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J O I N T C E N T E R

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The Regulation-Litigation Interaction

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The recent lawsuits involving cigarettes, guns, and other products have created a new phenomenon in which litigation either results in negotiated regulatory policies to settle the litigation or the litigation serves as a financial lever to promote support for governmental policies. The allocation of responsibilities for policy becomes blurred, as litigation increasingly becomes the mechanism for forcing regulatory changes. The policies that result from litigation almost invariably involve less public input and accountability than in the case of government regulation. The AEI-Brookings Joint Center held a conference on April 26—27, 2001 that explored the major lines of such litigation and examined the merits of these efforts and the potential problems they may create.

There are many policy contexts in which there is an interaction between the role of regulation and litigation. Many of the economic rationales for government regulation pertain to various forms of market failure, such as inadequate consumer information or failure to account for externalities to parties outside of a market transaction. These same forms of market failure often also lead to litigation as well, as injured parties seek to obtain damages for the harms that have been inflicted on them in contexts in which there was not appropriate recognition of their economic interests by the party inflicting the harm.[1] The policy task is to coordinate the influences of these two different sets of social institutions, recognizing their different strengths and different functions. In each case, however, it must be recognized that the ideal level of harm is not zero. A risk—free society is neither feasible nor desirable because of the inordinate costs of eliminating risk.

The potential importance of the interaction between regulation and litigation is not a new issue. This overlap of institutional responsibilities and functions was a central theme of an American Law Institute study on tort liability published a decade ago.[2] Traditionally, the focus has been on broad conceptual issues, such as the potential for institutional overlap with respect to the creation of economic incentives. The policy

[1] In some instances plaintiffs may also seek damages even if negligence is not alleged.
[2] See American Law Institute (1991a, 1991b).

concerns arising from these analyses of institutional functions often have focused on fairly narrow kinds of remedies, such as a regulatory compliance defense for firms that are in compliance with explicit government standards but are nevertheless subject to litigation.

The different functioning of these social institutions is apparent from considering their roles in promoting health and safety. Consider first the creation of economic incentives. Regulation is generally superior in addressing technical scientific issues because of the central role of specialized expertise in analyzing regulatory issues. Moreover, government regulation on behalf of society at large is especially appropriate when the policy decisions pertain to an entire product line rather than a specific product purchase by an individual. Assessment of design defects and hazard warnings, for example, should be on a product-wide basis. The issue of what any particular individual knew about the risks is not the key concern, but rather whether the firm provided adequate information within the market context for a representative product purchaser to make a knowledgeable risk-taking decision.

Difficulties arise if these matters are delegated to juries on a case-by-case basis. Recent literature has documented the failings of juries in thinking sensibly about risk, as jurors exhibit a wide variety of systematic biases in assessing accident situations, such as hindsight bias in the evaluation of past risk actions. Government regulations will usually provide a more sound approach to promoting health than litigation, which by its very nature tends to focus on particular individual circumstances rather than the functioning of an entire product market. From a benefit—cost standpoint, the stringency of government regulations can be excessive in some cases due to the restrictive nature of regulatory agencies' legislative mandates. Where this occurs, regulatory standards for health and safety typically should not require any additional augmentation through judicial proceedings.

If, however, regulations do not exist for a particular product, litigation can often play a constructive role in addressing gaps in the regulatory structure and in stimulating regulatory activity. One of the most prominent examples in which litigation played such a role is with asbestos. Historically, asbestos risks had not been strongly regulated, but the emergence of a wave of asbestos litigation induced both the Occupational Safety and

Health Administration and the U.S. Environmental Protection Agency to set stringent regulation. In this instance, the combination of litigation and subsequent regulation led to inordinately large safety incentives. Litigation plays an additional role that complements regulation where it provides for a transfer of income to injured parties to address the damages incurred.

A general problem with the existence of distinct roles for litigation and regulation is that there is no formal or informal mechanism for coordinating the roles of these two institutions. The fact that one institution is imposing economic penalties for a particular type of risk does not prevent the other from also imposing sanctions. The little coordination that does exist consists of the existence of regulatory compliance defenses, which typically are restricted fairly narrowly to punitive damages and are only pertinent in a few states. That there is a continuing inherent problem in coordinating the roles of regulation and litigation is well documented in the literature.

What is new is that the character of these coordination problems has changed dramatically since the mid—1990s. The advent of litigation involving products such as tobacco, guns, and lead paint went well beyond the historical interactions of regulation and litigation that have been of concern in the literature. No longer was the issue one of litigation itself creating incentives that overlapped with those resulting from regulation. Rather, litigation was being used as the financial lever to force companies to accept negotiated regulatory policies. Thus, litigation itself led to regulation, but not regulation that went through the usual rulemaking process as a result of a careful analysis by government regulatory agencies subject to legislative mandates. Rather, the parties in the lawsuit negotiated regulatory changes as part of the package to end litigation.

These negotiated solutions have also gone beyond simply specifying regulatory changes. In at least one instance, the settlement led to the imposition of what is effectively an excise tax on products. Rather than imposing a conventional damages award on the defendant, the tobacco settlement imposes charges on customers on a per unit basis in the future. Thus, the settlement establishes a tax on the product payable to the plaintiff and paid for almost entirely by the consumer rather than a damages payment paid for by the defendant. Litigation against health maintenance organizations (HMOs) proposes a similar tax—like structure. Thus, litigation has developed in a manner that not

only usurps the traditional governmental authority for government regulation, but also shifts the locus of establishing tax policy from the legislature to the parties involved in the litigation. Citizen interests are not explicitly represented and, as in the case of regulatory changes, there is no mechanism to ensure that these outcomes are in society's best interests. Moreover, there is typically no procedure for creating even an appearance of the level of legitimacy accorded to governmental policies.

If there is an error in the litigation settlements that impose regulatory and tax changes, the adverse consequences could be enormous. The stakes of the tobacco litigation exceeded $200 billion in expected penalties over the next 25 years. The regulatory changes also could have significant anti-competitive effects. While other litigation typically involves stakes that are not as great as those of tobacco the influences, in terms of the effects on particular industries, could be even greater.

I. Optimal Deterrence

The focus of this volume is on a series of case studies involving regulation through litigation. In the process, the chapters collectively shed light on the likely consequences of regulation through litigation for insurance markets and society at large.

These effects will be discussed in more detail shortly. In considering the merits of litigation, it is useful to assess how it performs from the standpoint of efficient deterrence and efficient insurance. One of the chief functions of a liability system and government regulations is to establish optimal levels of deterrence. The case studies in this volume focus almost exclusively on health and safety risks, where the main economic issue is whether the incentives created lead to the appropriate levels of health and safety. The optimal level of risk is not zero, but is rather an efficient level of risk that reflects the appropriate balancing between the benefits and costs of risk reduction.

More specifically, risk reduction measures should be undertaken only to the extent that their benefits exceed the costs. For example, when judging whether a particular safety device should be added to a machine, doing so is desirable if the benefits of the safety device exceed the costs of modifying a product. It should be emphasized that these benefits include not only financial consequences but are based more broadly on society's willingness to pay for the health reductions, recognizing the value of the risk

reduction that goes beyond the financial effects. Safety is optimized when the *marginal* benefits equal *marginal* costs. Often there is a continuum of risk choices that can be made, such as the level of exposures to toxic chemicals. So long as the incremental benefits of increased safety exceed the incremental costs, then further tightening of the regulation or the imposition of liability on the firm is desirable. Regulation or litigation is excessively stringent, however, when firms are pushed to enact measures when incremental costs outweigh incremental benefits.

Considerations of optimal deterrence and the incentives created by social institutions is always a central economic concern. In regulatory contexts, the implications of policies for choices about the level of health and safety are rarely neutral. Ideally, litigation should also be concerned with creating incentives for efficient levels of safety, but this objective may be compromised when the main focus of the litigation is to provide compensation.

The discussion by Kenneth Abraham in Chapter 7 distinguishes two different types of litigation, each of which will have different implications for economic incentives. Litigation that he terms "forward looking" focuses on setting up either requirements on firm behavior or a funding mechanism that will directly influence incentives for the future. The settlement of the tobacco litigation was forward looking in character in that it led to regulatory changes as well as a damages formula that was largely tantamount to an excise tax on cigarettes. Similarly, the litigation involving guns, which is reviewed in the chapter by Phillip Cook and Jens Ludwig, is forward looking to the extent that it seeks to impose safety requirements on the design of handguns as well as restrictions on the distribution of handguns. Although the litigation against HMOs, discussed in Chapter 6, is less well developed than that for cigarettes and guns, the overall model that is being adopted closely follows that for tobacco and is forward looking in character.

Litigation that Abraham terms "backward looking" is more similar in character to conventional tort litigation. The lawsuits by women suffering problems they attribute to breast implants and the lead paint litigation against landlords both fall into the backward looking category. These suits seek to obtain compensation for parties that have been injured. The provision of such compensation will establish payment structures that could

potentially alter future incentives because firms will expect to be subject to similar sanctions from future litigation. However, if all such decisions have already been made or if the product is no longer sold, there will be no incentive effect unless these suits impinge on current behavior in some manner. Thus, in the case of the lead paint litigation, there will be no incentive effect for lead paint manufacturers because lead paint is no longer produced in the United States. However, the lead paint suits against landlords potentially could have an incentive effect to the extent that they affect building maintenance, efforts to remove lead paint, and warnings to tenants about lead paint risks. Also, there may be more general deterrent effects for landlords beyond lead paint.

II. Optimal Insurance

A second potential function of social institutions dealing with risk is providing optimal insurance to those who have suffered injuries or illnesses. Regulatory policies by the federal government generally do not provide any insurance compensation for victims but instead are focused almost exclusively on establishing regulatory standards for health and safety. Insurance functions are typically handled through targeted government programs that focus on the disabled, the poor, or the elderly.

In contrast, litigation often has as its principal purpose an effort to transfer income to those who have suffered injuries. From the standpoint of optimal insurance this transfer should be sufficient to completely cover the economic loss in instances in which people have suffered a financial loss. The desirability of providing this insurance stems from the role of individual risk aversion, which makes insurance of such losses desirable. In the case of governmental entities that have suffered economic losses, such as the medical costs attributable to tobacco that were incurred by the states, this type of insurance rationale would not be pertinent. Governmental entities should be risk-neutral except with respect to extremely large losses because they can spread these losses across a large citizenry base. Thus, any optimal insurance rationale for transfers to the government must assume that the losses ultimately borne by individual taxpayers will be sufficiently great that risk aversion will come into play.

In the case of injuries and illnesses to individuals, there will be both financial losses as well as effects on individual health. Whereas the object of insurance for

financial losses is to restore individuals to their pre—accident level of utility, that objective is not pertinent in the case of health effects. Optimal insurance satisfies the property that it equates the marginal utility of income when one is healthy to the marginal utility of income when one is ill. Typically, it will not be desirable to purchase so much insurance so as to be as well off as he or she would have been had the illness or injury not occurred because these events reduce people's ability to derive welfare benefits from additional funds. Even enormous transfers of money to one after becoming disabled may not be adequate to restore the pre-accident welfare level. There is also the practical problem of ascertaining what a person's psychic losses are from such major injuries. Thus, in the case of the breast implant litigation, there will be an insurance objective but the proper role of the courts will typically fall short of restoring the plaintiff's pre—illness level of utility even in situations in which liability for the firm is established.

III. The Case Studies

This volume will present a series of case studies of different types of litigation as well as broader analyses of the role of mass torts and class actions and their implications for economic performance. Table 1 summarizes each of these areas of litigation. In each case, there is some alleged shortcoming from the standpoint of efficient behavior on the part of the firm as well as an alleged or actual failure on the part of government agencies. The third column of Table 1 indicates the particular remedy that is either sought by the litigation or has resulted from the litigation. These remedies go beyond conventional damages payments and include measures of a regulatory character as well as financial penalties that will affect the product cost. A summary of the efficiency effects of the different product litigation appears in the last column of Table 1.

IV. Tobacco

By far the most noteworthy example of regulation through litigation is that of the litigation against the tobacco industry. The most salient example of this litigation consists of the suits by the state governments that sought to recover Medicaid expenses that they attributed to cigarettes. The prospective suit that has been filed by the federal government also has a similar character. These parallels no doubt led the Federal government to

initiate the suit and presumably also led the Bush administration to suggest that an out—of—court settlement should be the appropriate solution.

The alleged market failure that gave rise to these suits is that there is a medical cost externality that has not been fully addressed. Why governmental entities such as the states and the federal government failed to tax cigarettes adequately to reflect this cost of cigarettes is a major unanswered question. Critics allege that the lobbying power of the tobacco industry has hindered taxes from being set at appropriate levels. The risks of smoking have been well known for decades and, indeed, have been subject to annual reports by the U.S. Surgeon General as well as government-mandated warnings. Given the knowledge that cigarettes do in fact increase health costs, what was the governmental failure that prevented legislatures from enacting taxes to cover these costs? The fundamental question raised by these suits from an institutional standpoint is why there was any need to resort to litigation rather than having traditional governmental processes address these costs.

W. Kip Viscusi's assessment of tobacco in Chapter 2 makes two general points with respect to this litigation. First, from the standpoint of economic cost externalities arising from cigarettes, there is no net cost imposed on the states or on the federal government, even if one excludes the role of excise taxes. Proper recognition of the full health consequences of smoking indicates that smokers will live shorter lives than nonsmokers and consequently will generate fewer nursing home expenses as well as lower pension and social security costs than nonsmokers. Indeed, smokers are self-financing for every state and for the federal government, even excluding the role of excise taxes already in place. Thus, there are no net economic damages to governments arising from cigarettes. The second major point made in the Viscusi paper is that there is no evident harm caused by the alleged wrongful conduct by the industry. Survey evidence indicates that smokers are in fact aware of the risks posed by cigarettes and have an exaggerated perception of the risk. Thus, in terms of misinformed decisions, there is no evidence that alleged wrongful conduct by the cigarette industry led people to smoke cigarettes. Indeed, the risks of smoking have been well known and highly publicized for decades and are perhaps the most highly publicized risks in society.

Chapter 9 by Richard Epstein takes a somewhat different approach to the tobacco litigation. He does not question whether cigarettes are self-financing or whether people overestimate the risks of smoking. No suits by the states or the federal government have any justification in Epstein's view unless there would be an appropriate basis for litigation on the part of the individuals who decided to smoke. He believes such litigation is without foundation because hazard warnings have been present on cigarette packages for decades. Moreover, the warnings since 1969 include provisions that preempt litigation against the industry based on inadequate warnings.

The remedy that was sought in the case of the tobacco litigation involved the transfer of money to the states. As indicated by Viscusi as well as John Calfee and Gary Schwartz, this monetary transfer did not take the form of a traditional damages payment but rather consisted largely of a penalty on future cigarettes that was tantamount to an excise tax. This "tax" was unusual, however, in that it was not assessed by any legislature, but instead emerged through litigation and ultimately from bargains between the state attorneys general and cigarette industry executives. These parties also negotiated a variety of regulatory changes, including restrictions on advertising that some view as having anticompetitive consequences. The cigarette litigation was also noteworthy in that it generated enormous levels of compensation for plaintiffs' attorneys that ran into the billions of dollars paid by particular states and hundreds of millions of dollars in compensation received by plaintiffs' attorneys. These attorney fee arrangements were controversial not only because of their size, but also because state attorneys general negotiated these arrangements without any open bidding process or public scrutiny. In the case of Massachusetts, the attorney general negotiated an arrangement that even the governor of the state regarded as excessive.

In terms of the optimal deterrence and optimal insurance objectives outlined above, the cigarette litigation provided for no insurance of individual losses but only a transfer to states. Moreover, states should be regarded as risk-neutral so that insurance does not really come into play. The incentives created on future cigarette sales involve a per pack tax that will discourage smoking generally. Whether doing so is desirable depends on one's assessment of the net economic consequences to society. At least from the standpoint of the financial effects, the results presented by Viscusi indicate that

additional taxation is not warranted. Thus, from the standpoint of the issues involved in the state cases, there is no efficiency—based rationale for the tax. The tax also is not structured in a manner to provide meaningful incentives. A key drawback of the tax—like structure of the damages is that the level of the tax does not vary with the riskiness of the cigarette product in any way. If companies were to develop risk-free cigarettes in the future, then these products would be subject to the same tax even though they would entail no medical costs. Ideally, any tax system should provide incentives for safety innovation.

The shortcoming of the tax structure of the damages payment in tobacco ultimately can be traced to the fact that this arrangement did not emerge from a careful analysis of what the tax structure should be. Rather, it was simply a financial settlement of litigation that happened to take the form of a tax.

V. Guns

The high stakes payoff of the cigarette litigation has not been lost on attorneys considering litigation in other areas. The next prominent example of the regulation through litigation phenomenon is the subject of Chapter 3 by Phillip Cook and Jens Ludwig. In the New Orleans guns suit, the plaintiffs allege that the companies neglected to provide adequate safety features for guns. The Chicago lawsuit has a different focus: a claim that firms created a public nuisance by not preventing illegal sales of firearms.

The financial resources of the gun industry are dwarfed by that of the tobacco industry. As a result, the stakes are considerably less in terms of the overall effect on the economy. This difference in the financial magnitudes involved lead Cook and Ludwig to conclude that the object of the gun litigation is primarily to lead to regulatory changes rather than to provide financial compensation. However, this difference may simply be a reflection of the more modest size of the gun industry. If it were not for the threatened financial sanctions, it is unlikely that the cities would have the leverage to force the regulatory changes that they are seeking through the litigation. Because this litigation is not as far along as the tobacco litigation, the ultimate emphasis on financial transfers as opposed to regulatory changes is not yet apparent. What the plaintiffs are seeking is a set of negotiated changes with respect to gun distribution and safety mechanisms for guns.

As Cook and Ludwig have observed, some firms have already exited the industry and others have changed ownership so that the financial consequences are significant for individual firms even if their aggregate impact on the overall economy is relatively small.

Cook and Ludwig assess the societal consequences of firearms by establishing a statistical relationship between the presence of guns to homicides. Their result: that there is an additional death associated with the presence of an extra 15,000 guns. As the commentary in this volume by Richard Epstein observes, however, this simple analysis is controversial for a variety of reasons, not the least of which is the fact that it does not distinguish whether the guns actually were involved in the homicides. For example, people in high crime areas may choose to purchase guns for self defense, but that does not imply that their guns led to homicides, which may have been committed with weapons other than guns. Epstein also notes that the fundamental difference between guns and other harmful products is that guns may have a legitimate use. The social objective should be to prevent guns from being used unlawfully, not to prevent gun use overall. This focused objective, in Epstein's view, creates a policy problem of a more targeted nature than simply eliminating guns altogether.

Based on their assessment that guns impose net economic costs, which is shared by many other economists, Cook and Ludwig explore various policy remedies that have been proposed. These proposals include personalized technologies for guns as well as various kinds of safety mechanisms. Many of these options appear to offer considerable potential. The question then becomes: what market failure has prevented companies from introducing these products? One gun industry view is that the personalized gun technology and other such proposals are not as sound or as well developed as advocates such as Cook and Ludwig suggest.[3]

Although Cook and Ludwig do not explore the sources of market failure in detail, they do address the possible role of governmental failure in establishing regulations that would have promoted such outcomes. They suggest that because of the diffuse public benefits from gun regulation, strong interest groups supporting gun use have been able to thwart the enactment of socially beneficial legislation. The result is a series of lawsuits by cities that did not need legislative approval but would nevertheless generate leverage to

[3] See Beretta USA Corp (1998).

produce regulatory changes. As with the regulatory policies that emerged from the tobacco litigation, these regulatory proposals do not go through the kind of detailed review and rulemaking process that is the normal course for governmental regulations.

VI. Lead Paint

Some of the lawyers who are veterans of the tobacco litigation have become engaged in various lawsuits involving lead paint. These lawsuits bear some similarities to the tobacco and gun litigation because they often involve government entities suing firms. However, the character of the litigation is distinctive in other respects.

Chapter 4 by Randall Lutter and Elizabeth Mader distinguishes two different kinds of lead paint lawsuits. The first type of lawsuit consists of suits against the lead paint manufacturers. These suits closely parallel the tobacco lawsuits. The second class of lawsuits consists of landlord-tenant suits. This litigation is more akin to standard personal injury litigation.

Consider first the suits against lead paint manufacturers. The fact that these suits are even being lodged at all is somewhat curious given that there has been a national ban on the use of lead paint enforced by the Consumer Product Safety Commission since 1978. Moreover, recently issued EPA standards for the presence of lead paint, which have been incorporated in rules promulgated by the Department of Housing and Urban Development impose standards on lead paint exposures. There are also required housing disclosures of the presence of lead paint to buyers and renters as well as state and local regulations pertaining to lead levels. Lead paint production has not been active for 23 years, and exposures to historical applications of lead paint are now strongly regulated. The lead paint lawsuits in which the defendants are the lead paint producing companies consequently parallel the tobacco and gun litigation because they focus on historical behavior. Moreover, as in the case of tobacco, there is often a latency period before the harm is done, so that the damages if paid may not always go to the particular individuals who suffered health losses but could go to other entities, such as local governments. Unlike the tobacco cases, however, there will be no excise tax financing mechanism that might influence future production of lead paint because this production has already ceased. Consequently, from the standpoint of optimal deterrence of lead paint

manufacturers, the lawsuits consequently will have no influence. To the extent that this litigation has any incentive effect it will be by generating an expectation among firms making other products that the legal system might eventually impose costs on them after they have ceased producing or selling these items.

The historical claims against lead paint manufacturers have also created difficulties in terms of assignment of liability. In any particular context, it is likely that there have been several applications of paint to a wall over time, and it is often impossible to ascertain the date of the paint application or the manufacturer of the lead paint. Some lawsuits have sought unsuccessfully to apply market share liability rules to assign responsibility for the historical applications of lead paint. These efforts have not been successful, in part because of the inherent uncertainties regarding when the lead paint was applied and the respective market shares of different companies at different points in time. Efforts to apply similar concepts of market share liability to guns have also not been successful.

The second set of lead paint lawsuits involving landlords and tenants could potentially function quite differently from the standpoint of both optimal deterrence and efficient insurance. Landlords continue to make decisions regarding building maintenance, which in turn affects exposure to lead. Moreover, to the extent that these lawsuits lead to compensation of people actually exposed to lead, there is potentially some insurance rationale for the litigation. As Lutter and Mader indicate, however, there are also strong government regulations already in place that address many of these exposure issues, thus reducing the deterrence rationale.

The pattern of lead paint litigation also yields some surprising results. Increasingly, these lawsuits lead to out of court settlements, but Lutter and Mader observe that notwithstanding the decline of lead levels in contaminated housing, the number of lawsuits has not diminished. Their statistical analysis suggests that higher blood—lead levels do not increase the probability that a plaintiff will win the case, but do increase the magnitude of the award. Lutter and Mader, as well as the commentary in this volume by Thomas Kniesner, conclude that litigation is a very poor mechanism for promoting control of lead and promoting individual health, which they believe can be done more effectively through better regulatory controls on lead-based paint hazards.

VII. Breast Implants

The role of government regulations also figures prominently in Joni Hersch's analysis of breast implants. The conventional view in the literature, which is shared by the commentary in this volume by Peter Schuck, is that the breast implant litigation epitomizes the extent to which class action litigation has led to undesirable social outcomes. According to this view, companies were punished and in one case driven into bankruptcy (Dow Corning) by claims of illnesses that were not supported by the scientific evidence. The chapter by Hersch challenges this conventional assessment by tracking the state of information at different points in time and the link of this information to the role of litigation.

Many observers suggest that the breast implant litigation should be a non-issue for the courts because of the role of regulation by the Food and Drug Administration (FDA). The commentary in the chapter by Epstein, for example, proposes that there should be an exemption for all products regulated by the FDA because this regulation already establishes appropriate tests of product safety. While that point of view is certainly pertinent to prescription drugs and many medical devices, Hersch shows that breast implants were in use before there was FDA medical device regulation. Even after the authority of the agency was extended to include medical devices, the FDA never explicitly reviewed breast implants and evaluated their properties in terms of the safety and efficacy of the devices. Thus, unlike more recently regulated products, the fact that breast implants ultimately fell under the jurisdiction of the FDA in no way ensures that there was another governmental entity that made the judgment that the product met adequate safety standards.

The litigation that resulted began with lawsuits involving adverse health consequences of breast implants other than life-threatening ailments. This litigation was based on well established medical consequences of breast implants such as capsular contracture around the implants, and led companies to provide hazard warnings to alert potential users of breast implants to these consequences. A more controversial and more recent line of litigation involving breast implants has involved individual suits and class actions regarding highly speculative ailments, such as connective tissue disease and

autoimmune diseases, such as lupus and scleroderma. Plaintiffs often waged successful legal battles based on the fact that they suffered identifiable ailments and that case reports often linked the presence of breast implants to such ailments. What was missing, however, were detailed epidemiological studies demonstrating that breast implants increased the risk of severe adverse effects and made it more probable than not that breast implants were the cause of their ailments. Many critics of the breast implant litigation consequently claimed that these cases had no merit because the risks had not been documented based on large scale epidemiological studies performed for this product.

Hersch challenges this view based on the nature of the information flows. Because government regulators never required companies to undertake this research and companies never did so on their own, she views it as being inappropriate to fault the litigation based on informational shortcomings. The availability of epidemiological data is controlled by the companies. Moreover, when the first such studies did emerge the samples were sufficiently small that one could still not rule out with any reasonable degree of confidence the hypothesis that the use of breast implants made it more probable than not that the patient's ailments were attributable to this product. After substantial additional research the courts have now concluded that there is no legitimate scientific basis for the claims for ailments such as connective tissue disorders.

The breast implant litigation was very much in the spirit of traditional personal injury litigation in that the beneficiaries of the damage awards consisted of injured individuals. However, because of the class action character of much of the litigation, the scale of it resembled that of the suits by governmental entities against tobacco, guns, and lead paint.

While the breast implant litigation itself did not lead to negotiated settlements that imposed regulation, it did serve to stimulate regulatory action by the FDA. The litigation led to the production of company documents that alerted the FDA to problems concerning the product, including leakage of the silicone gel from the implants and concealment of these problems by the company. Moreover, it may not be entirely coincidental that FDA Commissioner David Kessler suspended the use of breast implants shortly after a major court award in a breast implant case. Kessler's decision is widely viewed as one of overreaction to the scientific evidence and public pressures.

The upshot of the breast implantation litigation is that the scientific consensus is that the product does not pose long term risks. Hersch documents that breast implants remain a widely popular form of cosmetic surgery. However, the financial cost to the firms that produced the implants cannot be reversed. Moreover, the bottom line from the standpoint of efficiency is that, at least in retrospect, society is not better off. The current state of information indicates that there was not a significant shortfall in safety on the dimensions alleged in the most costly breast implant cases.

VIII. HMOs

The same kinds of lawsuits that have been lodged against products such as tobacco and lead paint have also focused on health maintenance organizations. This development may appear to be curious from a risk standpoint. Tobacco is certainly a risky product. Guns are often risky, particularly if they are misused. Similarly, lead paint and breast implants pose hazards. However, one would have expected that the main effect of HMOs would be to enhance health rather than to increase risk.

The focus of the most recent litigation is on the quality control problems of managed care facilities. The plaintiff group is known as the REPAIR team, which is an organization headed by a former prominent tobacco attorney, Richard "Dickie" Scruggs. What Scruggs and his colleagues are attempting to do is to impose a settlement patterned after that in tobacco. Perhaps in an effort to force a settlement, they claim their HMO litigation will threaten the entire HMO industry with bankruptcy. Thus, as in the case of many of the other litigation case studies in this volume, considerable financial pressures are being brought to bear in the hopes of generating some kind of settlement: principally, a tax on premiums paid by individuals purchasing managed care insurance. In the case of tobacco, one could easily make the argument that the excise tax discourages consumption of a risky product. However, for HMOs the effect of any kind of premium tax will be to discourage utilization of health care, which is presumably harmful to individual health rather than beneficial. Thus, extensions of the tobacco model appear to be particularly inappropriate in this case.

Chapter 6 by Daniel Kessler and Mark McClellan use survey data pertaining to physician practices to explore some of the presumed analytical linkages underlying the

use of litigation with respect to HMOs. Their empirical analysis suggests that there appear to be few demonstrable benefits of litigation. In fact, increased medical malpractice claims lead to defensive medicine and the use of low benefit treatments designed to decrease the risk of litigation rather than to foster patient health. In contrast, the increased role of managed care has led to more efficient health care utilization outcomes. Moreover, as was noted above, the character of the financial incentives created in at least one line of litigation is not structured to promote better quality care in any sense, but will simply reduce the quantity of medical care received by raising premiums.

The concept of treating HMOs as a dangerous product that should be discouraged, in much the same way as society discourages the use of tobacco and handguns, appears to be without any sound foundation and driven solely by the desire of attorneys to use the regulation through litigation concept to their own personal gain. As of yet, there has been no settlement of this litigation and there is no indication that it will lead to any broadly based regulatory changes other than the proposed tax on insurance premiums.

IX. Insurance Market Ramifications

Large scale lawsuits involving damages payments in the billions of dollars have profound ramifications for the defendant companies, but they also have influences that extend to insurers as well. In some instances, firms have purchased insurance to cover at least a portion of their losses. As Kenneth Abraham and the commentary on his chapter by J. David Cummins indicate, assigning responsibility for bearing the financial costs is often a highly complex matter. Many of the risk exposures that have been subject to litigation are subject to long latency periods. Although asbestos risks are perhaps the most noteworthy case, tobacco, breast implants, and lead paint also have effects that are not immediate. The levels and timing of the risk exposure from such cases create considerable problems from the standpoint of insurance. Assigning responsibility for any given ailment is difficult, particularly in situations in which there are multiple potential causes. The role of time also is important as well. Did the disease result from a risk exposure that took place during the period of time when the insurance company was writing coverage for such losses, or was it some other time period? In many instances, the character of the risks was not known at the time insurance companies wrote the policies.

As a result, the insurance premiums charged were inadequate to cover the losses that eventually emerged once new diseases were identified or new lines of litigation developed. Now that insurance companies are aware of such unanticipated costs, Abraham notes that they are beginning to raise premiums to cover such contingencies, thus boosting the cost of insurance to potential purchasers.

The character of the insurance policies that the companies are willing to write has also changed. Abraham explores the evolution of insurance contracts in the case of pollution coverage and, more generally, coverage for toxic torts. For example, did the damage done by breast implants occur "during the policy period" because that was the time at which the patient received the breast implants? Or did the harm occur at some later date? Such latent injuries often trigger substantial debates as to whether the injury occurred during this policy period and what the character of exposure should be to trigger coverage. As a result of this kind of litigation, insurance contracts now typically are written to provide "claims made" coverage for a particular policy period, thus reducing the uncertainties faced by insurance companies. However, even with a narrowing of the coverage of insurance contracts that are being written, Abraham concludes that firms are charging an uncertainty tax on premiums because of the difficulty in pricing risks that have a potentially long tail.

X. Class Actions and Mass Torts

While many of the studies identify problems that have arisen with respect to the large scale litigation case studies that were analyzed, Chapter 8 by Rosenberg suggests that this litigation in some instances can serve a constructive function. In particular, he claims that mass torts are far superior to a rash of individual cases in addressing cases that involve common questions of law, common questions of fact, common legal facts, and situations in which there are potential economies of scale. The role of such litigation is to avoid the duplication of individual lawsuits. In addition, Rosenberg makes the novel observation that the launching of mass tort suits leads to optimal investment in the litigation by plaintiffs because it avoids the collective action problems that would otherwise be present.

In many respects, one can view the Rosenberg model as one in which the judicial system in effect is the counterpart to regulatory agencies. In much the same way as government regulators find it efficient to establish broadly based regulatory standards for particular products, Rosenberg finds it more efficient for the legal system to address product-related concerns in a single suit rather than in a series of individual cases. This would enable the legal system to take more of a market based perspective. The focus of Rosenberg's chapter however, is on the superiority of mass torts to individual suits, rather than on the superiority of mass torts to government regulation.

One noteworthy aspect of mass torts is the all or nothing character of the potential payoffs. If firms are risk-neutral, then they will be indifferent to facing a series of individual lawsuits or one large scale lawsuit. An important caveat is that this conclusion assumes away the potential for learning and changing one's litigation strategy in a series of cases. Moreover, once the stakes are in the billions, risk aversion of shareholders enters as a factor. By raising the stakes of litigation in a manner that threatens firms with bankruptcy should they lose, class actions increase firms' willingness to settle such cases rather than put the viability of the firm at risk, especially where there is a fear of punitive damages. Thus, the merits of class action may vary substantially in different situations depending on whether we are more in Rosenberg's constructive world of ideal class action assumptions or the world of Judge Richard Posner, who views these lawsuits as no more than single class blackmail.

The analytical desirability of the Rosenberg class action model also hinges quite critically on the assumptions that he specifies pertaining to the character of the class action. As he emphasizes, homogeneity of the cases is of particular importance, and one can view his criteria for the constructive role of mass torts as a useful checklist for what conditions must be satisfied for these lawsuits to be superior to individual litigation.

XI. Policy Prognosis

Although several contributors to this volume cite constructive roles for class actions and the regulation through litigation phenomenon, many have identified potential problems as well. Moreover, many of these chapters have identified criteria for judging which forms of litigation serve a constructive role and which do not. Ideally, one would

like to discourage litigation that has undesirable consequences, such as usurping the traditional authority of government regulation agencies and the control of taxation by the legislature.

How constructive changes could be accomplished is more problematic. The difficulty is not one of faulty government policy. The usual calls for government reform will not be effective. However, the more that can be done to promote effective regulatory oversight of potentially risky products, such as breast implants, and the greater the ability of government entities to ensure appropriate quality levels for products, such as the health care provided by HMOs, the less chance there will be of successful litigation to address these concerns. In many instances, the litigation stems from a real or perceived failure on the part of regulators to address potential harms to society.

Directly discouraging litigation is a more difficult matter. The attorneys bringing these suits have no reason to discipline themselves and restrain from launching lawsuits that are in their financial interest but perhaps not society's. The stakes involve payoffs to them in the billions of dollars, which constitutes a considerable lure for even the most self—restrained. Changing the character of the reimbursement of attorneys to avoid the windfall gains that resulted in the tobacco litigation and are being sought in the lead paint and HMO litigation could do much to deter such lawsuits in the future. At the very minimum, there should be increased public scrutiny of such fee arrangements and a competitive open bidding process for all such deals involving government entities as the plaintiffs. The goals would be to discourage sweetheart deals with attorneys and litigation that is driven by the prospect of windfall private gains resulting from the threat of catastrophic losses by governmental lawsuits.

Whether the regulation through litigation phenomenon proves to be a temporary or permanent way to address risk issues will depend to a great degree on the extent to which the concept can be applied to other products. Alcoholic beverages, fast food, automobiles, sport utility vehicles, and other products that create risks to consumers and external risks to others are among the potential targets of litigation. Whether such litigation will ever materialize hinges largely on how the courts address such suits. Unfortunately, because the tobacco litigation was settled, we lost an opportunity for the courts to establish definitive legal guidelines for such litigation. Only time will tell

whether society will continue to regulate through the courts or through more conventional processes.

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Table 1

Summary of Justifications for Litigation in Case Studies

Product	Alleged Governmental Failure	Remedy	Efficiency Effects
Tobacco	Medical cost externality to state Medicaid programs not addressed.	Lawsuits to transfer money to states; led to excise tax equivalent and negotiated regulatory changes; billions in plaintiff attorney fees.	Adverse effects based on assessment of the financial costs of smoking.
Guns	Governmental failure because of diffuse public benefits and strong interest group pressure.	Lawsuits by cities threatening penalties, with prospect of regulatory changes.	Prospective effects on gun distribution and safety devices, but experts disagree on desirability of all such measures.
Lead paint	Vigorous existing federal regulations, with lead paint ban since 1978; landlords subject to state and local regulations, but issues of efficacy and victim compensation.	Lawsuits against paint companies seeking payment for historical acts; landlord lawsuits for current exposures seeking compensation.	Incentives for landlords to reduce exposures, fixed costs for producers.
Breast implants	In use before FDA medical device regulation and not regulated when authority extended; little company research, but company suppression of adverse information.	Lawsuits seeking compensation for morbidity effects and speculative ailments; led to FDA review and research, often exonerating the product.	Exit from market of breast implant producers, perhaps may stimulate more research on such medical devices.
HMOs	Quality control problems of managed care not adequately regulated.	Litigation to force tobacco-type solution of premium taxes to pay off plaintiff attorneys.	Negative effect in discouraging purchase of coverage.