The Effects of Product Liability Exemption in the Presence of the FDA[1]

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Abstract

In the United States, drugs are jointly regulated by the US Food and Drug Administration, which oversees premarket clinical trials designed to ensure drug safety and efficacy, and the liability system, which allows patients to sue manufacturers for unsafe drugs. In this paper, we examine the potential welfare effects of this dual system to ensure the safety of medical products, and we argue—on economic efficiency grounds—for product liability exemptions for activities regulated by the FDA. When the safety level mandated by the FDA is binding—in the sense that manufacturers will not conduct additional clinical testing beyond what is mandated by FDA—then product liability may reduce welfare by raising prices without pushing firms, who are already bound by the FDA's requirements, to invest further in product safety. We consider as a case study the National Vaccine Injury Compensation Program, which sharply reduced vaccine manufacturer's liability in 1988. We find evidence the program reduced prices without affecting vaccine safety, consistent with the welfare-enhancement of product liability exemption in the presence of the FDA.

Section 1: Introduction

In the United States, drug and medical device safety and efficacy are primarily regulated by the United States Food and Drug Administration (FDA) through pre-market activities, such as mandatory clinical testing, and post-market activities, such as the use of the Adverse Event Reporting System to monitor the incidence of adverse events. However, while the FDA is the primary and most visible regulator of drug safety, the presence of legal liability after a product has entered the market gives firms large incentives to provide safe drugs.

The overlap between the FDA and product liability in regulating drug safety has received substantial attention from policymakers, particularly in light of several high profile lawsuits against drug manufacturers, such as those involving the drug Vioxx (rofecoxib).[2] Of particular interest has been the issue of pre-emption, which states that FDA approval of a drug's label, which lists the indications that the drug is approved to treat as well as warnings about any side effects, gives the manufacturer immunity against lawsuits based on state law. In 2006, this doctrine was formally adopted by the FDA through a modification in the *Federal Register.* The FDA's adoption of the pre-emption doctrine has been controversial in legal circles, with lower federal courts offering conflicting views on the doctrine. Recently, in *Riegel v. Medtronic*, the Supreme Court of the United States upheld the pre-emption doctrine for medical devices, although in a 5-4 decision in *Wyeth v. Levine*, the Court ruled the doctrine did not apply to drugs.

Supporters of pre-emption argue that it frees pharmaceutical firms from the chaos of 50 separate States regulating drug safety, thereby reducing the potential that pharmaceutical firms will "over-warn" patients about the risks of drugs (Calfee 2008; Calfee et al., 2008). Opponents

[2] Vioxx, a selective COX-2 inhibitor, was withdrawn from the US market in 2004 after several high profile lawsuits alleging that the drug significantly increased patients' risk of adverse cardiovascular events. On November 9, 2007, the manufacturer of Vioxx, Merck, agreed to establish a $4.85 billion settlement fund to compensate Vioxx patients who experienced a myocardial infarction or ischemic stroke while using the drug.

argue that product liability is a useful complement to the FDA, and has resulted in safer drugs (Kessler and Vladeck, 2008; Curfman, Morrisey, and Drazen, 2008).

Despite the debate over the potential consequences of pre-emption, there has been little explicit economic analysis that has attempted to determine under what circumstances pre-emption might improve economic efficiency. In this paper we provide a formal analysis of the dual regulation of medical product safety and the potential efficiency gains or losses induced by pre-emption. Our main argument is that when the level of safety mandated by the FDA is binding, so that firms do not invest more in ensuring product safety than required by the FDA, pre-emption has the ability to significantly improve welfare.

This argument is best seen by considering the case of a 'strong and independent' FDA. This FDA will require higher levels of safety investments—that is, the size and scope of clinical trials—than product liability alone would induce for that activity. In this case, product liability does not have the traditional deterrence effect on firms to market unsafe products beyond the safety investments required by the FDA. However, it raises firms' costs and therefore product prices, since it requires firms to potentially pay damages to consumers. As this price increase comes without a corresponding rise in the safety investment, product liability in presence of FDA lowers efficiency by restricting output and lowering access to medical products. In other words, when product liability does not affect safety but raises prices, pre-emption may raise efficiency. This efficiency analysis for pre-emption should by no means be interpreted as abolishing product liability altogether, e.g. for fraud, but simply for those activities for which another public entity is overseeing the same type of behavior—the duplication of public layers of regulation is inefficient.

The National Vaccine Injury Compensation Program (NVICP) provides a useful case study. This program shielded vaccine makers from liability in exchange for a special compensation program funded by an excise tax on vaccines. This program therefore essentially mimicked pre-emption by lowering the cost of liability dramatically. Prior to the implementation of NVICP, there was a substantial increase in liability actions relating to vaccines, and this increase is associated with a rapid increase in prices. After the NVICP was implemented, prices fell. However, we find no evidence that the NVICP led to more unsafe vaccines. If the effects of this program are indicative of a more general pattern of no safety effects and reduced prices when reducing liability in presence of FDA, then pre-emption may be efficiency enhancing.

The paper is briefly organized as follows. Section 2 provides background on the dual regulation of drug safety. Section 3 presents and discusses our analysis of the efficiency effects of pre-emption. Section 4 discusses our case studies for vaccines covered by the NVICP. Lastly, Section 5 concludes and discusses future research.

Section 2: Background on US Medical Product Safety Regulation.

In the United States, the FDA is the federal agency charged with regulating drug safety and efficacy. The majority of the agency's efforts are devoted towards pre-market activities, whereby the agency supervises and evaluates a series of clinical trials undertaken by drug manufacturers in order to establish drug safety and efficacy. The clinical trial process begins when a firm files an Investigational New Drug application, which requests permission from the FDA to conduct clinical trials on humans. Typically, this application contains the available preclinical information, as well as protocols for the drug's clinical trials, and any data on trials conducted overseas.

Once the FDA gives its approval, the firm may begin conducting clinical trials for the drug, which proceed in three phases. The goal of Phase I is to evaluate the drug's safety and to obtain data on its pharmacologic properties. Typically, phase I trials enroll small numbers (20-80) healthy volunteers. Phase II trials then enroll slightly larger (100-130) numbers of sick volunteers. The goal of these trials is to begin investigating a drug's efficacy and optimal dosage, and to monitor the drug's safety in diseased patents. Finally, Phase III testing typically involves larger numbers (more than 1,000) of sick patients and is the most costly stage of the approval process. Phase III testing seeks to establish more definitively the efficacy of a drug, as well as to discover any rare side effects. Upon the completion of Phase III testing, the firm submits a New Drug Application to the FDA, which is accompanied by the results of the clinical trials. The FDA may then reject the application, require further clinical testing, or approve the drug outright.

In addition to issuing approval of the drug, the FDA must approve the label that accompanies it. This label provides data on the drug's pharmacologic properties and side effects,

as well as brief summaries of the clinical trials reported to the FDA. Perhaps most importantly, the label also lists the indications (or diseases) that the drug is approved to treat. Thus, approval by the FDA is not merely approval of the drug, it is approval of the drug for specific uses. If a firm wishes to obtain approval for additional indications, it typically must begin a new set of clinical trials for those indications. Use of a drug for an indication not listed on the label ("off-label use") is not illegal, and indeed occurs regularly in many areas, such as oncology. However, it is illegal for a manufacturer to advertise a drug for a non-approved indication. In addition, insurers may not always pay for off-label use of a drug.

The FDA also oversees the safety and efficacy of medical devices. Here, the process is more complex, because the statutory definition of a medical device is extremely broad[3] and includes a wide variety of implements, such as tongue depressors, home pregnancy tests, and drug eluting stents. All devices are categorized into one of three classes (I, II, and III), based on the degree of patient risk. Class I devices are the least risky, and typically require no premarket approval from the FDA, although the manufacturer must register with the FDA prior to marketing the device. Class II devices pose more risk to patients, and must receive prior approval via the 510(k) review process, which typically seeks to establish that the given device is substantially equivalent to another device that has received FDA approval. The most risky (class III) devices require approval via the premarket approval process (PMA), which, similar to the process for pharmaceuticals described above, involves the submission of a PMA application establishing the device's safety and efficacy, usually through the results of clinical trials. After

[3] According to the Food, Drug and Cosmetic Act, a medical device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

receipt of a PMA or 510(k) application, the FDA reviews it and decides whether to allow the device to be marketed in the US. For devices approved via PMAs, further changes require different types of supplemental applications (supplemental PMAs), depending on the nature of the modification. Large-scale changes to the device, such as changes in its indication or substantial changes in design, require a Panel Track Supplement, which is in effect equivalent to submitting a new PMA. More modest changes require a 180-day Supplement, and minor modifications require a Real-time Supplement. In addition, changes in the manufacturing process must be approved via a 30-day Supplement.

While the FDA is the primary and most visible player in drug and device safety regulation, product liability also plays a role in ensuring safety by allowing patients to sue manufacturers for unsafe drugs and recover damages for any adverse events that they suffer. Patients can generally sue manufacturers under one of three theories of legal liability. The first, *defective design*, allows a patient to sue on the basis that the design of a drug or device was inherently unsafe. Second, patients can sue for *defective manufacturing* of an otherwise safe drug or device. Finally, under the theory of *defective warnings*, patients can sue by showing that the firm failed to provide sufficient warning of the possibility of an adverse event if it knew or shown have known about the risks. Given that the FDA approval encompasses a drug or device's safety and the sufficiency of the warnings in the drug label, firms have tried to use FDA approval as a shield against product liability suits. For drugs, this argument has generally been accepted by the courts (Garber, 1993), under a widely cited comment included in *Restatement (Second) of Torts*, which states that drugs are an example of an "unavoidably unsafe product," in other words, drugs are not generally *unreasonably* dangerous, and the dangers associated with them are not evidence of defects in the drugs themselves. However, for medical devices, rather than

drugs, design lawsuits are more common, since there is more ability to design a device with a better safety profile. Since courts have generally held that drug manufacturers cannot be sued for faulty design, the vast majority of drug lawsuits to date have been for failure to warn, and here, courts have in general held that FDA approval of the warnings on the label does not provide a shield against liability lawsuits. Courts have generally held that compliance with FDA regulations is a minimum standard. Thus, failure to comply with the FDA leaves a firm extremely vulnerable to lawsuits, but compliance does not shield a firm against lawsuits. However, it is important to note that the FDA maintains tight control over the information that a firm can release about a drug, including the release of warnings. For example, the FDA can prohibit the firm from adding a warning to the product label. Even if the FDA prohibits the firm from adding a warning, the firm can still be found liable for failing to warn consumers (Garber, 1993; Calfee, 2006). Lawsuits against firms proceed under state laws, and therefore, the determination of whether the firm knew, or should have known, about a particular risk is based on state-specific legal standards. If the patient prevails at the trial, he can recover compensatory damages for the adverse event, as well as punitive damages, if it is found that the firm intentionally hid evidence from the FDA.

While estimates of the costs of liability for pharmaceuticals and devices are few, there are indications that these costs are substantial, especially when viewed as a share of marginal costs. The latter is an important issue, as from an economic perspective, legal costs will have a larger effect on welfare when they comprise a large portion of marginal costs. Given that the marginal costs of drug production are low for drugs, even small legal costs may account for a significant proportion of marginal costs. A report prepared by the Council of Economic Advisers (2002) found that in 2000, liability costs across all US industries were $180 billion, or roughly 1.8

percent of GDP. The same report suggested that the inefficiencies from the liability system were equivalent to the inefficiencies that would occur from a 2 percent increase in consumption taxes, a 3 percent tax on wages, and a 5 percent tax on capital income.

There is research suggesting these relative liability costs are even higher for drugs. Manning (1994) identified liability costs for the diphtheria-pertussis-tetanus vaccine by comparing changes in the vaccine's price against changes in the price of the diphtheria-tetanus vaccine, as the only difference in the vaccines is the pertussis component, which adds a negligible cost to the production price of the vaccine and was the subject of numerous lawsuits. Using this approach, Manning found that liability accounted for up to 90% of the price of the diphtheria-pertussis-tetanus vaccine's price. In addition, in related work (Manning, 1997), Manning finds that differences in product liability regimes can explain much of the difference in the Canadian and US prices of drugs.

Section 3: An Efficiency Analysis of Regulation and Liability of Medical Products

In this section, we analyze the efficiency effects of pre-emption. We consider standard models of product liability (see e.g. Shavell 2006 for a review) which concerns post-market activities, to which we add the presence of pre-market regulations governed by the FDA. We assume that FDA mandates and verifies a minimum safety level which may or may not be binding given the deterrence effect of product liability.

Product Liability in absence of FDA

Consider when marginal are constant and for a given level of safety s are given by[4]

$$C(s) = c(s) + d(s) \qquad (1)$$

where $c(s)$ is the marginal cost of production that rises in safety and $d(s)$ is the marginal cost of legal damages that falls in safety. It seems clear that product liability never improves efficiency in the case when consumers are fully informed of safety because then prices will reflect the degree of safety. There is no externality between the seller and buyer in that case. Therefore, we consider the case when consumers are uninformed so the demand curve $q(p)$ is simply a function of price and not safety. In this case, the firm chooses the price p and safety level s to maximize profits given by

$$\pi = q(p)(p - c(s) - d(s)) \qquad (2)$$

The first order condition for the optimal level of safety under product liability, denoted s^{PL}, is then given by

[4] Our notion of safety s is extremely flexible, and can accommodate a wide variety of specifications. For example, s could refer to a vector of drug characteristics, such as the safety of the drug itself, as well as the adequacy of warnings about the drug.

$$c_s + d_s = 0 \qquad (3)$$

This simply states that the firm chooses the level of safety that minimizes costs through equating increased costs of production with reduced liabilities. Given the minimized costs, the first order condition for price satisfies the familiar Lerner mark-up condition

$$p = \frac{\varepsilon}{\varepsilon - 1}\left(c(s) + d(s)\right) \qquad (4)$$

A special case would be competitive pricing in which the firm demand elasticity made the markup vanish. The social welfare for the quantity and safety level that results treats liability payments and transfers and is given by

$$W(q,s) = \int_0^q \left[p(x,s) - c(s)\right]dx \qquad (5)$$

This specification implicitly reveals the efficiency enhancing effects of product liability: given that safety is costly for firms to provide and that patients are uninformed, product liability gives firms incentives to provide safety by making them internalize the costs to patients of unsafe products. Thus, product liability essentially acts as a Pigouvian tax that causes firms to internalize the losses on consumers associated with unsafe products.

Product Liability in Presence of FDA

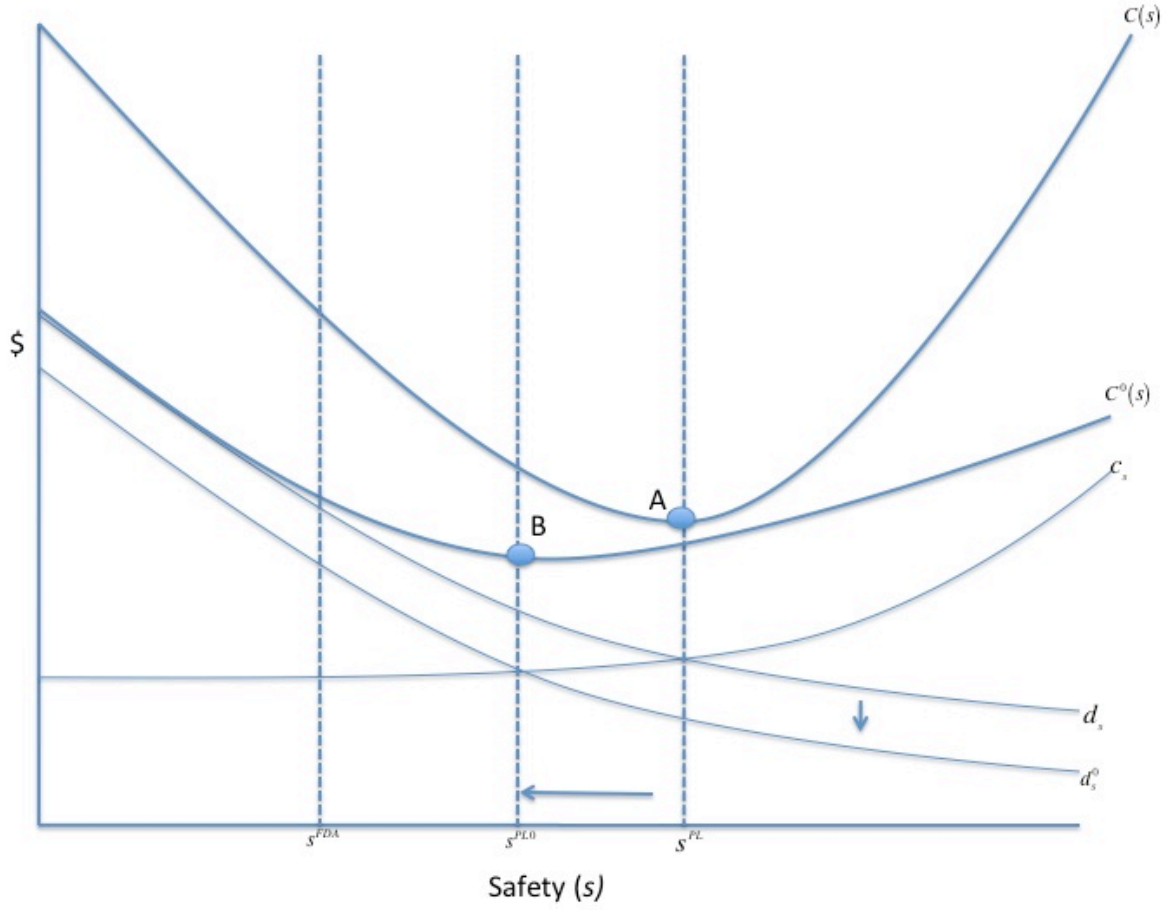
The previous section discussed the traditional efficiency role of product liability to give firms incentives to provide levels of safety by facing firms with the social cost associated with unsafe products. To extend our analysis to incorporate the FDA, suppose that the agency mandates and monitors a minimal level of safety denoted s^{FDA}. With the addition of the FDA, there are now two possibilities. If the level of safety the firm chooses to provide under product liability is higher than the level mandated by the FDA, then the firm will continue to provide the

safety level s^{PL} and in this case, the addition of the FDA has no safety-effects. However, if s^{PL} is less than s^{FDA}, then the firm will provide the minimal level of safety enforced by the FDA. We refer to the latter case as a situation where the FDA mandated level of safety is *binding* on firms. Thus, if product liability alone, perhaps through imperfect enforcement or under-estimation of risks, does not give firms sufficient incentives to provide safety, the addition of the FDA can improve safety if the FDA mandates a level of safety higher than what firms would choose to provide under product liability alone.

The Welfare Effects of Pre-emption

The pre-emption doctrine, as described in the introduction, would allow FDA approval to shield firms from lawsuits based on state law. In effect, the doctrine would set legal costs $d(s)$ equal to zero if the firm provided safety at least as high as the FDA mandated level. To analyze the effect of a product liability exemption on welfare, consider the Figure 1 below, where the x-axis shows the level of safety *s*. The upward sloping curve in the figure is the marginal cost of producing additional safety, c_s, the downward sloping curve is the marginal benefit to the firm of providing safety, given by the liability reduction d_s, and the U-shaped curve $C(s)$ is the firm's costs. The optimal choice of safety chosen by the firm s^{PL} is therefore given by the point where the two curves intersect and the total marginal costs bottoms out. Under a regime that lowers product liability, which in the extreme case would involve liability pre-emption. This induces the damages curve and the cost curve to shift down to d_s^0 and $C^0(s)$, respectively. Therefore, with the reduced liability, the optimal level of safety is reduced to s^{PL0} and its costs are given by point B.

Figure 1 – Product Liability Exemption and Social Welfare : non-Binding FDA

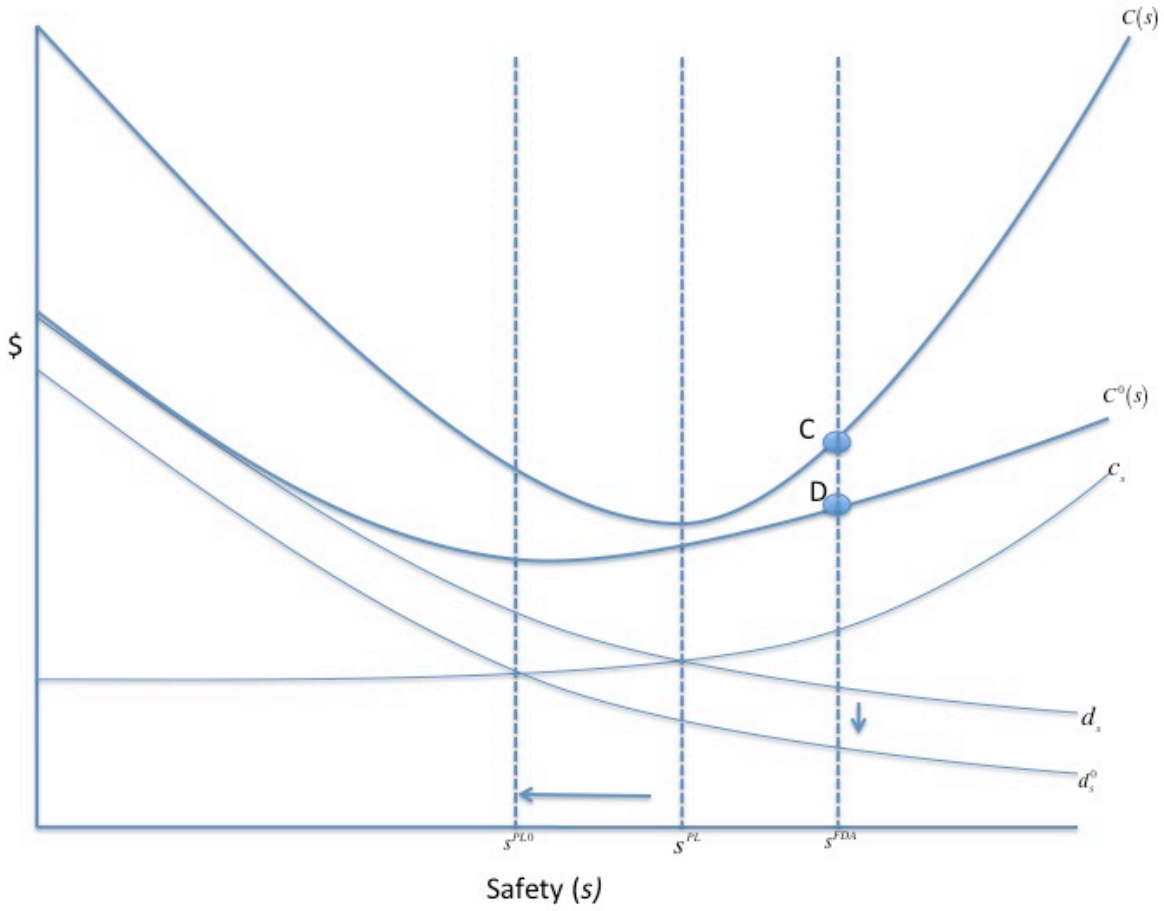


The level of safety mandated by the FDA, s^{FDA}, may lie to the left or to the right of the level of safety induced by liability s^{PL}, depending on whether FDA safety levels are binding. Consider the first case, as shown in figure 1. In this case the level of safety mandated by the FDA is not binding on firms, so they will provide safety s^{PL} in the absence of a product liability exemption and s^{PL0} with the exemption. In this case, the welfare effect of the exemption is ambiguous, as the exemption lowers marginal costs and price, but also safety.

On the other hand, suppose that the safety mandated by the FDA lies to the right of s^{PL}, as shown in figure 2. In this case, the level of safety mandated by the FDA is binding on firms, they will provide s^{FDA} with or without the reduced level of liability. In this case, the pre-

emption raises welfare by lowering marginal costs from point C to point D, while having no effects on safety.

Figure 2 – Product Liability Exemption and Social Welfare : Binding FDA



This analysis suggests that the pre-emption doctrine has the potential to increase welfare in the case where the presence of the FDA is binding on firms. Intuitively, product liability in general has two opposing effects on welfare. It positively affects welfare by inducing the firms to provide safe drugs, but negatively affects welfare by increasing marginal costs and price. When the level of safety mandated by the FDA is binding, the second effect dominates, since product liability has no *additional* effect on the level of safety firms choose to provide, but raises prices and thus restricts access.

Section 4: A Case Study of Recent Drug Liability Limitations

In this section, we consider a case study of the price- and safety effects of the National Vaccine Injury Compensation Program, which sharply reduced vaccine manufacturers' legal liability by creating a patient compensation fund supported by excise taxes on vaccine users. As discussed in the previous section, if FDA regulations are binding on vaccine makers, then a product liability exemption could reduce prices without affecting safety. Since the National Vaccine Injury Compensation Program shielded vaccine makers from the larger liability risk before the program, it serves as a useful case study of whether a product liability exemption would impact price and safety. Section 4.1 provides background on the program, while section 4.2 details our analysis.

4.1: Background on the National Vaccine Injury Compensation Program

Vaccines are credited with sharply reducing morbidity from several diseases, such as pertussis, polio, and tetanus (CDC, 1996). Currently, vaccinations for diphteria, pertussis, tetanus, measles, mumps, rubella, and polio are required for children attending kindergarten or middle school in all 50 states, and most states require vaccinations against hepatitis B and varicella zoster (chicken pox) virus as well. In addition to these required vaccines, several optional vaccines also exist for childhood and adult diseases, such as Hepatitis C and influenza.

Although vaccines are generally safe, as with all drugs, there is the potential for adverse side effects. For example, the pertussis vaccine (typically given in combination with vaccines for diptheria and tetanus) has long been associated with severe neurologic illnesses such as convulsions (Manning, 1994; CDC, 1996), while more recently, there has been controversy over the association between thiomersal, a preservative used in many vaccines, and autism.[5] Prior to

[5] While the IOM, AMA, CDC, and FDA have stated there is no causal link between thiomersal and autism, to date, over 5,000 claims relating to autism have been filed with the National Vaccine Injury Compensation Program.

the passage of the National Childhood Vaccine Injury Act in 1986, patients could sue vaccine manufacturers by alleging manufacturing defect, failures to provide proper warnings to the physician or patient, and/or failures to provide for safer alternatives (Ridgway, 1999). These lawsuits appear to have been substantial in the amount of damages relative to sales. For example, between 1980 and 1986, vaccine lawsuits alleged a total of $3.6 billion in damages (Davis and Bowman, 1991).

Concerns that lawsuits might lead vaccine manufacturers to exit the market, or reduce the supply of vaccines led Congress to pass the National Childhood Vaccine Injury Act in 1986, which established the National Vaccine Injury Compensation Program (NVICP) on October 1, 1988. The NVICP requires payment of an excise tax for the vaccines covered, which funds a pool of money, the Vaccine Injury Trust Fund, used to compensate victims of adverse events. Prior to 1998, excise taxes were set at the estimated level of liability costs. For example, the excise tax for the diptheria-pertussis-tetanus vaccine, which contains the pertussis component associated with neurologic disease and lawsuits, was $4.56, compared to only $0.06 for the diptheria-tetanus vaccine. In 1998, the program was changed so that all vaccine recipients pay a common excise tax of $0.75 per dose[6] to fund the Vaccine Injury Trust Fund. If a patient suffers an adverse reaction after vaccination, he must first file a claim with the NVICP before proceeding to civil litigation against the vaccine manufacturer. In order to receive compensation, the patient's claim must establish that the vaccine caused the adverse event. Alternatively, the NVICP also maintains a table of vaccines, associated adverse effects, and time periods. If the patient's adverse effect is listed on the table and occurs within the specified time period, causality is presumed and the patient is entitled to compensation.

[6] A dose is defined *per disease*, so combination vaccines, count as more than one dose. For example, the excise tax for the Measles-Mumps-Rubella (MMR) vaccine is $2.25, since it counts as having three doses.

Claims with the NVICP are decided by Special Masters of the Court of Federal Claims. Patients who are found to have suffered an adverse event that was caused by a vaccine are entitled to recovery of damages for medical and other expenses, such as lost earnings. However, in the case of death, payments to the patient's estate are limited to $250,000; this cap also applies to pain and suffering damages. As long as the claim meets certain minimal standards, legal expenses up to $30,000 are reimbursed, regardless of the Special Master's decision. Acceptance of the Special Master's decision forecloses future legal claims against the vaccine manufacturer. If a patient disagrees with the decision, he can proceed to sue the manufacturer, but is barred from utilizing several approaches, such as lawsuits based on failures to warn.

The above description of the NVICP applies to patients who received a vaccine from 1988 onwards, and generally applies to patients who received a vaccine prior to 1988, with a few differences. First, patients who received a vaccine prior to 1988 are allowed to bypass the NVICP and proceed directly to civil litigation. However, if they choose to file a claim with the NVICP, they must have done so by January 31, 1991. In addition, they face a limit of $30,000 for attorney's fees, pain and suffering, and lost income. Instead of an excise tax, payments to these patients are funded by general revenues.

Table 1 provides a brief summary of the economic costs of the program. For several vaccines, the table lists the CDC price per dose which is the price available to organizations receiving CDC grant funds, such as state health departments, as well as the private sector price which is the price mandatorily reported by the manufacturer to the CDC. Table 1 also reports the excise tax for each vaccine which is fairly small relative to the private sector price for most of the vaccines.

Table 1 – Prices and Excise Taxes for Selected Vaccines

DISEASE	BRAND NAME	CDC PRICE/DOSE	PRIVATE SECTOR PRICE/DOSE	TAX
Childhood				
Diptheria/Pertussis/Tetanus	Tipedia	$10.40	$21.40	$2.25
Diptheria/Pertussis/Tetanus/Polio/Hepatitis B	Pediarix	$45.00	$70.72	$3.75
Hepatitis A	VAQTA	$12.00	$30.37	$0.75
Hepatitis B	ENERGIX B	$8.75	$21.37	$0.75
Measles, Mumps, and Rubella	MMRII	$16.01	$46.54	$2.25
Adult				
Hepatitis A	VAQTA	$19.25	$63.51	$0.75
Hepatitis B	ENGERIX-B	$24.15	$52.50	$0.75
Diptheria/Tetanus	None	$11.45	$18.95	$1.50
Influenza	Fluzone	$9.22	$11.72	$0.75

Table 2 provides summary statistics on inflation adjusted payments made by the NVICP. Between FY 1990 and 2007, the NVICP paid out a total of nearly $3.2 billion for 3,499 claims. However, as previously noted, the NVICP reimburses legal costs even for dismissed claims, as long as minimal standards are met, so not all of these payments were made for successful claims against the Program. For vaccines administered from 1988 onwards, the Program paid out an average of roughly $1.3 million per compensable claim, of which an average of $53,277[7] was used to pay attorney's fees. The program paid an average of $28,296 for attorney's fees associated with dismissed claims. For vaccines administered prior to 1988, the NVICP paid an average of $762,530 per claim. Unfortunately, no further data are available to examine the

[7] We previously stated that the NVICP caps attorney's fees at $30,000 in nominal terms; the reason why this average is higher is due to discounting and adjusting for inflation.

average payment for dismissed and compensable claims, as well as the amounts paid for legal costs, for vaccines administered prior to 1988.

Table 2 – Summary Statistics on Payments Made by the NVICP

	VACCINES ADMINISTERED BEFORE 1988	VACCINES ADMINISTERED FROM 1988 ONWARDS
Total Number of Payments	2,542	957
Total Payments	$1,938,351,330	$1,273,206,719
Average Payment per Claim	$762,530	$1,330,414
Average Payment per Compensable Claim	N/A	$1,394,674
Average Attorney's Fee per Dismissed Claim	N/A	$53,277
Average Attorney's Fees per Compensable Claim	N/A	$28,296

Notes : Source is the July 1, 2008 statistics report from the National Vaccine Injury Compensation Program, available at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.

4. 2: The Price and Safety Effect of the National Vaccine Injury Compensation Program

We considered the price effects of the NVICP on 7 vaccines: measles, mumps, rubella, measles-mumps-rubella (MMR), diptheria-tetanus-pertussis (DTP), diptheria-tetanus (DT), and the oral polio vaccine (OPV). Table 3 shows the excise tax for each vaccine between 1988-1996 and the price of the vaccine in 1988. Recall that between 1988 and 1996, the excise taxes for each vaccine were set to represent expected liability costs. Thus, table 3 suggests significant variation in vaccine liability. The DT and OPV vaccines appear to have had low legal exposure, as excise taxes comprised between 2-4% of the 1988 prices. Conversely, the measles, mumps, rubella, MMR, and DTP vaccines appear to have had higher legal exposure, as the excise taxes accounted for 10-25% of their 1988 prices.

Table 3 – Vaccine Excise Taxes

VACCINES	1988-1996 EXCISE TAX	1988 PRICE	EXCISE TAX AS A % OF PRICE
Measles	$4.44	$23.94	18.54%
Mumps	$4.44	$26.50	16.76%
Rubella	$4.44	$24.73	17.96%
MMR	$4.44	$47.31	9.38%
DTP	$4.56	$18.49	24.66%
DT	$0.06	$1.35	4.43%
OPV	$0.29	$14.01	2.07%

Figure 3 below plots prices for the vaccines with higher legal exposure (measles, mumps, rubella, MMR, and DTP) between 1975 and 1995. These prices represent the total price paid by patients, and therefore include any excise taxes imposed by the National Vaccine Injury Compensation Program. Prices from 1975 through 1986 are Blue Book and Red Book wholesale prices collected by Manning (1994) who did not collect data after the NVICP program was implemented. To assess the time trend surrounding this program, from 1987 and beyond, we used private-sector vaccine prices reported by drug manufacturers and published by CDC. We chose 1995 as the end date because DTP prices were no longer available past this point, as the vaccine was replaced with the DTaP vaccine, a safer version of the DTP vaccine which uses an acellular form of the Pertussis pathogen.

Figure 3 –Vaccine Prices for Heavily Litigated Vaccines, 1975-1995

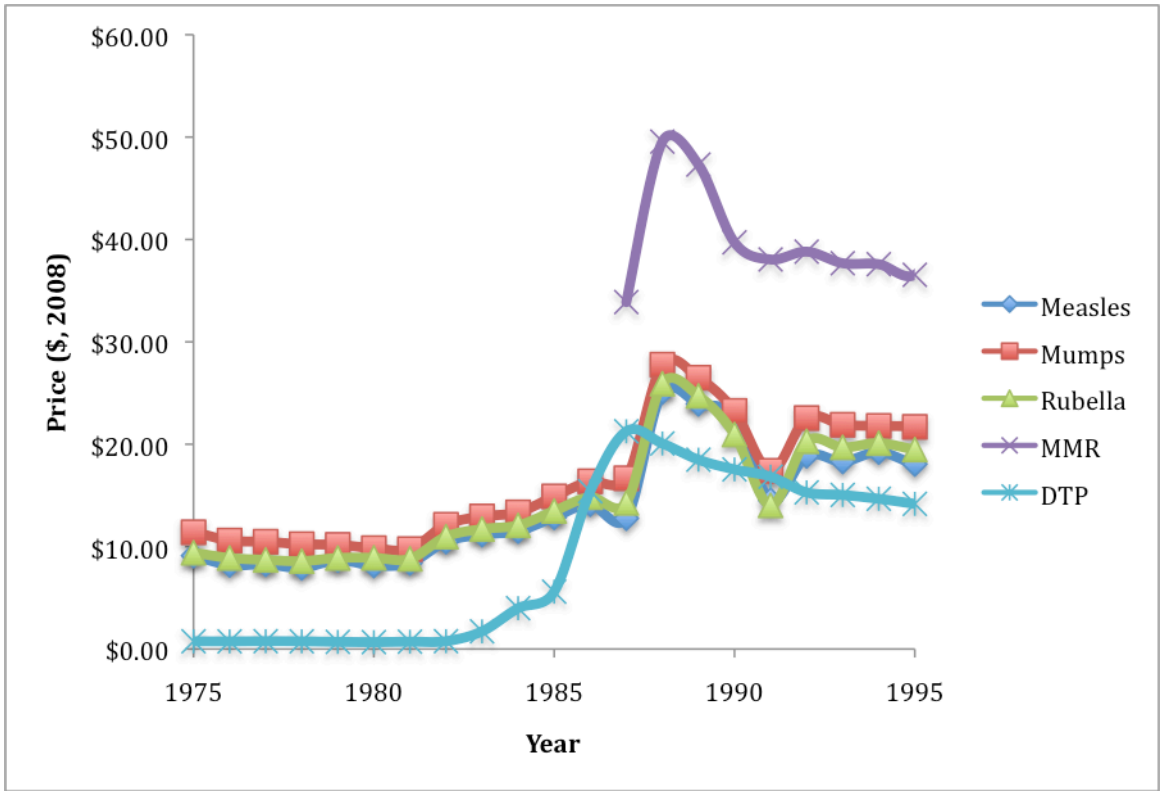
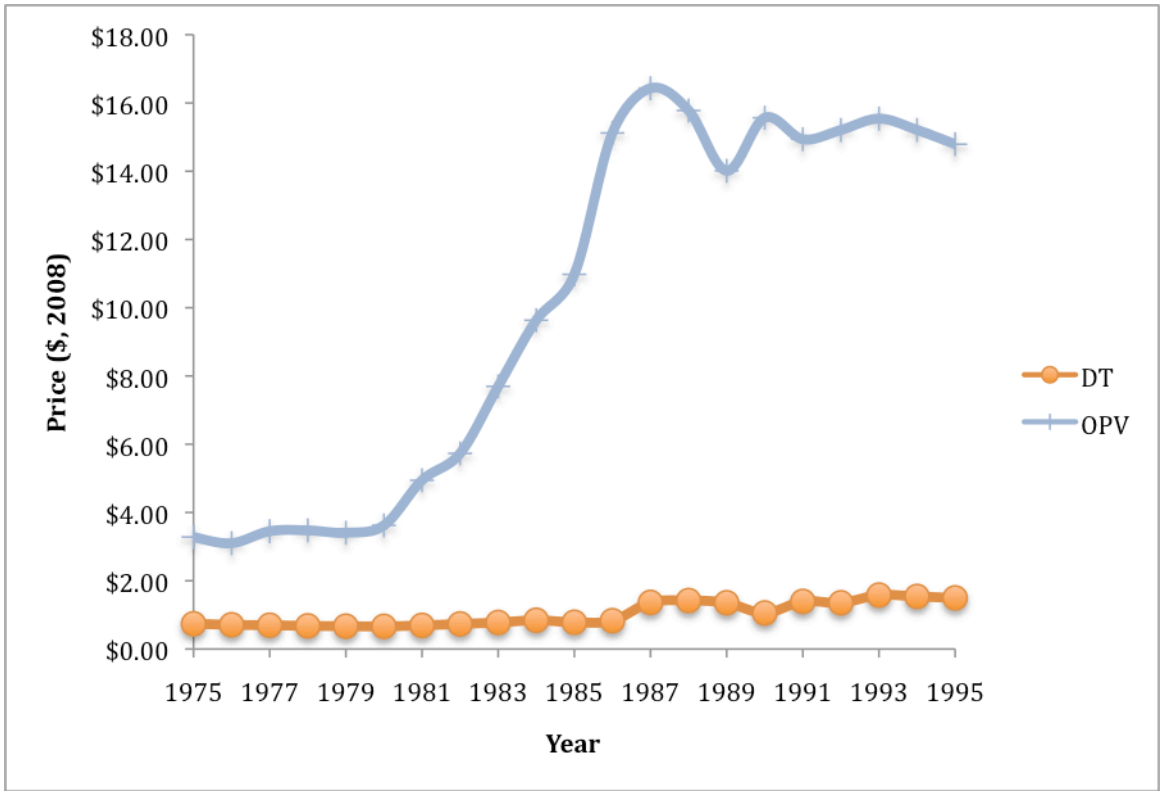


Figure 3 suggests that the NVICP has significantly reduced vaccine prices for the vaccines that faced particularly heavy liability, as the price of each vaccine fell considerably after 1988, the year in which the NVICP was created. For example, the DTP vaccine cost $20.07 in 1988; by 1995, the price had fallen to $14.18. Similarly, the MMR vaccine cost $49.56 in 1988 and fell to $36.55 in 1995. By contrast, figure 4 plots the time series of prices for the two less litigated vaccines, the OPV and DT vaccines. In contrast with the more heavily litigated vaccines, prices for these two vaccines appear to have remained relatively constant following the introduction of the NVICP.

Figure 4 –Vaccine Prices for Less Litigated Vaccines, 1975-1995



Comparing the prices of the DT and DTP vaccines is particularly helpful. As discussing in Manning (1994), these two vaccines are essentially similar except that the DTP vaccine contains the Pertussis component, which was the subject of numerous lawsuits over neurological adverse events. As Manning (1994) discusses, the prices of the DT and DTP vaccines were quite similar prior to 1982, when lawsuits were rare. For example, in 1975 one dose of DTP cost 73 cents and one dose of DT cost 71 cents, a difference that remained largely unchanged up until 1982. However, after 1982, when the number of lawsuits for adverse events for the Pertussis component began to rise sharply, the price of the DTP vaccine increased significantly compared to the price of the DT vaccine. Since the two vaccines are otherwise similar except for the presence of the Pertussis component and had similar prices prior to 1983, Manning (1994) interprets the post-1982 difference in the prices of the two vaccines as the cost of liability for the

Pertussis component. At its peak in 1986, the difference in the price of the two vaccines was $14.04, and liability costs accounted for nearly 96 percent of the DTP vaccine's price.

Figure 3 suggests that not only did prices of DTP rise with increased liability but they also fell after the introduction of the National Vaccine Injury Compensation Program in 1988, from $20.48 in 1987 to $13.65 in 1995, a 33% decrease. Since price of the DT vaccine slightly rose during the same period (Figure 4), the fall in the price of the DTP is likely due to changes in liability, as opposed to changes in the costs of production or increased competition.

With information about the demand for vaccines, standard methods can be used to estimate the welfare gains from these price reductions induced by reduced liability. Specifically, consider when demand function has a constant price elasticity, so that the inverse demand function is

$$p(x,s) = \left(\frac{x}{A(s)} \right)^{-\frac{1}{\varepsilon}} \qquad (6)$$

where ε is the elasticity of demand and $A(s)$ is a shifter of demand based on safety s. With this demand specification can easily be shown that increase in welfare from a z percent reduction in price is given by

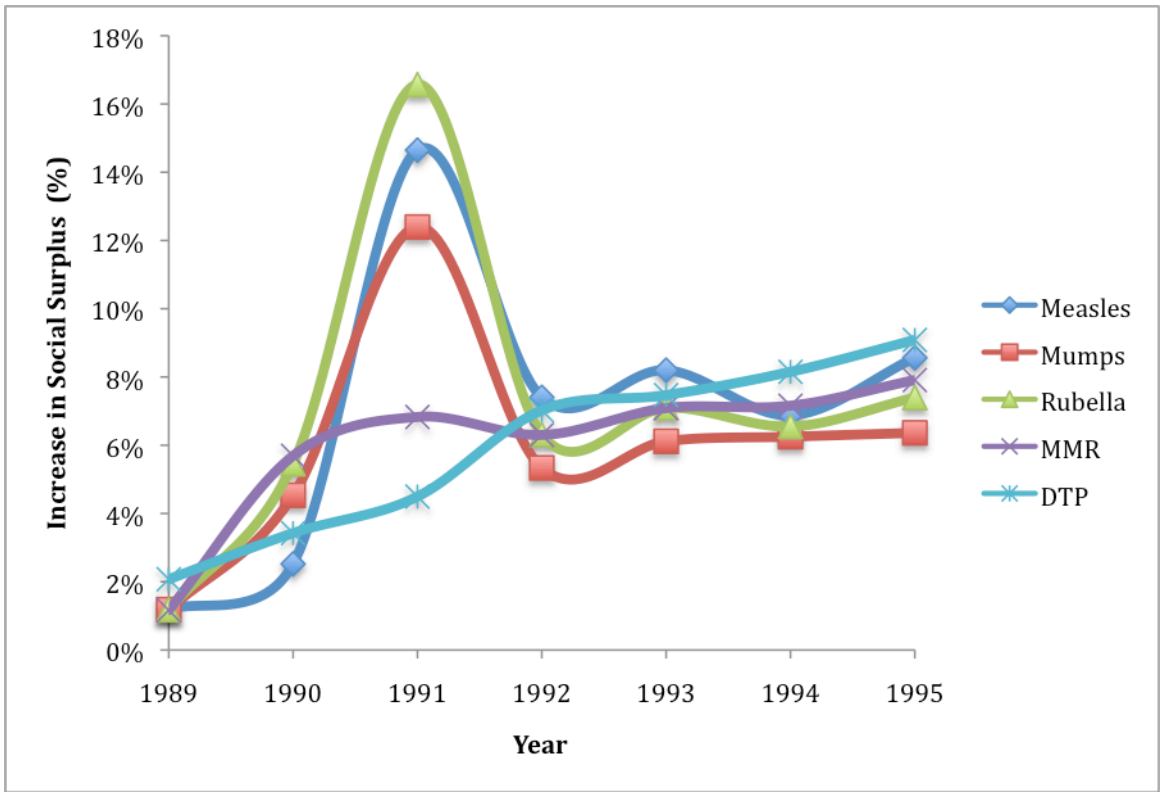
$$\Delta W = (1-z)^{1-\varepsilon} - 1 \qquad (7)$$

We consider an elasticity of 1.25, based on Philipson and Sun (2006). They utilize patent expiration evidence (Grabowski and Vernon, 1992; Berndt, Cockburn, and Griliches, 1996; Caves, Whinston, and Hurwitz, 1991), which implicitly estimates the demand elasticity for drugs by from supply-induced price-reductions from patent expiry. This elasticity of demand differs from the co-pay elasticity of demand estimated by others (Goldman, Joyce, and Karaca-Madic, 2006; Goldman, Joyce, and Zheng, 2007), because the latter is the elasticity of demand from

patients who already have insurance, and only need to pay their insurance co-pay for the drug. Our elasticity of demand is the elasticity of demand facing the manufacturer, which takes into account the demand for health insurance itself and other factors as well.

Given an elasticity of 1.25, figure 5 shows the social surplus increases (ΔW from equation 7) for the measles, mumps, rubella, MMR, and DTP vaccines, based on prices decreases from their peak values in each year of the NVICP. Overall, we find that the NVICP has substantial effects on consumer and producer surplus by lowering prices for the DTP. For example, our results suggest that in 1995, the DTP vaccine was 29% lower than its pre-NVICP price, suggesting an increase in social surplus of 9.1%. Across the vaccines that we consider, we find that the NVICP had increased social surplus by roughly six to nine percent in 1995.

Figure 5 – Effect of NVICP on Social Surplus



To consider the safety effects of the NVICP there are two margins in which it may affect safety. The first is on vaccines marketed before the program, in which the effect is zero[8] and the second is on vaccines marketed after the program for which it may reduce safety. Since the vaccines of the program remained unchanged, there was no change in safety for those vaccines. Thus, the NVICP appears to have unambiguously raised welfare in the case of the discussed vaccines.

An interesting question raised, and for which further analysis is warranted, is whether the NVICP affected vaccine safety on the second margin. As one approach for looking at this issue, we examined the incidence of reported adverse events to the vaccines listed in table 4. These vaccines were chosen because they comprise the recommended list of vaccinations for children, as given by the CDC. Table 5 also reports the recommended ages of administration for each vaccine, and the date each vaccine entered the market.

To estimate the incidence of adverse events, we used the Vaccine Adverse Event Reporting System (VAERS), which has collected reports on adverse events from immunizations since 1990. The VAERS consists of self-reported incidents of adverse events, from vaccine manufacturers (42%), health care providers (30%), state immunization programs (12%), patients (7%), and other sources (9%). It is important to reiterate that these events are self reported, and that VAERS makes no effort to identify whether the vaccine actually caused the adverse event. Table 5 shows the total number of adverse events reported to VAERS for each vaccine between 1990 and 2006. To obtain the incidence, we divided the number of adverse events by the total number of children in the recommended ages during the periods for which the vaccine was available, using US Census data on population estimates by single years of age between 1990

[8] This concerns design effects. If there are safety issues in manufacturing that are affected by liability, they may be affected after the product has been invented.

and 2006. Since the Census only reports population by single years of age, we rounded the recommended ages listed in table 4 up to the nearest whole year.

Overall, our results suggest that the newer vaccines are not less safe than vaccines introduced prior to the NVICP. For the five vaccines introduced prior to the NVICP, the mean number of adverse events per 1000,000 doses is 15.4 (s.d. 10.8), while for the eight vaccines introduced after the NVICP, the mean probability of an adverse event is 9.28 (s.d. 9.03). Although the incidence of adverse events is slightly lower with the newer vaccines, the difference between the groups is not statistically significant ($p<0.2$).

Table 4 – Incidence of Adverse Events for Childhood Vaccines, 1990-2006

VACCINE	YEAR OF INTRODUCTION	RECOMMENDED AGES	NUMBER OF ADVERSE EVENTS	TOTAL POPULATION AT RISK (MILLIONS)	NUMBER OF ADVERSE EVENTS PER 100,000 DOSES
Vaccines Introduced Prior to NVICP					
DTP	1950	<=6yrs	20,221	465	4.35
Poliovirus	1964	2-15mos, 4-6y	23,574	332	7.10
Hepatitis B	1981	<=18mos	29,741	199	19.0
Haemophilus B	1985	<=15mos	37,822	199	14.9
MMR	1987	12-15mos, 4-6y	41,866	133	31.6
Vaccine Introduced After NVICP					
Influenza	Annually	Children 6mos-18y;	28,203	1,262	2.23
DTaP	1994	<=6yrs	34,760	412	8.43
Varicella	1995	12-15mos, 4-6y	28,407	94	30.4
Pneumococcal (Conjugate)	2000	<=15 mos	13,268	166	7.99
Meningococcal Vaccine	2001	11-12y	1,150	20	5.68
Hepatitis A	2005	12-24mos	6,699	98	6.85
Rotavirus	2006	6-14wks	710	36	1.98
Human Papillomavirus	2006	11-12y	429	4	10.78

Overall, then, our analysis suggests that the NVICP has not resulted in more dangerous vaccines. However, it is useful to note several limitations to our analysis. First, as described above, the VAERS provide an accurate measure of the number of adverse events. On the one hand, VAERS may understate the true number of adverse events, since it the data is self-reported; however, since VAERS makes no attempt to verify whether a vaccine did cause a reported adverse event, it may also overstate the true of events. In addition, our measure of the total population at risk includes only the number of children who were at the recommended age for the vaccine. This value may understate the true number of patients receiving the vaccine to the degree that vaccinations are delayed and therefore received at later ages. Conversely, this approach may understate the number of patients taking the vaccine if compliance is not perfect. However, to the degree that these shortcomings equally affect the vaccines in our sample, they would not significantly affect our results. Overall, then, we find that the NVICP likely increased welfare by lowering prices, without affecting safety.[9]

Section 5: Concluding Remarks

Our analysis examined the value of pre-emption in presence of FDA regulations to ensure medical product safety. When one mechanism dominates the other in providing safety then there may be efficiency gains in eliminating the second. We argued that this may be the case in medical product safety when FDA safety levels are binding on firms so that reductions in

[9] It is also worth noting two additional ways in which the NVICP may have increased patient welfare. First, one of the stated goals of the NVICP was to compensate patients more quickly and with more certainty than would be the case with the legal system. While there have been no studies that have explicitly examined whether this has occurred, patient welfare could be improved to the extent that the NVICP has compensated patients more quickly. Second, patients receive the vast majority of payouts from the NVICP. For example, attorney's fees comprise only 2% of the total payout for compensable claims (Table 3), and 4% of total payouts more generally. By contrast, a recent study found that nearly half of compensation for medical malpractice cases was spent on administrative expenses (Studdert et al, 2006). Thus, the NVICP may have compensated patients in a more efficient manner, compared to the product liability system.

liability do not affect safety but lowers prices and hence expand output and access to medicines. We discussed qualitative evidence for a case study of the National Vaccine Injury Compensation Program which suggested that prices but not safety fell after the government reduced liability.

The fact that the NVICP program displayed these safety and price patterns is consistent with other observations that the level of safety mandated by the FDA is binding on manufacturers. First, because firms seldom exceed the safety investments required by the FDA, such as performing more clinical trials than what the agency demands (Garber, 1993). Second, trials in which a firm is alleged to have violated FDA standards or misled the FDA are rare (Garber, 1993). Given the strong possibility that the FDA mandates a higher level of safety than firms would be willing to provide under product liability alone, our analysis suggests that the adoption of the pre-emption doctrine could significantly increase welfare by the price reductions entailed.

Our analysis stresses the substitutability between FDA and liability and therefore suggests the lowest cost substitute to minimize costs. There are two other reasons why FDA may be the best substitute to minimize costs. The first is that the ex-ante regulations of FDA may tradeoff the safety of a product with the adverse R&D effects it may have by lengthening the time and cost to bring a product to market. Ex-post court decisions are unlikely to take into account this tradeoff at all. This is particularly true with lay juries who are spending other peoples' money to compensate victims of product failures ex-post with any deliberation about the R&D effects involved. The second argument against government provided product liability is that the market can, and often does, provide warranties by itself if welfare enhancing. Product liability is essentially mandatory warranties that the market has chosen not to provide, and it is not clear what market failure these mandatory warranties provides a solution to.

Given the potential for liability reductions in presence of FDA to improve welfare, it is encouraging to see several policies and court rulings that are attempting to reduce pharmaceutical firms' legal liability. The recent inclusion of the pre-emption doctrine in the *Federal Register*, as well as the Supreme Court's decision in *Riegel v. Medtronic* , which upheld the doctrine in the case of medical devices, represent promising recent legislative and executive branch policies that have also reduced firms' liability. However, in *Wyeth v. Levine*, the Court ruled 5-4 that preemption does not apply to pharmaceuticals. While there may or may not be good legal justification for applying pre-emption to medical devices and not to pharmaceuticals, our analysis suggests that the economic rationale for doing so is less clear.

There are several useful extensions to our analysis which we believe are of further interest. First, we examined the impact of safety regulation on static efficiency. Since regulation affects firms' profits and therefore their incentives to invest in R&D, further work should also try to determine what types of regulatory regimes maximize dynamic welfare taking into account innovation incentives. Second, further work should attempt to further quantify the discussed welfare gains from pre-emption. The model we developed suggests that potential welfare gains are larger when liability accounts for a significant fraction of marginal costs. Given that drugs and vaccines are typically thought to have low marginal costs of production, it likely that even small legal costs can account for a significant fraction of overall marginal costs. The larger are the price reductions from pre-emption, the larger gains in access and welfare. Third, it would be interesting to examine the interplay of the FDA and product liability in affecting off-label drug use. For example, firms may be less likely to invest in off-label studies, if doing so leads to increased liability exposure. Lastly, we did not discuss the potential complimentary roles of FDA and product liability, in which different forms of product safety is enhanced by the two

different public interventions. For example, liability may make up for poor enforcement of the FDA. When there are such complementarities pre-emption will still lead to price reductions but may now also induce a reduction in safety.

Overall, we hope that future theoretical and empirical analysis will better address the rationales for the dual nature of safety regulation and enforcement by governments around the world, and increase our understanding of when it adds costs larger than the benefits compared to using one form alone or compared to using the market itself.

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