Technology Assessment (1994, p. 13) defined defensive medicine as:

> Defensive medicine occurs when doctors order tests, procedures, or visits, or avoid high-risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice liability. When physicians do extra tests or procedures primarily to reduce malpractice liability, they are practicing positive defensive medicine. When they avoid certain patients or procedures, they are practicing negative defensive medicine.

The first definition, from the economics and law tradition, uses the concept of optimal care as the level of care which would maximize consumer well-being given available scarce resources. This optimal level of care calls upon health professionals' assistance to serve as the patient's agent to the extent that patients are not able to select optimal care on their own. From this viewpoint, the goal of tort liability is to encourage socially optimal choices. The OTA definition, based on a view shared by the vast majority of health professionals, begins with a

very different premise. Medical liability has little or nothing to do with optimal care. Instead, the threat of being sued is an unnecessary disruption, and changes in resource allocation attributable to the threat are wasteful.

Ideally, medical malpractice would lead to provision of optimal levels of care (see, e.g., Shavell, 1980). But, there may be under or over deterrence (the latter, called "defensive medicine"). If the threat of liability is excessive and/or imposed arbitrarily over deterrence could arise. For example, physicians may over prescribe diagnostic tests and therapeutic procedures, or avoid certain types of procedures and locations associated with higher probabilities of lawsuits. The asymmetric relationship between patients and physicians may cause under deterrence. Patients are typically not well versed in medicine and do not know that such care would potentially benefit them and as a result they may fail to request beneficial types of care. Such presumed deterrent effects are often used as a pretext for public intervention.

5.2.2 Legal Market

In the legal market, individuals who have experienced iatrogenic injuries and may have been passive in their role of patients become active participants as plaintiffs. In the vast majority of claims, as with other personal injuries, lawyers are paid on a contingent fee basis, which typically amounts to 33–40 percent of total compensation to plaintiffs (Sloan et al., 1993). In the event the case is dropped by the plaintiff or the plaintiff loses at verdict, the plaintiff's attorney receives no compensation. For this reason, attorneys have a strong incentive to accept only those cases which are likely to result in compensation which is greater than or equal to the legal expense they incur. Medical malpractice litigation can be quite complex in that technical details are often involved, at least relative to other legal disputes, as for example, automobile accidents, for which causation may be more easily determined and for which a police report exists. There is empirical evidence that attorneys specializing in medical malpractice litigation obtain higher levels of compensation for their clients (Sloan et al., 1993).

Critics of the legal market in the context of medical malpractice allege that (1) lawyers frequently encourage persons with adverse outcomes from the receipt of medical care and who have non-meritorious claims to file lawsuits, (2) liability laws unduly favor plaintiffs, and (3) plaintiffs are overcompensated for their losses. There are concerns that jury decisions are unduly swayed by the severity and circumstances of the plaintiff's injury, but these criticisms are disputed by other studies (Vidmar, 1998; 2004).

There is a plethora of research findings regarding various aspects of the medical malpractice system. There is theoretical and empirical evidence on: why injury victims file claims (Nalebuff, 1987; Nalebuff and Scharfstein, 1987; May and Stengel, 1990; Farber and White, 1991;, Hickson et al., 1992; 1994; 2002; Sloan and Hsieh, 1995; Sieg, 2000) variation in injuries relative to claims frequency (Mills et al., 1977; Weiler et al., 1993), the determinants of award sizes (e.g., Danzon and Lillard, 1983; Sloan and Hsieh, 1990), comparisons of injury cost with compensation (Sloan et al., 1993), awards obtained with the use of a specialist lawyer (Sloan et al., 1993), outcomes in medical no-fault versus tort (Bovbjerg and Sloan, 1998), effects of contingent fees on legal outcomes, and on jury behavior in tort litigation (Vidmar, 1995; 2003).

Extending prior theoretical research by Nalebuff (1987), Sieg (2000) develops and estimates a bargaining model for medical malpractice disputes, which explains the stylized facts about dispute resolution in medical malpractice. Such facts include: the vast majority of legal disputes are settled out of court. Only a minority of disputes ever reach verdict, and of those decided at verdict, only a minority result in a win for the plaintiff. With his estimation strategy, Sieg (2000) is able to recover the structural parameters of the underlying bargaining model and replicates key quantitative and qualitative patterns in the medical malpractice claims data he analyzes. The low rate of verdicts for plaintiffs, for example, rather than reflect a high rate of non-meritorious cases can be explained as a feature of a bargaining game. Similarly, allegations that medical malpractice plaintiffs are compensated for their losses are not supported by empirical evidence (Sloan et al., 1993).

5.2.3 Insurance Market

Medical malpractice insurance is one type of property-casualty insurance. Experience rating of premiums is uncommon in medical malpractice (see, e.g., Sloan, 1990; Mello and Studdert, 2006). There is an important tradeoff between risk sharing and maintaining an incentive for policyholders to exercise due care. If premiums go up after the policyholder incurs a loss, even if insurance is nominally complex, the insured eventually pays for at least some of the loss in the form of increased future premiums.

If all policyholders, regardless of the likelihood of injury in their work or their carelessness, pay the same premium, there are two potentially adverse consequences. First, physicians will have less incentive to exercise due care. Second, physicians with low claims risk end up subsidizing physicians with high claims risk.

The lack of experience rating in medical malpractice may reflect a widespread perception that outcomes of claims are random, and hence physicians should not be made to pay higher premiums after payment is made on their behalf. Another possible explanation is that charging higher premiums for physicians who engage in risky practices may cause physicians to stop such practices, such as delivering babies.

Unlike other lines of property-casualty insurance, the dominant form of insurance company ownership is not the commercial stock form in which equity holders are stock holders. Physician-sponsored mutual or reciprocal medical malpractice insurers were formed in many states in the mid-1970s following the withdrawal of commercial stock insurers from the medical malpractice insurance market. An underlying suspicion among physicians that they were not being well-represented by commercial insurers may have been a factor as well. As in motor vehicle liability insurance markets, there are "surplus line carriers," insurers specializing in hard-to-insure risks (Schwartz and Mendelson, 1989). These insurers charge higher premiums than do insurers that cover standard risks. In contrast to physicians, hospitals tend to be self-insured for much of their potential medical malpractice loss.

Many of these physician-sponsored insurers survive today. Even though physicians retain some control in deciding how much coverage

to purchase and from whom, insurers decide which markets to enter, how aggressively they will defend claims, and the amount of reserves to set aside for future losses incurred during the course of a particular year in which they insure risks ("policy year").

5.2.4 Government Market

Historically, medical malpractice in the United States has been primarily a state rather than a federal issue. Over the years, bills have been introduced in the U.S. Congress, but no legislation directly related to medical malpractice has been enacted (Kersh, 2006). All of the legislation affecting medical liability has been adopted at the state level.

Reforms (and we use this term reluctantly since reform implies a conclusion that the statutory changes consistently were improvements) that have been enacted can be divided into two categories, traditional or first-generation reforms and second-generation reforms. Traditional reforms typically make minor modifications to the existing tort liability system as it applies to medical malpractice, or, in some cases, to personal injuries more generally. Examples are caps on damages, changes in the common law collateral source rule, and limitations on the contingent fee percentage that attorneys representing plaintiffs in medical malpractice litigation can charge. In contrast, second-generation reforms are a newer development and involve fundamental changes to the system. The most prominent example is medical no-fault. Another example involves proposals for enterprise liability under which a hospital or health plan rather than individual physicians and hospitals are named as defendants. Perhaps because they are novel, but more likely because they lack advocates outside of the academic community, second generation reforms have rarely been enacted. Aside from not recognizing the intricacies of modern health care, none of the first-generation reforms deal with the fundamental problems of the current system, such as the misalignment of the financial interests of health care providers with the social objective of injury and claims prevention.

Viewed from a societal perspective, the primary role of the medical liability system must be quality assurance. When quality of care is maintained, the risk of iatrogenic injury decreases. (This point has been

made by several commentators (see, e.g., Danzon, 1994). Thus, a failure to regulate quality, and therefore deter injury, is a major deficiency of medical malpractice as it exists today.

5.3 Empirical Evidence

5.3.1 Medical Error Rates

Three major studies of the epidemiology of medical injuries among patients hospitalized in the United States have been conducted since the mid-1970s. The earliest study was based on reviews of 20,864 patient records in California in 1974 (Mills et al., 1977). Building on the methods of the California study, the Harvard Medical Practice study reviewed records of 31,429 patients hospitalized in the state of New York during 1984, and reviewed litigation records (Weiler et al., 1993). More recently, Colorado and Utah used the New York methodology in reviews of medical records of persons hospitalized in Colorado and Utah (Mello and Brennan, 2002).

In the Harvard study, the best known of the three, two physician reviewers, working independently, rated their confidence that an adverse event attributable to the receipt of medical care occurred, based on reviews of each medical record on a scale from zero to six. (The methodology is described in Brennan et al., 1991.) Similarly, the reviewers assessed negligence. When there was disagreement between the reviews, this was noted by a medical records analyst and resolved with an independent review by a supervisory physician. No sub-specialists in various fields served as medical record reviewers. This was an "implicit review," meaning that it was up to the physician to make an assessment of negligence without following explicit specialty specific criteria.

The study also included reviews of medical malpractice claims filed on behalf of the injury victims identified in their study. There were 7.6 times as many negligent injuries as there were claims; only two percent of negligent adverse events resulted in medical malpractice claims. Perhaps more importantly, "invalid" claims, those not matching the study's determination of liability from raters' evaluations of the medical records, outnumbered valid claims by a ratio of three to one (Studdert et al., 2004). From these studies, it seems errors occur in both direc-

tions, not enough valid claims were filed and too many invalid claims were filed.

Peters (2007) synthesizes a dozen empirical studies on the relationship between malpractice settlement rates and quality of care (Ogburn et al., 1988; Cheney et al., 1989; Rosenblatt and Hurst, 1989; Harvard Medical Malpractice Study, 1990; Sloan and Hsieh, 1990; Taragin et al., 1992; Sloan et al., 1993; Farber and White, 1994; Spurr and Howze, 2001; Peeples et al., 2002). In his synthesis, he finds that both the likelihood of a settlement payment and the amount paid in settlement are closely related to the quality of the underlying claim of medical malpractice. In fact, all but the Harvard study found a correlation between settlement rate and case quality. Peters found that the number of categories claims were divided into made a material difference. The studies that divided the claims into three categories, e.g., negligent, not negligent, and uncertain, showed a stronger link between negligence and settlement outcome than the studies using two categories, e.g., negligent or not negligent.

In addition, Peters (2007) finds that only 10–20 percent of claimants with low-odds claims receive a settlement. This figure corresponds with the rate of disagreement normally found when independent observers rate performance. Also, the studies generally used physician raters, increasing the likelihood of rater bias. Peters speculates that inter-rater variability and rater bias could account for much or all of the 10–20 percent payment rate. The studies also show that settlement size is much smaller in low-odds cases than in cases with more evidence of negligence.

Data from the Harvard study were extrapolated to the entire U.S. population, and results were published in 2000 by the Institute of Medicine (IOM) in *To Err is Human*. *Err*'s most stunning and well-publicized finding was that 98,000 persons die in U.S. hospitals annually because of medical errors committed during their stays (Mello and Brennan, 2002).

The estimate of 98,000 deaths per year has been subject to some criticism. The number of deaths per annum in hospitals due to medical errors may be "softer" than the IOM's message implies. Medical accidents are not discrete events; many persons enter the hospital in a

frail condition and are particularly vulnerable to medical errors. Even without medical error, many persons admitted to a hospital do not have a lengthy life expectancy. Thus, rather than calculate the number of lives lost, a more precise characterization of the harm attributable to errors would be life years lost. Since the publication of *Err*, many papers have been published which lend support to the notion that medical error rates are high. For example, Gandhi et al. (2006) report that their review of 307-closed malpractice claims shows evidence of many missed and delayed diagnoses in outpatient settings.

5.3.2 Empirical Evidence that Medical Malpractice Improves Patient Safety

Although medical malpractice, like tort liability more generally, has many goals; at the top of the list is injury deterrence. Whether or not the threat of tort liability actually deters is fundamentally an empirical question and cannot be decided based on theoretical arguments alone.

The quantitative evidence on this issue is conflicting and on balance does not reject the null hypothesis that the threat of medical malpractice suits does not reduce iatrogenic injuries. Medical errors remain frequent, even with the threat of tort claims in spite of the fact that tort liability has existed for years (Institute of Medicine, 2000).

Using data from 49 New York hospitals conducted for the Harvard study described above, Weiler et al. (1993) specified and estimated a two-equation model. One equation measured the effect of the threat of tort on the hospital's injury rate, and a second equation measured the relationship between the threat of tort and characteristics of the area in which the hospital was located which might affect the threat. Most importantly, the second equation contained exogenous variables that had no theoretical role in the first equation, urbanization and population density. The threat of a malpractice claim was measured as the fraction of negligent injuries (as determined by the researchers' assessments of medical records at the hospital) that actually resulted in a medical malpractice claim. Dependent variables for the main equation were the fraction of hospitalizations that resulted in injuries, and the

fraction of all injuries that were attributable to negligence. Results on the effect of the threat of medical malpractice litigation were not statistically significant at conventional levels.

The most cited scholarly paper on the topic of defensive medicine is Kessler and McClellan (1996) (KM). KM used longitudinal data on all elderly (aged 65+) Medicare beneficiaries who were hospitalized for a new acute myocardial infarction (AMI) or a new ischemic heart disease (IHD) in 1984, 1987, and 1990. Like subsequent studies, Hellinger and Encinosa (2003) and Kessler et al. (2005), KM's measures of the medical malpractice threat are variables reflecting tort reforms implemented in the state. The key covariates are tort law reforms implemented in the state in which the beneficiary was admitted for treatment. KM assessed the effect of the statutory changes on total hospital Medicare payments during the year after the admission for the AMI or IHD to measure the effect of the statutory changes on intensity of treatment. If the changes succeeded in reducing the extent of defensive medicine, one should see reductions in treatment intensity or cost attributable to these changes. KM also studied the impact of the tort reforms on patient outcomes.

Using KM's methodology, defensive medicine will be reduced if the reforms reduced treatment intensity but did not adversely affect patient outcomes. The outcome measures used were mortality within one year of admission for the index event (admission for AMI or IHD) and whether the patient experienced a subsequent AMI or heart failure, measured by admission for either condition in the year following the index event. KM combine reforms into two variables: "direct" and "indirect." Direct reforms include caps on damage awards, abolition of punitive damages, no mandatory prejudgment interest, and collateral source rule reform.[1] Indirect reforms include other reforms that may affect pressure from tort on care provision, but only affect awards indi-

[1] Punitive damages may be awarded when the defendant's action is found to have deliberatively harmed the patient or represented conduct not befitting of a professional. A few states have abolished punitive damages in medical malpractice cases even though punitive damages are rarely paid in the context of medical malpractice. Prejudgment interest refers to interest payments on the loss between the date of injury or date a lawsuit is filed and the date the verdict is reached. Limits on prejudgment interest have the effect of reducing such interest payments.

rectly, such as limitations on plaintiff attorney contingency fees, which may make it more difficult for injury victims to file medical malpractice claims. Indirect reforms are limits on contingent fees, mandatory periodic payments, joint-and-several liability reform, and the availability of a patient compensation fund. The study controls for the effects of other factors by including explanatory variables for state and year.

KM find that in states adopting direct reforms, compared to states without reforms, Medicare payments for hospital care during the first year declined from five to nine percent. Similarly, indirect reforms declined 1.8 percent. Mortality was almost entirely unchanged in reform and non-reform states. KM conclude that liability reforms can reduce defensive medicine practices, given their results showed reforms reduced cost of care, while not adversely affecting outcomes.

KM's study has both strengths and weaknesses. Among the strengths are its assessment of effects of reforms on both cost and outcomes, national scope, and large sample size (200,000+ hospital admissions).[2] But there is a question whether the results from one set of medical conditions performed on elderly persons generalizes. While it is an important category of admissions, admission for AMI and IHD constitute only a small part of Medicare hospital admissions and Medicare hospital admissions constitute less than half of total hospital admissions to hospitals in the United States.

Recognizing this deficiency, in a later study Kessler and McClellan (1997) use national data to study effects of direct and indirect reforms. Using a national survey of physician data from the American Medical Association, the study focuses on effects of reforms on claims frequency and premiums, finding some evidence that direct reforms affected both but with a lag.[3] Further, they find that a variable for direct and indirect reforms reduced referrals for consultation and time

[2] KM admit that the elderly are less likely to file medical malpractice claims than others (United States General Accounting Office, 1993); however, as KM argue, results from analysis of a group that is not suit-prone provides a conservative estimate of the extent of defensive medicine.

[3] The lag may be relevant for claims frequency and premiums since there is a delay from the date of injury to the date the claims is filed and the constitutionality of some reforms may be subsequently challenged. However, practice patterns are likely to respond much more quickly to such statutory changes.

spent with patients. It is not clear that less record keeping and time spent with patients would be desired by most well-informed patients. With the limitations noted, the KM study does provide empirical evidence for positive defensive medicine in a much more rigorous fashion than the anecdotal accounts and the studies based on surveys of physician opinion.

The potential effect of the threat of liability may interact with how the physician is paid. For example, any deterrent benefit of liability may be greater under capitation since capitated providers have a greater incentive to reduce services for financial reasons independent of the threat of lawsuits. Perhaps facing the threat of lawsuits, physicians would be more reluctant to cut services. But, under fee-for-service, physicians may have strong incentive to provide tests and perform surgery. The threat of being sued may reinforce this incentive to provide services. However, there is no empirical evidence on this issue (Danzon, 1994).

Several studies have assessed the effect of the threat of medical malpractice lawsuits on the probability that a cesarean section was performed as opposed to a vaginal delivery. These studies are useful as birth injuries are a frequent allegation in medical malpractice suits, more frequent than suits involving failure to perform a cardiac procedure (Sloan et al., 1993). Results of these studies have been mixed. Using data from Florida, Sloan et al. (1997a) find no effect of malpractice pressures on the method of obstetrical delivery (cesarean versus vaginal delivery). However, an earlier study using data from New York State had found an effect (Localio et al., 1993). More recently, Dubay et al. (1999) used data from birth certificates, from 1990 through 1992, to assess the impact of medical malpractice risk on cesarean rates and infant health. They found that a $10,000 reduction in malpractice premiums could result in a 1.4–2.4 percent decline in the cesarean section rate for some mothers, except those of the highest socioeconomic status. The authors conclude that caps on total damages could reduce the number of cesarean sections by three percent and total obstetrical charges by 0.27 percent.

Viewed as a group, it is difficult to find evidence of a consistent link between the threat of tort liability and a reduction in medical

errors. There is some evidence for positive defensive medicine. However, the case that positive defensive medicine is a *major* factor driving up spending on personal health services, as is often alleged, is weak at best.

5.3.3 Empirical Evidence on Negative Defensive Medicine

Critics of medical malpractice as it exists today frequently allege that not only does the system not deter injuries, but both the threat of medical liability and rising premiums are making medical care less accessible. The critics, often representing the medical profession, argue that pro-defendant tort reform is needed to reduce both negative and positive defensive medicine.

Decreases in access under some circumstances may be welfare enhancing. Physicians who consistently commit errors and are found to be negligent should be identified and removed. In their absence, one would expect that more qualified physicians would fill their vacancies. This also applies to the provision of services; when care is below standard, the office, unit, or hospital should be closed. Cutbacks in service provision may sometimes be desirable. For example, there has been concern that rates of cesarean section are too high; some declines in these rates may be a welcome outcome. Low volume providers tend to provide lower quality care, holding other factors constant (Luft et al., 1979; Luft, 1980).

Negative defensive medicine could have undesirable consequences. However, the presumption of many advocates of tort reform that medical malpractice forces physicians out of practice is not supported by evidence. A study conducted in the 1980s revealed that physicians with adverse claims experience were less likely than others to make subsequent changes in their practices, such as quitting practice or moving to another state (Sloan et al., 1989). Also, the rate of actual sanctions was very low even though physicians with adverse claims histories were more likely to have complaints filed against them with the state's licensing board. While an adverse claims history does not necessarily imply poor quality of care, it would seem appropriate to examine practices of such physicians.

An increase in patient travel time is expected to the extent that hospitals are closing units at their facilities. Using hospital inpatient utilization data from Florida for the years 1997, 2000, and 2003, Dranove and Gron (2005) assess utilization of inpatient procedures in two high-risk specialties, obstetrics and neurosurgery. Between 2000 and 2003 — before and during the medical malpractice crisis in that state — travel time for craniotomies increased from 37 to 42 min from home to hospital. Travel time for high-risk obstetrical deliveries increased by less than 0.5 min on average.

Baicker and Chandra (2004) include several alternative measures in their study of physician supply. Measures of the threat of tort are premiums, frequency of paid claims, severity of paid claims, and the loading factor on medical malpractice insurance.[4] They find that the threat of medical malpractice suits has no effect on physician location.

Another study examines physician location patterns during 1985–2000 (Hellinger and Encinosa, 2003). Because limits on damages have been shown to be the most effective in terms of reducing medical malpractice payments and premiums, the study assessed the impact of dollar limits on damages in medical malpractice cases as the key variable explaining the geographic distribution of physicians. Hellinger and Encinosa (2003) reach two main conclusions. First, states with caps on non-monetary damages had about 12 percent more physicians than states without caps. Second, states with relatively high caps were less likely to experience an increase in numbers of physicians during the observational period than were states with lower caps.

5.3.4 Medical No-Fault in the United States

No-fault is for all practical purposes the only type of second-generation reform that has been implemented in the United States to date, albeit on a very limited basis. The first no-fault program in the United States was Virginia's Birth-Related Injury Fund (BIF) in 1988, followed by the 1989 establishment of the Florida Neurological Injury Compensation Association (NICA). The argument was that by improving access, one

[4] A loading factor represents a dollar amount added to the expected loss in arriving at a premium.

would be doing a lot for young, low-income families without focusing on the compensation aspect. The loss to families with children born with severe neurological impairments can be substantial and if litigation is pursued, these costs can be substantial as well (Sloan et al., 1993).

Both programs were established as true no-fault programs. However, criteria for coverage are so narrow that most birth-injured children are ineligible. Benefits are not scheduled, but determined on a case-specific basis by the agencies operating the no-fault programs. The expenses covered include medical, custodial, rehabilitative, and educational; payments for special vehicles and modifications to homes necessitated by care of the child are also eligible. The payments for covered expenses are given on a periodic basis and are paid at the time the expense is incurred.

BIF and NICA have many similarities; for one, they are both run by independent public governmental agencies. This is in contrast to motor vehicle no fault and workers' compensation for which the states set the framework, but private organizations operate the programs. NICA and BIF enroll so few injury victims, it is unlikely that private for-profit firms would have been interested in operating programs at such a small scale. In addition, the designers of both programs intended that no fault would totally replace tort for eligible cases. Even though applications for compensation are voluntary, neither program has actively sought out applicants in case finding. Since the programs rely on a narrow premium base, case finding would be disastrous to their finances. Though, compared to the tort system, overhead has been quite low (Sloan et al., 1997b). Of total BIF disbursements in 2001, administrative, financial service, and legal costs totaled nine percent.[5]

The primary goal of the no-fault concept is compensation of a broad range of injuries (see, e.g., Weiler et al., 1993). Despite this, the narrow criteria for eligibility meant that the no-fault assessments on physicians and hospitals were low. In Virginia, the first payment to a claimant did not occur until five years after the establishment of BIF. In BIF's first 15 years, 1987–2002, only 72 claimants received pay-

[5] Joint Legislative Audit and Review Commission of the Virginia General (2002, p. 9). In comparison, the tort system overhead is approximately 50 percent (Kakalik and Pace, 1986).

ment (Joint Legislative Audit and Review Commission of the Virginia General, 2002, p. 83). This may seem like a windfall to providers at first glance, but narrow eligibility criteria means there would not have been significant reduction in medical malpractice insurance losses and premiums either. The experience in Florida has been similar. Only "permanently and substantially mentally and physically" impaired infants weighing at least 2500 grams at birth are eligible for compensation under NICA. Until 2003, 161 claimants had been awarded compensation, fewer than 12 paid claims per year (State of Florida, 2003). Of these, the vast majority were for cerebral palsy, even though the statute does not restrict eligibility to those with this diagnosis (Freeman and Freeman, 1989). In 1990, an estimated 500 children in Florida and approximately half as many in Virginia were diagnosed with cerebral palsy at birth (Sloan et al., 1998). About two percent of children with cerebral palsy have been compensated by no-fault in Florida and Virginia. In both states, injuries attributable to "genetic" or "congenital" abnormalities are excluded. Injuries caused by "maternal substance abuse" are excluded in Virginia. The exclusions contribute to some of the discrepancy; nonetheless, the evidence appears to support the idea that these no-fault programs are underutilized. On the other hand, in a survey by Sloan et al. (1997b) families compensated by NICA indicated they were satisfied with most aspects of the medical no-fault program.

An advantage of the Virginia and Florida programs' small size appears to have been the ability to more closely individualize the management of benefits (Bovbjerg and Sloan, 1998, p. 112). The same would not be true for a larger, national no-fault program. In order for a national program to function efficiently, there would need to be formal rules and procedures to reach a similar level of performance.

A major strength of the programs is their ability to provide individualized compensation to families quickly and with less administrative cost than the tort system. But these programs did not serve the purpose intended by the programs' advocates. NICA did not succeed in averting a new malpractice crisis for Florida obstetricians after 2000.

Many of the goals of no-fault find no supporting evidence in the Virginia and Florida programs. First, the experiences of these programs

do not support the notion that a more general medical no-fault program would be less expensive than tort. It is true that operating on such small scales allows the use of informal procedures and a small staff. But if the programs were expanded to cover a less narrow set of injuries, administrative cost per accepted case would increase as more formal administrative procedures would be needed. Second, the assertion that no-fault can reduce tort claims frequency for covered injuries is not supported by the Florida experience, although there is some support for this in Virginia (Sloan et al., 1997b; 1998). The experience in Florida suggests that due to overly narrow definitions of covered injuries, lawyers had strong financial incentives to steer no-fault claims back to tort. As a result, the programs never became substitutes for tort. A desire for retribution may have also kept some cases in the tort system.

5.4 International Medical No-Fault Programs

Australia, New Zealand, Canada, and Sweden all have no-fault programs, but they differ from the programs in Florida and Virginia. In particular, the relative breadth of coverage and distribution of compensation varies considerably (Cohen and Korper, 1976; Palmer, 1979; Gellhorn, 1988, p. 1; Rosenthal, 1988). International medical no-fault programs typically include a wider range of benefits (e.g., such as special education services), but do restrict coverage eligibility to iatrogenic injuries rather than to acute and chronic medical conditions.

Sweden has received much recognition for the success of its patient injury compensation program. Formed in 1975, Sweden's No Fault Patient Insurance Scheme (NFPI) retained alternative remedies for injury victims; all of which function autonomously (Fallberg and Borgenhammar, 1997). The no-fault program, known as Patient Compensation Insurance (PCI), receives approximately 9000 claims per year, accounting for only 0.16 percent of personal health care expenditures. This compares favorably to U.S. medical malpractice insurance premiums, which consume one to two percent of total health care expenditures (Danzon, 1994). The costs of the system are internalized with

funding coming from levies on Swedish county councils that provide medical care (Danzon, 1994).

As in Florida and Virginia, only a small subset of injuries are eligible for compensation.[6] In its first two decades, 40 percent of the about 100,000 complaints resulted in compensation (Fallberg and Borgenhammar, 1997). In the mid 1970s, approximately 75 percent of claims received payment; during 1986–1991 this figure dropped to only 18 percent (Danzon, 1994). More recent estimates of compensation rates puts the figure at close to 50 percent of all claims, suggesting a reduction in barriers to payment, even so, a large percentage of claims, about 42 percent, are rejected outright (Danzon, 1994; Fallberg and Borgenhammar, 1997; Studdert and Brennan, 2001; Espersson, 2005). Claimants retain a limited right to appeal and may contest the rejection of his or her claim or the amount of compensation. Reasons for PCI's low overhead include the speed of the claims resolution process,[7] the ability to process claims with little attorney involvement, a fixed benefits schedule (Studdert and Brennan, 2001), and social insurance programs (Danzon, 1994).

The experience with medical no-fault in New Zealand is also instructive. In 1972, a broad and inclusive no-fault program was created. As in Sweden, the scope of covered injuries were substantially restricted.[8] During the reforms an element of fault was introduced which limited claims to injuries resulting from medical error or mishap, in effect removing the problem of having to distinguish between injuries resulting from medical care and unavoidable or inevitable injuries (Weiss, 2004).

Since its inception in 1972, New Zealand's no-fault program has been funded from levies on employers, motor vehicle owners and subsi-

[6] To be eligible, the claimant has to have been in the hospital for at least 10 days, been ill for at least 30 days, or have died (Danzon, 1994; Studdert and Brennan, 2001). In addition, the claimant must establish a causal relationship between the injury and the health care services received, based on a preponderance of probability (Espersson, 2000).

[7] From the time of filing a claim until its final determination is usually around six months (Studdert and Brennan, 2001).

[8] The time within which claims could be brought was shortened, lump sum payments for pain and suffering were eliminated, and a 14-day hospital stay or 28-day sick days were required (Studdert et al., 1997; Studdert and Brennan, 2001).

dies from the government, each of which was placed in a separate fund. The funding changed dramatically over the course of three decades; pay-as-you-go financing structure was established, a new levy for registered health professionals was created, seven separate funds administered by the ACC were formed, and the government retained the power to require risk rated premiums for health professionals (Flood, 2000; Weiss, 2004; Hitzhusen, 2005). Administrative costs, however, are still only 10 percent of total expense (Bismark and Paterson, 2006). Even with such small administrative costs, the overall costs of New Zealand's no-fault program have proven to be burdensome (Lowes, 2003).

Linking a national claims database from the ACC to records reviewed in the New Zealand Quality of Healthcare Study, Bismark and Paterson (2006) find that only three percent of eligible persons seek compensation in New Zealand. The small proportion of New Zealand claimants is very close to the proportion estimated to file tort claims for medical injury in tort systems in New York in the late 1980s and in Utah and Colorado in the late 1990s.

6

Tobacco Litigation

6.1 Rationale for Regulation of Tobacco Products

The economic rationale for tobacco litigation is threefold. The first relates to consumer misperceptions of the harms of smoking. If tobacco manufacturers have misrepresented the harms from consuming their product, *and* persons injured by smoking believed these claims, they are entitled to compensation for the losses they incurred. That smoking causes health harms is universally accepted today. However, if anything, the empirical evidence indicates that smokers as a group are not misinformed about the health risks of smoking (see Viscusi, 1990; 2002; Khwaja et al., in press).

Second, smoking imposes health and financial external costs on others. If smokers are not made to pay for the external costs they impose, consumption of the good is excessive. Payments made to society to reflect such external costs are shifted forward to consumers of tobacco products in the form of higher prices. Smoking imposes some external costs but the major costs of smoking are to the individual him or herself (Manning et al., 1989; Sloan et al., 2004b).

Third, for various reasons, including the political influence of tobacco manufacturers and sellers of tobacco products, governments

may be unable to provide effective regulatory oversight. Private action in the form of litigation is said to be needed because of the failure of governments to act. While the rationale for tobacco litigation remains controversial, measured in terms of both numbers of lawsuits and payments resulting from such litigation, tobacco torts grew appreciably starting in about the early 1990s, especially in the United States.

6.2 Latency of Tobacco-Related Injuries

The latent character of tobacco-related injury sets it apart from motor vehicle, dram shop, some injuries occurring as a result of medical treatment or from medical products, and industrial accidents. The harm from speeding, failure to monitor an intoxicated patron, a slip of the knife, and adverse side effects from many prescription drugs are either immediate or occur within a relatively short time span. Unlike the injuries resulting from auto accidents, medical malpractice,[1] or drunk drivers, the harm from tobacco consumption comes after many decades of use.

Similarly, injury from environmental tobacco smoke (ETS) is equally distant from the source. It is difficult to prove conclusively smoking or exposure to second hand smoke is the proximate cause of an injury. Most suits based on ETS claims are unsuccessful.[2] Using

[1] It is important to note that not all injuries from medical malpractice are immediate. Some injuries, although they may occur immediately, are not discovered for several years. States have enacted discovery rules to extend statute of limitations until it would have been reasonable for the patient to discover their injury. Many states also have statutes of repose which place a firm cap on the time in which a suit may be brought. For example, the statute of limitations may be three years for medical malpractice injuries or two years from when the injured discovers, or reasonably should have discovered, their injury. A statute of repose may require all medical malpractice suits be brought within ten years of the injury, regardless of the time of discovery. This provides some stability to the system and protects physicians from suits decades after the medical treatment.

[2] However, a class action suit by flight attendants on an ETS claim had some success. *Broin v. Philip Morris Cos.*, Inc., 641 So. 2d 888 (Fla. 3d DCA 1994). The suit was brought on behalf of 60,000 flight attendants in 1994, and the complaint alleged the tobacco companies were liable for injuries caused by ETS. The suit resulted in a settlement. Philip Morris agreed to fund a research foundation with $300 million and pay attorney's fees and a number of other concessions. These included waiving the statute of limitations for further suits and shifting the burden of proof on generic causation as to lung cancer, chronic obstructive pulmonary disease, chronic bronchitis, chronic sinusitis, and emphysema. Other concessions of note include providing a copy of the video of the trial, including expert testimony for use in individual lawsuits, and support Federal

different areas of law, ETS cases have resulted in plaintiffs' verdicts.[3] Even when causation can be proved, because of the substantial delays in the first appearance of personal injury, it is difficult to see how the threat of tobacco litigation can deter injury. Rather the goal is compensation for past harms and perhaps making a lesson out of tobacco manufacturers so that manufacturers of other products may take note.

In the other areas of litigation, the injury is often largely exogenous to the injury victim. Certainly this is the case for the injury victim run over by an intoxicated driver who had consumed excessive amounts of alcohol at a bar or a victim of medical practice which arises because the surgeon operated on the wrong organ. In tobacco litigation, the primary victim is the consumer of the product. In general, the doctrine of consumer sovereignty implies that consumers are best positioned to weigh the benefits and costs of consuming a product. However, many advocates of tobacco litigation argue that consumers of tobacco products are not well positioned to make rational consumption decisions about tobacco products.

6.3 Four Markets

The four-market construct also differs for tobacco litigation from the other applications. Here the consumer voluntarily consumes a product

legislation that would impose a smoking ban on all international flights. Soon after the settlement, flight attendants brought 3000 individual suits. Even though the burden of proof had been shifted, the plaintiff still needed to prove ETS was the cause of the alleged injury. As a result, almost all verdicts were for the defendant. Nevertheless, a suit in 2004 by an individual flight attendant was successful, and she recovered an award of $500,000. *Philip Morris Inc., v. French*, 897 So. 2d 480 (Fla. 3d DCA 2004). cert denied. While neither case involved a suit against a tobacco company, in both cases the court found ETS as the cause of death of the plaintiff.

[3] For instance, a teacher brought a worker's compensation claim for tonsil cancer he had developed from exposure to ETS at work. The court ruled his injury was a result of exposure to ETS and thus work related entitling him to worker's compensation benefits. *Magaw v. Middletown Board of Education*, 731 A.2d 1196 (Superior Court of New Jersey, Appellate Division 1999). In another case, a wrongful death action was brought under the liability provisions of the Warsaw Convention. The decedent was an asthmatic passenger on an international flight where he was seated three rows in front of the smoking section. After repeated requests to be moved to another seat were refused, the decedent inhaled significant amounts of second-hand smoke and died. The court found decedent's death was caused by the ETS, and the defendant airline was liable in the amount of $700,000. *Husain v. Olympic Airways*. 316 F.3d 829 (9th Cir. Cal. 2002).

that is harmful to his or her own health. Consumers do not exercise care to prevent an injury from occurring, quite the contrary. Thus, we substitute the term "the market for tobacco products" for "the injury prevention market." Suppliers of tobacco products sell a good to make profit, as in other markets. Yet, they may also be well-positioned to convey the harms of their products to consumers. In the context of tobacco litigation, there is essentially no market for third party insurance. No insurers that wanted to remain solvent would insure a loss for which risks are so highly unrelated. All relevant insurance is first party. Financial externalities may cause first party insurers to incur higher losses than they would in a world in which no tobacco products were consumed.

6.3.1 The Market for Tobacco Products

As in other markets, the market for tobacco products has both a supply and a demand side. Although most of the complexities are on the demand side, two issues on the supply side are pertinent to tobacco litigation. Confidential documents obtained as a result of tobacco litigation revealed an internal memo from a scientist at Lorillard documenting that studies of a cancer link were supported by just enough evidence to justify a presumption of a link although the author of the memo hedged his conclusion by stating that the link had not been established absolutely (Sloan et al., 2003). Internal memos, which were uncovered later at other companies, contained more definitive conclusions than this.

Regardless of regulations, cigarette manufacturers have advertised their products by creating an image desirable to its consumers. Admittedly, the same could be said about car advertisements which show drivers speeding around curves. These ads also suggest that the product has the capability of generating a lot of pleasure, and the adverse side effect of driving off a cliff is mentioned only in a fine print warning.

Although cigarette advertising may once have been provocative and certainly not factual, to place such advertising in context, at the same time, the popular media portrayed smoking as the thing to do.

As Rabin (1992, p. 855) notes, "Observers of popular culture remind us of the dramatic impact of cigarettes in the movies: Paul Hendreid, in *Now Voyager*, lighting two cigarettes at once to consummate his affair with Bette Davis; Lauren Bacall asking for a smoke, in *To Have and Have Not*, to ignite not just her cigarette but her larger-than-life romance with Humphrey Bogart; legions of *film noir* heroes lighting up the only companion that they could trust in a pinch."

The issue here is not whether the tobacco manufacturers had prior knowledge that their products were harmful. Rather the issue is whether the lack of information dissemination on the harms of smoking and some advertisements, which suggested that smoking is safe, such as "More doctors smoke Camels than any other cigarette," led to consumer underestimation of the health risks of smoking (Calfee, 1986). That tobacco manufacturers attempted to dupe consumers has been clearly established. However, that consumers believed the companies' claims is a far more questionable proposition.[4]

There are many reasons that people may engage in a behavior that is harmful to their personal health, which includes smoking. In general, according to the standard economic framework, consumption decisions are made by comparing benefits from an activity to its costs. In the context of smoking, the first gut response is that people smoke because they are addicted. While physiological addiction is undoubtedly a factor in continued smoking, about half of smokers do eventually quit (Sloan et al., 2004b).

[4] Explicit medical and dental endorsements like this one occurred as early as 1930 and continued until 1954, though the majority occurred during the 1930s and were relatively infrequent after 1940 (Ringold and Calfee, 1989). A key reason why these medical endorsements ceased is due to a U.S. Federal Trade Commission regulation adopted in 1955. This rule prohibits advertisements from implying that smoking is actually good for your health. The FTC adopted guidelines in 1955 prohibiting any reference to the presence or absence of a physical effect of smoking. However, the guidelines did not prohibit references to taste and pleasure. See Ringold and Calfee (1989) and Garner and Brandt (2006). In 1965 the U.S. Congress enacted a law requiring that advertisements be accompanied by a warning stating "cigarette smoking may be hazardous to your health" (Derthick, 2002). Later, in 1970, the Public Health Cigarette Smoking Act of 1969 became law in the United States. Among other things, it required a conspicuous warning label that states "the Surgeon General has determined that cigarette smoking is dangerous to your health." In addition, the act banned cigarette ads from television and radio. These strict governmental regulations on cigarette advertising control the allowable content and required warnings for advertisements.

As explained more fully below, with caveats noted there, the empirical evidence overall indicates that people do not continue to smoke because they misperceive the health risks of smoking. This is a weakness in the plaintiffs' cases against the tobacco companies.

6.3.2 Legal Market

In the United States, tobacco litigation has experienced approximately three upsurges; 1954–1973, 1983–1992, and 1994–present (Douglas et al., 2006). The first increase in litigation began when evidence suggesting a link between smoking cigarettes and cancer was first publicly disclosed in the popular media (Rabin, 1992). Suits during this time were brought under theories of fraud, breach of warranty — both implied and express, and negligence (Boulton, 1987). Tobacco companies defended many of these cases, with success, using contributory negligence and assumption of risk defenses. The tobacco companies were successful, in part, because science could not objectively prove tobacco caused illness or cancer. Perhaps more importantly, the companies had major resources that they could devote to defending their cases in comparison to the resources available to individual plaintiffs (Rabin, 1992; Haltom and McCann, 2004).

The second wave came during a time of substantial product liability litigation in the United States. Corporate liability had emerged as a means to hold the tobacco industry liable. Suits during this time were also brought under theories of public deception, failure to warn, and fraud. Many of the plaintiffs argued that cigarettes were unreasonably dangerous and advertising campaigns did not warn consumers of the dangers of cigarettes. Tobacco's defenders took an affirmative defense arguing any harms tobacco usage may foster — not cause — are well known and consumers have the ability to make informed decisions as to their tobacco use (Haltom and McCann, 2004). In the end, as in the first wave, the second wave of tobacco litigation failed to produce a single clear victory for plaintiffs.

Several prompting events led to the third and most recent wave of tobacco litigation. First, evidence of the tobacco industry's manipulation of nicotine content in cigarettes was made public (Douglas et al.,

2006).[5] It was during this time that the public costs of tobacco use were raised, both for third parties and also for the states. Second, beginning in the mid-1990s state attorney generals began filing suits against tobacco companies testing whether they had a legal right to be reimbursed for the health-related costs state programs incurred due to cigarette use. These suits resulted in a Master Settlement Agreement with a record setting damage payment. The cigarette industry settled these cases before encountering a single adverse jury verdict.

In fall of 1998 the major tobacco manufacturers and 46 state attorney generals settled all litigation filed by the states with the Master Settlement Agreement. The tobacco companies committed to pay 206 billion in damages over a 25 year period as well as an additional 11–38 billion[6] dollars in plaintiffs' attorneys' fees (Sloan et al., 2004b).

During the third wave of litigation, many plaintiffs rode on the coat tails of state settlements. From 1993 to 1998, 807 cases were pending against the tobacco industry. Of these, there were 55 class-action lawsuits, more than 600 individual claims, and claims from health care plans, governmental bodies, and Indian tribes (Haltom and McCann, 2004). It is important to note that the suits filed against the tobacco companies by individuals differed substantially from litigation filed by states. The primary difference was that not one state had smoked a single cigarette.

Although there are proponents of the view that tobacco manufacturers won some important battles in the Master Settlement Agreement,[7] the Master Settlement Agreement (MSA) represented a loss for the tobacco industry, and ultimately to smokers on whom the added cost was shifted. But it was a victory for the states who received the revenue; by contrast, the first two waves of tobacco litigation were a loss for plaintiffs. Before 1992, few cases made it to trial, and the cases that

[5] The U.S. Food and Drug Administration (FDA) revealed the fact that American manufacturers of cigarettes were manipulating nicotine levels with the aim of creating a perfect balance to addict consumers.

[6] The exact figure for the legal fees has not been made public, thus the range in figures. Data from 21 states obtained from a Freedom of Information Act request by the United States Chamber of Commerce places the figure at the lower end of the spectrum, 11 billion. Viscusi (2002).

[7] Such as a provision which allows reductions in payments if the market shares of the firms participating in the agreement declines (see, e.g., Cutler et al. (2002) and Dagan and White (2000) for criticisms of the anticompetitive agreement).

did make it to trial were met by jurors who consistently concluded the risks of cigarettes were well known and voluntarily incurred (Viscusi, 2002). The MSA led to predictions that it heralded the beginning of a series of government-initiated lawsuits to recover lost taxpayer funds from offending industries (Wood, 2003, p. 600).

6.3.3 Insurance Market

As mentioned above, no market for third-party insurance exists for losses incurred by defendants in tobacco litigation. However, the effect of smoking on first-party insurance is cited as a rationale for such litigation. Smoking has two external effects on parties other than the household to which the smoker belongs: health and financial. The financial costs occur because premiums for first-party insurance, especially group health and disability coverage, are not based on the individual policyholder's risk, but rather on the experience of the group. As a result, some part of the expense resulting from smoking-related illness falls on other group members.

6.3.4 Government Market

Government involvement in tobacco policy has a long history in the United States. During the late 1800s and early 1900s, several states enacted restrictions on use of tobacco products (Kagan and Vogel, 1993, p. 34). By 1909, as a result of pressure from antismoking organizations, 13 states had enacted such legislation (Gottsegen, 1940; Davidson, 1996). Reasons given for supporting such statutes were to (1) reduce the risk of fires, and (2) to improve public morality (Jacobson and Warner, 1999). Although charged with regulating the safety of food and drugs in general, the U.S. Food and Drug Administration has not been responsible for regulating tobacco products. The U.S. Federal Trade Commission, however, completed seven formal cease-and-desist order proceedings for medical or health claims against cigarette companies, including one against Brown and Williamson to prevent further claims that *Kool* cigarettes cured colds.

The role of government has changed substantially over the decades. During World War II, the U.S. government sold cigarettes to soldiers

at subsidized prices. More recently, the FTC has been involved in requiring and enforcing warning labels on cigarette packs. It has also been involved in some enforcement actions, the first being pursuant to the Comprehensive Smokeless Tobacco Act in 1992, a case in which the FTC alleged that Pinkerton Tobacco Company's *Red Man* brand name had appeared illegally on television. All U.S. states and the U.S. government levy an excise tax on tobacco products, but in widely varying amounts. Courts in the United States have played a limited role in reviewing challenges to tobacco control regulations (Jacobson and Warner, 1999).

Critics argue that governments' actions in regulating the harms of tobacco product have been insufficient, given that tobacco litigation plays a role both as a substitute for what has worked and a complement to governments' activities and hence acts as a stimulus to ensure that government stays active in this domain. The role of tort litigation as a complement or stimulus to promoting the public health seems to have more widespread support than does the role of tort as a substitute for other forms of government intervention.

Jacobson and Warner (1999) cite several advantages of tort over regulation, but one of the greatest advantages is to prod public policymakers into enacting and enforcing tobacco control laws and regulations. However, in other respects, courts, unlike public regulation, are unlikely to have positive effects on public health. For example, they are unlikely to require that manufacturers reduce nicotine levels in their products. The authors further expressed a fear that litigation could reduce governments' ability to raise excise taxes on cigarettes, a prediction, as seen below, that did not materialize. In the end, they see a role for public policymakers rather than for the judiciary in educating the public about health harms and requiring modifications in product to promote public health. Policy decisions in a democracy should be vested in organizations that are directly or indirectly accountable to the public. A final aspect is the cost of litigation, a concern that is shared across the political spectrum (Jacobson and Warner, 1999; Viscusi, 2002; Posner, 2003). This is probably the most substantial difference between tort in the form it has been applied to tobacco versus public regulation. In such private litigation, a substantial amount of

the payments goes to pay lawyers' fees. Regulators who abide by the law in the course of performing their duties are not enriched.

6.4 Empirical Evidence

6.4.1 Evolution of Empirical Evidence on the Health Harms of Smoking

Current, but not historical, evidence indicates that smoking is the world's leading cause of preventable premature deaths, making up 35–40 percent of all deaths annually in the United States (Sloan et al., 2004b) and with major health consequences in other countries of the world as well (McGinnis and Foege, 1993; Jha et al., 2006). Evidence on the harmful effects of tobacco use date back as early as 1900 when analysts of vital statistics noted an increase in cancer of the lung. Rather than represent conclusive evidence, the finding in 1900 was an important starting point for studies on the relationship of smoking with cancer, cardiovascular disease, and diseases of the lower respiratory tract (United States Surgeon General, 1964). By 1939, there were 29 retrospective studies of lung cancer alone. A few decades later, during 1952–1956, several studies were published, drawing widespread attention to the issue (United States Surgeon General, 1964). The studies were also accompanied by criticism, skepticism, and counterattacks, especially from those with a financial stake in the sale of tobacco products.

In 1956, a scientific study group comprised of the U.S. National Cancer Institute, the National Heart Institute, the American Cancer Society, and the American Heart Association, released a report, which appraised 16 independent studies from five countries. This group concluded that there was a causal relationship between excessive smoking and lung cancer (United States Surgeon General, 1964). As a result of this report, the United States Surgeon General (1964, p. 7) issued a statement the following year stating, "The Public Health Service feels the weight of the evidence is increasingly pointing in one direction; that excessive smoking is one of the causative factors in lung cancer."

In 1964, two years after the Royal College of Physicians in the United Kingdom published the first official report specifying the

dangers of smoking, the United States Surgeon General (1964, p. v) commissioned a working group to evaluate and review new and old data in order to reach "definitive conclusions on the relationship between smoking and health in general." Among other findings, the committee reported a 70 percent higher death rate for cigarette smokers than for non-smokers (United States Surgeon General, 1964).

In a follow-up study of more than 30,000 male British physicians (the British Doctor's Study), Doll, Peto, and Wheatley report that mortality rates were twice as high for smokers who had continued to smoke from the baseline date in 1951–1994 as compared to persons who had never smoked (Doll et al., 2004). Smoking increased the probability of death threefold at ages 35–69 for men born in the 1920s (Doll et al., 2004). A similar study of female British physicians found the rates of mortality from lung cancer, chronic bronchitis, and emphysema is roughly the same for the female physicians.

To be liable under the negligence rule, tobacco consumption must have caused adverse health, which it does, the manufacturers must have failed to release information about health consequences of smoking, which they did, and the failure to release such information caused more people to smoke more than they otherwise would have smoked. It is the last link in this chain that is the most controversial. On the one hand, people start smoking when the information about smoking's harms is widespread. Many people who may have been duped or started smoking for some other reason have long since quit or died (Sloan et al., 2003). On the other hand, perhaps a subset of smokers were duped many years ago, and are so physiologically addicted that they are literally *Dying to Quit* (Brigham, 1998). The strict liability rule under which products liability cases are often filed does not require failure to exercise due care, but rather evidence that harm occurred as a result of the use or consumption of a defective product. This clearly occurred.

6.4.2 Why People Smoke

Benefits from smoking have not been quantified. Although difficult to quantify, it seems likely that smokers derive various benefits from

consuming tobacco products, including enjoyment, stress relief, social interactions with other smokers, and so on.

The issue most closely related to tobacco litigation is that smokers misperceive the health risks of smoking. The first of these potential explanations was first investigated by Kip Viscusi (1993) and results of his work and others are discussed in detail in a book by Viscusi (2002). Some of the evidence is based on these questions: (1) "Among 100 smokers, how many of them do you think will get lung cancer because they smoke?" and (2) "Among 100 smokers, how many of them do you think will die from lung cancer, heart disease, throat cancer, and all other illnesses because they smoke" Although smokers tended to give lower probabilities to adverse health outcomes from smoking than did non-smokers, even the estimates for smokers were far in excess of the objective probabilities of harm calculated from epidemiological data.

Viscusi's research has been subjected to a substantial amount of criticism. One of the alleged shortcomings was said to be that the questions Viscusi analyzed were phrased in the third- rather than the second-person. The critics argue that smokers may believe that smoking is harmful in general, but not to them personally. However, questions phrased in the second person yield similar patterns as those phrased in the third person (Khwaja et al., 2007b). Smokers now know that smoking is harmful to one's health. One could argue that although people now know that smoking is bad for them, when many persons started the habit, in particular mature adults, the harms were less widely disseminated. And now they are hooked; at least some smokers face substantial quitting costs.

Using data from the Health and Retirement Study, Khwaja et al. (2007b) assess the accuracy of subjective beliefs about mortality and objectively estimated probabilities for individuals in the *same* sample in contrast to earlier studies that compared subjective beliefs about mortality from one survey with evidence from other samples, e.g., standard life tables. Overall, Khwaja and colleagues find subjective beliefs and objective probabilities to be very close. For the sample as a whole, which includes current, former, and never smokers, the mean difference between the subjective and objective probability of dying 10 years after the subjective beliefs were elicited from respondents is 0.004, which is

not statistically different from zero. On average, the difference in hazards among current smokers is −0.015, which is statistically different from zero. Thus, current smokers tend to be optimistic about their survival. For former smokers, the difference between subjective and objective hazards on average is 0.006, which is not statistically significant. For never smokers, on average, the difference is 0.016, which is statistically significant, implying that such persons tend to be pessimistic. There are differences conditional on behaviors, with current smokers being relatively optimistic and never smokers relatively pessimistic in their assessments, which may be attributable to: (1) overestimation of widely publicized low-probability risks, and/or (2) Bayesian learning in which individuals rationally underpredict high and overpredict low probability events when learning is partial.

Should the finding that current smokers are somewhat overoptimistic about their longevity be taken as evidence that people smoked toward the end of the 20th century because they were convinced by cigarette manufacturers several decades earlier that smoking is not harmful to one's health? At best, optimism would be a secondary or tertiary factor in smoking among persons who in Khwaja et al.'s analysis were in their 50s and 60s in 1992. Although statistically significant, the difference between the subjective and objective hazards is small. We recognize that one could argue that the smokers who believed the manufacturers' claims had died of smoking-related diseases by 1992, but there is no empirical support for this speculation. And as of 1992, current smokers clearly assessed their longevity to be lower, holding other factors constant, than did former or never smokers. Another possibility is that people were duped by the manufacturers, started smoking, become addicted, and then learned that smoking is harmful, but then did not quit because of the high quitting cost. This is a possibility, but again, there is no empirical evidence to support this speculation.

Other reasons people may smoke is that the full price of tobacco consumption, which includes losses associated with mortality, morbidity, and disability are lower for smokers than for others. This possibility is explored by Khwaja et al. (2007c), who find that smokers attach a lower value to avoiding a major smoking-related disease, Chronic

Obstructive Pulmonary Disease (COPD) than do others. According to this reasoning, whatever the benefits, if the costs are relatively low for certain group of individuals, they will be more likely to engage in this activity. One likely objection to this finding is that smokers are worse in gauging the utility loss of being in the sick state than are others. While this is possible, there are no data to either confirm or refute this type of criticism. An empirical test would presumably require longitudinal data on individuals with questions asking both before and after a person acquires an illness.

Or smokers could be more present-oriented than others. Some have argued that smokers are hyperbolic discounters. That is, in comparing benefits from smoking today with future costs brought to present value today, smokers apply a higher discount rate than they do to the costs brought to present value tomorrow. We have all heard people say, "I'll quit smoking tomorrow," or, "I'll start dieting tomorrow. That dessert looks awfully good." In essence, the benefit of that apple pie is in the here and now. One's waistline will not expand immediately. This will start occurring tomorrow and the next day. But today's discount rate applied to these future costs is high, giving little influence to future costs in present choices. Tomorrow, I will also enjoy the apple pie, but tomorrow I will also apply a lower discount rate to future physical appearance and health and costs. Since the discount rate is in the denominator, discounted future costs are larger tomorrow than they are today and thus weigh more heavily on smoking and apple pie decisions today than they do tomorrow.

A well-cited paper by Gruber and Köszegi (2001) investigates theoretical issues as they apply to hyperbolic discounting among smokers. Empirically, the authors conclude that people are forward-looking in their cigarette consumption decisions but they do not perform any conclusive empirical tests of the hyperbolic discounting hypothesis as it applies to smoking. More recently, Khwaja et al. (2007a) investigate whether or not (1) smokers are more present-oriented than others, and (2) whether or not adults, including smokers, are hyperbolic discounters. On the first issue, the authors do find that smokers have shorter financial planning horizons than do other adults. But they do not find that smokers have higher subjective rates of discount. On the latter,

based on a formal test, they find no empirical evidence of hyperbolic discounting.

6.4.3 External Cost of Smoking

The basis for state suits against the tobacco industry was the health care costs incurred by the states from smoking-related illnesses. The state governments alleged that smoking had resulted in additional costs to their Medicaid programs, which was borne by taxpayers and they sued to recover this amount. Analysis was conducted for the state of Massachusetts by Cutler et al. (2000). In subsequent analysis on Massachusetts, Cutler et al. (2002) concluded that the far more substantial effect of the MSA was on the longevity benefits of reduced smoking due to higher prices of cigarettes which resulted from the damages tobacco manufacturers paid to states pursuant to the MSA. Such savings in health costs accrue almost entirely to persons who smoked before the MSA was reached. These are internal and not external costs.

Whether or not savings in internal costs should be considered a benefit is controversial. Under the doctrine of consumer sovereignty, people are expected to bear the costs which result from the consumption decisions they make. On the other hand, if assumptions underlying the doctrine of consumer sovereignty are violated, for example, if people are inconsistent in their consumption decisions, then there is a case for counting reductions in internal costs as a benefit of tort or regulatory interventions in general (see, e.g., Gruber and Köszegi, 2001).

Other researchers have investigated the cost of smoking, both as it pertains to the MSA and more generally. Viscusi (2002) and others have pointed out that the relevant framework for analysis of cost of a harmful behavior is longitudinal, not cross-sectional of which the research on Massachusetts is only one of many examples. From a financial standpoint, it is important to consider that while conditional on being alive, medical expenditures are higher as a consequence of a person smoking, but smokers die earlier. Thus, the pool of persons subject to Medicaid coverage is reduced by smoking. Viscusi's (2002) analysis has been subject to attack on grounds that killing off people can hardly

be viewed as a benefit, and it has been questioned by legal scholars as well (see, e.g., Dagan and White, 2000; Posner, 2003).

From a financial standpoint, Viscusi's argument, which generalizes well beyond Medicaid to Medicare, Social Security, and private defined-benefit pensions, to name the most important ones, is correct. What is relevant is the effect of a policy on the present value of future cash flows. And future cash flows will be appreciably affected by individuals' longevity, among other factors.

Reflecting his argument that the shorter longevity of smokers generates savings for the public sector, Viscusi (2002) reports that smokers generate savings to the state and federal governments. More specifically, he finds that smokers generate a net savings of 46–53 cents per pack for the federal government, and between 8–9 cents per pack for states (Sloan et al., 2004b).

Sloan et al. (2004b) study the cost of smoking, but their study is more general, namely to quantify the costs of smoking to smokers — internal costs — the cost of a person smoking to others in his or her household, which they term "quasi-external costs," and external costs. The notion of quasi-external costs is controversial. Historically, economists have viewed the household as a single decision making unit. But over time, families have become much less permanent. Thus, the cost of illness to a spouse resulting from secondary smoke may not be borne by the spouse who smokes. For reasons briefly stated above, the authors use a longitudinal rather than a cross-sectional approach. They quantify internal, quasi-external, and external costs from a person who smokes at age 24. They select the age of 24 because this is above the age of initial youthful experimentation with smoking, and very few persons initiate the smoking habit beyond this age. In their analysis, they consider the probabilities of a person aged 24 living to each age, the probabilities at quitting smoking at each age, as well as the probabilities of becoming disabled.

They find that the cost of a 24-year old smoking is $39.66 pack in 2000 U.S. dollars. Internal, quasi-external, and external costs per pack are $32.78, $5.44, and $1.44, respectively, which confirms the conclusion of others (see, e.g., Cutler, 2000; 2002) that the major portion of cost is the internal cost.

The external cost is most directly pertinent to analysis of the MSA. Exclusive of federal and state excise taxes on cigarettes, which are treated as a cost offset, the external cost per pack of cigarettes is $2.20. The $1.44 represents external cost not covered by payments by smokers in the form of excise taxes on cigarettes. Interestingly, medical care cost attributable to smoking but not borne by the smoker or the smoker's family is $0.49 per pack. This is about equal to the payment per pack by cigarette manufacturers participating in the MSA. The $0.49 includes all medical expenditures attributable to smoking, which are external to the smoker's household, not just for Medicaid. Judged in these terms, the MSA was a very good deal for the states. That is, if anything, the states and more generally taxpayers in the states were overcompensated by the MSA.

6.4.4 Effects of the Master Settlement Agreement

The Master Settlement Agreement between major tobacco companies and the state attorneys general in November 1998 resulted in an immediate increase in cigarette prices of 43.5 cents per pack, or nearly 20 percent of the pre-settlement price, and the price continued to rise for the next two years. This price rise reduced smoking rates by 13 percent among youths and by five percent among adults. However, smoking by pregnant women fell by less than three percent in response to the price hike (Sloan et al., 2004a).

Trogdon and Sloan (2006) study the impact of the MSA on excise taxes on cigarette taxes set by the states. As noted above, there was some concern that the MSA would reduce state excise taxes below what they would have been in the absence of the MSA. This is disturbing to the extent that the external cost of smoking per pack net of excess taxes is well above a $1.00. Consideration of the MSA would bring the external cost net of such taxes down to about a $1.00, suggesting that there was ample room for increases in excise taxes on cigarettes. Using a difference-in-difference approach, with excise taxes on beer as a control group, they conclude that the MSA increased excise taxes by about $0.10 a pack post MSA. They argue that the MSA and publicity accompanying the release of documents from the manufacturers and conduct

admitted by executives of tobacco companies during testimony weakened the manufacturers politically and reduced their political power in opposing increases in taxes on their products. In the end, however, it is the smoker, not the tobacco company, on whom the incidence of higher cigarette taxes and damage payments falls (Sumner, 1981; Merriman, 1994; Barnett et al., 1995; Dahiya and Yermack, 2003; Sloan and Trogdon, 2006). So in the end, it is the smoker who is being asked to cover more of the external costs smoking generates.

7

Litigation Involving Pharmaceutical, Medical Device, and Vaccine Manufacturers

7.1 Rationale

Except for over-the-counter drugs, which are not part of this review, and vaccines, which are often offered in settings with only general medical oversight, use of pharmaceutical, medical device, and some vaccine products is conditional on having an authorization by a physician. Thus, the thrust of these manufacturers' marketing efforts traditionally has been to physicians.

Prescribing is based in part on the physician's experience with the product (see, e.g., Crawford and Shum, 2005). Pharmaceuticals, in particular, are experience goods that both the physician and individual patient experience (e.g., presence or lack of adverse side effects). Many outcomes, however, are quite rare and may be difficult to distinguish from outcomes other than from use of the product. This is due in part to the fact that outcomes often manifest years after the product is first consumed. In contrast, high levels of alcohol consumption result in outcomes, i.e., accidents, that occur quite soon after consumption. In some applications, for example, a vaccine to prevent disease following an attack with a biologic weapon, or following an onset of severe

heart irregularity in a person with ischemic heart disease, it will be too late to gauge whether or not the vaccine or device is effective after such attacks occur. Thus, there are limits to which reliance for quality assurance can be based on prior experience. At a minimum, there is much than can be gained from collective learning rather than learning on an individual basis. For these reasons, there is a case for pre-market regulation and disclosure after the products are marketed.

An important question is whether or not firms would voluntarily engage in optimal amounts of testing for safety and efficacy pre-market and disclose an optimal amount of information post-market (after the good is offered for sale) absent regulatory interventions and tort liability. Both public regulation and tort are resource using. So for regulation and tort to be welfare-improving, there must be benefits such as these.

The issues for an individual profit-maximizing firm are not trivial. For one, learning in a few instances that a drug has resulted in a specific adverse side effect, does not necessarily imply that the side effect was due to the drug. Alerting consumers at the first indication of an adverse side effect may cause users who might benefit from the product to discontinue use. The resources needed to assure a device failure rate of zero might require such a high investment that there would be little or no demand for the product. As prices rise, there is a loss in consumer surplus.

The goal of public intervention and the rationale for tort is to make for more pre-market testing and post-market monitoring than would occur in its absence. Whether or not these policies result in too much testing and monitoring with the result that product launches are delayed unnecessarily, product innovation is reduced, and product prices are higher than they would be with the socially optimal amounts of testing and monitoring are important, but unresolved issues.

7.2 Background: Regulation of Pharmaceuticals, Medical Devices, and Vaccines in the United States

7.2.1 Pharmaceuticals

Pharmaceuticals are highly regulated by the U.S. Food and Drug Administration (FDA). While the FDA engages in post-marketing

surveillance, pharmaceutical regulation tends to focus on determining the safety and efficacy of pharmaceutical products before a product is marketed. Tort liability's focus, by contrast, is the post-market entry phase.

FDA's authority to regulate pharmaceuticals stems from the Pure Food and Drug Act of 1906, which was created to ensure drugs in interstate commerce were safe, unadulterated and accurately labeled (Dorfman et al., 2006). The Act of 1906 was amended on three separate occasions to increase the authority of the FDA, 1938, 1963, and in 1997 (Dorfman et al., 2006). The FDA is responsible for evaluating safety and efficacy of pharmaceuticals before market entry, approving drug labeling, and monitoring drug safety after approval. In order to obtain FDA approval, drug manufacturers need to engage in a lengthy and costly process of testing the safety and efficacy of the drug (DiMasi et al., 2003). In contrast to tort, in which private parties bring claims, the FDA is a public agency subject to public oversight and political pressures from a variety of stakeholders.

7.2.2 Medical Devices

The FDA also regulates medical devices, though the FDA did not have the authority to do so until the 1938 Food, Drug, and Cosmetics Act. Even then, regulation was limited to adulterated or misbranded devices. Over time, the FDA's responsibility in regulating medical devices has increased. In 1962, the FDA's authority was expanded to create a requirement of pre-market approval from the FDA (Monsein, 1997). In 1976, the FDA was authorized to categorize devices, and created two types of pre-marketing procedures, pre-market approval, and pre-market notification (Monsein, 1997). In 1990, the FDA received stronger authority to monitor products, and in 1992, the FDA received enforcement authority for post-market surveillance (Monsein, 1997). The FDA may order manufacturers to conduct post-market surveillance studies and has the discretion to order manufacturers of devices to track medical device performance at the individual patient level.

7.2.3 Vaccines

In contrast to pharmaceuticals and medical devices, vaccines are biologics. Vaccines are produced from or use living cells and organisms and complex growth materials obtained from living sources. For this reason, FDA regulation extends to oversight of the process of vaccine production. This has added another layer of regulation, which manufacturers often describe as onerous. Over time, substantial shifts have occurred in both the interpretation and enforcement of federal regulations (Institute of Medicine, 2004, pp. 126–127). As explained below, the United States has operated a no-fault program for vaccines since the mid-1980s.

7.3 Four Markets

7.3.1 Injury Precaution Market

In addition to the manufactured product, sellers provide two goods in varying combinations — compensation in the event an injury involving use of the product occurs and additional safeguards which reduce the probability of an injury occurring. Following Miceli (2004), which draws on earlier literature (e.g., Spence, 1977; Polinsky and Shavell, 1984), first consider compensation with the probability of injury fixed at a value p. Then it is easily shown that the output of the manufactured product is independent of whether the firm is not subject to liability in the event of an accident — no liability or it is responsible — strict liability. However, the product price differs by the amount of compensation per unit of output the firm expects to pay to injury victims. Consumers are willing to pay this amount extra for the good since they correctly anticipate how much compensation they will receive if injured. Thus, under such circumstances, the choice of no liability versus strict liability is irrelevant.

Alternatively, the manufacturer can alter the good so as to reduce the probability of an injury occurring from use of the product. Consumers perceive that the product is safer and thus are willing to pay extra for the product. Equilibrium output occurs at the level at which consumer marginal willingness to pay equals the marginal cost of

producing the good. Again, the equilibrium output is the same whether or not the companies are subject to a no liability or a strict liability rule. The only difference is that under strict liability, the product price is higher, reflecting expected injury compensation per unit of output.

In the above analysis, consumers are able to value quality of the product at the time it is purchased. If, however, there are consumer misperceptions of the probability of injury associated with the product, the above analysis breaks down. Under no liability, if consumers overestimate (underestimate) the probability of a mishap, equilibrium output of the good will be lower (higher) than is socially optimal. However, under strict liability, consumer misperceptions do not result in output being different from the optimal level since the consumer internalizes damages through the market price. This assumes that the manufacturer does not misperceive the probability of injury which reflects the amount of care embedded in the product. The general rule is the party which more accurately perceives risk should bear liability. In the unlikely case that consumers are better informed than manufacturers, a no liability rule is the right one and conversely if manufacturers are better informed than are consumers. In this case, the strict liability rule is the appropriate one.

7.3.2 The Legal Market

In the United States, state law governs products liability suits. Although laws vary by state, the ways in which manufacturers can be held liable are similar across states. Most suits against pharmaceutical companies are brought under defect theories. There are three types of defect liability: manufacturing defect; design defect; and warning defect. A manufacturing defect occurs when a product does not comply with manufacturers' standards and causes injury; products with a design defect cause injuries even when manufactured according to standards; a warning defect exists when the instructions or warnings accompanying the product are inadequate and cause injury (Garber, 1993). Most often, claimants use a warning defect theory to argue the drug in question is "unreasonably dangerous as marketed" due to inadequate warnings (U.S. Office of Technology Assessment, 1993).

Manufacturing defects typically result in strict liability. This means the manufacturer is held liable for the harms caused by the product no matter how much care was taken during manufacturing to make the product safe. This type of defect is not as common with pharmaceuticals, but is used frequently with medical devices. Design defects can also result in strict liability, but this theory is used relatively infrequently. To encourage and sustain pharmaceutical innovation and development in the face of litigation, an exemption was made from strict liability in product liability cases. Under the Second Restatement on Torts, comment k, prescription drugs are under an exemption from strict liability so long as the products are "properly prepared and accompanied by proper directions and warnings."[1] Despite this exemption, courts have nonetheless used strict liability in some pharmaceutical cases.

With comment k providing a wide exemption, the most prevalent theory for liability is the warning defect. Using a negligence standard, the manufacturer is liable for failing to warn of risks of which they knew or should have known (Garber, 1993). Historically, pharmaceutical companies were only responsible for warning physicians, who are considered "learned intermediaries," and not responsible for providing warnings directly to the consumer.

The reasoning underlying the learned intermediary rule is threefold. First, physicians are better positioned to inform patients of the risks of a particular drug than is a manufacturer. Second, some courts see warnings directly to consumers as intrusive on the physician patient relationship. Finally, manufacturers do not have an efficient way of communicating the risks of a drug to patients (Mello et al., 2003a).

[1] Restatement (Second) of Torts, S 402 A, comment K. It states in relevant part,

> *Unavoidably unsafe products.* There are some products which, in the present stage of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs ... Such a product, properly prepared, and accompanied by proper direction and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines and the like (Garber, 1993).

However, as direct-to-consumer advertising becomes more prevalent, this duty to warn has evolved.[2]

The Supreme Court in New Jersey tackled the application of the learned intermediary to warning defect cases in 1999.[3] The court held that the justifications for the learned intermediary rule did not apply to direct to consumer advertising. Pharmaceutical companies had assumed a role where they were able to effectively communicate the risks of a product without interfering in the physician patient relationship (Mello et al., 2003a).

After a court determines that the manufacturer can be held liable for the product, they must determine whether the drug caused the injury. Causation, as we have seen, tends to be difficult to prove and often is the one element lacking in a tort case. The tobacco companies rested on the lack of evidence to prove causation for most of the litigation they faced. The standard for creating a causal connection between injury, scientific evidence, and a pharmaceutical product differs enormously between science and the law. As a result, pharmaceutical products face the threat of litigation, sometimes based on uncertain or questionable scientific support. When strict liability does not apply, courts apply the preponderance of the evidence standard, which is simply more than 50 percent probability the drug and injury are causally related, typically proven through the testimony of expert witnesses (Goldberg, 1999). Compare this to the medical standard requiring a 95 percent probability of connection that must be proved through medical evidence published in peer reviewed publications.

The precedent setting case, *Daubert v. Merrell Dow Pharmaceuticals*, attempted to distinguish between scientific evidence and "junk evidence" by setting four requirements for determining whether testimony of a scientific theory is reliable.[4] While the *Daubert* case only

[2] Amidst controversy, direct-to-consumer advertising began in the 1980s in the United States. Since that time, the practice has grown considerably with mixed views by health professionals. Regulated by the FDA, direct to consumer advertising changes the way patients receive information about prescription drugs.

[3] *Perez v. Wyeth Laboratories, Inc.*, 734 A2d 1245 (NJ 1999).

[4] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); the four standards are (1) its ability to be falsified; (2) its established or potential error rate; (3) its history of peer review; and (4) its general acceptance in the scientific community.

binds federal courts and has been criticized by scholars, many states have modeled rules of evidence around the decision. In addition, the standard continues to be that judges play a major role as "gate keepers" in determining the reliability of a scientific theory (Damiani, 2003).

7.3.3 The Insurance Market

The principal type of insurance for businesses in the United States is commercial liability insurance. There are often upper limits on payments per claim which are far smaller than the exposures to which major manufacturers are often subject.

It is unknown to what extent pharmaceutical, medical device, and vaccine manufacturers carry commercial insurance to cover the costs of litigation (Garber, 1993). A survey conducted by the U.S. Office of Technology Assessment (1993) indicated that most pharmaceutical firms could not obtain insurance coverage in the traditional liability insurance market. Those that could obtain coverage faced higher deductibles and premiums and upper limits on payments per claim. As a result, pharmaceutical manufacturers frequently self-insured or sought special coverage (Viscusi, 1991). Ways of self-insuring for loss include establishing special lines of credit to cover unanticipated liability, creating "captive" insurance companies that are owned by the insured pharmaceutical company, and transferring some of the liability risk to insurance companies created in consortia with other pharmaceutical manufacturers. Even when insurance is provided through captive insurers, it is likely that reinsurance is purchased to cover particularly large losses.

Abraham (2001; 2002) discusses problems with commercial liability coverage for the types of liability risks that large manufacturers face. In particular, the long claims tail — the time from the policy year for which insurance is sold and the time claims are paid are a benefit to insurers in that there is time for income to earned on premium income. However, the downside is that a long claims tail make predicting future losses more difficult, and insurers may be expected to charge a risk premium to compensate them for bearing this extra

risk. Even worse, insurers diversify away risk by pooling independent risks. However, risks in mass tort are not independent. Thus, for self-preservation, insurers have to charge higher premiums and/or higher deductibles, called "self-insured retentions," have more exclusions from coverage (e.g., limits on the difference on date of occurrence of an injury and claim filing in claims made policies), and limits on paid loss per injury and per policyholder. Reinsurance provides a mechanism for risk sharing, but at a considerable cost to the primary insurer or self-insured entity.[5]

7.3.4 The Government Market

States have developed their case law and enacted statutes regarding products liability. The U.S. Congress has not successfully enacted any type of legislation regarding products liability. Thus product liability laws are governed by state statutes. The 101st Congress considered "The Product Liability Reform Act" which would have barred punitive damages for drugs or medical devices receiving FDA approval (U.S. Office of Technology Assessment, 1993). An exception to this bar would have existed only if the manufacturer withheld or misrepresented information to the FDA.

More recently, there has been a push for federal preemption of state product liability laws. Some states such as Arizona[6] and Ohio[7] have already enacted statutes that do not allow manufacturers of pharmaceuticals to be held liable for punitive damages so long as the drug is labeled and sold in accordance with its FDA approval (O'Steen and O'Steen, 2006). The FDA has expanded its authority for the regulation of labeling of prescription drugs by introducing a rule that preempts state law allowing claims based on failure to warn (O'Steen and O'Steen, 2006; U.S. Department of Health and Human Services, 2006).

[5] On corporate demand for reinsurance, see, e.g., Cole and McCullough (2006).
[6] Ariz. Rev. Stat. Ann. § 12-701 (2007).
[7] Ohio Rev. Code Ann. § 2307.80(C)(1) (2006).

7.4 Empirical Evidence: Case Studies

A complete history of litigation involving pharmaceutical, medical device, and vaccine manufacturers is beyond the scope of this paper; however, a brief review of several notable products liability cases is instructive. Dalkon Shield, Bendectin, Diethylstilbestrol (DES), silicone breast implants, and Vioxx are just a few pharmaceutical products that have faced mass litigation, either in the form of private suits, class actions, or both. Table 7.1 presents a summary of the cases we discuss.

7.4.1 The Dalkon Shield

The Dalkon Shield, manufactured by A. H. Robins, was an inter-uterine device (IUD) marketed for birth control in the 1970s.[8] The FDA categorized the Dalkon Shield as a "device" not a "drug," thus the company was not required at the time to submit to the same rigorous testing as drugs for FDA approval (Zimmer, 1996). As a result of the less rigorous testing, the Dalkon Shield became one of the largest mass tort actions in this country, involving over 195,000 claimants (Zimmer, 1996). The exact number of users is unknown, but it may be as high as five million women (Bacigal, 1990). The company used marketing that was misleading and sometimes false; advertisements claimed a virtually 100 percent effectiveness in preventing pregnancies, however clinical studies had placed the failure rate at close to 5.5 percent (Bacigal, 1990). The Dalkon Corporation faced public opposition from physicians questioning its safety and efficacy shortly after its introduction to the market. However, with no follow up from the FDA, the Shield stayed on the market until 1975 when the company abandoned plans of re-marketing the device due to the mounting lawsuits against the company.

After years of litigation, A. H. Robins entered into bankruptcy — resulting in the sale of the company to American Home Products.

[8] Unlike other IUDs on the market, the Dalkon Shield contained a multifilament string for removal. This string allowed wicking of bacteria from the vagina into the uterus, a normally sterile organ. Consequences of the Dalkon Shield's poor design were pelvic inflammatory disease (PID), spontaneous septic abortions, infertility and birth defects.

Table 7.1 Brief description of important medical product liability cases.

Drug name	FDA approval	Number of lawsuits filed[a]	Removal of product from market	Compensation victims received[b]
Dalkon shield	1971	195,000	Withdrawn in 1975	Over $2.3 billion
Bendectin	1956	2100	Withdrawn in 1983	None
Diethylstilbestrol	1947	1000+	FDA issued Bulletin urging doctors to cease prescribing DES to pregnant women in 1971	Over $2 billion
Silicone breast implants	1962	20,000–30,000 individual and 400 class action suits	Voluntary moratorium in 1992, moratorium lifted in 2006	Settlement for $4 billion over 30 years
Vioxx	1999	10,000 individual and 190 class action suits	Withdrawn in 2004	n/a

[a]Estimated.
[b]This includes both verdicts at trial and out of court settlements.

Proceeds from this sale went directly into a trust set up to compensate claimants, the Dalkon Trust, initial funding totaled approximately $2.25 billion.[9] The trust also received funding from A. H. Robins' insurer, Aetna, and both the chairman and president of A. H. Robins paid $5 million each into the trust (Vairo, 2004). Because the trust offered a less expensive alternative to litigation, many women took advantage of this option. In fact, the Trust was able to resolve over 99 percent of its claims without litigation or formal arbitration (Vairo, 2004). The efficiency of the Trust allowed 300,000 claims to be resolved in less than 10 years (Vairo, 2004). The Dalkon Trust was terminated in 2000 after paying all claims and the bulk of the fund distributed. The Trust efficiently handled the thousands of claims, but the impact on A. H. Robins and IUD usage in the United States has been long lasting.

Evidence of the Dalkon Shield's effect can be seen with the Copper-7, another IUD. The Copper-7 was determined by the FDA to be a drug because of its copper-releasing characteristic and unlike the Dalkon Shield, was required to perform clinical and animal studies to demonstrate its safety and efficacy. The manufacturer provided safety and efficacy data from over 16,000 women over a span of 10 years. Despite the lack of evidence connecting the IUD to pelvic inflammatory disease (PID) and the continued endorsement by the FDA, the World Health Organization (WHO), Planned Parenthood, the American College of Obstetrics/Gynecology, and the Population Council, the Copper-7 became subject to heavy litigation (Zimmer, 1996). Soon after the litigation began, the manufacturer took the product off the market. A major cause of their decision to remove Copper-7 from the market was they had spent $1.5 million defending themselves against four lawsuits brought during the course of one year. After all was said

[9] To avoid liability, many women's claims for compensation were challenged based on a link between the newly discovered Chlamydia and PID. The sexual history of many women was paraded before juries and often women were forced to take a mandatory Chlamydia test. A trust was seen by many women as the only means to preserving their privacy. However, there are many accounts of the process being as adversarial as trial. This was due partially to the fact the trust was run by many of the same attorneys who represented A. H. Robins prior to their bankruptcy.

and done, 2000 suits were brought against the company and litigation costs exceeded $130 million, a number far outweighing Copper-7's profits of less than $80 million (Zimmer, 1996; Segal, 1999).

IUDs in general are more effective than the pill and are currently the world's most popular form of reversible birth control. However, less than 1 percent of women in the United States who use medical contraception choose the IUD, compared with 40 percent of women in other countries (Zimmer, 1996). Besides diminishing the availability of IUDs in the United States, the Dalkon Shield litigation influenced contraceptive research. In 1970 there were nine firms that engaged in contraceptive research, by 1987, that number had dropped down to one (Shulman and Lasagna, 1989). Presently, of the 20 largest pharmaceutical companies in the world, only two have made serious commitments to developing new contraceptives, Wyeth and Ortho, a branch of Johnson & Johnson (Holden, 2002). Other companies that are involved with contraceptive devices are working on modification of existing devices rather than developing new products.

Products liability insurance premiums also affect the number of manufacturers engaged in research and development in the contraceptive field. For an uncertain reason, liability premiums are higher for contraceptive products. Certainly, the Dalkon Shield disaster affected the insurance premiums for contraceptive products. In this case, tort had a twofold effect. With the Dalkon Shield, tort allowed victims to be compensated for their injuries caused by the device. In addition, tort, not government intervention, was responsible for removing a hazardous drug that had gone through the regulatory approval process. On the other hand, the effects of the Dalkon Shield litigation caused intrauterine devices to be virtually eliminated from the marketplace. IUDs such as the Copper-7 were forced off the market despite worldwide popularity, backing from several major health agencies, and studies validating its efficacy and safety. Whether the science was there to back up the suit or not, the costs of litigation can be devastating for a company. In addition, pharmaceutical companies and their insurers are now more reluctant to enter into contraceptive R&D, which directly and negatively impacts the public health of women in the United States.

7.4.2 Bendectin

Bendectin was a drug marketed to pregnant women to treat morning sickness, introduced by Merrell Dow in 1956. Allegations of birth defects resulted in 2100 lawsuits, and costs associated with defending the case led Merrell Dow to agree to a class action settlement of $120 million (Jacobi, 2005). In 1983, production was stopped worldwide due to negative media, legal costs and insurance premiums (Ornstein et al., 1995). As with the Dalkon Shield, Bendectin was never banned from sale in any country, and the FDA did not order its removal from the market; rather, the manufacturer withdrew the drug voluntarily because of liability issues.[10]

The $120 million settlement occurred despite the fact that both the FDA and the scientific community failed to find a connection between Bendectin and fetal deformity.[11] In fact, consensus among teratologists[12] is that Bendectin was one of the best-studied drugs of all time for use during pregnancy, and the evidence demonstrates the risk of harmful effects on a developing fetus is very small (Ornstein et al., 1995). Nevertheless, the inability to find a connection between the alleged harm and the pharmaceutical product is a recurring theme for many pharmaceutical lawsuits.

[10] The FDA reported in 1999, "The Food and Drug Administration has determined that the drug product Bendectin ... for the prevention of nausea during pregnancy was not withdrawn from sale for reasons of safety or effectiveness" (Brent, 2003).

[11] Jacobi (2005). As Sanders notes, there has been little scientific disagreement about Bendectin since 1984. He quotes the testimony of a court-appointed expert in the DePyper case who was discussing a symposium on Bendectin at an annual meeting of the Teratology society,

> Q: And please tell us what occurred at that time?
> A: There was a symposium held concerning the data about Bendectin's teratogenicity and then there was to be a debate.
> Q: Was there such a debate?
> A: No
> Q: Why not?
> A: After the data were presented there was no one willing to stand up and defend the opposite that was that Bendectin was a human teratogen. (Sanders, 1998)

[12] Teratology is the branch of biology concerned with the development of malformations or serious deviations from the normal type of organism.

As with the Copper-7, tort caused the removal of an effective product from the market without a clear medical or scientific basis. The removal of Bendectin, some would argue, has greatly affected the health of pregnant women. Because of Bendectin's removal from the market, the number of pregnant women admitted to the hospital for severe nausea and vomiting in the United States has doubled.[13] Bendectin was the most studied antiemetic on the market, so its removal created a gap in treatment for pregnant women with severe nausea. Doctors are now forced to either not treat nausea with pharmaceuticals or use antiemetics such as dimenhydrinate (Gravol) that have not been adequately studied (Ornstein et al., 1995).

7.4.3 Diethylstilbestrol (DES)

DES is a synthetic estrogen used by millions of pregnant women in the 1950's and 1960's to prevent miscarriages. It was approved for treatment of vaginitis, menstrual bleeding, and menopause in 1941. Six years later, the FDA approved its use to aid in the prevention of miscarriages. In 1952, DES was no longer considered a "new drug" under the terms of the Food, Drug, and Cosmetic Act and as a result, manufacturers did not have to submit data concerning its safety and effectiveness (Ference, 1998). Between 3 and 6 million mothers took DES during pregnancy, exposing 1.5 to 3 million daughters in utero (Siegler et al., 1987). In a 1971 Drug Bulletin issued by the U.S. FDA (1972), physicians were warned about the adverse reactions from DES that had been noted in several studies. Most notably, a study was published in the *New England Journal of Medicine* which confirmed a link between the drug, adenocarcinoma, a rare form of vaginal cancer, and the daughters of DES users who had been exposed to the drug in utero (Ference, 1998). The FDA also changed labeling of DES to include a warning of its link to cancer in the offspring of users. Since the time the bulletin was issued, the drug

[13] Ornstein et al. (1995). However, anecdotal evidence suggests 25–33 percent of obstetrician's recommend a "Bendectin cocktail" for patients suffering from severe morning sickness. The "cocktail" can be created with readily available over the counter ingredients (Green, 1996).

has been linked to breast cancer, immune disorders, bone loss, cervical dysplasia, adenosis, and infertility. In addition, the sons of DES users have an increased risk of testicular cancer. Newer research links genetic deformities, cerebral palsy, and brain damage to DES exposed grandchildren.

As can be expected, thousands of women filed lawsuits against DES manufacturers. However, due to the latent nature of the tort, many statute of limitations barred claims and several manufacturers no longer existed.[14] Congress, and several states extended the statute of limitations for DES claims to address the problem caused by the extended latent period.[15] The problem of identifying the manufacturer of the drug was even more difficult. Hundreds of manufacturers made DES during its 20-year span on the market, some of whom had long since stopped manufacture of DES. Courts addressed the problem of unidentifiable defendants in various ways. Some dismissed claims for failing to identify the proper defendant while others allowed alternative theories of liability. For example, the concerted action theory holds all defendants jointly and severally liable so long as they participated in a common plan or design to commit a tortious act (Ference, 1998). Another widely used approach was the "market share" liability theory. Liability is assigned based on the defendant manufacturer's percentage of the market. With this approach, the costs of DES are shifted from the innocent plaintiff to the manufacturer who reaped profit from the unsafe pharmaceutical. Enterprise liability was also used.

Many manufacturers of DES did not go into bankruptcy as a result of litigation, but they continue to face liability issues. Manufacturers are now facing third-generation DES claims. These suits are based on preconception injuries sustained as a direct consequence of their mothers' exposure to DES. One plaintiff also has alleged that DES causes genetic mutation that leads to cancer in third generations (Mascaro,

[14] Many of the daughters of DES users did not develop health problems until they reached puberty or later — which could be more than 20 years after their mothers used the drug.

[15] Congress revived time barred DES claims for one year. California, Florida, and New York were among the courts that instituted a discovery rule to allow access for DES plaintiffs (see Ference, 1998).

1995). Several courts have drawn a line of liability and disallowed recovery for grandchildren of DES users.[16]

The adverse effects of DES are still being felt as is evidenced by the lawsuits of third generations. The product was on the market for 30 years before the FDA issued a Bulletin urging doctors to cease prescribing DES to pregnant women and then only after a study published in the New England Journal established a link between DES and increased risk of cancer. It is not clear tort played a major role in the removal of the drug from the market, but it is clear tort has allowed victims to be compensated for their injuries.

7.4.4 Silicone Breast Implants

During the early 1990s, the FDA asked manufacturers to halt the sale of silicone breast implants voluntarily. A few months after this request, Dow Corning stopped manufacturing of the product. In 1995, Dow Corning filed for bankruptcy protection because of the "potentially enormous financial and management drain" of the implant litigation. This came only one year after implant makers and plaintiffs agreed to create a settlement fund that would pay $4 billion over 30 years to women claiming they were injured. Suits brought against manufacturers were based on several liability theories; defective product design, inadequate product warning, manufacturing defect, failure to warn, strict liability, and breach of warranty.

As with Bendectin, studies have failed to provide a conclusive link between breast implants and any type of disease including cancer and autoimmune diseases (Hedén et al., 2006). The Institute of Medicine (2000) issued a report that found no link between silicone implants and systemic neurological or connective-tissue diseases (Rundle and Mathews, 2006). The IOM report did conclude there was cause for concern about complications such as infections, scar tissue, and leaking. Nevertheless, the lack of direct evidence connecting implants with disease

[16] *Grover v. Eli Lilly & Co.* (1992) 63 Ohio St. 3d 756, 591 N.E.2d 696. See also *Enright v. Eli Lilly & Co.* (1991) 77 N.Y.2d 377, 570 N.E.2d 198; *DeMayo v. Schmitt*, No. 625, 1989 Phila. Cty. Rptr. LEXIS 73.

led the FDA to lift the 14-year ban in November of 2006 (Rundle and Mathews, 2006).

Breast implants differ in a fundamental way from other pharmaceutical products and medical devices subject to litigation. Despite concerns regarding safety, there has been a continued demand for silicone implants. Some plastic surgeons say they have a waiting list of women who want silicone implants (Rundle and Mathews, 2006). Also, the European market for silicone implants has remained strong, 90 percent of all implant sales are silicone. Demand has had a positive impact on innovation. Despite lawsuits that caused many companies to go out of business or declare bankruptcy, other companies have actively been developing new silicone implants. The fact that Allergan Inc. and Mentor Corp. were ready to ship a fourth generation silicone implant as soon as there was FDA approval is evidence of this.

7.4.5 Vioxx

An example where the FDA's post marketing surveillance failed to protect the public health is with Vioxx. The drug, manufactured by Merck, went through the lengthy FDA approval process. After three phases of clinical trials and approval by the FDA, Vioxx was heavily marketed, and became popular for treating osteoarthritis. Vioxx was touted as the only Cox-2 inhibitor that reduced stomach irritation and lowered the risk of ulcers (Rubenstein and Mathews, 2007). Over the course of five years, 105 million prescriptions were filled in the United States (Thomas, 2006). In 2000, the results of a study known as VIGOR (Vioxx Gastrointestinal Outcomes Research Study) were published in the *New England Journal of Medicine* in 2000. The study confirmed there were fewer gastrointestinal complications than standard non-steroidal anti-inflammatory drugs, e.g., naproxen, but it also revealed that patients using Vioxx had four times as many myocardial infarctions as those using naproxen (Waxman, 2005). After release of another study demonstrating a twofold increase in cardiovascular events in a double-blind, randomized trial, lawsuits were filed, and Merck took the product off the market in 2004.

In this case, tort served as a mechanism to question the post-market safety and efficacy of a FDA approved pharmaceutical. While the FDA had continued post-marketing surveillance of the product and requested labeling changes advising consumers of the risk, the FDA did not require Merck to withdraw Vioxx from the market, but actually voted in February of 2005 to allow Merck to resume sales of Vioxx, one year after Merck had pulled the drug due to litigation (O'Steen and O'Steen, 2006).

As of the middle of the first decade of the 21st century, there were 10,000 cases and 190 class action lawsuits pending (Smith, 2006). It is unclear the amount of damages that would be paid to plaintiffs as most of the cases are pending, but litigation cost estimates were $10–15 billion (Horton, 2004). Despite the steep litigation costs, Merck continued research and development on another Cox-2 inhibitor called Arcoxia. Merck is forging ahead with Arcoxia because they see an unmet need for arthritis suffers (Rubenstein and Mathews, 2007). In this case, the cost of liability insurance and litigation are outweighed by the potential profit from this drug.

7.5 Medical No-Fault for Vaccines

During the early 1980s, vaccine manufacturers began to face increasing numbers of lawsuits from injury victims seeking damages (Evans, 1998). Between 1980 and 1984, injury victims sought $3.5 billion in damages, causing six of the eight manufacturers of the diphtheria-tetanus-pertussis (DTP) vaccine to leave the market (Cantor, 1995). Many of those manufacturers claimed product liability insurance was unavailable, and they could not bear the possible costs from litigation. With the flight of manufacturers from the vaccine market, there was only a six month supply of several vaccines for the United States during 1986 (Damiani, 2003).

The largest experiment with medical no-fault and the only such national program in the United States is the National Childhood Vaccine Injury Act of 1986 (VICP). Its creation was an attempt by Congress to control the vaccine supply problems resulting from tort claims and compensate injuries associated with routinely administered

childhood vaccines (Lloyd-Puryear et al., 1998). While the Act allows plaintiffs to sue manufacturers under state products liability laws, Congress limited the theories of recovery for those who choose to forego the VICP.[17] In addition, the Act creates a presumption that so long as a manufacturer's warning complies with FDA standards, state courts are prohibited from performing an independent assessment (Cantor, 1995). The U.S. Department of Health and Human Services (DHHS), the U.S. Court of Federal Claims, and the U.S. Department of Justice (DOJ) jointly administer the VICP. All vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children are covered under the program.[18]

The claims process begins with a petition to the U.S. Court of Federal Claims where a physician at the Division of Vaccine Injury Compensation reviews the information and makes a recommendation to the U.S. Department of Justice.[19] There are three ways a claimant can qualify for compensation from the VICP: (1) the injured person received a vaccine listed on the Vaccine Injury Table and the first symptom of the injury/condition on the Table occurred within the period listed in the Table; or (2) by proving that the vaccine caused the condition; or (3) by proving the vaccine aggravated a condition pre-existing before the vaccine was administered.[20] A claimant may take the case to tort if their case is found to be ineligible by the VICP. However, if the claimant accepts payment from VICP, s/he is barred from the tort system.

The Vaccine Injury Compensation Program has been well utilized; by August of 2007, 12,302 claims had been filed with VICP since 1989. Of these, 2082 were compensable, 4551 were dismissed, and the rest were pending.[21] The number of claims per year varied widely among states as did the number of claims filed for the United States as a whole.

[17] Cantor (1995). Comment K of the Second Restatement of Torts also applies.

[18] http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm Influenza and Hepatitis A vaccines have recently been added to the program as well.

[19] A "special master" oversees a hearing deciding compensation; the amount of the award is determined in a separate hearing. This decision can be appealed first to the Federal Claims court and if still dissatisfied, the plaintiff can take their case to the Federal Circuit Court of Appeals.

[20] http://www.hrsa.gov/vaccinecompensation/filing_claim.htm#types.

[21] http://www.hrsa.gov/vaccinecompensation/statistics_report.htm#post_2.

For the fiscal year 2007,[22] there were $78.2 million in total awards, excluding attorney's fees. Compensation is drawn from a trust fund composed of a $0.75[23] excise tax on each vaccine sold, as of January 2007, the balance of this fund was over $2.5 billion (Division of Vaccine Injury Compensation, 2006).

There are issues regarding how safety concerns are being communicated to vaccine manufacturers and what they are actually doing about them. There is evidence that VICP has, along with other policies, increased incentives for vaccine innovation. The VICP has been a demand-side pull for vaccine R&D by stabilizing the costs of product liability (Finkelstein, 2004). During much of the time since implementation, VCIP seems to have ensured a steady supply of vaccines by halting the exit of vaccine manufacturers. The most striking evidence of the VICP's success in this way is the sharp rise of vaccine-related lawsuits peaking in 1986 at about 250 that year and then just as dramatically declining after the start of the program to level off since 1990 (Evans, 1998). Vaccine-related lawsuits also stopped leading to large-scale press coverage. Nonetheless, perhaps for other reasons, vaccine manufacturers have continued to exit the industry and periodic supply shortfalls have continued to occur.

However, if manufacturers do not think they could gain coverage under VICP, vaccines may be delayed in R&D. The hepatitis A virus vaccine and trivalent influenza virus vaccines have been added to the VICP in an attempt to address this problem (Evans, 1998, p. 8). Also, it has been suggested that VICP be extended to cover vaccines in clinical trials (Advisory Commission on Childhood Vaccines, 2004). The question remains, has the no-fault program led to less deterrence of injuries by the vaccine manufacturers? Despite being administered to such large percentages of the population, vaccine-related injuries and deaths are extremely rare. Nevertheless, it is difficult to know what safety precautions might exist in the absence of the no-fault program. Would there

[22] Petitions are not typically adjudicated the same fiscal year as they are filed; it takes on average 2–3 years.

[23] The excise tax on vaccines is $0.75, however, the Department of Treasury authorized a rule wherein only 75 percent of this amount is deposited in the trust fund, and thus the true amount deposited in the fund is $0.56 per vaccine sold.

be genetic screening of persons prior to vaccination to determine who would be among the unlucky few to have a serious reaction such as anaphylaxis?

A potential shortcoming of any non-universal no-fault program appears to be that since attorney compensation and client awards are potentially large in the tort system and almost always limited in a no-fault program, there are incentives to find a loophole, which permits the case to be tried in tort. A source of ambiguity in VICP is whether vaccine preservatives fall under the jurisdiction of the program. This ambiguity has been used by lawyers to enable them to bring cases involving vaccines containing thimerasol to the tort system.

Thimerosal is a mercury-containing preservative once used in most vaccines and still used in some vaccines and pharmaceuticals. Thimerasol was not explicitly covered under VICP. In 1999, researchers at the FDA showed that it was possible for infants to be exposed to ethylmercury in levels exceeding federal safety guidelines for the ingestion of methylmercury from the cumulative effect of vaccine doses on the CDC recommended immunization schedule.[24] Currently, all recommended childhood immunization vaccines in the United States are available free of thimerosal, though it is still used internationally.[25]

As of the middle of the first decade of the 21st century, the VICP had not yet compensated a single autism/thimerosal case, yet they are continuing to receive hundreds of petitions a year. During the discovery phase of the proceedings, respondents have produced 92,268 documents related to thimerasol. The petitions appear to be leveling off, but additional funding was needed to process the increase in petitions.[26] Beginning in 2001, claimants began taking their thimerosal claims straight to tort; 375 law-

[24] Ball et al. (2001). Thimerosal in the body is metabolized into ethylmercury. Note that there are no federal safety guidelines for ethylmercury, only for methylmercury, however, both are known to be nephro- and neuro-toxicants at high doses (U.S. Environmental Protection Agency, 1997).

[25] http://www.fda.gov/cber/vaccine/thimerosal.htm#t1.

[26] Since 1996, the appropriations necessary to staff the VICP program have stayed flat. However, the President's Budget for FY 2005 sought an increase of $2,305,000 (50% of the past appropriations) to handle the growth in vaccine injury claims caused by thimerosal-related claims (Keisler, 2004).

suits have been brought in more than 22 states on behalf of 2300 individual plaintiffs (Klein and Helms, 2006). One class-action suit against a manufacturer filed on behalf of 175 million people, sought 30 billion in remedies (Klein and Helms, 2006). Vaccine manufacturers have spent more than 200 million defending these lawsuits (Klein and Helms, 2006). The thimerasol/autism claims have continued despite the fact that the IOM issued a final report in 2004 concluding that there is no connection between thimerasol and autism (Institute of Medicine, 2004).

There is the issue of causation in general and in the specific case of the injured individual. Much of the debate on thimerasol has centered on different degrees and definitions of causation. Legal causation is different from scientific causation so the question is presented whether merely "plausible" or "credible" biological mechanisms must be demonstrated or if epidemiological studies are necessary. Often medical and scientific experts are brought in to testify in these cases, yet much of their testimony has been rejected or given little consideration by the "special masters" who decide these cases. They have preferred to rely on the Institute of Medicine reports or on broader legal notions of causation and on a "preponderance of evidence" rather than more limiting legal criteria. This has led some scholars to note that the program has become essentially "no proof of causation" instead of the "no proof of negligence" program that it was intended to be, initially.

A similar problem has arisen with the birth injury no-fault programs in Florida and Virginia. The connection between the performance of C-sections and children subsequently developing cerebral palsy has been debated.

The crux of the issue seems to be that vaccine no-fault has worked because of lenient rules for establishing causation, as those rules become less lenient, there becomes a greater incentive to circumvent the program and bring cases back into the tort system. One important question for anyone designing a medical no-fault program is if "special masters" and the associated Injury Tables can be established for all other classes of medical conditions in a way that does not leave open this opportunity to chip away at the borders of the criteria.

7.6 International Experience

Products liability litigation exists in the United States at a much higher rate than any other country. During the late 1980s, there were 70,000 product liability lawsuits annually in the United States but only 200 in the United Kingdom (Segal, 1999). This figure can be misleading as it does not include claims filed prior to litigation. In the United States, claims are typically settled after litigation is initiated whereas in other countries claims are settled before litigation; this may give a falsely elevated statistic in the United States (Reimann, 2003). Even so, products liability appears to be less frequent outside the United States. Between 1945 and 1994 Japan had 200 reported product liability judgments, including appeals (Reimann, 2003). Other countries echo this sentiment; an Australian report suggests "modest" amounts of products liability cases and a South African Report suggests products liability cases are "very rare" (Reimann, 2003).

Rates of recovery are considerably different in foreign countries, partially because pecuniary damages must be clearly documented and pain and suffering are not well compensated, if at all. In addition, the United States is the only country where a plaintiff can recover more than $300,000 for non-pecuniary damages.

7.7 Empirical Evidence: Consumer Risk Perceptions, Static and Dynamic Efficiency

7.7.1 Risk Perceptions of Consumers

To our knowledge, there are no specific studies of consumer risk perceptions for specific products that have been involved in pharmaceutical, medical device, and vaccine litigation although misperception of risk on the part of consumers provides the strongest rationale for imposing strict liability on manufacturers of medical products.

In an earlier study comparing actual number of deaths per year to estimated number of deaths per year owing to various causes, lay persons tended to overestimate the probability of low-risk events and underestimate the probabilities of high-risk ones (Lichtenstein et al., 1978). Respondents overestimated the frequency of such rare causes of

death as tornados, botulism, and floods, and underestimated probabilities of getting cancer, heart disease, and diabetes. The objective probabilities of injury from most medical products is quite low, much lower than for motor vehicle crashes due to excessive alcohol consumption, mortality and morbidity from smoking, and even mishaps arising from many surgical procedures.

One reason that people overestimate very small probabilities is simply for cognitive reasons. It is difficult for many people to work with very small probabilities. Furthermore, publicity about illness and injury in the media can lead to people overstating small probabilities of such adverse outcomes (Combs and Slovic, 1979; Johnson and Tversky, 1983).

7.7.2 Effect of Products Liability on Quantity of Product Demanded

To the extent that individuals overestimate the probabilities of low probability events occurring, one would expect that this would lead to higher demand for precautions embodied in the goods and higher demand for insurance for injuries incurred in the course of consuming the good. However, Manning reports no rightward shift in the demand curve for vaccines as products liability litigation became more frequent in the United States, implying that people do not value having insurance bundled with vaccine (Manning, 1996). At least at first glance, it would appear that if people overestimated the probability of getting a disease, they would overvalue, not undervalue having insurance in the bundle.

It is possible that consumers value insurance protection for adverse effects of the vaccines, but they believe that obtaining compensation from a large corporation in the event of an injury would be costly. By contrast, compensation in money or in kind provided through a new car warranty or third-party motor vehicle insurance for bodily injuries. Also, they may realize that defendants can be judgment proof if they are subjected to much litigation. In the end, these considerations lend support to Manning's statement that products liability is an inefficient form of insurance for losses from product-related injuries.

7.7.3 Effect of Products Liability on Product Prices

As indicated above, imposing liability on manufacturers should increase price, but the price increase should reflect the added commitment of resources to product quality improvement and the additional cost of the obligation to compensate persons injured by the use of the product. However, Manning documents two disconcerting consequences of the growth of strict liability in the market for diphtheria-pertussis-tetinus (DPT) vaccine: (1) prices of DPT vaccine rose much more than could be attributed to the growth of product liability claims; and (2) introduction of VCIP did not result in a decrease in the price of DPT vaccine (Manning, 1994). He explains the second consequence partly as response to the excise tax that the VCIP imposed on manufacturers for vaccines covered by the program and partly because manufacturers may have reasoned that VCIP would be subject to legal challenges. His time series only includes the first two years VCIP was in effect.

Some overshifting of the cost of compensating injury victims and defending tort claims can be anticipated. For one, there is empirical evidence that excise taxes are overshifted (Sumner, 1981; Merriman, 1994; Barnett et al., 1995), possibly because competitors recognize that all firms will be increasing the price in response to an increase in a factor price that they all face. The bundled product includes insurance coverage for future claims resulting from the date of the vaccination. That is, it is an occurrence insurance policy. Insurance pricing is inherently forward-looking and depends on future claims rather than those being filed at the time the vaccine is administered. As a hedge against the uncertainty of future claims, the manufacturer may be expected to increase vaccine prices more than it otherwise would.

Manning compares prescription drug prices in Canada versus the United States (Manning, 1997). Among many other things, the legal climate in Canada differs substantially from that of the United States. Canadians do not enjoy a right to trial by jury in civil cases, punitive damages are rarer, contingent fees are not used, and damages, both punitive and compensatory, are set by the judge (Manning, 1997). A more hostile litigation environment, such as that of the United States, may create additional effort by a manufacturer to reduce liability, such

as more careful marketing, packaging, or the discontinuation of products that could be subject to litigation.

Manning reports that, controlling for regulatory and market factors, the remaining differences between the United States and Canada in prices of the 121 of the 200 most commonly prescribed drugs in the United States are attributable to liability cost anticipated by manufacturers; moreover, the effect of liability cost on prices is large. A more recent well-controlled study of differences in biopharmaceutical prices in nine countries, including the United States, finds that prices for identical formulations are not higher on average in the United States than in the other countries on average (Danzon and Furukawa, 2006). This raises the possibility that a study with a direct comparison of products sold in the United States and Canada may have yielded findings different from Manning's (1997). However, as the authors of the nine-country study caution, their results may not apply to non-biologic pharmaceuticals. Thus, at least for now, Manning's results serve as a warning that imposing liability on these medical products is likely to have had substantial inflationary effects on drug prices.

7.7.4 Dynamic Efficiency: Effect of Product Liability on Rates of Product Innovation

Dynamic efficiency refers to the optimal allocation of resources over time. In this context, dynamic efficiency calls for an investment in research and development at a level in which the marginal willingness to pay for new technology equals the marginal cost of such investments. Although manufacturers assert that liability is a major deterrent to innovation, empirical support for this assertion is lacking. As we have seen, silicone breast implants and the development of Arcoxia are products companies have determined the profits are outweighed by the cost of product liability insurance and litigation.

7.7.5 Does Tort More Effectively Promote the Public Health than Does Public Regulation?

The FDA faces a huge workload and must operate with marginal funding. These factors make it easy to foresee how details in the drug

approval process can be overlooked. In part, tort serves to regulate the safety of medical devices and pharmaceuticals where regulation has failed. As we have seen, tort has caused the withdrawal of harmful, e.g., the Dalkon Shield and DES, as well as beneficial drugs, e.g., Bendectin and the Copper-7. Regardless of whether or not a drug or device pulled from the market is indeed associated with the alleged harm, the safety of that product is reconsidered by regulatory agencies, the public and medical professionals.

For example, while it is still not entirely clear how related Vioxx is to cardiovascular events, its successor, Arcoxia, will no doubt be subject to more public and regulatory scrutiny. Physician and public awareness is heightened and the FDA will require more clinical evidence of its safety before approving the drug for sale in the United States (Rubenstein and Mathews, 2007). The problem lies when beneficial drugs are withdrawn, their safety is established, but manufacturers believe the risk of liability outweighs the potential profit. This directly, and negatively, affects the public health when another pharmaceutical product does not fill the treatment gap caused by the removal of a drug. In this sense, tort decreases the public's health.

On the other hand, without government intervention and regulation, vaccine supply and R&D would have continued to dwindle due to the costs of litigation and anticipated litigation. The VICP is by no means a perfect system and will face increasing challenges in the future, but it has provided manufacturers enough assurance they will not face unreasonable amounts of liability for them to continue production of necessary vaccines.

8

Workers' Compensation

8.1 Rationale

Accidents and illnesses associated with work are common, and were especially common when attention was initially drawn to this issue in the 19th century (see, e.g., Witt, 2001). However, to the extent that workers are paid a compensating wage differential that offsets the disutility of any job-related risk to health and longevity above some very minimal probability, and that wage differential suffices to make the employee as well off as when working at a very low risk job without the wage differential, there is no reason, at least on grounds of efficiency, for government intervention in the transaction between the employer and the employee.

There is a rationale for public intervention on efficiency grounds if (1) employees underestimate the probability of being injured or acquiring a job-related illness (2) the cost to employees of obtaining information on job-related risk *ex ante* is substantial, and/or (3) labor markets are not competitive, i.e., employers have monopsony power. Aside from considerations of efficiency, these reasons also provide a rationale for government intervention on equity grounds.

For about a century, workers' compensation in the United States has offered an administrative alternative to tort. No longer does the injury victim need to prove fault, but rather, s/he only needs to prove causation; i.e., that the injury resulted from work related activities (Viscusi, 1989). Workers' compensation regulation is in the state domain, with the exception of a federal law for federal employees. Though there are variations, workers' compensation laws shift liability to the employer, who is then responsible for the injured worker's medical expenses and some of his or her lost wages. This shift occurs regardless of the cause of injury as long as it happened out of and in the course of employment (Ruser, 1985).

The workers' compensation administrative system has not supplanted product liability suits against manufacturers of products used in course of employment. However, employers cannot be named as co-defendants in such lawsuits.

8.2 Four Markets

8.2.1 Injury Precaution Market

The risk of illness or injury is one determinant of wages. To the extent that some jobs are riskier than others is reflected in compensating wage differentials. In a study using data from 1977 to 1982, Moore and Viscusi (1990) document these cost offsets. They also find that the offsets diminish as benefits increase, which implies that high levels of mandated benefits may not be completely offset by reductions in other components of employers wage bills. Higher benefit levels, especially if the added cost is not shifted backward to employees, give employers an added incentive to invest in job safety. At some benefit level, benefit mandates may result in employers over-investing in job safety.

However, if job risks are underestimated by workers *ex ante*, employers' investment in job safety may be suboptimal, justifying imposition of liability on employers or a mandatory compensation scheme to indemnify workers in the event of work-related injuries and illnesses.

Workers under the no-fault insurance market that has emerged in the United States are subject to two types of moral hazard. The first

pertains to the injury precaution market. The prospect of compensation in the event of a work-related injury or illness may be expected to lead workers to take more risks on the job than they otherwise would, holding other factors constant. This is *ex ante* moral hazard. The fact that workers' compensation is not complete but rather only replaces a proportion of lost compensation between a minimum and maximum benefit level (see, e.g., Butler and Worrall, 1983) tends to limit the extent of *ex ante* moral hazard.

8.2.2 Legal Market

In the legal market, injury victims file tort claims which are defended by parties named in the case. Prior to the enactment of worker's compensation laws, workers with job related injuries were required to prove negligence by their employer. This meant the worker had to show the employer did not exercise due care in protecting the worker from injury, and this absence of care was the proximate cause of the injury (Kantor and Fishback, 1996). While imposing liability on an employer provides an incentive to provide a safe working environment, the costs associated with tort are high and rates of compensation for injury victims is low. Based on figures for men killed by work related accidents in Illinois before 1911, the percentage of families receiving zero compensation for their loss was placed as high as 60.9 percent (Kantor and Fishback, 1996).

Since an administrative system has supplanted tort for work-related injuries, claims are filed by injury victims through what amounts to a no-fault insurance system. In most states, original jurisdiction over workers' compensation disputes has been transferred by statute from trial courts to special administrative agencies. Within such agencies, disputes are usually handled informally by administrative law judges. Appeals go to an appeals board and from thereto a state court. Appeals tend to be difficult and are regarded skeptically by most state appellate courts. The intent of replacing tort with an administrative system was to substantially replace tort with an administrative system. A few states still allow the employee to initiate a lawsuit in a trial court against the employer.

8.2.3 Insurance Market

In the United States, employers generally purchase workers' compensation insurance. Self-insured workers' compensation plans are relatively rare (Victor, 1985). Large firms are almost always self-rated; either self-funding or purchase of self-rated insurance preserves employers' incentives to provide a safe work environment for their employees.

Given workers' compensation benefits, in the event of an accident or illness, workers have an incentive to file claims and exaggerate the severity of illnesses and injuries on their claims to obtain higher benefits and also to linger off the job, that is, to extend the length of time the injury or illness keeps the worker out of work. This is a second type of moral hazard, *ex post* moral hazard (see, e.g., Victor, 1985; Dionne and St-Michel, 1991) *Ex post* moral hazard is likely to be greater for occupational illnesses than for occupational injuries. If an industrial knife severs a worker's finger, the injury is fairly well defined. The worker will be precluded from work that requires use of that finger in the future. However, the latency period is long for many occupational illnesses, making the task of establishing causation that much more difficult.

Most employers are required to acquire workers' compensation for their employees; employers who do not are subject to financial penalties. Several U.S. states have public uninsured employer funds to pay benefits to workers employed by companies who illegally fail to purchase insurance. Most employers purchase workers compensation insurance from commercial insurance companies. For employers determined by the market to be high risk, coverage can sometimes be obtained from an assigned-risk program. A few states operate state-run monopoly workers' compensation insurers.

Workers' compensation represents a major line of commercial insurance. As in other lines of insurance, especially ones with a long claims tail, such as for medical malpractice insurance, there are cycles in premiums. During one phase, insurers compete for business by offering low premiums. But seeing their costs rise, insurers raise premiums substantially, leading to premium shocks for employers.

8.2.4 Government Market

While the United States lagged behind other industrial countries in their development of workers' compensation, legislation was quickly adopted by the states after 1910.[1] This legislative development was, in large part, due to support from employers' and organized labor groups. As a result of their support, during the years between 1910 and 1930, all but four states had adopted workers' compensation (Fishback and Kantor, 1998). Employers' support for these regulations was not altruistic; workers' compensation regulations developed more quickly in states where employers' accident liability was expanding (Fishback and Kantor, 1998).

In spite of the fact that much of the workers' compensation premium is shifted to workers in the form of reduced wages and other fringe benefits, employers perceive that workers' compensation is a major cost of business for employers. This has led to lobbying of state legislatures by business for workers' compensation reform. In California, such reform has been a major element of the governor's program to make the state competitive in attracting and retaining businesses (see State of California, 2006).

8.3 Empirical Evidence on Effects of Workers' Compensation on Injury-Illness Duration

Meyer et al. (1995) use data from natural experiments in which Kentucky and Michigan raised the benefit maximums by about 50 percent. Since benefits are a function of wages, defining the benefit maximum defines the threshold above which a higher wage does not result in higher replacement income to workers covered by the program. Since incentives facing lower-wage workers, i.e., those workers with wage rates below the benefit maximums before the maximums were increased, such workers' behaviors following the statutory changes make an excellent control group. The authors report that time out of work among those

[1] Austria, Denmark, Finland, France, Germany, Great Britain, Italy, and Norway all had workers' compensation schemes in place by 1900 (Fishback and Kantor, 1998).

workers for whom benefits increased rose while time out of work for those in the control group did not.

The extent of moral hazard varies directly with the extent to which behavior and outcomes can be observed. For example, in the lost finger case, it is clear what happened and what the extent of the injury is, except perhaps for the injured worker's complaints of throbbing pain at the site of the lost finger. Only the worker's brain can perceive such pain. Dionne and St-Michel (1991) examine the effect of changes in workers' compensation benefit coverage interacted by injury type. Not surprisingly, they find a stronger effect on duration of injury with changes in workers' compensation coverage on types of injuries which are not as easily evaluated by persons other than the injury victim, such as those for back-related injuries.

8.4 Experience Rating of Workers Compensation Premiums and Rates of Occupational Injuries and Illnesses

Workers' compensation premiums paid by large employers tend to be more highly experience rated than those of smaller employers and very large employers are likely to self-insure. Thus, given compulsory workers compensation coverage, it may be expected that large employers would be more likely to invest in the health and safety of their employers than would smaller ones.

Using a microdata set for nearly 2800 manufacturing employers followed over the years 1979–1984 and variety of alternative econometric approaches, Ruser (1991) finds that higher workers' compensation benefits lead to a rise in nonfatal reported injury rates but, consistent with what one would expect under experience rating, higher benefits lead to a smaller increase in rates in larger establishments, i.e., those with more than 500 employees. Since workers' incentive to take precautions are not directly affected by experience rating, this type of result suggest that decisions on the part of both workers and firms affect the health and safety of the workplace. Ruser (1985) obtains similar findings using data from 25 three-digit manufacturing industries for the period 1972–1979.

9

The Experiences Compared

9.1 Does Tort Liability Improve the Public's Health?

The answer to the question "Does Tort Liability Improve the Public's Health" is "sometimes, it does and sometimes it does not." Of the applications included in this paper, the clearest evidence on deterrence is for dram shop liability, followed by motor vehicle liability. For dram shop liability, the technology of accident prevention is rather straightforward — not continuing to serve obviously intoxicated adults and not serving minors. And if patrons are intoxicated, servers are to take other measures such as arranging for transportation home for the intoxicated patron.

What tort liability has to counter is (1) the commercial interests of the alcohol seller and the server to sell more alcoholic beverages and (2) possible reluctance on the part of the server to act in the role of a parent in monitoring alcohol consumption of customers. If the alcohol seller has commercial liability insurance, premiums are likely to be experience rated so that, even if losses are covered by third-party insurance, failure to exercise due care will result in higher premiums subsequently. For those sellers without coverage, many sellers' equity

is low (Sloan et al., 2000a) with the consequence that a single lawsuit could result in bankruptcy.

Driving involves many complex decisions. Yet certain intuitively plausible precautions can greatly reduce accident frequency, such as not driving at excessive speeds, and not driving under the influence of alcohol or when excessively fatigued. Although results are mixed, the best evidence indicates that eliminating the threat of tort liability as part of a no-fault program increases accident frequency. Liability insurance is often compulsory and premiums are often experience rated, thus giving vehicle operators an incentive to exercise due care. In this field, police typically file reports soon after the accident. As in dram shop liability, causation is often not a major issue in legal disputes.

There is no empirical evidence that the threat of tort liability is a deterrent to injuries resulting from actions or inactions of health care providers. There are errors in both diagnosis and therapy. Causation can be very difficult to determine, but sometimes determining causation is straightforward, e.g., operating on the wrong body part, mixing up drugs in a hospital setting so that patients get the wrong drugs, failing to watch for potential drug interactions. On the other hand, there are extremely complex causation issues such as whether or not failure to perform a cesarean-section at birth in a timely fashion resulted in the patient being diagnosed with cerebral palsy as a young child. There are disputes about what the due care standard is in specific cases.

The empirical evidence on deterrence in the context of products liability cases involving pharmaceuticals, medical devices, and vaccines is much too meager to permit a conclusion on deterrence. Like medical malpractice, injury causation issues can be very complex.

The switch to no-fault for vaccines has not eliminated complex causation issues as the continuing controversy with thimerisol serves to emphasize. To the extent that no-fault programs cover certain injuries and exclude coverage of others, there is substantial debate in specific cases about whether or not an injury is to be covered under the no-fault program. Even a universal medical no-fault program would require some evidence that an injury was related to receipt of medical care. If causation is to be eliminated entirely from decisions about coverage, the only real solution is universal first-party medical

and disability insurance. Such insurance, of course, would not cover some of the expenses covered by no-fault programs such as expenditures on special schools and day care, coverage which is offered by the two no-fault programs for birth-related injuries in Florida and in Virginia.

What is difficult to explain is why medical no-fault has the support in the U.S. academic community that it does, not only given the empirical evidence from other countries, which is far from uniformly positive on the concept, but also because of institutional differences between the United States and the other countries with no-fault for medical injuries. The United States is more litigious than the other countries with no-fault programs (Rosenthal, 1988). Civil actions for negligence are viewed in the United States as a fundamental right that should not be removed. In addition to lower rates of litigation, other countries often have much different health systems compared to the United States. Health care services are publicly financed and cost less than services in the United States, which often have private funding. These factors tend to make no-fault in the other countries more affordable.

An administrative no-fault system has completely been substituted for work-related injuries and illnesses in the United States and in other high-income countries. So the focus of attention by researchers has been on how well the administrative system enhances or at least preserves incentives that employers have to promote employee safety. In this regard, the empirical evidence clearly implies that experience rated premiums are important for providing a financial reason for employers to invest in job safety.

Litigation against the tobacco companies has been for actions the companies undertook decades before the suits were filed. The litigation has an objective of sending a message to manufacturers that they have a legal obligation to disclose harms from consuming their products in a transparent form. For tobacco, the Master Settlement Agreement led to increased prices per pack of cigarettes. This in turn reduced rates of smoking, which can be expected to lead to health improvements. Bans on advertising to youths should if anything have the effect of improving the health of adults in the coming decades. Disclosures of information

the tobacco manufacturers possessed on the health harms of smoking tend to reduce these companies' political power and hence made them less effective opponents of legislation proposing an increase in cigarette excise taxes.

Thus, for tobacco, tort liability has improved health, but not for the reasons that supporters of tort would usually give. Since litigation arose many decades after the worst transgressions of the cigarette manufacturers occurred, the manufacturers faced no *ex ante* incentive to promote safety and avoid making baseline claims about the safety of their products. Further, the rationale for the lawsuits against the states is questionable on at least two grounds: (1) the lack of evidence that cigarette advertising caused people to smoke; and (2) the relatively small financial externalities smoking imposed on state Medicaid programs.

In tobacco and for pharmaceuticals, medical devices, and vaccines, tort has provided a method for organizing consumers and their interests. Without tort, individuals would have to confront regulatory agencies which, though organized to serve such interests, may for various reasons fail to do this.

At least as much as the expense of litigation, the reason organized medicine and business groups oppose it has much to do with loss of control and having to respond to claims of aggrieved individuals. These special interests have been very effective in portraying plaintiffs and their attorneys as greedy, while all they say they want to do is to promote the general wellbeing (see Haltom and McCann, 2004; Baker, 2005). By contrast, advocates for plaintiffs and the trial bar have tended to work behind the scenes.

Probably the weakest record of all is in products liability where causation issues arise that are often not resolved. Perhaps the threat of products liability lawsuits has kept companies on their toes, reminding them to conduct post-marketing surveillance of the safety of their products, modify their products as warranted by these findings, and to warn consumers of newly-found risks. Unfortunately, there is no empirical evidence that these actions are more commonplace because of the threat of tort.

Coupled with a mixed track record on deterrence are other deficiencies of tort. In particular, a substantial part of payments for loss go for administrative expense, especially payments of attorneys' fees, especially in mass torts litigation. Limits on fees can unduly limit access of injury victims to legal counsel, particularly in cases involving individual plaintiffs.[1]

9.2 If Not Tort, What are the Alternatives?

For those case types in which the current system is operating at least moderately well, which includes motor vehicle, dram shop, and the part of medical malpractice in which causation issues are not murky, there is no issue about selecting an alternative. Rather there are opportunities for improving the current system. To enhance deterrence, it is important that liability insurance preserve a financial incentive for potential injurers to exercise care. As Abraham documents, throughout much of the past century, thinking by legal scholars and persons in the legislative and judicial branches of government has emphasized the compensation role of liability insurance with efficiency, that is, to the incentives that insurance can provide to policyholders, taking the back seat (Abraham, 2005). However, while it is important that insurance retain its role in risk-spreading and risk-protection, incentives to take care should be preserved. This can be done by risk classification/experience rating (see, e.g., Lemaire, 1985; Abraham, 1986).

When and if the individual policyholder is not a satisfactory experience-rating unit, then units, which aggregate across policyholders, are appropriate. Recently, we wrote about using the hospital as the experience-rating unit for care delivered within the walls of hospitals (Sloan and Chepke, 2008).

Although lawsuits against tobacco companies continue, given the Master Settlement Agreement, this litigation has probably peaked, at least in the United States. In recent years, the issue of making cigarettes subject to regulation by the FDA has been discussed, but without resolution. Certainly, for virtually anyone alive, the harms of smoking

[1] See, e.g., discussion in the context of medical malpractice in Sloan and Chepke (2008), Section 6

are well-known, and the MSA has placed restrictions on advertising to youths. Marketing efforts in other countries, especially in middle- and low-income countries bear further scrutiny, however.

The most directly-pertinent area for "if not tort, what are the alternatives?" and one in which tobacco litigation is part, is products liability. In this context, there is clearly a role for some sort of government intervention. The health harms of product use and appropriate use of these products is not as widely disseminated as it is for alcohol, tobacco, and many medical services. Given the low probability of health risks, there is no way that people can always learn about the risk from their own consumption or the consumption of others that they know. As the products become more widely used, adverse effects become known. The long latency period between consumption and disease/injury onset is also a complicating factor. Thus, the choice is not between no intervention in these markets and some intervention, but rather in what form that intervention should take.

As with liability insurance in general, there has been substantial emphasis on compensating injury victims with less attention being paid to incentives. As a vehicle for injury compensation, first-party insurance tends to have a much lower administrative cost than does third-party insurance. Thus, if there is a role for tort, it must be in providing an additional incentive to take care. If tort is not an appropriate vehicle, then the role must fall to some other organization external to the companies' product market. What we would like the companies to do is continue to monitor the safety of their products and to disclose information about injury which is relevant to consumers, recognizing that not all bad outcomes stem from the use of a product. Regulatory agencies can be slow and subject to political influences. As Baker (2005) and Haltom and McCann (2004), among others, have documented, tort law has not been immune from media attention and political influences either.

When scientific issues of causation are involved, the probability that controversies will be resolved in the courtroom are close to nil. Largely because of high levels of U.S. and state funding, there is a substantial amount of research on issues related to medical malpractice. Further, there has been and continues to be substantial research on tobacco

and excess alcohol use by epidemiologists, economists, and others. By contrast, there is comparatively little research on the safety of particular products. Rather than allocate resources to a battle of expert witnesses in the courtroom, a better allocation would be to fund independent research on these issues and permit introduction of research by independent investigators as evidence in court. This would not eliminate the experts retained by the opposing parties, but rather would supplement information provided to courts now.

9.3 Public Policy Implications

Elsewhere, we have commented on the limited value of first-generation tort reforms in medical malpractice (Sloan and Chepke, 2008) and the usefulness of shifting the focus on medical malpractice suits to the enterprise, especially the hospital. This same type of approach is not useful for motor vehicle and dram shop liability which seem to be functioning well in any case. For tobacco and products liability more generally, the defendant is naturally the enterprise, and suing the enterprise rather than individuals working within the enterprise is the current practice.

In the United States, no-fault insurance has been used for motor vehicle liability, medical care on a very limited basis, for vaccines, and for employment-related injuries and illnesses. The rationale for such insurance is both speedier compensation and lower administrative cost. The disadvantage of this approach is attenuation of incentives to take care. Although fault is eliminated as a criterion for making awards under no-fault, experience-rating of premiums is not incompatible with the concept and in fact has been proposed (see, e.g., Weiler et al., 1991). Overall, the empirical evidence on no-fault is not overwhelmingly positive. Most attention has been on the speed and administrative cost of distributing compensation under no-fault.

The record on preserving incentives for potential injurers to take care is mixed. Further, the history of thimerisol under the no-fault program for vaccines leaves much to be desired. At least from the perspective of deterrence, the programs implemented to date do not represent an improvement.

9.4 Future Research

Effects of motor vehicle and dram shop liability are fairly well researched. Although according to the *Web of Science*, there are more journal articles on medical malpractice than all of the other areas discussed in this review combined, there is a paucity of studies measuring deterrent effects of medical liability. More research on this important topic is warranted.

On tobacco, it is amply clear that tobacco consumption is bad for a person's health and that the tobacco manufacturers failed to exercise due care in failing to disclose harms that they had documented and for promoting their products in ways that implied that smoking is not harmful. However, this story has been told (Glantz et al., 1996; Mollenkamp et al., 1998; Kessler, 2001; Derthick, 2002) and makes interesting reading, but further research should not be a priority.

The area that has been most neglected is empirical research on products liability. The growth in legal claims has been well-documented (see, e.g., Viscusi, 1991), but we know little about many key issues. At the top of the list is risk perception of injury that consumers have about specific pharmaceutical, medical device, and vaccine products. After all, the primary rationale for products liability is that consumers misperceive risk. Another related research topic is how consumers and physician prescribers learn about characteristics of these products. Initial work by Crawford and Shum (2005) on physician prescribing of one pharmaceutical product, using data from Italy is promising.

Direct tests of deterrence effects of the threat of products liability are much more difficult to conduct. Since the threat of products liability varies appreciably by country, one approach would be to conduct multi-country studies of products produced primarily for a domestic market. Such research would be well worth doing if the data are available.

9.5 Bottom Line

There are many sharp curves along the road from law to incentives to public health. The important principle of maintaining incentives for potential injurers to take care has often been lost in the discussion of

injury compensation. Incentives to deter injuries have not always been as clear as they should have been. Tort works better when causes of specific injuries are well understood than when the causes themselves are subjects of scientific dispute. Finally, although there are substitutes for tort, they too have their advantages and deficiencies. Thus, proposals to substitute or drop tort entirely should be handled with considerable care.

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