Who Needs the FDA? An Analysis of the Roles of Regulation and Product Liability in Ensuring Drug Safety

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Abstract

In the United States, drug safety is 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 joint regulation. Overall, we find that when the level of safety mandated by the FDA is binding, then product liability reduces welfare, as it gives firms little additional incentive to provide safety, but increases marginal cost and price. We conclude with a discussion of several recent initiatives that have reduced pharmaceutical firms' legal liability, such as the National Vaccine Injury Compensation Program, as well as recent Supreme Court rulings.

Section 1. Introduction

In the United States, drug 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, several other entities also play an important role in ensuring drug safety and efficacy. First, since physicians are unlikely to prescribe dangerous or non-efficacious drugs to their patients, markets have an important role in ensuring safety and efficacy (Peltzman, 1976). In addition, the presence of product liability gives firms large incentives to provide safe drugs, since patients can sue firms for unsafe drugs.

The overlap between the FDA, product liability, and the market in regulating drug safety has received substantial attention from policymakers, particularly in light of several high profile lawsuits against drug manufacturers, such as the lawsuits against Merck over the drug Vioxx (rofecoxib).[1] In several court briefs, the Bush administration has consistently promoted the doctrine of pre-emption, which states that FDA approval of a drug's label, which lists the indications (or diseases) 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*:

> "FDA believes that, under existing pre-emption principles, FDA approval of labeling…preempts conflicting or contrary state law. Indeed, the Department of Justice (DOJ), on behalf of FDA, has filed a number of amicus briefs making this very point."

[1] Vioxx, a selective COX-2 inhibitor, was 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.

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 doctrine for medical devices, and in a case pending before the Court, *Wyeth v. Levine*, will decide on whether the doctrine also applies to drugs. In addition to arguments over whether the doctrine is legally valid, there has also been substantial debate over whether pre-emption is a useful policy to adopt. Supporters argue that pre-emption frees pharmaceutical firms from the chaos of having to deal with 50 separate state regulation regarding drug safety, thereby increasing efficiency by reducing prices and reducing the potential that pharmaceutical firms will "over-warn" patients about the risks of drugs (Calfee 2008; Calfee et al., 2008), while opponents argue that product liability is a useful complement to the FDA in ensuring drug safety (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 how, and under what circumstances, pre-emption might improve economic efficiency. The central issue concerns the overlap between product liability, the markets, and the FDA in regulating drug safety. Although it might seem that three mechanisms are better than one, each mechanism imposes costs, and therefore, these costs, as well as the consequences of any interaction between the three mechanisms, need to be considered in evaluating the welfare effects of any regulatory regime. Therefore, the first contribution of this paper is to develop an economic model of drug safety regulation and to use this model to evaluate the potential welfare effects of pre-emption. Our analysis finds that when the level of safety mandated by the FDA is binding, so that firms do not provide more safety than what the FDA requires, then pre-emption has the ability to significantly improve welfare. For

example, consider is situation in which the FDA mandates a *binding* level of investment in a given activity, like the intensity of clinical testing, which is higher than what product liability alone would induce for that activity. Thus, product liability does not have a additional deterrence effect beyond the FDA. However, it raises firms' costs and therefore product prices, since it requires firms to pay damages to consumers, and this increase in price for no corresponding gain in product safety reduces social welfare.

Having developed an argument for pre-emption, we then discuss several attempts to reduce drug manufacturers' liability in light of our argument, such as the Supreme Court cases mentioned above and the National Vaccine Injury Compensation Program, which shielded vaccine makers from liability in exchange for a special compensation program funded by an excise tax on vaccines. Overall, we find that these efforts will likely increase patient welfare, and could serve as potential models for future policies.

This paper is organized as follows. Section 2 provides background on the regulation of drug safety, and section 3 presents and discusses our model and our analysis of pre-emption. Section 4 discusses Vaccine Compensation Program and current Supreme Court cases in light of our model, while section 5 concludes.

Section 2. Drug and Medical Device Safety Regulation.

In the United States, the FDA is the government agency charged with regulating drug safety and efficacy. Most 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.

Once the FDA gives its approval, the firm may begin conducting clinical trials for the drug, which proceed in three phases. Phase I trials seek to evaluate a drug's safety and to obtain data on a drug's pharmacologic properties. Typically, these trials enroll small numbers (20-80) healthy volunteers. Phase II testing then enrolls slightly larger (100-130) numbers of sick volunteers, seeking 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 also approve the label that accompanies it. This label typically provides information 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[2] 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 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

[2] 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."

modifications require a Real-time Supplement. In addition, changes in the manufacturing process must be approved via a 30-day Supplement.

Section 3. A Model of Drug Safety Regulation

In this section, we develop a model of drug safety regulation and use this model to analyze whether and under what circumstances pre-emption raises social welfare. Our model is begins with the standard product liability model developed by others (for a review, see Shavell 2006), to which we add the presence of the FDA. In this model, the FDA mandates and verifies a minimum safety level, which firms can evade, but at additional cost. Thus, a firm take into account both the costs of evading the FDA and the costs imposed by the legal system in deciding what level of safety to provide. In this section, we begin with a discussion of a simple model of product liability. We then extend this model by incorporating the presence of the FDA and discussing how the addition of the FDA to product liability alone might increase welfare. Finally, we discuss the conditions under which pre-emption can improve social welfare.

A Model of Product Liability

Suppose that the marginal costs of producing a drug with safety *s* are constant and given by[3]

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

where $c(s)$ is the actual marginal cost of producing the drug and $d(s)$ represents the legal damages the firm expects to pay given safety *s*. We assume that consumers are uninformed about the drug's actual safety level, so the demand curve $q(p)$ is simply a function of price. In this case, the firm chooses price *p* and safety *s* to maximize profits given by

[3] 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.

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

where is the demand curve. The choice of safety which maximizes profits, denoted s^{PL}, satisfies the first order condition:

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

where (3) simply states that the firm chooses the level of safety that sets the marginal benefits (lower legal payments) equal to marginal costs. The first order condition for price satisfies the familiar Lerner equation

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

Since consumers are uninformed about the drug's safety, the market quantity is determined by the demand curve $q(p)$. However, the social value of the drug, $p(x,s)$, is the consumer's willingness to pay for the drug taking the safety into account, so social welfare is therefore

$$\int_0^{q(p)} p(x,s) - c(s) \qquad (5)$$

Equation (3) emphasizes the purpose 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 forcing them to internalize the costs of unsafe products. For example, suppose that the social value of a drug is simple the willingness to pay for a perfectly safe drug $p(x)$ minus the economic losses associated with a given level of safety $l(s)$, so that

$$p(x,s) = p(x) - l(s) \quad (6)$$

In this case, equation (5) implies that the socially optimal level of safety sets the marginal cost of increased safety equal to the marginal reduction in economic losses, so that

$$c_s + l_s = 0 \qquad (7)$$

Comparison of equations (7) and (3) show that product liability can induce firms to provide the socially optimal level of safety by setting expected damages $d(s)$ equal to economic losses $l(s)$. Thus, in this case, product liability can achieve the optimal level of safety by acting as a Pigouvian tax that causes firms to internalize the losses associated with unsafe products.

The FDA and Product Liability

The previous section showed that product liability gives firms incentives to provide safety by increasing the cost associated with producing unsafe products. Indeed, under some simple assumptions, a correctly designed product liability scheme can induce firms to provide the socially optimal level of safety. However, the need for the FDA arises because product liability may not serve to fully deter firms for several reasons. For example, firms may evade judgments against them by declaring bankruptcy or through legal machinations. Since product liability may serve as an incomplete deterrent, regulatory bodies such as the FDA may enhance welfare by establishing safety standards and performing inspections to ensure that firms adhere to these standards.

To extend our analysis to incorporate the FDA, suppose that the agency mandates and verifies a minimal level of safety s^{FDA}. Firms can still choose to provide a lower level safety, but doing so raises marginal cost by $e(s)$ in order to evade the FDA's inspections. Thus, the firm's marginal costs are now

$$\begin{array}{ll} c(s)+d(s)+e(s) & s<s^{FDA} \\ c(s)+d(s) & s\geq s^{FDA} \end{array} \qquad (8)$$

Note that the firm only pays the evasion costs $e(s)$ if it chooses a level of safety lower than s^{FDA}. Given that it chooses the evade the FDA, the level of safety the firm chooses to provide s^e satisfies the following first order condition

$$c_s + d_s + e_s = 0 \qquad (9)$$

With the addition of the FDA, there are now two possibilities. If the level of safety the firm chooses to provide under product liability (s^{PL}) is higher than the level mandated by the FDA (s^{FDA}), then the firm will continue to provide safety s^{PL}, and in this case, the addition of the FDA has no effect on the firm's provision of safety. However, if s^{PL} is less than s^{FDA}, then the firm will provide either evade the FDA and provide safety s^e, or choose to provide the minimal level of safety recommended by the FDA, depending on which choice maximizes profits. We referring to the latter case as a situation where the FDA mandated level of safety is *binding* on firms, because while firms would choose to provide the lower level of safety s^{PL}, the presence of the FDA induces them to produce the minimum level of safety mandated by the FDA.

Thus, if product liability alone 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. In order to avoid paying the costs of evasion, firms may simply choose to provide this mandated level of safety. Moreover, even if firms choose to evade the FDA, comparison of equations (3) and (9) shows that they will still choose a higher level of safety than what product liability alone would induce.

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 0 if the firm provided safety at least as high as the FDA mandated level, while leaving legal costs unchanged if the firm provided a level of safety lower than this amount. Thus, the firm's marginal costs are now

$$\begin{array}{ll} c(s)+d(s)+e(s) & s < s^{FDA} \\ c(s) & s \geq s^{FDA} \end{array} \quad (10)$$

Consider the case where the level of safety mandated by the FDA is binding, so that while product liability alone induces firms to provide s^{PL}, the presence of the FDA causes firms to provide the minimum mandated safety level s^{FDA}. In this case, note that firms will continue to provide safety s^{FDA} in the presence of pre-emption. To see why, note that since firms chose not to evade the FDA in the absence of pre-emption, they will not do in is presence, since pre-emption lowers marginal costs only if the firm continues to provide the minimum level of safety mandated by the FDA. Therefore, pre-emption will have no effect on the level of safety that firms choose to provide. However, by lowering marginal costs, pre-emption increases welfare since prices are now lower.

Our results therefore suggest 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 safety 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

increases firms' marginal costs. Indeed, it appears likely that the level of safety mandated by the FDA is binding on firms, for several reasons, because firms seldom exceed the safety investments required by the FDA, such as performing more clinical trials than what the agency demands (Garber, 1993). Moreover, 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.

Section 4. An Analysis of Recent Drug Liability Policies

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 adulthood diseases, such as Hepatitis C and influenza.

Although vaccines are generally safe, as with all drugs, there is the potential for adverse 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.[4] Prior to

[4] 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 (see below), 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 had significant economic effects. For example, between 1980 and 1986, vaccine lawsuits alleged a total of $3.6 billion in damages (Davis and Bowman, 1991), while Manning (1994) estimates that in 1989, expected liability costs accounted for over half of the price of the diptheria-pertussis-tetanus vaccine.

Concerns that lawsuits might lead vaccine manufacturers to exit the market and 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). In essence, the NVICP is a form of mandatory insurance for vaccine users. Since 1988, all vaccine recipients pay an excise tax of $0.75 per dose[5] in order to fund the Vaccine Injury Trust Fund. Proceeds from the fund are then used to compensate patients who suffer adverse reactions from a vaccine. 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.

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,

[5] 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 prevents three diseases, and therefore counts as having three doses.

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 (the price available to organizations receiving CDC grant funds, such as state health departments), as well as the private sector price (the price reported by the manufacturer to the CDC). Table 1 also reports the excise tax for each vaccine. While the excise tax is small relative to the private sector price for many of the vaccines, for some vaccines, it raises price significantly over the CDC price. For example, in the case of Tipedia (Diptheria/Pertussis/Tetatnus), the excise tax is 22% of the of the CDC price, and in the case of MMRII (Measles/Mumps/Rubella), the tax is 14% of the CDC price.

Table 1 – Prices and Excise Taxes for Selected Vaccines

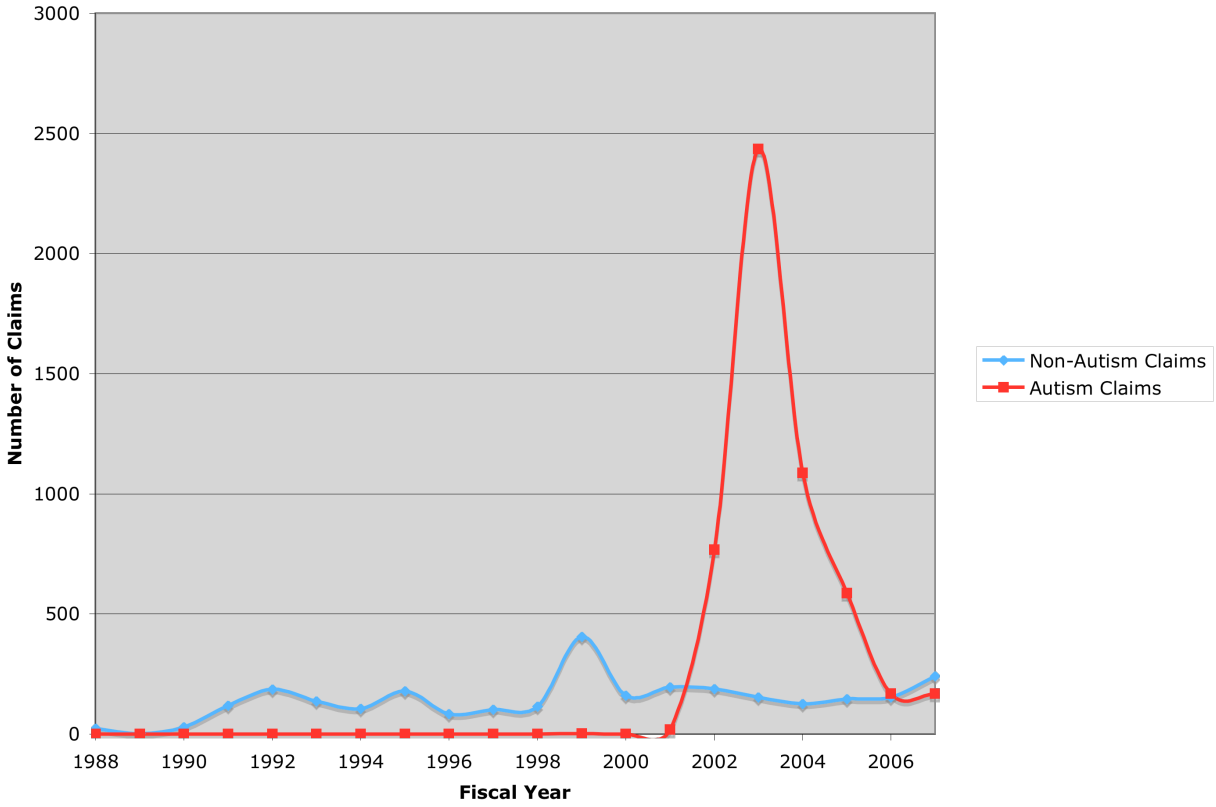
DISEASE	BRAND NAME	CDC PRICE/DOSE	PRIVATE SECTOR PRICE/DOSE	TAX
Childhood				
Diptheria/Pertussis/Tetanus	Tipedia	$10.40	$21.40	$2.25
Diptheria/Pertussis/Tetanus/Polio/Hepatitis B	Pediarix	$45.00	$70.72	$3.75
Hepatitis A	VAQTA	$12.00	$30.37	$0.75
Hepatitis B	ENERGIX B	$8.75	$21.37	$0.75
Measles, Mumps, 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

Figure 1 provides an overview of the number of claims filed with the NVICP between 1988 and 2007 for vaccines administered from 1988 onwards.[6] During this time period, there were 2,854 claims alleging injuries other than autism, compared to 5,236 claims alleging autism. Claims alleging injuries other than autism increased at a fairly 13% annual rate over this period, from 24 claims in 1988 to 241 claims in 2007. By contrast, claims alleging autism show much more fluctuation. No claims alleging autism were filed until 2001, and the number of claims peaked in 2003 and fell dramatically afterwards. This patterns may be potentially explained by the timing of two reports from the Institute of Medicine. In 2001, the Institute released a report stating that there was no evidence to confirm or deny a causal relationship between thiomersal and autism, but that a valid biologic basis existed to support a causal relationship. However, the

[6] As previously stated, injuries from vaccine administrations prior to 1988 are also covered under the NVICP, but separate limits apply, and funding for any payments comes from general revenues, as opposed to excise taxes.

Institute later re-examined the issue and in 2004, released a report that strongly rejected the notion of a causal relationship.

Figure 1 – Annual Number of NVICP Claims Filed, FY 1988-200



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. Claims shown are for injuries occurring from vaccines administered from 1988 onwards.

Table 2 shows the outcome of claims filed with the NVICP, by presenting the number of decisions in each fiscal year, and the number of decisions where the claim was dismissed.[7] Between FY 1989 and FY 2007, the NVICP issued decisions for 4,259 claims pertaining to injuries suffered from vaccines administered prior to 1988, of which 1,189 were dismissed, suggested that nearly three-quarters of persons filing a claim received compensation. By

[7] Since there is a delay (on average, 2-3 years) between when a claim is filed and when a decision is made, the number of decisions shown in table XXX do not correspond to the number of claims shown in figure XXX.

contrast, well over half (1,482) of the 2,396 decisions pertaining to injuries suffered from vaccines administered from 1988 onwards were dismissed. During this time period, the NVICP resolved 329 claims pertaining to autism by dismissing each claim. Thus, it appears that recent efforts to seek compensation for autism related injuries have been largely unsuccessful.

Table 2 – Annual Number of NVICP Decisions, FY 1988-2007

	VACCINES ADMINISTERED PRIOR TO 1988		VACCINES ADMINISTERED 1988 ONWARDS	
FY	TOTAL	DISMISSED	TOTAL	DISMISSED
1989	21	9	21	12
1990	130	96	2	0
1991	557	132	32	22
1992	580	136	73	43
1993	634	103	79	57
1994	524	121	84	43
1995	636	112	99	51
1996	442	112	128	78
1997	275	129	111	51
1998	200	91	125	72
1999	126	60	111	73
2000	86	57	142	75
2001	25	18	145	79
2002	13	8	197	99
2003	7	4	147	95
2004	3	1	293	233
2005	0	0	181	121
2006	0	0	250	184
2007	0	0	176	94
Totals	4,259	1,189	2,396	1,482

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.

Table 3 provides summary statistics on payments made by the NVICP. Between FY 19990 and 2007, the NVICP paid out a total of nearly $3.2 billion[8] for 3,499 claims. However, as previously noted, the NVICP reimburses legal costs even for dismissed claims, as long as

[8] All dollar values were inflated to 2008 dollars using the CPI. In addition, all dollar values were discounted to 2008 at a 3% interest rate.

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

Table 3 – 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	$28,296.35

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.

Whether the NVICP has improved patient welfare is a subject for further analysis. In the framework of our analysis in section 2, the introduction of the NVICP has the effect of shifting *d(s)*, payments for adverse effects, from the manufacturer to the consumer. Standard economic theory, then, would suggest that this should have no effect on efficiency. However, several aspects of the NVICP may improve efficiency compared to product liability. First, one of the

[9] 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.

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).[10] Thus, the NVICP may have compensated patients in a more efficient manner, compared to the product liability system.

Recent Supreme Court Decisions Regarding FDA Pre-emption of State Liability Laws

In 1996, Charles Riegel underwent a coronary angioplasty after suffering a myocardial infarcation. During the operation, physicians used an Evergreen Balloon Catheter, manufactured by Medtronic, Inc., in order to widen a coronary artery. However, his physician overinflated the catheter, leading to further complications. Three years later, he and his wife brought a lawsuit against Medtronic, Inc., arguing that the catheter's design, labeling, and manufacture were defective according to the standards of New York Common law, and that the resulting defects were responsible for his injuries. Medtronic, Inc. countered by arguing that the Medical Device Amendments of 1976 (MDA) precluded a lawsuit based on failure to meet state standards. Medtronic's defense was based on a specific clause in the MDA:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

[10] Note that this study included the costs of the court system in addition to attorney's fees, so the two figures are not completely comparable.

(2) which relates to the safety or effectiveness of the device or to any other matter included in requirement applicable to the device under this chapter. §360k(a)."

Ultimately, the Supreme Court of the United States decided *Riegel v. Medtronic* in favor of Medtronic, Inc. The Court's decision was based on two premises. First, the Court held that the FDA pre-market approval process imposed specific Federal requirements for the catheter, since the catheter could receive approval only be meeting standards for safety and efficacy. Second, the Court held that Riegel's claims that the device was defective under New York common law standards amounted to imposing additional requirements on the device, in direct opposition to the MDA. Accordingly, the Court held that FDA approval pre-empts lawsuits based on state law for devices approved under the pre-market approval process.

The question of whether the pre-emption doctrine applies to pharmaceuticals is currently pending before the Supreme Court in *Wyeth v. Levine*. In this case, Diana Levine received the drug Phenergan (promethazine) via IV injection as treatment for migraine headaches. However, she suffered an adverse reaction which resulted in the amputation of her hand and forearm. As a result, she sued the manufacturer, Wyeth, Inc., alleging that the failed to properly warn of the potential risks from IV administration of the drug. She ultimately received $6.8 million in damages after her lawsuit proceeded through the courts for the state of Vermont. After the Supreme Court of the State of Vermont upheld the damages, Wyeth, Inc. filed a petition for certiori with the Supreme Court of the United States, arguing that FDA approval of Phenergan's labeling, which included some warnings about the potential adverse effects of IV administration, pre-empted Levine's claims. The case is currently awaiting a decision from the Court. While many of the legal principles and arguments in the case are similar to those in *Riegel v.*

Medtronic, a crucial difference is that the MDA, which applies to medical devices, contains the specific pre-emption clause outlined above. By contrast, the regulations which give the FDA authority over pharmaceuticals do not, making it more difficult to decide how the Court will rule.

Section 5. Conclusions.

Our analysis examined the potential costs and benefits from regulating drug safety jointly via the FDA and product liability. Since the goal of product liability is to give firms incentives to provide the socially efficient level of safety, we find that the FDA can serve as a useful complement to product liability if a given liability regime is not stringent enough to provide firms with the proper incentives. However, we find that if the level of safety mandated by the FDA is binding on firms, then product liability may actually reduce welfare because it has little effect on the safety that firms provide, but increases marginal cost, thereby lowering output. In practice, it appears likely that the FDA is binding on firms, since they seldom perform more safety investment that what the FDA requires, and seldom attempt to evade the agency's regulations.

Given the potential for liability to improve welfare, it is encouraging to see several policies and court rulings that are attempting to reduce pharmaceutical firms' legal liability. While the National Vaccine Injury Compensation Program served to shift the legal costs of liability from the firm to the patient, it may likely have increased welfare by compensating patients in a more efficient and timely manner. 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. Similarly, *Wyeth v. Levine*,

currently pending before the Supreme Court, presents another opportunity to lower firm's liability and increase welfare.

There are several useful extensions to our analysis, which 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 total welfare. Second, further work should attempt to quantify the potential 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. Indeed, Manning (1994) finds that liability costs accounted for nearly half of the cost of the DPT vaccine.

Our results are clearly a starting point, and provide room for more analysis on how to optimally regulate drug safety. More generally, we believe that rigorous, economic based analysis can greatly inform an area whose thinking is driven primarily by physicians and policymakers. Given that the vast amounts spent on developing these drugs, it would appear that there are substantial welfare gains to be made by examining how to optimally ensure their safety.

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