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ADMINISTRATIVE COMPENSATION FOR PHARMACEUTICAL- AND VACCINE-RELATED INJURIES

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I. INTRODUCTION

Over the last four years, the Supreme Court has decided a trilogy of federal preemption cases running the gamut of modern medical product liability litigation: 2008's *Riegel v. Medtronic*,¹ finding that state tort claims stemming from injuries allegedly caused by certain medical devices were

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1. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

expressly preempted by the 1976 Medical Devices Amendments to the Food, Drug, and Cosmetics Act (“FDCA”);² 2009’s *Wyeth v. Levine*,³ failing to find that a state common law failure-to-warn claim for a drug was impliedly preempted by the broader FDCA; and 2011’s *Bruesewitz v. Wyeth*,⁴ finding that the 1986 National Childhood Vaccine Injury Act (“NCVIA”)⁵ expressly preempted state common law design defect claims for children’s vaccines. These cases demonstrate the interplay between the two very different systems used in the United States to regulate medical products: the comprehensive, *ex ante* review and oversight administered by federal regulatory agencies; and the decentralized, *ex post* private tort system enforcing state common law rules through civil juries in state and federal court.

In recent years, I have been both a critic of the tort system’s handling of pharmaceutical litigation and an advocate for much broader preemption of such claims, in light of federal regulatory oversight. I have also advocated, concurrently, that the federal government implement an administrative compensation program—akin to the Vaccine Injury Compensation Program (“VICP”) at play in *Bruesewitz*—to provide a remedy to at least some classes of individuals injured by drugs and devices notwithstanding the federal regulatory scheme.⁶

This essay, adapted from a presentation at the American Association of Law Schools, considers, in turn, each of the American systems of pharmaceutical regulation. The essay then briefly describes the Vaccine Injury Compensation Program and considers how the law and economics of the vaccine market varies from that of the broader market for pharmaceuticals and medical devices. The essay concludes with a proposal for broad preemption of state tort law claims, alongside an administered system that would process product-related injuries.

II. PHARMACEUTICAL REGULATION I: THE FOOD AND DRUG ADMINISTRATION

Under the FDCA, the federal Food and Drug Administration (“FDA”) oversees a comprehensive regulatory regime governing the U.S. market for all pharmaceuticals and medical devices. In this section of this essay, I briefly overview the FDA’s process and assess the degree to which the tort

2. See 21 U.S.C. § 360.

3. *Wyeth v. Levine*, 555 U.S. 555 (2009).

4. *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011).

5. See 42 U.S.C. §§ 300aa-1 *et seq.*

6. See generally JAMES R. COPLAND & PAUL HOWARD, MANHATTAN INST. FOR POL’Y RES., IN THE WAKE OF *WYETH V. LEVINE*: MAKING THE CASE FOR FDA PREEMPTION AND ADMINISTRATIVE COMPENSATION (Mar. 2009), available at http://www.manhattan-institute.org/html/fda_01.htm.

system—or any supplementary regulatory regime—is needed as an adjunct regulatory regime.

Before a drug is introduced into the market, it undergoes a multi-stage approval process. Pharmaceutical companies engage in substantial preclinical testing, in the laboratory or with animals, to make preliminary assessments of a new drug's safety and efficacy. Companies submit promising compounds to the FDA through an Investigational New Drug (“IND”) application.⁷ Once an IND is approved, three phases of clinical testing follow.⁸ Phase I testing, typically with healthy volunteers, examines absorption, distribution, metabolism, and excretion to uncover side effects and establish safe dosing limits.⁹ Phase II targets a small sample of individuals suffering from the targeted disease or ailment in order to make a preliminary determination of efficacy.¹⁰ If Phases I and II show general success, and costs in terms of side effects that do not outweigh the benefits expected due to the compound's efficacy, potential new drugs undergo Phase III testing, which is a randomized, controlled trial of a larger population of suffering or infected individuals.¹¹ If Phase III tests show efficacy at a ninety-five percent confidence interval, companies submit a New Drug Application (NDA) to the FDA for approval.¹²

The FDA's approval process for new drugs is complex, time-consuming, and expensive. New drug development typically takes a decade to complete and costs close to \$1 billion dollars.¹³ Moreover, according to industry estimates, only about one in 10,000 investigated compounds ultimately makes it to the market.¹⁴

In assessing the FDA's regulatory process, it is important to understand that regulation inherently entails two types of errors: “Type I” errors, in which approved drugs turn out to be unsafe or ineffective; and “Type II” errors, in which reasonably safe and effective drugs are withheld or delayed, to the public's detriment. The FDA's critics have contended that the agency is much more likely to commit Type II errors than Type I errors,

7. See 21 C.F.R. § 312.20.

8. See 21 C.F.R. § 312.21.

9. See 21 C.F.R. § 312.21(a).

10. See 21 C.F.R. § 312.21(b).

11. See 21 C.F.R. § 312.21(c).

12. See generally 21 C.F.R. § 314.

13. Health economists estimate a total pre-approval drug development cost of over \$800 million for pharmaceuticals generally and over \$1 billion for biotechnology products. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH & ECON. 151, 151-85 (2003); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, MANAGERIAL AND DECISION ECON. 28, 469-79 (2007). See also BENJAMIN ZYCHER ET AL., MANHATTAN INST. FOR POL'Y RES., THE TRUTH ABOUT DRUG INNOVATION: THIRTY-FIVE SUMMARY CASE HISTORIES ON PRIVATE SECTOR CONTRIBUTIONS TO PHARMACEUTICAL SCIENCE (June 2008), available at http://www.manhattan-institute.org/html/mpr_06.htm.

14. See *Innovation*, PHARMA.ORG, <http://www.phrma.org/innovation> (last visited May 1, 2011).

due to the high visibility of the latter, and the propensity for the media, public, and Congress to react when approved drugs turn out to have serious side effects undiscovered in the approval process. As noted by the late John E. Calfee and others in their *amicus brief* submitted to the Supreme Court in *Wyeth v. Levine*:

Because the harmful side-effects of the drug may be highly visible, a Type I error can and often does lead to impassioned criticism of the agency. On the other hand, a Type II error—the failure to permit marketing of a drug that would in fact provide benefits in excess of harms—is typically known only by the relatively few persons who are intimately involved in developing the drug and are largely hidden from patients and the larger medical community.¹⁵

In general, FDA regulators face far more incentive to worry about the next thalidomide, Fen-Phen, or Vioxx than about exercising undue caution in delaying or denying new drug approval.¹⁶

Empirical testing to weigh the prevalence of Type I versus Type II errors in FDA decision-making is difficult, given that Type II errors essentially involve counterfactuals. The best empirical evidence, however, tends to support the theoretical case that the agency is more likely to err on the side of caution or delay.

In 1992, Congress passed the Prescription Drug User Fee Act (“PDUFA”),¹⁷ which “allowed the FDA to levy user fees [on] firms filing a New Drug Application or Biologic License Application, in exchange for guarantees on review times.”¹⁸ The PDUFA regime has allowed researchers to examine whether accelerated drug approvals have created net benefits or harms, and thus, by proxy to assess the FDA’s propensity to commit Type I and Type II errors. Comparing pre-PDUFA and post-PDUFA data, researchers have concluded that “by the most plausible measure, [PDUFA]

15. See Brief of John E. Calfee et al. as Amici Curiae Supporting Petitioner, *Wyeth v. Levine*, 555 U.S. 555 (June 3, 2008) (No. 06-1249), available at http://www.aei.org/docLib/20080612_Brief0801_topost.pdf.

16. There have, however, been a limited category of cases in which general public alarm has placed substantial pressure on the FDA to avoid Type II errors, most notably for AIDS, which were generally available abroad before being approved in the U.S. See, e.g., Kenneth I. Kaitin & Jeffrey S. Brown, *A Drug Lag Update*, 29 DRUG INFO. J. 361, 361-73 (1995). In response, the FDA “allowed AIDS patients (and others) access to promising experimental drugs early in the development process, long before their safety and efficacy had been proved.” FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 54 (2005).

17. PDUFA was renewed in 1997, 2002, and 2007 and is up for renewal in 2012.

18. Tomas J. Philipson & Eric Sun, *Is the Food and Drug Administration Safe and Effective?*, 22 J. ECON. PERSP. 85, 87 (2008).

did not, in fact, have *any* effect on drug safety: neither the proportion of drugs eventually withdrawn (two to three percent), nor the speed with which they were withdrawn, changed in any statistically significant way since the law's passage."¹⁹ Moreover, researchers calculated the cost of avoidable deaths for drugs approved and withdrawn under PDUFA at 56,000 life-years, as against 180,000 to 310,000 life-years saved through the more rapid introduction of drugs under the act, a benefit far outweighing the cost even under the dubiously conservative assumption that all life-years lost were attributable to the PDUFA regime.²⁰

In short, there is every reason to suspect that the FDA, both in theory and based on the empirical data, is more likely to commit Type II than Type I error. Thus, any additional regulatory regime that is likely to discourage the introduction of new drugs is also likely to have costs outweighing its benefits, given the Type-II-loaded FDA regulatory backdrop.

III. PHARMACEUTICAL REGULATION II: THE TORT SYSTEM

State common law tort remedies are, of course, just such a regulatory system. Given the FDA's bias toward committing Type II error, the extra layer of review that the tort system provides almost certainly generates a net social welfare loss, rather than, as the product liability regime's defenders insist, serving as a useful complement to the FDA's regulatory scheme. That said, at least a basic assessment of the tort system as it exists in handling pharmaceutical claims is in order.

While the decentralized tort system obviously predates the FDA regulatory regime, the modern product liability regime essentially postdates not only the 1938 Food, Drug, and Cosmetic Act, but also the 1962 Kefauver Harris Amendment that established the modern FDA drug testing process. Justice Traynor's strict product-liability doctrine first became the law of California in *Greenman v. Yuba Power Products* in 1963,²¹ and modern design defect and failure-to-warn product liability doctrine dates to the American Law Institute's 1965 Second Restatement of Torts.²² Modern product liability litigation for pharmaceuticals thus grew up in the shadow of FDA regulation.

In contrast to the FDA's regime, the tort system is *ex post*, involves lay decision-makers, and, by its very nature, avoids the complex cost-benefit assessment undertaken by the regulatory body. Each of these features is potentially problematic. The *ex post* feature of tort litigation is extolled by its defenders as a virtue, and indeed, given the high cost of FDA

19. See Tomas J. Philipson et al., *How Safe Is Too Safe?*, 2 MILKEN REV. 38, 44 (2006) (emphasis in original).

20. See *id.* at 45.

21. See *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963).

22. See *generally* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

regulation and its bias toward Type II error, there is a strong theoretical case for *ex post* punishment rather than *ex ante* delay in an optimal drug-regulatory regime. That said, in practice, the tort system's *ex post* feature likely exacerbates hindsight bias—the tendency to infer causation and negligence inappropriately given injury—particularly when a decision-making body of unsophisticated lay jurors is involved, along with the potential for punitive awards.²³

Moreover, the product liability regime charges civil juries to focus solely on the facts of the cases at hand, without considering the broader societal repercussions. Given that all drug compounds have side effects, the jury's inability to engage in the sort of cost-benefit decision-making undertaken by the FDA can lead the civil justice system to reach results that effectively contradict the FDA's own cost-benefit analysis. For example, in *Wyeth v. Levine*, the failure-to-warn claim consisted of an attack on a side effect specifically known and contemplated by the FDA, listed with a product warning given FDA approval.²⁴

In addition to these problematic regulatory features, the modern American tort system has a host of defects in handling modern mass tort claims, including pharmaceutical litigation, which I and others have extensively written about elsewhere.²⁵ The multistate, multijurisdictional nature of the American judicial system, under the now-longstanding choice-of-law

23. Juries' weakness at handling scientific evidence in many product-liability cases is well-documented. See generally PETER W. HUBER & KENNETH R. FOSTER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* (MIT Press, 1997); PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* (Basic Books, 1991). Cf. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

24. Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54, 59 (2008) (noting, "*Levine* presents a situation where the FDA gave explicit approval to the exact treatment, notwithstanding the precise side effect mentioned in the original warning. What would count as new information to render that explicit authorization obsolete? The mere occurrence of the identified side effect can't do it because it was warned of in advance. And in *Levine* the sketchy record reveals no evidence collected after the drug hit the market indicating a higher incidence of this failure (and perhaps others) that might call for a reevaluation of the risk/reward ratio for that procedure.").

25. See, e.g., COPLAND & HOWARD, *supra* note 6; James R. Copland, *Tragic Solutions: The 9/11 Victim Compensation Fund, Historical Antecedents, and Lessons for Tort Reform* 2-10 (Manhattan Institute for Pol'y Research, Working Paper, 2005), available at http://www.manhattan-institute.org/pdf/clpwp_01-13-05.pdf; MANHATTAN INST. FOR POL'Y RES., TRIAL LAWYERS, INC.: HEALTH CARE; CONDITION CRITICAL: THE LAWSUIT INDUSTRY'S EFFECT ON AMERICAN HEALTH (2005), available at <http://www.triallawyersinc.com/TLI-HealthCare.pdf>; MANHATTAN INST. FOR POL'Y RES., TRIAL LAWYERS, INC.: ASBESTOS; A REPORT ON THE ASBESTOS LITIGATION INDUSTRY (2008), available at http://www.wyliecom.com/TLI_Asbestos.pdf. See generally WALTER OLSON, *THE LITIGATION EXPLOSION: WHAT HAPPENED WHEN AMERICA UNLEASHED THE LAWSUIT* (Truman Talley Books 1991); PETER HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* (Basic Books 1988); George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461 (1985).

and personal jurisdiction doctrine,²⁶ permits the phenomenon known as “forum shopping,”²⁷ in which attorneys move mass tort cases into states or jurisdictions with favorable regimes,²⁸ due to plaintiff-leaning legal rules, pro-plaintiff judges,²⁹ pro-plaintiff juries,³⁰ and judicial “innovations” such as consolidations or bouquet trials that substantially increase expected jury awards.³¹ Because of the American Rule in which the winners of litigation assume their own costs,³² companies facing mass tort lawsuits face enormous pressures to settle lawsuits, which in turn generates incentives for plaintiffs’ attorneys to recruit dubious claims.³³

26. See, e.g., *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938) (eliminating federal common law); *International Shoe Co. v. Washington*, 326 U.S. 310 (1945) (establishing minimum-business-contacts personal jurisdiction).

27. See, e.g., JOHN H. BEISNER & JESSICA DAVIDSON MILLER, MANHATTAN INST. FOR POL’Y RES., THEY’RE MAKING A FEDERAL CASE OUT OF IT . . . IN STATE COURT (Sept. 2001), available at http://www.manhattan-institute.org/html/cjr_3.htm.

28. Former lawyer Dickie Scruggs, an asbestos attorney who led state litigation against the tobacco companies leading to the multistate master settlement agreement, described such jurisdictions openly to a group of investment researchers: “[W]hat I call the ‘magic jurisdiction,’ . . . [is] where the judiciary is elected with verdict money. The trial lawyers have established relationships with the judges that are elected; they’re State Court judges; they’re popul[ists]. They’ve got large populations of voters who are in on the deal, they’re getting their [piece] in many cases. And so, it’s a political force in their jurisdiction, and it’s almost impossible to get a fair trial if you’re a defendant in some of these places. The plaintiff lawyer walks in there and writes the number on the blackboard, and the first juror meets the last one coming out the door with that amount of money. . . . The cases are not won in the courtroom. They’re won on the back roads long before the case goes to trial. Any lawyer fresh out of law school can walk in there and win the case, so it doesn’t matter what the evidence or the law is.” Richard Scruggs, Asbestos for Lunch, Panel Discussion at the Prudential Securities Financial Research and Regulatory Conference (May 9, 2002), in *INDUSTRY COMMENTARY* (Prudential Securities, Inc., N.Y., New York), June 11, 2002, at 5.

29. See Eric Helland & Alexander T. Tabarrok, *The Effect of Electoral Institutions on Tort Awards*, 4 AMER. L. ECON. REV. 341 (2002) (empirically demonstrating that tort awards against out-of-state defendant corporations are positively correlated with partisan judicial elections).

30. See Eric Helland & Alexander T. Tabarrok, *Race, Poverty, and American Tort Awards: Evidence from Three Data Sets*, 32 J. LEGAL STUD. 27 (2003) (empirically demonstrating that low-income and minority jury pools are associated with higher tort awards).

31. See Michelle J. White, *Asbestos Litigation: Procedural Innovations and Forum Shopping*, 35 J. LEGAL STUD. 365, 393 (2006) (empirically demonstrating that forum-shopping and consolidated, bifurcated, and bouquet trials are associated with higher tort awards in asbestos cases).

32. For a good review of the American Rule as against loser-pays systems in practice, and the incentives generated by each, see MARIE GRYPHON, MANHATTAN INST. FOR POL’Y RES., GREATER JUSTICE, LOWER COST: HOW A “LOSER PAYS” RULE WOULD IMPROVE THE AMERICAN LEGAL SYSTEM (Dec. 2008), available at http://www.manhattan-institute.org/html/cjr_11.htm.

33. See, e.g., Joseph N. Gitlin, et al., *Comparison of ‘B’ Readers’ Interpretations of Chest Radiographs for Asbestos Related Changes*, 11 ACAD. RADIOLOG. 243 (2004) (finding lung abnormalities associated with asbestos exposure in 4.5 percent of cases, as compared to 95.9 percent identification rates by “B” readers hired by plaintiffs’ attorneys); Alison Frankel, *The Fen-Phen Follies*, AMER. LAW., March 1, 2005, available at <http://www.law.com/jsp/article.jsp?id=1109597691121>.

As a regulator of pharmaceuticals, then, tort litigation leaves much to be desired. Particularly given the backdrop of FDA regulation, there is little reason to assume that the tort system does much more than serve as mandatory product insurance that increases company costs, which deters innovation and raises consumer prices.³⁴ And in the vaccine context, Richard Manning's empirical studies have shown a strong association between the threat of litigation and product price.³⁵

Of course, the tort system is not only concerned with its regulatory role of operating to deter corporate misbehavior and create safety incentives. In fact, the tort system has a compensatory role, in which it offers payment to make those adversely affected by drug side effects whole. Wholesale preemption of tort litigation by FDA regulation would necessarily leave injured parties without their classic tort remedy and, absent an alternative form of compensation, might be subject to an equity or fairness critique.

IV. A SPECIAL ADMINISTRATIVE SYSTEM: THE VACCINE INJURY COMPENSATION PROGRAM

In 1986, Congress created just such an administrative regime when it passed the NCVIA, which created the VICP.³⁶ The law was a reaction to a wave of lawsuits filed against manufacturers of the diphtheria-pertussis-tetanus and polio vaccines that had led to the price effects explored by Manning and prompted many companies to exit the field of vaccine manufacture altogether.³⁷

Jointly administered by the Department of Health and Human Services and the Department of Justice, and under the jurisdiction of the U.S. Court

34. See Philipson & Sun, *supra* note 18, at 93 (noting, "Given that the FDA's mandated level of [product safety] investment is binding, product liability in this case does not have additional deterrence effect beyond the FDA's regulations. However, product liability 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.")

35. See Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J. L. ECON. 247 (1994) (showing the price of the polio vaccine jumped sevenfold, while that of the diphtheria-pertussis-tetanus ("DPT") vaccine rose to forty-fold, in comparison to a doubling of price in the overall vaccine market in the 1980s after a surge in litigation involving these two vaccines); see also Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J. L. ECON. 203 (1997).

36. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1), reads as follows: "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

37. See generally PAUL A. OFFIT, *THE CUTTER INCIDENT: HOW AMERICA'S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS* (Yale University Press, 2005).

of Federal Claims, the VICP is a no-fault system insuring against childhood vaccine injury. Injuries listed on a “Table” updated by the Centers for Disease Control are automatically covered if the listed injury occurred within a set time frame after taking a vaccine. Claimants can recover for non-Table injuries, but they bear the burden of proving causation. The program is funded by a seventy-five cent excise tax levied on every administered vaccination in the United States.

In general, the VICP must be judged as an unqualified success. From 1990 to 2010, the VICP compensated 2518 claims, for a total award value of \$1.96 billion.³⁸ Administrative costs are a relatively low eleven percent, with only three percent going to attorneys’ fees.³⁹ The existence of the VICP, and the preemption of tort claims, has not seemed to deter continuing safety innovation in the vaccine market, as companies have expanded and modernized production capabilities, developed new and safer vaccine technologies (such as the safer acellular pertussis vaccine, replacing old whole-cell technology), and brought new vaccines to market (including Gardasil, the first vaccine proved to prevent cancer in humans, introduced in 2006).

V. PHARMACEUTICAL ECONOMICS: PUTTING VACCINES IN CONTEXT

Before we decide if and how the VICP can serve as a template for a broader federal administrative compensation regime, we should assess, in a big picture sense, how the economics of the vaccine market vary from those of broader pharmaceutical market. The supply-side economics of the drug development market are generally similar to that of its vaccine subset, but the vaccine market has unique demand-side characteristics and vaccines generate unique positive externalities, which complicate formation of any administrative compensation regime for the pharmaceutical market in its entirety.

A. Supply-Side Factors

On the supply side, the manufacture of pharmaceuticals roughly parallels that of the vaccine subset of the pharmaceutical market. Drug compounds, whether vaccine or otherwise, have high fixed-costs of manufacture, but low marginal costs of production. For example, pharmaceuticals are inexpensive to produce once researched and developed; however, as already discussed, with testing and regulatory approval considered a part of fixed research and development costs, new drug development costs

38. See *National Vaccine Injury Compensation Program*, HRSA.GOV, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.

39. See *Detailed Information on the Vaccine Injury Compensation Program Assessment*, EXPECTMORE.GOV, <http://www.whitehouse.gov/omb/expectmore/detail/10003807.2005.html> (last updated Sept. 6, 2008) (assessing cost breakdown between fiscal years 2001 and 2004).

upwards of \$1 billion dollars per drug.⁴⁰ Absent the intellectual property protection offered by patents, private new drug development could substantially disappear because new entrants to the market would effectively drive prices down to the marginal cost of production and manufacturers who develop new compounds would be unable to recoup their investments beyond the window of time it would take for competitors to replicate compounds, in addition to the barriers to entry afforded by branding, marketing campaigns, and distribution networks.⁴¹ Medical devices may not consistently follow this economic model, as the marginal cost of manufacturing at least some devices may be substantial, and reverse engineering and manufacturing complex devices is substantially more difficult than for pharmaceutical compounds. Nevertheless, patent protection is still important to the medical-device market due to high research and development costs.

B. Demand-side Factors

Although vaccines fit generally within the broader pharmaceutical market on the supply side, the vaccine market is distinctive on the demand side. Unlike most FDA-approved drugs, vaccines target a broad population set, rather than a narrow patient group, and are primarily limited-dose rather than ongoing in usage. Such characteristics profoundly affect the economics of vaccine development. The first demand-side characteristic—the size of the population target—mitigates in favor of vaccine development, since high up-front costs can be recouped over a larger sales volume. Sales are limited, however, because most vaccines are single- or limited-dosage, with only occasional boosters required. In contrast, blockbuster drugs, like those treating high cholesterol, depression, arthritis, impotence, blood pressure, and diabetes, require ongoing, repeated use. One exception is the influenza vaccine, which must be taken annually to be effective, and consequently, has an estimated market size of \$2.8 billion in the seven largest developed economies.⁴² In general, however, vaccines have a fairly limited market

40. See *supra* note 13, and accompanying text.

41. See, e.g., FRANK R. LICHTENBERG & GAUTIER LUFLOS, MANHATTAN INST. FOR POL'Y RES., TIME RELEASE: THE EFFECT OF PATENT EXPIRATION ON U.S. DRUG PRICES, MARKETING, AND UTILIZATION BY THE PUBLIC (Oct. 2009), available at http://www.manhattan-institute.org/html/mpr_11.htm. “The pharmaceutical industry is the most research-intensive industry in the world. Indeed, drug development remains an expensive and uncertain undertaking in which failure is far more common than success. To encourage investment, exceptionally high risks to companies and investors must be accompanied by the promise of limited monopoly profits.” For a fuller discussion of patent economics, see generally Richard J. Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. OF ECON. 106 (Spring 1990); see also FRANÇOIS LÉVÊQUE & YANN MÉNIÈRE, *THE ECONOMICS OF PATENTS AND COPYRIGHT* (Berkeley Electronic Press 2004), available at <http://www.bepress.com/cgi/viewcontent.cgi?article=1001&context=leveque>.

42. See Hedwig Kresse & Holger Rovini, *Influenza Vaccine Market Dynamics*, 8 NATURE REVIEWS DRUG DISCOVERY 841-42 (Nov. 2009).

size, which makes vaccine development very sensitive to litigation and other supply-side shocks.

C. Externalities

Certainly the most distinctive aspect of the vaccine market lies in vaccines positive externalities, for example, the fact that a vaccination benefits not only the vaccinated individual, but also society at large. In assessing how externalities affect the vaccine market, it is useful to categorize pharmaceuticals across two dimensions: (1) is the treatment for an infectious agent?; and (2) is the treatment *ex ante* or *ex post*? In general, only those pharmaceuticals that target infectious agents generate positive externalities. The cost of pharmaceuticals designed to treat or prevent ailments such as cancer, heart attack, stroke, arthritis, depression, or impotence is largely internalized to the individual taking the medication, save for public financing concerns.

Vaccines are unique among pharmaceuticals targeting infectious agents because vaccines are preventive rather than remedial. Thus, vaccines pose a significant free-rider problem that does not exist for other infectious-agent-targeting drugs. For example, while an individual already infected with a dangerous strain of virus or bacteria has a powerful incentive to take a drug attacking that agent, notwithstanding the positive externalities generated by warding off social infection, the already-healthy individual may decide not to risk potentially dangerous side effects caused by a vaccine, and instead take a “free ride” on others’ decisions to vaccinate. And indeed, the greater the percentage of the population that is vaccinated, the lower the potential costs from such free-riding behavior becomes.

If an insufficient percentage of the population is vaccinated, however, both vaccinated and unvaccinated individuals are endangered. A decline in a population’s vaccinated, also stated as reducing a population’s “herd immunity,” can lead to potential outbreaks of disease, even those previously effectively vanquished, as has happened of late with the whopping cough due to dropping vaccination rates among those worried about the side effects of the DPT vaccine.⁴³

VI. ADMINISTRATIVE COMPENSATION FOR PHARMACEUTICALS AND MEDICAL DEVICES

The peculiarities of the vaccine market justify its special administrative program. The powerful effects of herd immunity and the public health

43. See James R. Copland & Paul Howard, *The Whooping Cough’s Unnecessary Return*, CITY J. ONLINE, Feb. 2, 2011, <http://www.city-journal.org/2011/eon0202phjc.html>.

imperative of encouraging universal vaccination, rather than the free-riding otherwise endemic in this market, make a special carve-out for vaccines particularly defensible. Moreover, the fact that most vaccines are single- or limited-dose administrations makes the economics of vaccines particularly sensitive to tort litigation or other stressors.

In addition, the peculiarities of the vaccine market also serve as a cautionary tale for any attempt to extend the VICP to pharmaceuticals and medical devices. A no-fault system for vaccines makes sense: the approach lowers administrative costs, and linking severe side effects to vaccines is somewhat intuitive, since vaccines are given to individuals who are generally healthy. Moreover, to the extent that the VICP overcompensates, it largely operates to encourage vaccination, which has positive societal spill-over effects.

With the broader pharmaceutical market, however, a no-fault approach may not be workable. To start, the risk of overcompensation is far greater, since non-vaccine pharmaceuticals are given to individuals who are already unhealthy, and tend to skew toward old age, rather than infancy, which substantially complicates questions of causation. Moreover, the FDA often knowingly accepts side effects with the knowledge that they are outweighed by a drug's expected benefits. In contrast to the positive herd immunity generated by encouraging vaccination, the benefits of other pharmaceuticals are already largely internalized to the patient, and in many cases passed on to the public through social safety net financing programs.

Given these considerations, my colleague Paul Howard and I have proposed an administrative compensation system for all pharmaceuticals modeled loosely on the VICP but different in several salient respects. We believe that the following features are essential to the success of such a program:⁴⁴

A. Field Preemption of Pharmaceutical Claims, with Limited Carve-Outs

The challenge brought to the VICP in *Bruesewitz*, and the narrowness of conflict- and obstacle-preemption under *Levine*, highlights the importance of adopting a broad preemption doctrine. If individual cases could be brought with particular claims alleging a lack of conflict with an FDA decision, an administrative remedy could serve as an additional cost on drug development, thus exacerbating the already-significant Type II bias in the drug-regulatory system. Individuals would retain the right to sue health care providers for malpractice if they prescribed a contraindicated drug, or if they improperly administer a drug or device, the medical errors really at the heart of the *Riegel* and *Levine* litigation. Individuals would

44. For a fuller discussion of our proposal, see COPLAND & HOWARD, *supra* note 6.

not, however, be able to file “fraud on the FDA” suits, which would still be proscribed by the Supreme Court’s decision in *Buckman*.⁴⁵

B. Limitation of Most Claims to Unforeseen Adverse Events

Unlike for vaccines, individuals injured by a known side effect, considered by the FDA with labeling approval, should not be compensated by any administrative compensation system for pharmaceuticals, unless the medication in question is deemed essential in targeting an epidemic or another serious outbreak of a highly serious, communicable disease. Such a limitation recognizes that individuals, through learned intermediaries, internalize the risks and benefits of medications taken in reaction to already-existing ailments. In addition, this limitation encourages safety by encouraging manufacturers to disclose adverse events, to take advantage of the regulatory shield.

C. Clearly Defined Causation and Injury Requirements

Given the difficulties associated with determining causation and injury, no-fault compensation should be limited to cases in which expected overcompensation is less costly than administrative savings. In the general case, adverse outcomes should be tabled—as with the VICP—but individuals should have to prove causation, with administrative decision makers weighing relative risk factors according to pre-specified criteria. Payouts should also be tabled by category of injury, for consistency and predictability.

D. Independent Post-Market Drug Monitoring

One clear advantage of moving from a decentralized tort system to a central administrative system is the potential to improve safety through careful consideration of post-market adverse-event data, based on claims submissions, sophisticated data mining, and quantitative analysis. Adequate firewalls should separate post-market review from the FDA’s drug approval team to avoid potential conflicts.

E. System Funding

While a simple tax system analogous to the VICP’s makes sense at the outset, system funding could be risk-adjusted over time based on the compensation system’s payouts. Such an approach would generate clear incentives for manufacturers to invest in safety innovation, testing, and

45. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001).

disclosure, given the program's refusal to grant awards for injuries related to already-known side effects.

VII. CONCLUSION

On its own, the federal regulatory system, as implemented by the FDA, costs far more lives by delaying and denying new drug entry and by increasing the costs of drug development, than it saves by preventing drugs with unknown, harmful side effects from entering the market. The concurrent state tort law system is an overlapping regulatory regime that exacerbates this tendency, complicated by a host of features that reduce rather than promote public health and safety. The federal government's demonstrated success in administering a compensation program for vaccines should serve as a useful template for a broader system to be applied to all medical products, alongside a full field preemption of state common law tort claims for FDA-regulated drugs and devices. Though differences between the vaccine market and the broader medical markets complicate the structure of such a program, these obstacles are not insurmountable, and an administrative compensation system could facilitate innovation, safety, post-market testing, and disclosure relative to the status quo.