University of Nevada at Reno

Preemption Justice:

Restoring the Legal Rights of Persons Injured by Medical Devices and Generic Drugs

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Judicial Studies

By:

Joseph J. Maltese

Dr. James T. Richardson, Dissertation Advisor

May, 2014

The Graduate School

We recommend that the dissertation
prepared under our supervision by

Joseph J. Maltese

Entitled

Preemption Justice:
Restoring the Legal Rights of Persons Injured by Medical Devices and Generic Drugs

be accepted in partial fulfillment of the
requirements for the degree of

Doctor of Philosophy

James T. Richardson, Ph.D., J.D., Senior Dissertation Advisor

Michael D. Green, J.D., Committee Member

Joseph Sanders, Ph.D., J.D., Committee Member

Catherine M. Sharkey, J.D., Committee Member

Richard A. Bjur, Ph.D., J.D., Graduate School Representative

David W. Zeh, Ph.D., Dean, Graduate School

May, 2014

Abstract

This study reviews the U.S. Constitutional foundations that empowered the Congress to preclude state regulation of medical devices, vaccines and generic pharmaceutical drugs approved for marketing and distribution by the U.S. Food and Drug Administration (FDA).

The study initially travels through the history of how the states, under their "police powers," attended to the health and welfare of the public, by regulating food and drugs and how the Congress and the FDA through the "Supremacy Clause" and the "Commerce Clause" of the U.S. Constitution encroached into that domain incrementally over the past 100 years. In the past decades the FDA has almost totally dominated the area of drug, vaccine and device safety standards empowered by a series of federal statutes and regulations. But the greatest domination over the states has been through a few recent U.S. Supreme Court decisions that have expanded federal regulatory preemption into precluding state common law suits by individuals, who sought compensation from the manufacturers of FDA approved medical devices and generic drugs, which they claimed caused them injury or death.

This study addresses the competing national interest of maintaining the public health with the necessity of maintaining a business environment where drug and device manufacturers can conduct research and development while limiting the cost of defending lawsuits throughout the fifty states and territories, with their disparate

regulatory schemes and restoring the legal rights of individuals, who are injured by medical devices and generic drugs.

To accomplish these goals, this study proposes Congressional legislation expressly preempting state regulation of FDA approved drugs and devices while also precluding individuals from suing drug and device manufacturers in state or federal courts for injuries or deaths caused by those FDA approved products. The same proposed legislation would create a specialized non-jury court to adjudicate claims where the Secretary of the U.S. Department of Health and Human Services, rather than drug and device manufacturers, will be the defendant in such actions, which is similar to the National Childhood Vaccine Injury Act of 1986. Medical expenses of the injured persons would be paid for by the affordable health care act mandatory health care insurance policies. Compensation for claimants' pain and suffering, and other compensatory damages such as lost wages along with attorney fees would be paid from an established fund to pay and administer those claims. An excise tax on FDA approved drugs and devices will be levied on the sales of such products to finance the fund.

Table of Contents

Chapter I

Introduction

This text will acquaint the reader with the concept of federal preemption of state common law and statutory enactments, as well as state rules and regulations. It will discuss the constitutional foundation of preemption as it has been applied in the American system of federalism and how it has endured in the modern regulatory state. While there are numerous examples of federal preemption of state laws and regulations, this paper will use the Food, Drug and Cosmetics Act of 1938 (FDCA) as amended, which is found in Title 21 of the U.S. Code, as the model statute to be examined and the U.S. Food and Drug Administration (FDA) as the sample agency, along with its rules and regulations found in Title 21 of the Code of Federal Regulations. This study will be limited to Congressional and FDA regulation of prescription drugs – both brand name and generic drugs, as well as vaccines and medical devices. The study will not cover the regulation of food or cosmetics.

This text will explore these and other issues by reviewing the constitutional underpinnings of federal preemption of state common law tort and products liability claims, and show how they have evolved in the American regulatory arena. In addition, this paper will explore the enactment of the FDCA, 21 USC 301 *et. seq*. and the creation of the FDA, along with its rule making authority in the area of prescription drugs, vaccines, medical devices, and generic drugs. This paper will also outline the leading cases from the U.S. Supreme Court, and other federal courts, as well as some state court

decisions ruling on prescription drugs, vaccines, medical devices, and generic drugs. The paper will survey the scholarly literature supporting and opposing federal preemption of state common law and statutory tort and products liability claims against FDA regulated products.

The concept of federal preemption starts with the U.S. Constitution to include the Enumerated Powers Clause of Article 1, Section 8, the Commerce Clause, the Supremacy Clause, the Tenth Amendment and the Necessary and Proper Clause.

In order to access the application of federal preemption to state law, a summary of state tort and product liability law is reviewed as background. Congressional legislation and regulations of the FDA governing prescription pharmaceutical drugs, vaccines and medical devices have been the source of much litigation in federal and state courts over the past decade. The leading cases will be used as examples of disparate treatment of these FDA approved products from other consumer products under traditional tort and products liability law and the recent interpretation of the drug and medical device statutes and regulations by the U.S. Supreme Court. How these cases have been handled by attorneys for injured claimants and counsel for the manufacturers, as well as the courts will also be explored. The recent rulings by the U.S. Supreme Court in preempting certain classes of FDA approved products, as opposed to other FDA approved products and the rationale behind those decisions are examined in detail. Lastly, a proposal to stabilize the inconsistent treatment of pharmaceutical drugs and medical devices by the courts will be explored.

On June 24, 2013, Justice Samuel Alito delivered the U.S. Supreme Court 5-4 decision in *Mutual Pharmaceutical Co. v. Bartlett,* 133 S. Ct. 2466 (2013), holding that individuals injured by generic drugs are preempted from maintaining a design defect products liability lawsuits against generic drug manufacturers. Two years earlier on June 23, 2011, Justice Clarence Thomas ruled in *PLIVA Inc. v. Mensing,* 131 S. Ct. 2567 (2011), a similar Supreme Court 5-4 decision, that generic drug defective warning claims were also preempted. The Court in *PLIVA* interpreted that under the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, that a generic drug manufacturer must mirror the FDA approved ingredients and warning label of the brand name drug it is copying, it is impermissible for the manufacturer of a generic drug to either alter their chemical components or unilaterally amend or enhance its warning label, notwithstanding the fact that it knew that there were several adverse events reported about that drug. Consequently, the Supreme Court found that persons injured by generic drugs were barred from recovery where they may have had a right of recovery if they had taken the same brand name drug. The High Court stated in both generic drug cases that such actions were impliedly preempted because there was a conflict between a federal statute and state common law that made it impossible for the defendant manufacturers to comply with both federal and state law.

Earlier on February 20, 2008, the U.S. Supreme Court in *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008), in an 8-1 decision written by Justice Antonin Scalia, held that injured parties were prohibited from recovering from the manufacturer of an FDA approved balloon catheter lead, a Class III medical device. The High Court, for the first

time in the 32 years since its passage, found that the 1976 Medical Device Amendments to the FDCA precluded individuals from maintaining state common law suits against the manufacturer of an FDA approved Class III medical device. Never before had the U.S. Supreme Court ruled in such a manner to ban injured persons from seeking redress for FDA approved products. Indeed, the Court's prior rulings upheld state common law claims. See *Cipollone v. Liggett Group Inc.,* 505 U.S. 504 (1992); *Medtronic v. Lohr*, 518 U.S. 470 (1996).

Historically, individuals had a right to sue under common law tort and product liability theories either in state or federal courts those who were responsible for designing and distributing a product that caused them harm. The recent pronouncements of federal preemption by the Supreme Court that deny injured persons the right to pursue in court those that have made or distributed the injurious product started with the Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Act of 1969 that precluded state court actions. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). While cigarettes were not regulated by the FDA, the preemption of state regulation over such federally regulated products has altered the playing field and has caused great uncertainty in the legal community, which has given generic drug and medical device manufacturers virtual immunity from liability for their products. While this is an evolving trend in American jurisprudence, its proponents cite various sections of the U.S. Constitution and federal statutes to justify what others may call creative reasoning and a grave injustice.

Black's Law Dictionary, 9th edition defines preemption, in part as:

> * * *
> 5. *Constitutional Law*. The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation. – Also termed . . . *federal preemption* (Garner, 2009, 1297).

Professor Catherine Sharkey of the New York University School of Law in her article, Against Categorical Preemption: Vaccines and the Compensation Piece of the Preemption Puzzle (*61 DePaul L. Rev. 643, Winter 2012*) succinctly outlined the parameters of Federal Preemption as follows:

> Preemption is the doctrine whereby federal law displaces state law. Preemption doctrine is divided into express preemption, which occurs when Congress includes an explicit preemption provision in a statute, and implied preemption when there is no such express provision but preemption may nonetheless be inferred from the statutory and regulatory scheme. Implied preemption is further divided into field preemption, when federal law so dominates an area such that there is no room left for state law to operate, and conflict preemption, a narrower form of preemption that occurs when federal law displaces only that state law with which it is at odds or in tension. The degree of conflict spawns further doctrinal categories: impossibility preemption, when an actor could not follow the dictates of state law while complying with federal law, and obstacle preemption, when state law obstructs or frustrates the purpose of the federal statutory or regulatory scheme.

Professor Sharkey continues her review of federal preemption by pointing out that those neat doctrinal categories offer little in terms of a coherent analytical framework for the resolution of preemption disputes. Frequently when Congress includes an express preemption provision or an express savings clause in a statute to permit certain state regulation, the scope of what was intended is often ambiguous. This leaves the analysis of the text to the courts, which may resort to some form of inferential implied preemption to

fill in that which is silent. The result is that often both express and implied preemption are applied to the same case. Sharkey, 2012, 643-644.

Indeed, there is a place for preemption to establish a uniform national public policy through laws enacted by elected representatives. However, Congress sometimes abdicates its oversight role by permitting federal agencies to publish and establish policies that preempt state law without express Congressional authorization. Agency policies and regulations have eviscerated the rights of individuals who are injured by the products those agencies approved for manufacture and sale to the public. Congress also abdicates its role in sitting silently while courts through judicial interpretation of statutes remove the rights of individuals that was never intended by Congress. Such judicial decisions have taken away the rights of the people to be heard in courts of law seeking damages from those manufacturers who caused them serious harm and, in some instances, death from a defective product or an inadequate warning of an inherently dangerous product.

Disputes over the interpretation of statutes or agency rules generally wind up in state or federal courts. However, most federal courts yield to federal agency claims that their rules and procedures are comprehensive. Consequently, many claims are impliedly preempted. Professor Sharkey addressed this phenomenon in an article entitled Inside Agency Preemption, *110 Michigan L. Rev. 521 (2012).* In that article she points out that in the 21st century, the Court frequently looks to the regulatory agency for guidance in interpreting the thousands of pages of rules promulgated by the agency rather than the loose Congressional intent in enacting the underlying legislation. Id. at 525.

Under the doctrine of "sovereign immunity" the federal government cannot generally be sued for the actions or inactions of its regulatory agencies such as the Food and Drug Administration (FDA). However, even the Federal Torts Claims Act waives federal sovereign immunity for a number of federal activities, and generally allows recovery in federal court for harm tortuously caused by federal employees, but only if the law of the state where the injury occurred would hold a private person liable for such an injury. 28 USCA §§2671-2680. But now the Supreme Court has extended that sovereign right – not to be sued on most product liability theories – to the manufacturers of FDA approved medical devices and generic drugs. This is something relatively new.

It is akin to creating another form of the "government contractor defense," where the government contracts for a specifically designed product and the manufacturer, who makes the product in accordance with the government's specifications, is immune from liability for that product. *Boyle v. United Technologies Corp*., 487 U.S. 500 (1988). However, where the federal government is not specifying how the product is to be made, but is only approving the manufacturer's design and warnings and not assessing whether a better design might be available, there is no rationale for preempting common lawsuits by injured persons.

Recently, the U.S. Supreme Court has paid much attention to preemption law, especially in the area of pharmaceutical and medical devices. There are large economic stakes for manufacturers where success or failure in products liability litigation can be very costly. Professor James T. O'Reilly of the College of Law at the University of Cincinnati in his text *Federal Preemption of State and Local Law: Legislation,*

Regulation and Litigation, published in 2006 by the American Bar Association outlines some of the issues. Professor O'Reilly points out that plaintiffs' trial lawyers have a major economic stake in limiting federal preemption of tort remedies for injured persons, from suing the manufacturers of the products that injured them. O'Reilly (2006) 3. But the defense bar will also lose considerable legal business if the recent trend in Supreme Court decisions continues to insulate manufacturers from liability.

It is interesting to note that Professor O'Reilly's comments in his 2006 book were most prescient. They preceded the Supreme Court's 2008 decision in *Riegel v. Medtronic*, 522 U.S. 312 (2008), its 2011 decision in *PLIVA v. Mensing,* 131 S. Ct. 2567 (2011) and most recently the 2013 decision in *Mutual Pharmaceutical v. Bartlett,* 133 S. Ct. 2466 (2013), where the High Court precluded large classes of claimants from proceeding with their suits against generic drug and medical device manufacturers.

Professor O'Reilly has argued that the social policy repercussions of the tort debate are significant: What is the proper balance for our society? Should we substitute a nationwide minimum safe design rule in place of a deterrent remedial sanction that punishes negligent and unsafe design choices? Is the current wave of advocacy favoring preemption just a subset of "tort reform," being done comprehensively by industry advocates with some resistance from the American Association for Justice (AAJ), which is comprised of members of the plaintiff's bar? Should there be a due process right of the injured person to have his or her "day in court" for a defect that caused an injury; or should the desired efficiencies of national uniformity justify rejection of the potential for multiple damage awards, which may stimulate product redesigns? O'Reilly (2006) 3.

Harvard Law Professor Daniel J. Meltzer in an article entitled Preemption and Textualism, *112 Mich. L. Rev. 1 (October 2013)* argues that in the area of preemption, the Supreme Court's approach to statutory interpretation differs from the approach it follows elsewhere. He states that "the Court's preemption decisions reflect a highly purposive approach to reading statutes, most notably through the application of obstacle preemption analysis." Professor Meltzer further argues that "Congress lacks the capacity, foresight, and linguistic tools to be able adequately to specify in statutory text the proper resolution of the range of preemption issues that invariably arise under regulatory statutes of any complexity. Consequently, the task of fashioning a workable legal system that integrates state and federal law necessarily falls to courts (with assistance in some instances from federal administrative agencies)." Id. He concludes that preemption cases are not known for their methodological consistency and highlights the limits of textualism and the limited capacity of the Congress to prescribe a comprehensive set of statutory directives that provide a sensible set of directives that will resolve the full range of preemption issues. Thus, there remains a vital role for courts and, to some extent federal agencies, to integrate federal legislation with state and local governments to craft a working and effective legal order. Id at 56-57.

While some scholars have suggested alternatives to strict federal preemption of state products liability law applied to FDA approved products, none of them has outlined a specific remedy. This paper will specifically outline a proposal that may give the Congress a textual remedy that would reinstate its role as the dominant player in ascertaining when and how federal statutes and regulations will specifically preempt state

law. Moreover, it will give people injured by FDA approved products a source for a remedy, rather than barring them from the courthouse. Lastly, the paper will outline proposals to give those injured by prescription drugs and medical devices a mechanism to recover compensation for their losses.

The current injustice of preemption is manifested in the fact that Congress, by drafting ambiguous statutes that expressly preempt the rights of states to impose additional duties and requirements upon manufacturers of drugs and devices, has also quite unintentionally precluded the rights of injured persons to sue the makers of those products approved for marketing by the FDA.

Other Issues

An overarching issue that is discussed is where does Congress have the right to exempt certain manufacturers from liability to those persons harmed by their products? Our forefathers in enacting the Bill of Rights to the U.S. Constitution not only included a right to trial by jury in criminal prosecutions in the Sixth Amendment, but also included the Seventh Amendment right to a jury trial in suits at common law. The Seventh Amendment provides:

> "In suits at common law where the value in controversy shall exceed $20, the right of trial by jury shall be preserved and no fact tried by a jury shall be otherwise re-examined in any court of the United States, than according to the rules of the common law."

While the Seventh Amendment has been rarely invoked in the context of precluding the rights of the people to seek redress from those that harmed them, such invocation of this right to a jury trial has not until recently been necessary because

Congress and the states have provided alternative sources of redress through such workers' compensation laws and no-fault automobile insurance coverage.

Both the Congress and the Supreme Court have unintentionally disregarded the right afforded the people in the Bill of Rights to a jury trial in civil trials against those that injured them. Most torts treatises trace the history of torts to the nineteenth century, after the adoption of the Bill of Rights in 1791. While there existed at common law rights in trespass on the person and trespass on the case, which were the forerunners to the intentional torts of assault and battery, what grew to become negligence actions that were later embellished into the products liability causes of action in the twentieth century were not part of British common law in 1791. Therefore, there is no prohibition from creating alternative means of redress short of a common law jury trial.

Over the years there have been several measures that have eliminated the need for jury trials. When legislators in Maryland in 1902 examined the problem of employees injured on the job having to sue their employers, it created a no-fault Workman's Compensation Law. In 1906 Congress passed the Federal Employers Liability Law, which was declared unconstitutional in 1908 by the U.S. Supreme Court. However in that same year Congress passed the Federal Employers Liability Act (FELA) to protect railroad workers injured on the job. See 42 USC sec 51 et seq. By 1949 virtually all states had some form of workers' compensation, which obviated the need to subject the injured employees to the rigors of proving fault against their employer, along with cumbersome discovery and the costly jury trials.

Other Non-Jury Avenues of Redress

Another system, which has limited jury trials is No-fault automobile insurance which was initially developed to reduce insurance claims and to stem the overwhelming tide of automobile negligence actions in trial courts, especially those of a minor nature. No-fault auto insurance is a type of automobile insurance in which claims for personal injury (and sometimes property damage) are made against the claimant's own insurance company, no matter who was at fault, rather than against the insurer of the party at fault. Under most state "no-fault" statutes, only persons who are injured seriously may bring an action against another motorist or owner of a vehicle. No-fault statutes vary from state to state in terms of scope of coverage, threshold amounts and threshold types, such as monetary or verbal thresholds. While no-fault automobile statutes may not have appreciably reduced auto insurance premiums, it has drastically reduced the number of automobile trials in courts. But more importantly, it has given those injured in automobile accidents some compensation for medical expenses, lost wages and household expenses more quickly than waiting years for a case to arrive on a court calendar.

The development of Alternative Dispute Resolution (ADR) through arbitration and mediation have also reduced the need for costly jury trials in commercial cases as well as products liability and medical malpractice cases.

Lastly, Congress implemented a non-jury system in response to lawsuits against vaccine manufacturers. In the 1970s and early 1980s most vaccine manufacturers had left or threatened to leave the marketplace due to litigation expenses and the risk of being

held liable by sympathetic jurors in favor of persons injured by vaccines. See, Offit, Peter A., *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis* (2005); see also, Manning, R., "Changing Rules in Tort Law and The Market for Childhood Vaccine," *37 J.L. Econ. 247* (1994). In 1986, Congress enacted the National Childhood Vaccine Compensation Act, which created a viable alternative to compensate those injured by vaccines without making them prove fault at a jury trial. At the same time, Congress limited the economic exposure of vaccine manufacturers from large jury verdicts that could put them out of the business of creating vaccines for the benefit of the overwhelming majority of the public.

While the federal codes do not include negligence or products liability causes of action, those claims have existed in some form at common law, which have been exclusively state causes of action. Even when suing in a federal court the causes of action were virtually all based upon state common law or state statutory law. The division of power between the federal government and the states and the rights of the people had generally been preserved until the Supreme Court reassessed the extent of the Commerce Clause and the Supremacy Clause of the Constitution beginning in the 1930s during the New Deal. Thereafter, the federal government moved incrementally to dominate various sectors of the economy to include the pharmaceutical and medical device industry through laws and regulations.

Congress should reassess the impact of express preemptive language in statutes that are being interpreted by the courts to mean that injured persons are precluded from maintaining a suit against the manufacturer who produced a product that caused their

injury. Congress should either reconsider the meaning of the Seventh Amendment to allow jury trials in cases where persons are harmed by others to include drug and device manufacturers, or in the alternative, create a no-fault system of compensation for all drug and medical devices similar to that employed by the Vaccine Court in the U.S. Court of Federal Claims. Since the volume of drug or medical device claims would exceed that of vaccine related injuries, the Vaccine Court would not be large enough to administer those claims. Consequently, regional federal administrative courts should be created to exclusively handle drug and medical device claims. Those courts should employ the same uniform federal statutes and regulations with regard to the production of a safe and effective product, without imposing the burden of proving on the injured party to prove negligence or design defects or manufacturing defects or inadequate warnings against the manufacturer. If the Congress created a no-fault compensation system for those injured by approved drugs and medical devices, that would obviate the need for jury trials. Since prior to 1791 when the Seventh Amendment was ratified and became effective a no-fault compensation system did not exist. Accordingly, the arguments that the federal government took away injured parties' rights of redress before a jury by would be muted.

Congress found a solution in the area of FDA approved vaccines to compensate the recipients who inevitably would have adverse effects from a vaccine that was created to eradicate disease for the overwhelming majority of recipients. The lessons learned from the National Childhood Vaccine Injury Act (NCVIA) form a foundation to create a more extensive drug and device system of adjudication. The NCVIA has minimized the cost to vaccine manufacturers and has been a relatively successful endeavor. This text

will demonstrate how the NCVIA should be tailored and expanded to all prescribed drugs and medical devices.

This text is divided into several chapters. This introductory chapter defines the concept of federal preemption and its prominence in modern constitutional decision making, as well as some need for change by the Congress and the Supreme Court.

The methodology employed in this research paper is described in Chapter II and a literature review is included in Chapter III. However, most of the literature discussed are U.S. Supreme Court decisions and scholarly commentary, which are outlined throughout the text.

A more detailed development of federal preemption of state common law is the subject matter of Chapter IV. In order to fully understand the concepts being discussed in the later chapters, I have included an overview of product liability law in Chapter V. A brief history of the Food, Drug and Cosmetics Act and the Food and Drug Administration is covered in Chapter VI, along with the 1976 Medical Device Amendments, which were the subject matter of *Riegel v. Medtronic*. However, not all of the FDCA statutory amendments and regulations are discussed in Chapter VI. Those dealing with vaccines and generic drugs are discussed in Chapters VIII and IX when those topics are more fully discussed.

Chapter VII covers the U.S. Supreme Court on preemption of FDA approved products and cites to the High Court decisions in a chronological fashion to demonstrate

the progression of Supreme Court decisions while attempting to point out some of its inconsistencies.

Chapter VIII deals with Congress' enactment of the National Childhood Vaccine Injury Act of 1986 and the creation and use of the Vaccine Court in the U.S. Court of Federal Claims, which preempted or at least limited common lawsuits against vaccine manufacturers.

Chapter IX discusses generic drugs and the Hatch-Waxman Amendments to the FDCA. Generic drugs now constitute approximately 80% of the purchased drugs in the market and how they have been placed in a unique posture due to the Supreme Court's interpretation of those amendments. The FDA's 2013 proposed regulations in response to *PLIVA* and *Mutual Pharmaceutical* will also be discussed in this chapter.

Chapter X contains the Conclusion and Recommendations.

This study acknowledges the inconsistent and confusing state of the law, where most persons injured by FDA approved products are preempted from seeking compensation for their losses. Injured parties are expressly preempted from seeking compensation from a medical device manufacturer. However, they may seek compensation for an inadequate warnings claim against a brand named drug manufacturer, but are expressly precluded from seeking compensation from the generic manufacturer, who produced the exact same product. The ultimate recommendation is to restore the legal rights of persons injured by pharmaceutical drugs and medical devices. The proposal is outlined in the Appendix, which contains a legislative proposal modified

from the National Childhood Vaccine Injury Act of 1986. The proposed legislation would embellish the Vaccine Court concept into a Federal Drug and Device Court within the U.S. Court of Federal Claims, which would not only adjudicate claims in Washington, D.C., but regionally within the established Federal Judicial Circuits. The Drug and Device Court will be comprised of Special Masters, who will adjudicate claims without a jury. The Court will cover not only FDA approved generic drugs, but also brand name drugs and all Class III medical devices. By acknowledging the trend to preempt FDA approved pharmaceutical drugs and medical devices from state court claims, the proposal obviates the need for long and costly jury trials, while at the same time affords some measure of justice to those injured by those products.

Chapter II

Methodology

The methodology employed herein is legal library research utilizing the WestlawNext and Lexis search engines to find original sources, such as cases, statutes, regulations and Executive Orders on federal preemption of state law. Secondary sources such as journal articles, books and treatises on federal preemption were also searched. Heinonline was also accessed to obtain articles that were published before the period covered by WestlawNext and Lexis. Specifically, U.S. Supreme Court decisions were researched that involve the U.S. Food and Drug Administration. Articles and books were also located using WestlawNext and Lexis as well as the Google Scholar search engine.

The search terms included various combinations of preemption, federal preemption, common law tort claim, products liability, pharmaceuticals, generic drugs, brand name drugs, devices, medical devices, vaccines, Federal Drug Administration, FDA, due process, supremacy clause, commerce clause. The U.S. Constitution was also searched in Articles I and VI, and the Seventh, Ninth, Tenth and Eleventh Amendments. All cases were cite checked utilizing either WestlawNext key cite or Shepherds citations on the Lexis legal search engine.

Chapter III

Literature Review

The literature reviewed comprises primary sources such as U.S. Supreme Court, U.S. Court of Appeals and U.S. District Court decisions as well as state trial and appellate decisions concerning federal preemption of state common law claims involving defective drugs, medical devices, and vaccines. Those decisions that will be outlined throughout the dissertation will appear in the Table of Cases in the Bibliography. The other primary sources are the Food, Drug and Cosmetics Act in Title 21 of the U.S. Code, as well as the Administrative Procedure Act in Title 5 of the U.S. Code. In addition, sections of the Uniform Commercial Code Article 2 of sales dealing with warranties have been examined as another primary statutory source.

The Code of Federal Regulations dealing with Drugs and Devices have also been reviewed. Executive Orders from the Presidents dealing with preemption round out the primary sources relied upon throughout this paper. All of the primary sources are included in the: Table of Statutes, Rules and Regulations and the Table of Executive Orders. The secondary sources include scholarly texts and journal articles listed in the Bibliography.

Some of the leading texts include the American Law Institute's *Restatement of the Law, Torts (Second) (1964)* and the *Restatement of the Law, Torts (Third) Products Liability (1998, Cum. Pocket Part 2013).*

In reviewing the literature on federal preemption of state police powers to regulate the general health and welfare of its citizenry four major texts have been published from 2006 through 2013. The earliest of those books was written by Professor James T. O'Reilly of the College of Law of the University of Cincinnati in 2006, entitled *Federal Preemption of State and Local Law: Legislation, Regulation and Litigation,* which was published by the American Bar Association, Section on Administrative Law and Regulatory Practice. It is an excellent primer of the law of federal preemption that includes chapters outlining the basics and categories of preemption. Interestingly he also includes a chapter on the constituencies of preemption, which include not only federal agencies, but also state officials, federal and state judges, congressional majority members, corporate planners, and defense counsel. It also includes injured plaintiffs and their lawyers, as well as investors and small businesses. Professor O' Reilly covers the constitutional background for preemption as well as the political and policy debates. He outlines the mechanisms for agency preemption and discusses congressional express and implied preemption. O'Reilly describes the use of federal preemption in the defense of a case and the modern trends in preemption litigation. He then turns to specific areas of regulation and demonstrates how preemption affects those sectors of the economy. O'Reilly also covers specific products that are preempted such as consumer products, food labels, medical devices, drugs, and agricultural pesticides. He concludes with suggestions for congressional express disclosure of the extent of federal preemption, and ends with a discussion of the benefits and downsides of preemption.

In 2007, Professor Richard Epstein, who now teaches at New York University School of Law and who formerly taught at the University of Chicago Law School, together with Michael S. Greve, the John G. Searle Scholar of the American Enterprise Institute (AEI), where he conducts the Federalism Project and the Liberty Project, edited a scholarly reader entitled, *Federal Preemption: States' Powers, National Interests,* which was published by the AEI in Washington, D.C. The American Enterprise Institute is a leading conservative think tank whose stated mission is "to defend the principles and improve the institutions of American freedom and democratic capitalism—limited government, private enterprise, individual liberty and responsibility, vigilant and effective defense and foreign policies, political accountability, and open debate." AEI's Organization and Purposes (http://www.aei.org/about, last accessed on July 7, 2013). The editors introduce preemption in context and include ten chapters written by renowned legal scholars. Part I covers the Constitutional Context to include federal preemption displacing state law in the nineteenth century as well as a discussion of the Commerce Clause and its progression from the *Lochner* era through the New Deal. Part II deals with the application of preemption and starts out with "The Case for FDA Preemption" not surprisingly written by a former Chief Counsel of the FDA, Daniel E. Troy, who is a former scholar at the AEI and a partner at Sidley and Austin in Washington, DC. Other chapters cover preemption of cellular phones and the financial industry. More relevant to this study is Chapter Seven written by NYU Law Professors Samuel Issacharoff and Catherine M. Sharkey entitled "Supreme Court Preemption: The Contested Middle Ground of Products Liability," which concluded that when Congress decides to assert the commerce clause to regulate an area it could be supreme. But

nonetheless "[T]he products liability area is one in which congressional action is typically partial, most often seeking to find a coordinated liability standard across a national market but leaving in place a stratified world of state remedies." Issacharoff and Sharkey claim that the resulting case law from this muddled regulatory arena is that federal courts, in an attempt to add logic to the regulation of products, which must move across the nation, often yield to federalization of marketplace regulations, which in essence preempts state regulation.

Professor Thomas O. McGarity of the University of Texas School of Law, who is also a Scholar at the Center for Progressive Reform wrote a book in 2008 entitled: *The Preemption War: When Federal Bureaucracies Trump Local Juries,* which was published by the Yale University Press. "The Center for Progressive Reform is (as its title implies a progressive) a nonprofit research and educational organization with a network of member scholars working to protect health, safety and the environment through analysis and commentary." (www.progressivereform.org/about crr.cfm, last viewed July 8, 2013).

Professor McGarity observes that, notwithstanding the fact that most conservatives advocate for limited government and state's rights, the Administration of George W. Bush (2001-2009) and the conservative majority on the Supreme Court of the United States have inconsistently made a federal government "power grab" utilizing federal preemption of traditional state common law actions as a form of "tort reform." He bristles with the proposition that federal bureaucrats are using the U.S. Constitution's Supremacy Clause so aggressively to shield negligent companies from liability, instead of

protecting the public from dangerous products and activities. In this 2008 book, he correctly predicted that the preemption wars would not go away anytime soon, and that the courts are powerless to end it. He asserts that ultimately the remedy must come from the Congress. McGarity outlines how the preemption war was waged in the courts, in Congress, and in federal agencies. He outlines in separate chapters the case for preemption as well as the case against preemption, and recommends how to end the preemption war.

The last of the preemption texts is *Preemption Choice: The Theory, Law and Reality of Federalism's Core Question,* published in 2009 which was edited by William W. Buzbee, a Professor of Law at Emory University School of Law and the Director of the Emory Environmental and Natural Resources Program. Professor Buzbee amassed fourteen legal scholars, in addition to himself, who have covered topics ranging from the history of federal legislation, agency and court actions in a variety of fields, which heretofore had overlapping, shared responsibilities with state legislation and agency regulation.

Buzbee and his contributors demonstrate how the balance of power in the federal-state relationship has shifted due to the actions of federal agencies, the courts and an inattentive Congress. While Professor Buzbee briefly reports on the U.S. Supreme Court's *Riegel v. Medtronic* decision, which was published on February 20, 2008 just as the draft of his book was going to the press, the impact of *Riegel* was not yet fully appreciated at that time.

Other scholars have written more extensively on the impact of *Riegel* and predicted that the preemption it provided for Class III medical devices would be the rule for all other FDA approved products and pharmaceutical drugs. Many reasoned that since federal regulation was controlled by the FDA, state products liability law would conflict with and make it impossible for drug and device manufacturers to comply with federal law as well as the law of the 50 states. Consequently, the field of pharmaceutical drugs and medical devices (at least Class III medical devices) should be preempted under field preemption. However, at least the First Circuit Court of Appeals applied field preemption to some FDA regulation of pharmaceutical drugs and medical devices. *See, Pharmaceutical Industry Average Wholesale Price Litigation v. Astra Zenica Pharmaceuticals, L.P.*, 582 F3d. 156, 177-178 (1st Cir. 2009), cert. dismissed, 131 S. Ct. 60 (2010).

Scholars have assessed the balance between the need for uniform regulation by federal agencies and the problem of persons injured by products approved by those federal agencies. Professor Robert Rabin of Stanford Law School in his article "Reassessing Regulatory Compliance," *88 Geo. L.J. 2049* (2000), argues that in addition to federal regulation, product liability litigation through the discovery process uncovers product defects and misrepresentations that might not be uncovered or addressed by the manufacturers. Hence, tort liability enhances the federal regulatory process and provides incentives for product safety that are not dealt with by the federal agency.

Richard A. Epstein an Emeritus Professor at the University of Chicago School of Law and now at New York University, School of Law outlines in The Case for Field

Preemption of State Laws in Drug Cases, 103 *Nw. L. Rev. 463* (2009), that imposing tort litigation on top of strict federal agency regulation creates confusion in the manufacturing marketplace and costly litigation which may or may not result in compensation for the injured claimant. Other journal articles listed in the bibliography will be discussed in the various chapters herein. Background material from several treatises and casebooks on torts, products liability, toxic torts and mass torts were also reviewed.

Professor Mark A. Geistfeld of New York University Law School, the author of *Principles of Products Liability, 2nd Ed.* (2011) and a casebook entitled *Product Liability Law* (2012), outlines the development of products liability law from its tort (negligence) and contract (warranty) bases. He highlights the implied warranty requiring that manufacturers and sellers should produce products that are fit for their ordinary purpose. The implied warranty of fitness for ordinary purpose resulted in strict liability where the claimant does not have to prove negligence in order to recover from the manufacturer or seller of a defective product. Geistfeld traces the evolution from the Restatement of the Law of Torts (Second) through the Restatement of the Law of Torts (Third), which dealt with products liability. He discusses consumer expectations and lauds the fairness of efficient products liability rules. However, he also introduces the reader to the risk-utility rule, which balances the cost of additional safeguards with the safety benefits and costs to the consumer to purchase the product.

Peter Barton Hutt of the law firm of Covington Burling, LLP in Washington, D.C., teaches a course on Food and Drug Law at Harvard Law School. Professor Hutt, together with Professors Richard A. Merrill of the University of Virginia and Lewis A.

Grossman of American University, have co-authored a comprehensive text entitled *Food and Drug Law, Third Edition*, which outlines in a thorough fashion the history of the FDCA and the FDA. The text also highlights the procedures for new drug and device applications, as well as other FDA procedures. The text is accompanied by a statutory supplement of *Food and Drug Statutes and Rules, 2013 Edition*.

When a product such as a pharmaceutical drug or medical device that is mass produced fails and causes injury to its end user, it is generally not an isolated event. The failure occurs over and over again to various people living in various locations who individually seek legal redress and compensation through the courts. Since multiple state and federal jurisdictions may be involved, the federal courts established the Multi District Litigation (MDL) Panel. The panel is comprised of several federal judges, who assess whether the multiple cases pending in the various federal district courts should be jointly managed and coordinated before an individual Coordinating Judge in a single U.S. District Court.

The Coordinating Judge manages all of the cases pending in the federal courts throughout the nation for pre-trial purposes. The Coordinating Judge issues a Case Management Order (CMO) in consultation with a Plaintiffs and Defense Attorney Committees to coordinate discovery of documents, the scheduling of depositions of the key defendant witnesses who would otherwise be deposed numerous times at great expense. The Coordinating Judge, in consultation with the attorneys in order to organize and manage the cases efficiently, establishes uniform interrogatories and fact sheets about each individual plaintiff's pedigree and claims. The claims may vary greatly from a mild

physical ailment to serious debilitating injuries to suicide and sudden death. The claimants are categorized by various factors to include the wide disparity of claims.

David F. Herr, an attorney from Minneapolis, wrote the *Multidistrict Litigation Manual 2013*, which is published by Thomson Reuters. It is an excellent treatise on handling mass tort litigation in an MDL proceeding. Herr points out that expert witnesses are required to prove that the product caused the injury and medical expert witnesses are required to demonstrate and document the extent of the plaintiff's injuries. Economic experts may also be required to demonstrate and project economic losses of each individual plaintiff. In order to demonstrate punitive damages, an evaluation of the defendant's net worth may also be required. The Coordinating Judge must rule on various motions to dismiss for failure to state a viable cause of action, as well as rule on the various statutes of limitations that are governed by the various states.

Several states have instituted a state version of the federal MDL to coordinate similar complex matters such as mass torts. In these "mini-MDLs," cases are coordinated for uniform discovery before a single Coordinating Judge who consolidates all of the cases pending in the various counties of the state and coordinates the discovery and rules on summary judgment motions. In New York the Litigation Coordinating Panel, maintain their own version of the MDL Coordinating Judge. See, N.Y. Uniform Rules – Trial Courts §202.69. The state Coordinating Judge handles multiple cases either in conjunction with a Federal MDL Judge, or alone if there is no Federal MDL Judge. Coordination of the cases pending in the respective state courts may also be coordinated between various state court judges from different states cooperating together to avoid

scheduling conflicts of the same defendant witnesses and a conflict on scientific relevancy of the underlying issues. Both the federal MDL and the state mini-MDL process is long, arduous and costly.

In order to establish uniformity in the process, the Federal Judicial Center has, since the 1960s, published a manual on how to handle protracted complex litigation. That manual grew and developed into the *Manual on Complex Litigation, Fourth Edition*, last published in 2004. While the Manual was created primarily for federal district court judges, it is widely used by state court judges and litigators. Indeed, Chapter 20 of the Manual deals with coordination between federal and state courts. Mass torts in general are addressed in the manual and model Case Management Orders are included.

When discovery is complete, the Coordinating Judge will usually entertain motions for summary judgment by the plaintiff to establish liability and then deal with individual damages. The defendants similarly will seek summary judgment to dismiss the claims outright or to preclude the plaintiff's experts and/or their opinions as being not scientifically reliable under the Federal Rules of Evidence §702 and/or §703 at a *Daubert* hearing (or a *Frye* hearing in *Frye* jurisdictions), which may be dispositive of the entire case. Such hearings generally would apply to all of the cases which creates an all or nothing at all situation for the plaintiffs, who are generally seeking to resolve all of the cases in a global settlement.

Since every toxic tort, pharmaceutical or medical device case requires the scientific testimony of qualified experts, several treatises have been authored by attorneys and scientists. Since 1994 the Federal Judicial Center (FJC) has published the *Reference*

Manual on Scientific Evidence. In 2011 the FJC, in conjunction with the National Academies of Science, published the *Manual on Scientific Evidence, Third Edition,* which covers not only the admissibility of expert testimony and how science works, but a wide array of scientific topics from forensic identification through DNA, statistics, multiple regression, survey research, economics, damages, exposure science, epidemiology, toxicology, medical testimony, neuroscience, mental health evidence and engineering.

David F. Herr also writes the *Annotated Manual for Complex Litigation, Fourth Edition* (2013), which includes and embellishes the FJC manual. The *Annotated Manual* has numerous citations to cases and journal articles, as well as the author's comments.

James M. Beck, an attorney with Reed Smith in Philadelphia who represents drug and medical device manufacturers, and Anthony Vale wrote the *Drug and Medical Device Products Liability Handbook* (2004) which is updated annually. It is an excellent guide to handling drug and device cases. While the text is presented in a straight forward manner, it has an emphasis on the defense prospective. The authors in Chapter 5 have an entire chapter entitled "Federal Preemption," which heralds the Supreme Court and lower court dominance over state courts in this arena.

From a claimant's perspective, Charles S. (Bucky) Zimmerman, a plaintiffs' attorney, who has served as lead counsel in several pharmaceutical and medical device consolidated legal actions, published *Pharmaceutical and Medical Device Litigation* in 2006, which is a two volume primer on the law and how to handle that litigation generally from a plaintiff's perspective. The treatise is updated annually. Like Beck &

Vale's book, Zimmerman covers the role of the FDA. He devotes chapters on FDA post approval oversight, which includes a section on reforming the FDA monitoring system into being more in line with the FDA mission to protect an individual's health or safety. He also discusses voluntary drug and device monitoring by health care plans, trade associations and patient advocacy groups.

Beck & Vale's treatise on the other hand does not discuss involvement by non-governmental actors and emphasizes that under *Buckman v. Plaintiff's Committee,* 531 U.S. 341 (2001), the only monitor to police manufacturers of drugs and devices is the FDA – all others are intermeddlers in the federal regulatory scheme. Both Beck & Vale and Zimmerman's texts discuss the tactics and methods of bringing to trial drug and device cases which, due to the cost of prosecuting such a claim against pharmaceutical corporations, is generally handled *en masse* as part of a mass tort series of claims.

Paul P. Rheingold, a leading products liability plaintiffs' counsel, published in 2006, *Litigating Mass Tort Cases*, which includes the procedural and substantive measures to be considered in handling such litigation against pharmaceutical and device manufacturers. The treatise is updated annually. Also in 2006, The American College of Trial Lawyers, Complex Litigation Committee published the *Mass Tort Litigation Manual*, which is a fine summary of the issues involved in a mass tort, but it has not been updated since its publication.

There are several online sources that were researched for this paper. Legal blogs have been written about the impact of the U.S. Supreme Court's decision in *PLIVA v. Mensing* (2011), *Mutual Pharmaceutical v. Bartlett* (2013), as well as *Riegel v.*

Medtronic (2009). James M. Beck, an attorney with Reed Smith in Philadelphia which represents drug and medical device manufacturers and several other drug manufacturing defense counsel, publishes the *Drug and Device Law Blog* weekly on the internet. It outlines current cases and issues concerning pharmaceutical drugs, devices, and other musings of the bloggers from a defense perspective. (http://drugandevicelaw.blogspot.com).

The Food and Drug Administration publishes an internet blog known as "FDA Voice" (https://blogs.fda) which is an official blog produced by FDA's senior leadership and staff to share news, background, announcements, and other information about the work done at the FDA. There is also an "FDA Transparency Blog" (www.fda gov/aboutfda/transparency) published by the U.S. Department of Health and Human Services, U.S. Food and Drug Administration, which was launched in 2010 to provide basic information about the FDA and public disclosure in a "Transparency Report," which discloses information about FDA regulated products for firms and transparency of FDA operations and decision making.

Several plaintiffs and defense counsel publish law blogs concerning food, drug and device matters.

Sheppard Mulleir, a law firm that deals in Food and Drug Regulatory law amongst several other specialties, publishes its own "FDA Law Blog" which outlines FDA regulatory law issues. Another blog with an identical title "FDA Law Blog" (https://www.fdalawblog.net) is published by Hyman, Phelps & McNamara, P.C., another law firm.

"FDAzilla Blog," as in the mythic monster, Godzilla, issues postings directed at "How can we work smarter with the FDA?" It shares stories outlining interactions with the FDA both good and bad, with suggestions for how to deal smarter with the agency from a manufacturer's perspective.

The Washington, D.C., law firm of Olsson Frank Weeda Terman Matz, PC (OFW) has a blog entitled the "AG/FDA Blog" (http://agfdablog.com), which claims to provide legal bipartisan government affairs representation to companies, individuals, and trade associates in the agriculture, food, drug and medical device industries to include matters of interest in modern agriculture and environmental law.

Tom Lamb, a North Carolina personal injury attorney, publishes the Drug Injury Watch (http://www.drug-injury.com), that comments on some of the latest drug litigation and monitors the number of adverse events reports published on various drugs and devices, which is useful to plaintiff's attorneys.

The Orange Book Blog (http://www.orangebookblog.com) reports on the intersection of patent law and FDA law for manufacturers.

The literature published on federal preemption outlines various examples of how the Congress, federal agencies and the courts have dealt with these issues in the past. What is missing is how the Congress and the courts can strike an efficient and equitable balance in the future. Hopefully this text will crystalize those issues and outline a proposal to fill that gap.

Chapter IV

The Development of Federal Preemption of State Common Law and Statutory Claims

Constitutional Foundations

The genesis of federal preemption is found in the U.S. Constitution. The Founding Fathers in their debates over the roles of the national government and the state governments devised a scheme whereby the national government of the United States would have certain "enumerated powers" that are recited in Article 1, Section 8 of the U.S. Constitution. Amongst those "enumerated powers" of the Constitution is the Commerce Clause, which states:

> The Congress shall have Power…to regulate Commerce with foreign Nations, and among the several States, and with Indian Tribes.

The Commerce Clause has three distinct areas affecting preemption: 1) cases of express assertion of the Commerce Clause; 2) cases not expressly asserting the commerce clause that imply preemption to shield federal programs regulating commerce; and 3) the "Dormant" Commerce Clause cases where state action would interfere with a topic or field, and in which the Congress could have adopted laws under the Commerce Clause.

The express Commerce Clause cases are those in which a federal statute regulating interstate commerce is used to override a barrier posed by a state law. In implied preemption claims, Congress has not expressed its intention about preemption,

but the courts implied such preemption in order to protect federal interests. The Dormant Commerce Clause, which is not explicit in the Constitution, restricts the power of the states from enacting legislation that would improperly burden interstate commerce, which is expressly relegated to the federal government.

The Tenth Amendment provides:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Traditionally, the states maintained the police powers to regulate the health and welfare of its inhabitants. Where there was a conflict between the laws enacted by the federal Congress and a state legislature, the Supremacy Clause of the U.S. Constitution in Article VI provides that:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land: and the Judges in every State shall be bound thereby, anything in the Constitution or Law of any State to the contrary notwithstanding.

As a result, federal laws will sometimes preempt state laws. There is, however, a strong presumption against the federal preemption of state law. *Medtronic, Inc. v. Lohr*, 552 U.S. 312 (1996); *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947). This is so particularly in areas traditionally governed by state law, such as areas concerning health and welfare. *New York State Conf. of Blue Cross and Blue Shield Plans v. Travelers Ins. Co*., 514 U.S. 645 (2005).

There is also a presumption against preemption when it would deprive a plaintiff of all state remedies without granting a federal remedy, thus denying a plaintiff any remedy *Medtronic, supra; Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 251-52 (1984).

The strong presumption against preemption is rebutted only by clear evidence of Congress' intent. *Medtronic*, *supra* n.2. Congressional intent to preempt state law may be expressly provided for in a statute. *Cipollone v. Liggett Group, Inc*., 505 U.S. 504 (1992). It may also exist by implication, as when congressional legislation is in actual conflict with state law, making it impossible to comply with both, thereby frustrating "the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

When express statutory preemption exists, the court must interpret the text to determine the full scope of preemption, using rules of statutory construction, and when necessary look "to the structure and purpose of the Act in which it occurs. *N.Y.S. Conference, supra*.

Other Constitutional Foundations

The Supremacy Clause was crafted at a time when many were skeptical of a strong central government. The debates amongst the Federalists and Anti-Federalists manifested in the Federalist Papers which discussed the intent of the Supremacy Clause within the framework of the limited bureaucratic powers of the national government.

At the end of the Enumerated Powers Clause is the "Necessary and Proper" Clause which states:

> To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers and all other Powers vested by this Constitution in the Government of the United States, or in any Department or officer thereof.

It may be argued that federal preemption dates back to some of the earliest judicial decisions of the Supreme Court in *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819); and in *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824). In *McCulloch*, the state of Maryland imposed a tax requiring all banks chartered outside the state to print their bank notes on stamped paper if they established any branch office within Maryland's boundaries. The tax was similar to those passed in other states during a period of strong state sentiment against the Bank of the United States. The taxes were aimed at excluding the Bank of the United States from operating branches within those states. The Bank of the United States operated a branch in Maryland, but issued notes on unstamped paper. Accordingly, Maryland brought an action for debt collection against McCulloch, the cashier of the Baltimore branch of the Bank of the United States. The state courts imposed penalties on McCulloch, and he appealed that decision.

The issue in *McCulloch* was does the Congress have the power to incorporate a bank under its implied powers? And is the federal government supreme over the states to the extent that a bank created by the federal government pursuant to its constitutional powers is immune from taxation by the states? The court answered both questions yes, and reversed the Maryland judgment. Accordingly, under the Necessary and Proper Clause, Congress may use any appropriate means to attain a legitimate end that is not prohibited by the Constitution and that is consistent with the letter and spirit of the Constitution.

In *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824), New York State granted to Robert Fulton, one of the developers of the steamboat, and Robert Livingston, the Minister to France in the Jefferson Administration, the exclusive right to navigate by steamboat between New York City and Elizabethtown, New Jersey. Livingston and Fulton in turn conveyed that right to Aaron Ogden. Thomas Gibbons obtained a federal license under the Federal Coasting Act to operate boats along the same Hudson River route. Indeed, he hired the famed Staten Islander, Cornelius Vanderbilt as his chief ferry boat driver. T.J. Stiles (2009), *The First Tycoon: The Epic Life of Cornelius Vanderbilt*, 45-53. Ogden sought and obtained a New York state court injunction prohibiting Gibbons from operating his steamboat. Gibbons appealed claiming that the power of Congress to regulate interstate commerce under the Commerce Clause is exclusive.

The issue presented to the Supreme Court was may a state regulation, which governs commercial navigation exclude federally licensed operators? The Supreme Court held no and reversed the injunction. The Court asserted that one of the primary objectives of the creation of the federal government was to grant the power over commerce, including navigation between states. The power of Congress does not stop at the boundary lines of a state; it follows interstate commerce into the territory of the state. Therefore, the federal license must be recognized, and state laws prohibiting the use of that license is void.

Textual Interpretation

The necessary and proper clause is also referred to as an "elastic clause" because it gives great leeway in interpreting the extent of the enumerated powers given to the federal government. Typically, loose constructionists of the Constitution use this clause to expand the powers of the federal government. At the other end of the judicial interpretative spectrum are the strict constructionists that look to the strict meaning of the text of the Constitution, statute, or document. Some have argued that strict constructionism and originalism are different. U.S. Supreme Court Justices Antonin Scalia and Clarence Thomas are currently the chief proponents of originalism. Justice Scalia distinguishes originalism from strict constructionism. He claims that the words of the Constitution or a statute should be given the plain meaning of what those words meant at the time they were written and not with a contemporary meaning or by divining what the writers meant by interpreting the legislative history. Antonin Scalia (1989). Originalism: The Lesser Evil, 57 *U.Cin.L.Rev*. 849. As will be discussed later, it is the reading of the constitution and regulatory statutes and regulations that are the front lines of the recent disputes over strict federal preemption and a co-existence with some states' rights.

Professor Linda S. Mullenix of the University of Texas School of Law, who wrote Strange Bedfellows: The Politics of Preemption, *59 Case W. Res. L. Rev. 837 (Summer 2009)* gave a most insightful history of how preemption at the Supreme Court has developed since the first modern tort preemption case in the 1992 decision in *Cipollone v.*

Liggett Group, Inc., 505 U.S. 504 (1992). Professor Mullenix points out that since that time several scholars have focused on the purported justifications for express v. implied preemption, which also includes conflict and field preemption. *Id*. at 838. She states that the generalizations about the conservative shift on the Supreme Court has resulted in limiting access to justice and at the same time has favored states' rights in its robust enforcement of the Eleventh Amendment sovereign immunity defenses. *Id*.

But Mullenix also points out that "preemption cuts off a claimant's ability to pursue state-based claims. Thus, federal courts' application of preemption doctrine both restricts access to justice while undermining state sovereignty." *Id*. Mullenix's theme in her article is exploring the political and policy bases of preemption by illustrating how preemption doctrine is at war with itself and consequently, has engendered strange political bedfellows, arrayed along interesting political fault lines. *Id*. at 839.

Mullenix lists the three sets of strange bedfellows as: 1) the pro-business states' rights and libertarian wings of the conservative movement; 2) conservative business interests with some liberal advocates of consumer protection; and 3) that preemption has fractured the plaintiffs' bar between advocates of aggregate litigation such as class action and mass tort attorneys versus individual tort litigators. *Id*. at 840.

Mass torts are for the most part a products liability cases writ large. But some mass torts involve financial misfeasance. It generally starts when several people complain about a physical condition they sustained after using a given product. Most of those products are pharmaceutical products or medical devices, which have been approved by the U.S. Food and Drug Administration. Many drugs contain biologically

active agents that have a beneficial effect, but also come with adverse effects. When the benefits outweigh the adverse effects, the FDA generally approves the product and secures a warning about the adverse effects.

Mass tort plaintiffs' attorneys collect numerous claimants by advertising on television and on the internet – "If you have taken **…**'faulty product,' call 1-888-LAWYERS to find out whether you are entitled to compensation for your injury."

The business community manufactures various consumer products that are regulated in whole or in part by federal agencies such as the Consumer Products Safety Commission (CPSC), the Federal Trade Commission (FTC), the U.S. Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA) and the Department of Transportation (DOT). Since many businesses are subject to federal regulatory standards from the foregoing federal agencies, it is confusing costly and unfair to also subject them to the regulatory standards of the 50 states. That situation creates a conflict with compliance making it virtually impossible to comply with federal standards while simultaneously complying with multitudes of state standards. The U.S. Chamber of Commerce appears to be the chief spokesperson for the business community. It frequently submits amicus briefs in cases that effect manufacturers and the business community.

Professor Mullenix traces the emergence of the preemption strategy of the conservative pro-business advocacy to the 1980s and the Republican movement for civil justice reform. She asserts that this confluence came together in the 8-1 decision in *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008), where the court's conservative and liberal

wings united to uphold express preemption of state law claims. Senator Edward Kennedy, an author of the 1976 Medical Device Amendment, along with Congressman Waxman submitted an amicus brief, written in part by Professor Michael D. Green, which informed the Court that removing an injured party's right to sue the manufacturer of a medical device was never the intent of the law. Nonetheless, the eight member majority of the Supreme Court swept that fact aside. *Riegel v. Medtronic, Inc.*, 2007 WL 2456945 (US) Amicus Brief. Finally, the forces in favor of preemption prevailed – big time! Only Justice Ruth Bader Ginsburg even mentioned that right to sue in her dissent. 128 S.Ct. at 1014.

Professor Mullenix's observation that the Class Action Fairness Act of 2005 (CAFA), which she characterizes as President George W. Bush's pro-business victory legislation, enabled the removal of most state class actions or aggregate litigation into the federal court, and thereby converted the plaintiff's mass tort bar into advocates of federal preemption of state filed mass tort claims.

However, Professor Mullenix's opinion of the plaintiffs' bar advocating for federal court action is a bit overstated. It is true that after the Class Action Fairness Act (CAFA) of 2005 was enacted many class action plaintiffs' attorneys have been forced out of favorable state forums into the federal arena. The federal courts provide major impediments to class certification of nationwide class actions due to the disparity of choice of law issues. Many mass tort claims start out in state courts. And many of those state cases are removed to federal court, where they generally become part of the inventory of cases in a Multi-District Litigation (MDL). While CAFA only requires a

minimal amount of diversity, cases may still remain in state courts due to a lack of diversity, i.e., where the plaintiffs are residents of the same state where the defendant manufacturer or distributor does business, and where numerous state court actions are filed. In the Vioxx litigation, the largest mass tort settlement to date ($4.85 Billion) hundreds of actions were maintained in the New Jersey Superior Court of Atlantic County, which was the home state of Merck, the defendant manufacturer. At the same time, thousands of cases maintained in the MDL court in the U.S. District Court in New Orleans, Louisiana, and after Hurricane Katrina struck New Orleans, in the U.S. District Court for the Eastern District of Texas in Houston.

None of those plaintiffs' attorneys ever argued that federal preemption of state failure to warn or warn adequately, or the design defect causes of action should have been impliedly preempted because the federal regulation covered the field of prescription brand name drugs, or that there was conflict between FDA regulations and state common law claims making it impossible for the manufacturers to comply with those multiple, sometimes conflicting standards. Indeed, these were the arguments raised by the defendant manufacturer that were denied in both the U.S. District Court and the New Jersey Superior Court of Atlantic County.

While Professor Mullenix has much experience in handling asbestos class action cases and has written a large treatise, entitled *Mass Tort Litigation 2d ed*., West (2009), she does not demonstrate where and when the plaintiff's mass tort bar has ever advocated for federal preemption of state common law claims. Whether they are prosecuting a claim in state court or in federal court, the claims against manufacturers are based upon

state product liability theories of strict liability; breach of express and/or implied warranties; failure to warn or inadequate warnings and negligence. By advocating for federal preemption, those state claims would all be in peril. This is hardly what the plaintiffs' bar has advocated whether representing claimants individually or collectively in a mass tort proceeding.

The American Association for Justice (AAJ), formerly known as the American Trial Lawyers Association (ATLA), the Trial Lawyers for Public Justice (TLPJ) and the Center for Constitutional Litigation (CCL) are the leading advocates for access-to-justice and consumer protection laws. They are also the plaintiffs' bar groups that generate *amicus* briefs in most of the cases that affect access to justice or trials and consumer claims against manufacturers. Their position has consistently been one of advocating the state's rights position against federalizing all regulation of consumer products, drugs and medical devices. Those groups have regularly opposed federal preemption in their *amicus* briefs and in their literature. Their argument is that preemption limits, if not bars, injured victims of defective products from seeking restorative justice from those who produced the offending products. Brief of Amici Curiae Constitutional and Administrative Law Scholars in Support of Respondent Wyeth (29 S.Ct. 1182 [No. 06-1249]).

On the other hand, manufacturers and distributors generally take on a conservative position of preemption that is consistent with the goals of the civil justice reform movement – to curb frivolous litigation and contain state tort litigation, which may limit access to justice for injured claimants. This is in stark contradiction to the

position of the plaintiff's tort bar. The current debate over federal preemption is not new. It has surfaced at various times throughout American legal history.

During the New Deal of the 1930s, President Franklin D. Roosevelt and the Congress enacted a series of laws and created the alphabet soup of federal agencies to dominate the economy in an attempt to centralize control of certain aspects of the economy to pull the nation out of the Great Depression of the 1930s. The National Labor Relations Act 29 U.S.C. §§ 151-69, and several federal statutes and regulations preempted numerous state laws in an attempt to regulate the economy for the benefit of the public.

The rationale for much of the New Deal legislation to regulate the economy was the commerce clause of the U.S. Constitution. Interstate commerce played a major role in federal preemption. See *Jones v. Rath Packing Co*., 430 U.S. 519 (1977). Only recently has products liability become an area of federal preemption. While federal regulatory powers have grown, congressional regulation of products in the marketplace has become commonplace. Congress routinely passes laws and adopts regulations that govern the use of products through federal agencies such as the Consumer Product Safety Commission that routinely oversee and regulates the safety of manufactured products. A product manufacturer's failure to comply with what Congress has mandated would result in substantial penalties for violation of federal law.

There are sound purposes for federal preemption in the modern regulatory state. These purposes have been explained by several scholars and judges. But the underlying problem is that the law of products liability, whether prosecuted in a state court or a

federal court, is based upon state common law or state statutes. While attempts have been made to enact a federal products liability statute, those attempts resulted in failure, thus leaving only state common law or state statutory remedies. See Victor E. Schwartz & Mark A. Behrens, The Road to Federal Product Liability Reform. 55 *Md. L. Rev.* 1363 (1996).

Several areas of the economy other than drugs and medical devices have been subject to federal preemption.

Cigarette Labeling and Advertising

In 1992 the first modern case to deal with federal preemption by the U.S. Supreme Court was *Cipollone v. Liggett Group, Inc*., 505 US 504 (1992). In *Cipollone,* the U.S. Supreme Court analyzed the preemptive effect of the Cigarette Labeling and Advertising Act of 1965, as amended by the Public Health Cigarette Smoking Act of 1969. 15 U.S.C. §§ 1331-1341. The court, in a sweeping decision, held that while the 1965 Act was limited, the 1969 Act preempted positive enactments by state and federal rulemaking bodies that mandated particular warnings on cigarette labels or cigarette advertisements. Therefore, the defense of preemption would apply only to a claim based on failure to warn. Other theories of recovery such as breach of warranty, fraudulent misrepresentation or concealment of facts, and conspiracy were not preempted by the acts. Yet the Court declined to decide the issue on the grounds of implied preemption. Instead it determined that when Congress has considered the issue of preemption and has included an express provision addressing it, then that provision provides the basis for determining congressional intent to preempt state authority. *Cipollone,* 505 U.S. 504 at

520 et seq. But nothing was ever discussed about an injured party's right to a jury trial to compensate the harm done to them from the deceptive advertising that already existed as to the safety of smoking cigarettes.

Pesticides

The increasing number of claims for exposure to pesticides has led manufacturers for the pesticide industry to routinely assert the federal preemption defense, based on the congressional regulatory scheme contained in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 7 U.S.C. § 136. Suits against several pesticide manufacturers have sought damages for injuries sustained from exposure to pesticides. Judge Jack Weinstein of the U.S. District Court for the Eastern District of New York addressed the issue of express preemption of state tort common law claims under FIFRA in *Burke v. Dow Chemical Co.,* 797 F. Supp. 1128 (E.D.N.Y. 1992). *Burke* claimed that the plaintiff's children had suffered brain damage as a result of their mother's exposure to household insecticides while she was pregnant. The court ruled that FIFRA expressly preempted any claim that the defendant's products were mislabeled, but did not expressly or impliedly preempt any other failure-to-warn claim, nor any claims based on negligence or design defect. Thirteen years later, the U.S. Supreme Court addressed FIFRA in *Bates v. Dow Agrosciences L.L.C.,* 544 U.S. 431 (2005). The *Bates* Court held that FIFRA only preempts competing state, statutory or common law labeling standards, but it does not preempt any state rules that are consistent with federal requirements. In its reasoning, the Court relied on its previous analysis in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), where it noted that FIFRA was not "a sufficiently comprehensive statute

to justify an inference that Congress had occupied the field to the exclusion of the States. Thus, the plaintiff's fraud and negligent-failure-to-warn claims, which were premised on a deficiency in the labeling or packaging of the product at issue, would be preempted by FIFRA, unless the duties that the claims implicated were simply equivalent to FIFRA's own misbranding provisions, rather than adding to or differing from the FIFRA provisions.

Automobile Airbags

Automotive safety has also attracted several cases at the U.S. Supreme Court. In *Geier v. Am. Honda Motor Co., Inc.,* 529 U.S. 861 (2000) the plaintiff's claims arose out of a car accident, where the plaintiff sued the defendant car manufacturer, alleging that the defendant had "designed its car negligently and defectively because it lacked a driver's side airbag." *Id*. at 865.

The U.S. Supreme Court addressed the issue of whether Federal Motor Vehicle Safety Standard ("FMVSS") 208, promulgated by the Department of Transportation ("DOT") under the authority of the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C.§ 1381 *et. seq.*, which is now codified as amended in 49 U.S.C. § 30101 *et. seq.* (the "Safety Act"), preempts a common law tort action "in which the plaintiff claims that the defendant auto manufacturer, who was in compliance with the standard, should nonetheless have equipped a 1987 automobile with airbags." *Id*., 529 U.S. at 864-65. The court held that plaintiff's common law tort claim conflicted with the objectives of FMVSS 208 and, therefore, was impliedly preempted. *Id*., 529 U.S. at 866.

The court considered whether the Safety Act's express preemption clause preempted the plaintiff's claims. At the relevant time of the suit, the Safety Act contained an express preemption clause which provided that:

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal Standard. *Id*. citing 15 U.S.C. § 1392(d) (now codified as amended in 49 U.S.C. § 30103 (b)).

The Safety Act, however, also included a savings clause, which provided that: "'compliance with' a federal safety standard 'does not exempt any person from any liability under common law.'" *Id*., 529 U.S. at 868 citing 15 U.S.C. § 1397(k) (now codified as amended in 49 U.S.C. § 30103(e). The Supreme Court in *Geier* stated that:

> Without the saving clause, a broad reading of the express preemption provision arguably might preempt [plaintiff's claims], for . . . it is possible to read the preemption provision, standing alone, as applying to standards imposed in common law tort actions, as well as standards contained in state legislation or regulations. And if so, it would preempt all nonidentical state standards established in tort action covering the same aspect of performance as an applicable federal standard, even if the federal standard merely established a minimum standard. On that broad reading of the preemption clause little, if any, potential "liability at common law" would remain. And few, if any, state tort actions would remain for the savings clause to save. *We have found no convincing indication that Congress wanted to preempt, not only state statutes and regulations, but also common law tort actions, in such circumstances.* Hence the broad reading cannot be correct. The language of the preemption provision permits a narrow reading that excludes common law actions. Given the presence of the savings

> clause, we conclude that the preemption clause must be so read (emphasis added).

Therefore, the Court held that plaintiff's common law tort claims were not expressly preempted, stating that such a holding "gives actual meaning to the saving clause's literal language, while leaving adequate room for state tort law to operate – for example, where federal law creates only a floor or a minimum safety standard."

The second question the Court considered was whether the express presumption or savings clause "foreclose or limit the operation of ordinary preemption principles insofar as those principles instruct the court to read statutes as preempting state laws (including common law rules) that 'actually conflict' with the statute or federal standards promulgated thereunder." *Id*. at 869. The Court held that neither the savings clause nor the express preemption clause bars the ordinary working of conflict, such as implied preemption principles. The majority of the Court held that the preemption provision, saving clause, or a combination of both do not give rise to any 'special burden" that would "disfavor preemption." *Id*. at 870-74. Thus, ordinary implied preemption principles apply, even in the presence of such clauses.

The Court also considered and held that "a common law 'no airbag' action . . . actually conflicts with FMVSS 208." *Id*. at 874. The Court found that the DOT had affirmatively considered and rejected a proposed FMVSS 208 "all airbag" standard. Instead, the DOT sought a variety of different passive restraint systems by "setting a performance requirement for passive restraint devices and allowing manufacturers to choose among different passive restraint mechanisms, such as airbags, automatic belts," etc. It concluded that safety would best be promoted if manufacturers installed

alternative protection systems in their fleets. However, plaintiff's tort claim would impose a duty on all car manufacturers to install airbags rather than other passive restraint systems in their fleets thereby presenting "an obstacle to the variety and mix of devices that the federal regulation sought." *Id*. at 878-81.

The Court stated that it placed "some weight" on the DOT's interpretation of FMVSS 208's objectives and the DOT's conclusion that the plaintiff's tort action would create an obstacle to the accomplishment of those objectives. *Id*. 883. The Court found that a "formal agency statement of preemptive intent" is not a prerequisite to concluding that a conflict exists. *Id*. at 884. The Court noted that "while preemption fundamentally is a question of congressional intent" . . . "[a]nd though the court has looked for a specific statement of preemptive intent where it is claimed that the mere 'volume and complexity' of agency regulations demonstrate an implicit intent to displace all state law in a particular area . . . the court has never before required a specific, formal agency statement identifying conflict in order to conclude that such a conflict in fact exists." *Id*.

Other federal agencies have dealt with preemption of state common law and state regulations. There has been a serious disconnect between the federal government through its agencies such as the Federal Trade Commission (FTC), Consumer Product Safety Administration (FCSA), and the Food & Drug Administration (FDA) to regulate certain products without additional state regulations and the right to sue manufacturers for defectively designed or manufactured products or products with inadequate warnings. The mere fact that a federal agency approves a product for marketing to the public and

approved its warning labels should not be the catalyst for precluding a person injured by that product from seeking compensation from that private manufacturer.

The Seventh Amendment Right to a Jury Trial

A Constitutional Amendment that is rarely addressed is the Seventh Amendment which states that:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

The Federal Rules of Civil Procedure provide as follows:

Rule 38, Right to a Jury Trial; Demand

(a) Right Preserved. The right of trial by jury as declared be the Seventh Amendment to the Constitution – or as provided by a federal statute – is preserved to the parties inviolate**...**

The American Association for Justice (AAJ), the former American Trial Lawyers Association, which comprises mostly plaintiff's attorneys, are the leading advocates for the Seventh Amendment right to a jury trial in all civil cases. Indeed, the AAJ has a Seventh Amendment Fund, which "provides the resources necessary to protect the civil justice system and every American's right to a trial by jury." The AAJ has submitted amicus briefs on behalf of the injured parties in *Riegel v. Medtronics, Id., Wyeth v. Levine, Id., Bruesewitz v. Wyeth, Id*. and *PLIVA v. Mensing, Id*. AAJ website www.justice.org/CPS/rde/xchg/justice/hs.xsl/13552.htm, (last visited April 10, 2014).

The AAJ generally stands at the opposite pole from the U.S. Chamber of Commerce, which is also active in submitting amicus briefs in most cases that may affect businesses, such as the pharmaceutical and medical device industry.

There have been a series of decisions that have preserved the right to a jury trial for injured persons in civil cases throughout American legal history. Neither the courts nor Congress can deprive a litigant of the right to a jury trial guaranteed by that provision. *Raytheon Mfg. Co. v. Radio Corp. of America*, 76 F.2d 943 (C.C.A. 1st Cir. 1935), aff'd, 296 U.S. 459 (1935). In actions at law, factual issues that are proper for the jury must be submitted to it in order to preserve the right to a jury's resolution of the ultimate dispute, as guaranteed by the Seventh Amendment. *City of Monterey v. Del Monte Dunes at Monterey, Ltd*., 526 U.S. 687 (1999). Courts look to history to determine whether the particular issues, or analogous ones, were decided by a judge or by a jury in suits at common law when the Seventh Amendment was adopted in 1791. Where history does not provide a clear answer, a court will look to precedent and functional considerations. *Id*. However, the Amendment guarantees the right only as it existed at common law. *Martin v. C.I.R.*, 756 F.2d 38 [6th Cir. 1985] and it neither enlarged nor abridged the right. *Fitzpatrick v. Sun Life Assur. Co. of Canada*, 1 F.R.D. 713 (D.N.J. 1941). The American Association for Justice (AAJ), the former American Trial Lawyers Association (ATLA), and it state affiliate organizations, which are comprised of primarily plaintiff's attorneys, is perhaps the biggest supporters of the Seventh Amendment right to a jury trial.

Indeed, the U.S. Supreme Court held that class action plaintiffs have a Seventh Amendment right to obtain a jury trial on such obscure legal issues, such as certification of a mandatory class, followed by settlement of its action for money damages. In *Ortiz v. Fibreboard Corp*., 527 U.S. 815 (1999), the court considered the Seventh Amendment jury trial rights of absent class members to deny the settlement class.

The Seventh Amendment right to a civil jury trial in federal court applies only to legal, as distinct from equitable, actions and only to those types of cases in which such a right existed in 1791. *Granfinanciera S.A. v. Nordberg*, 492 U.S. 33 (1989); *Lorillard v. Pons*, 434 U.S. 575 (1978); *Phillips v. Kaplus*, 764 F.2d 807 (11th Cir. 1985); *U.S. v. State of La*., 339 U.S. 699 (1950), judgment entered, 340 U.S. 899 (1950). However, whether a remedy is legal or equitable in character is liberally interpreted. *Waldrop v. Southern Co. Services, Inc.*, 24 F.3d 152 (11th Cir. 1994). The showing of equity jurisdiction must be real and substantial, *DiGiovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 56 S.Ct. 1 (1935). Courts have held that ambiguities should be resolved in favor of a jury trial. *Bower v. Bunker Hill Co.*, 675 F. Supp. 1254 (E.D.Wash. 1986); *Deborah Leslie, Ltd. v. Rona, Inc*., 630 F. Supp. 1250 (D.R.I. 1986); *In re O.P.M. Leasing Services, Inc*., 48 B.R. 824 (S.D.N.Y. 1985).

Yet, the Seventh Amendment right to a civil jury trial in federal court does not establish the jury as the exclusive mechanism for fact finding in civil cases. Indeed, other tribunals may adjudicate claims. *Atlas Roofing Co., Inc. v. Occupational Safety and Health Review Com'n*, 430 U.S. 442 [1977]). It does not apply in all cases. *Nimrod Marketing (Overseas) Ltd. v. Texas Energy Inv. Corp*., 769 F.2d 1076 (5th Cir. 1985).

The Seventh Amendment applies if the cause of action was either tried at law at the time of the founding of the nation or is at least analogous to a type of claim tried by the courts at that time. *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 116 S.Ct. 1384 (1996).

The Seventh Amendment applies to causes of action created by Congress. *Chauffeurs, Teamsters and Helpers, Local No. 391 v. Terry*, 494 U.S. 558 (1990). It also applies to actions enforcing statutory rights *Curtis v. Loether*, 415 U.S. 189, 94 S. Ct. 1005 (1974); *Waldrop v. Southern Co. Services, Inc*., 24 F.3d 152, 5 A.D.D. 910 (11th Cir. 1994) that are analogous to common law causes of action ordinarily decided in English law courts in the late 18th Century, as opposed to those customarily heard by courts of equity or admiralty. *Feltner v. Columbia Pictures Television, Inc*., 523 U.S. 340, 118 S. Ct. 1279 (1998); *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989); *Spinelli v. Gaughan*, 12 F.3d 853 (9th Cir. 1993). The Amendment requires a jury trial upon demand if the statute creates legal rights and remedies enforceable in an action for damages in the ordinary courts of law. *Curtis v. Loether*, 415 U.S. 189 (1974); *Waldrop v. Southern Co. Services, Inc*., 24 F.3d 152 (11th Cir. 1994). The Seventh Amendment jury guarantee extends to statutory claims unknown to the common law, so long as the claims can be said to sound basically in tort and seek legal relief. *City of Monterey v. Del Monte Dunes at Monterey Ltd*., 526 U.S. 687 (1999).

The state constitutions generally contain express guarantees of the right to a jury trial, and the typical provision states that the right shall be and remain inviolate or that the right, as heretofore enjoyed, shall remain inviolate. *Rowe v. Superior Court*, 15 Cal.

App. 4th 1711, 19 Cal. Rptr. 2d 625 (2d Dist. 1993); *South Eastern Indiana Natural Gas Co., Inc. v. Ingram*, 617 N.E.2d 942 (Ind, Ct. App. 1st Dist. 1993); *Cook v. Hansen*, 499 N.W.2d 94 (N.D. 1993). Such a provision guarantees the right to a jury trial in those cases in which such a right existed at common law, *Blum v. Merrell Dow Pharmaceuticals, Inc.*, 626 A.2d 537 (Pa.1993) or by statute at the time of the adoption of the state constitution. *State v. Moseley*, 436 S.E.2d 632 (Ga.1993).

However, the provision that the right to a trial by jury shall remain inviolate does not carry with it the corresponding right that all court rules, procedures, and methods current at the time the state constitution was adopted remain unchanged, and new devices may be used to adapt the ancient institution to present needs and to make of it an efficient instrument in the administration of justice. *Canning v. Lensink*, 221 Conn. 346, 603 A.2d 1155 (1992).

Generally, state constitutional provisions guaranteeing an absolute right to a jury trial in actions at law provide that the controversy must exceed a stated dollar amount. *Murphy v. Edmonds*, 325 Md. 342, 601 A.2d 102 (1992). The right to a jury trial granted by a state constitution may include the right to have the jury determine the amount of damages to be awarded. *State ex rel. Ohio Academy of Trial Lawyers v. Sheward*, 86 Ohio St. 3d 451, 715 N.E.2d 1062 (1999).

The Seventh Amendment right to a jury trial is not limited to suits which were recognized at common law. It also applies to analogous statutory actions, negligence and products liability actions.

Some may argue in view of the most recent decisions of Supreme Court in *PLIVA v. Mensing*, 1315 S. Ct. 2567 (2011) and now *Mutual Pharmaceutical v. Bartlett,* decided in 2013, that persons injured by generic pharmaceutical drugs do not have the "equal protection of the laws" under the 14th Amendment that would have been afforded them had they been prescribed or given the original brand name drug as opposed to the generic brand, which now appears to be immune from liability. This raises, yet another constitutional argument that needs to be addressed in the future.

The constitutional underpinnings of the right of the Congress to expressly preempt state law be it statutory or common law is a well-accepted principle. But implicit in that principle is that there is a conflict between federal and state law. Historically, the Congress has recognized our federal system of division of powers between federal and state governments with little dispute. However, this delicate balance has been tampered with not necessarily by the Congress, but by federal regulatory agencies, like the FDA, which inserted preemption language into the preamble to the 2006 FDCA amendments and by federal courts. It is understandable that a specialized regulatory agency would take the position that its judgment as to the safety and efficacy of the products it approves for distribution after their extensive application and approval process should not be second guessed by jurors from the 50 states, who may have more sympathy for a severely injured plaintiff rather than for a drug or device manufacturer. Jurors may not typically appreciate the cost benefit analysis of injuring a few to help the many. This was Justice Scalia's rationale in *Riegel. Id.*

This text will hopefully compare and contrast the benefits and liabilities of the FDA approval process and the court decisions that have yielded near immunity for generic drug and medical device manufacturers and how that can be made more equitable for both the claimants and those that created and distributed the overwhelmingly helpful products that inevitably injure some people.

Chapter V

An Overview of Product Liability Law

In order to focus on federal preemption of FDA approved products, it is necessary to review the development of modern tort and products liability law. The goals of tort law are compensation, deterrence and corrective justice. Tort law generally deals with the duty one owes to another not to cause harm. When harm or physical injury is caused by a product made or distributed by another, the victim generally has the right to seek compensation from the one who manufactured, distributed, or sold a defective product. Judge Guido Calabresi of the U.S. Court of Appeals for the Second Circuit, when he was a law professor published a book entitled *The Cost of Accidents* in 1970, which became one of the leading treatises in law and economics theory. Under a law and economics approach to tort law, the actors generally seek a socially optimal solution, where the marginal costs of further injury prevention measures equals the marginal benefit in saving persons from injury. Calabresi posits that tort law should impose incentives that induce individuals to make efficient decisions that minimize the overall cost of accident. Paying those costs is a form of deterrent and social justice may require that the one causing harm to another may need to take corrective action in improving their product or withdrawing it from the market.

Law Professors David A. Fischer, William Powers, Richard L. Cupp, Jr., Michael D. Green, and Joseph Sanders in the introduction to their text *Products Liability Case and*

Materials, Fifth Edition, Thomson-West (2014) have outlined the parameters of products liability as follows:

> "Products liability" refers to civil liability for injuries caused by defective products. It generally covers several different theories of liability—including negligence, breach of warranty so-called strict liability, and misrepresentation—which are not mutually exclusive but can be combined in the same lawsuit. The Restatement (Third) of Torts: Products Liability, adopted by the American Law Institute in 1998 . . . suggests that courts may combine some of these traditional theories into a single theory of liability for selling a "defective product." Restatement (Third) of Torts: Products Liability § 1, cmt. a; § 2 cmt. n (1998). Nevertheless, most courts still speak the language of the traditional categories.
>
> Negligence, warranty, and misrepresentation were developed primarily outside of the context of products liability litigation. Negligence applies to products liability litigation pretty much the same way it applies to other personal injury litigation. Warranty law was developed primarily in the context of commercial dealings, and its roots are in contract law. The law of misrepresentation was also developed primarily in the context of commercial dealings, but its roots are in tort law. Unlike the other three theories, so-called strict tort liability was developed as a special theory to deal with injuries caused by defective products . . .
>
> The main historic advantage of product liability has been that the plaintiff can recover without a showing of fault. The defendant is not an insurer, however. The plaintiff must still prove that the product was defective at the time it left the defendant's hands, that the product was used in a foreseeable manner, and that the defect was both the cause in fact and the proximate cause of the injury . . .

Products liability law did not develop until the mid-twentieth century. The problem of product-caused injuries was deemed to be an aspect of the contract law of product warranties, except for those cases in which the product seller negligently caused physical harm to another. Justice Roger Traynor of the California Supreme Court asserted in *Escola v. Coca Cola Bottling Company,* 150 P.2d 436 (Cal. 1944) that

contaminated food cases justify a tort rule making product sellers strictly liable for physical harms caused by defective products.

Much of the judge made common law topics are summarized by the American Law Institute (ALI). ALI is an independent organization that produces scholarly work to clarify, modernize, and otherwise improve the law. ALI, which is made up of 4000 lawyers, judges, and law professors of the highest qualifications, drafts, discusses, revises, and publishes the Restatements of the Law for agency, contracts, torts, property and various other legal topics. These model statutes and principles of law are enormously influential in the courts and legislatures, as well as in legal scholarship and education. ALI website, last visited July 5, 2013.

Restatement of the Law (Second) of Torts [hereinafter referred to as Restatement of Torts (Second)]

In 1965, the American Law Institute adopted Section 402A of the Restatement of the Law (Second) of Torts, which provides in Comment k that manufacturers are not subject to strict liability in tort for harm caused by certain "unavoidably unsafe" but useful products, notably prescription drugs, solely on the basis that their inherent characteristics make it feasible to be designed in a better manner. Most pharmaceutical drugs and Class III medical devices by definition are "unavoidably unsafe." Most states within the next ten years adopted Section 402A.

Comment k states as follows:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the

> Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

The definition of "defective condition" found in the Restatement of Torts (Second), Section 402A, Comment g was written with manufacturing defects in mind. These are defects in which the product leaves the control of the manufacturer in a condition that is different from what the manufacturer intended. In other words, the product was not made correctly and the mistake escaped the manufacturer's quality control. When the mistake makes the product unreasonably dangerous, it is considered "defective" under section 402A. Comment j also recognized that a product could be defective if the manufacturer failed to provide the consumer with necessary warnings or instructions for use. All three types of defect could result in strict liability under section 402A and each different type of defect called for different standards for the imposition of liability. In dealing with manufacturing defects, for example, it was always possible to

compare the product to the standard the manufacturer itself had established. With both design and warning defects, however, the product had to be compared to an external standard of "proper" design or warning.

Comment k suggests that it would be unfair to hold pharmaceutical manufacturers strictly liable simply because their "unavoidably" dangerous yet "apparently useful and desirable" products bear "known but apparently reasonable" risks. Many scholars have supported this stance, believing that "pharmaceutical drugs and devices comprise one category of products that challenges the underlying policies of strict products liability." The reporters of the Restatement of Torts (Second) were anxious that imposition of strict design defect liability on pharmaceutical companies "for injuries unavoidably caused" by medical drugs and devices would hinder research, development, and marketing efforts and thus prevent valuable products from reaching patients. Nonetheless, the possibility of harm to consumers from "unavoidably dangerous" pharmaceutical products was an abiding worry. Comment k reflects the compromise of these rival policy concerns.

Several policy justifications buttress Comment k's exception from strict liability for pharmaceutical products, including: (1) pharmaceutical products have the potential to injure some patients while helping others; (2) the FDA's approval process functions as a counterweight to the unavoidable dangers pharmaceutical products pose for patients; (3) physicians, who supervise patients' use of prescription drugs and medical devices, can and do prevent some of the harms attendant to pharmaceutical products' use (the learned intermediary doctrine); (4) a strict liability regime would trigger excessive litigation that would chill pharmaceutical innovation; and (5) safe alternative designs for

pharmaceutical drugs and devices typically are unavailable, obviating the need for design defect litigation in the pharmaceutical area. D.A. Rudin (2005) Toxic Tort Litigation, 411-412.

Comment k is a balance between policy goals of encouraging pharmaceutical research and development, and protecting patients from potentially dangerous drugs and devices. But Comment k has not reconciled the policy interests of strict liability such as consumer protection and safety enhancements with the competing interests of affordable prescription drugs. But, Comment k did not clarify whether it should apply to other FDA products in addition to prescription drugs or whether pharmaceutical companies should bear the burden of proof with respect to the unavoidably unsafe nature of their products. It also left open whether judges or juries should be able to review FDA approved product design choices on the basis of negligence.

The few pages devoted to the problem of product defects in the Restatement (Second) subsequently led to a body of law requiring over 300 pages of exposition in the Restatement of Torts (Third): Products Liability, which was adopted by the American Law Institute in 1998.

Restatement of the Law of Torts (Third) – Products Liability [hereinafter referred to as The Restatement of Torts (Third)]

The Restatement of Torts (Third) defined the categories of product defects as follows:

> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

> (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
> (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
> (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Elements of Products Liability

Products liability deals with a defendant who is liable for an injury caused by a defective product. There are five fundamental elements to any products liability case. First, the defendant must have manufactured, sold, distributed, leased, or otherwise marketed an item. Second, the item constitutes a product. Third, the product is defective, or does not perform as warranted. Fourth, the plaintiff sustained personal injury or property damage other than injury to or loss of the product itself. And fifth, the defect was a substantial factor in causing the plaintiff's injury.

Products liability may be founded in negligence, strict liability, or breach of express or implied warranties. Some of these causes of action derive from common law, others from statutes. Not all products liability is based on tort theories. Some liability relies on contract law, such as express or implied warranties or on a combination of tort

and contract law. Furthermore, a product defect case can be based on improper design or manufacture or failure to warn of the product's hazards. L.S. Kreindler, B. Rodriguez, D. Beekman & D.C. Cook (1997) *New York Law of Torts*, 415.

There are three basic claims in products liability law. They are negligence, strict liability, and a lack of adequate warnings about the use of the product. Strict products liability for design defect differs from a cause of action for a negligently designed product in that in a strict products liability action, the plaintiff is not required to prove that the manufacturer acted unreasonably in designing the product. The focus shifts from the conduct of the manufacturer to whether the product, as designed, was not reasonably safe.

Negligent design is distinguished from design defect based on the fact that strict liability imputes liability to the manufacturer not on the basis of the manufacturer's negligence but because the product is not reasonably safe as it was designed. *See Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102 (1983); *Pierre-Louis v. DeLonghi America, Inc.*, 66 A.D.3d 859 (2d Dep't 2009). Therefore, to establish a prima facie case in strict products liability for design defects, the plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing the plaintiff's injury. *See Smith v. 2328 University Ave. Corp*., 52 A.D.3d 216 (1st Dep't 2008).

Uniform Commercial Code

There are warranty issues involving the sale of goods that affect the law of products liability that are found in the Uniform Commercial Code (UCC) Article 2 entitled "Sales." In addition, to negligence and strict liability there are breaches of express warranty made by the manufacturer or distributor/seller found in the *Uniform Commercial Code (UCC) § 2-313*. The implied warranty of fitness for ordinary use or merchantability is found in *UCC § 2-314*. And the implied warranty of fitness for a particular purpose is found in *UCC § 2-315*. Virtually every state has adopted these sections of *Uniform Commercial Code* in whole or in part. These UCC sections, which are based on contract law rather than tort law, are discussed here because most product liability complaints cite to one or more of them as a separate cause of action.

UCC §2-313. Express Warranties by Affirmation, Promise, Description, Sample

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation of promise.
(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

Virtually all product liability claims cite to a violation of the implied warranty of merchantability which reads as follows:

UCC § 2-314. Implied Warranty: Merchantability; Usage of Trade

(1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.
(2) Goods to be merchantable must be at least such as
  (a) pass without objection in the trade under the contract description; and
  (b) in the case of fungible goods, are of fair average quality within the description; and
  (c) are fit for the ordinary purposes for which such goods are used; and
  (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
  (e) are adequately contained, packaged, and labeled as the agreement may require; and
  (f) conform to the promises or affirmations of fact made on the container or label if any.

UCC § 2-315. Implied Warranty: Fitness for Particular Purpose

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

Most products liability lawsuits assert all or most of the causes of action listed herein arguing alternatively that there was a design defect and/or a manufacturing defect in the product for which adequate warnings were not provided.

While virtually all product liability law is based upon state common law or statutory law, there is a federal statute which deals with warranties. The Magnuson-Moss

Warranty Act (15 USC § 2301-12) is a federal statute which supplements the Uniform Commercial Code adopted by most states. It provides consumers with additional rights as to product warranties, and enables them to vindicate those rights in state or federal court.

Professor Mark A. Geistfeld of New York University Law School argues in his treatise *Principles of Product Liability*, (2nd Foundation Press 2011) that "[T]he growth of products liability has been astounding, particularly when compared to the slowly evolving tort rules of the common law. In light of this rapid growth, many do not find it plausible that products liability is based on well-established principles of tort law. According to one view, the growth of products liability can be attributed to a conceptual revolution that is among the most dramatic ever witnessed in the Anglo-American legal system." Geistfeld, 2011, 2.

The seeming departure from firmly established principles makes it possible to forcefully criticize the modern tort system. Some critics claim that unfettered jury discretion and sympathy for injury victims largely explain the rapid growth of products liability. In this view, well-established tort principles have given way to the massive redistribution of social wealth from manufacturers and distributors to injured persons.

Professor Geistfeld continues, that "[S]ince the 1980s, the growth of products liability has subsided. Once again, the change is subject to differing interpretations. It may reflect a changing political mindset that distrusts governmental regulation in favor of market competition: The courts should not determine issues of product safety; the market should. Or the increasingly apparent limitations of tort liability may be attributed to

those very same legal principles that gave rise to the modern regime of strict products liability." *Id.*

Not surprisingly, the political controversy over products liability finds expression in doctrinal debates. "According to the Restatement of Torts (Second), the rationale for strict products liability is that a defective product frustrates consumer expectations of product safety. The Restatement of Torts (Second) accordingly frames the rule of strict products liability to protect consumer expectations. The rule has been enormously influential. It has largely shaped the development of products liability, having been widely adopted by states and other jurisdictions around the world, including the European Union and Japan."

The Restatement of Torts (Third) rejects consumer expectations as the basis for liability in the most important classes of product cases, those involving defects of product design or warnings. The Restatement of Torts (Third) instead evaluates the defectiveness of a product design or warning in cost-benefit terms known as the *risk-utility test*. Whether this liability rule should be framed in terms of consumer expectations or cost-benefit analysis is now the most controversial doctrinal issue in products liability. A liability rule protecting consumer expectations appears to protect fairly the victims of product accidents, whereas cost-benefit analysis is the calculus of efficiency preferred by the business community. Critics of the Restatement of Torts (Third) claim that its cost-benefit risk-utility test is based upon a pro-business political bias, rather than the fair tort principles that gave rise to strict products liability.

Many legal scholars have argued that tort law, including products liability, is justified by moral principles for which efficiency considerations are irrelevant. Others argue that tort law should efficiently minimize accident costs, and thereby maximize social wealth. Richard A. Posner, *The Economics of Justice* (1981).

Professor Geistfeld contends that "[B]y adopting cost-benefit analysis as the guide to liability, the Restatement of Torts (Third) appears to have taken a side in this controversy. In an effort to stay neutral, the Restatement of Torts (Third) argues that the cost-benefit rule is fair, but these arguments do not address the concerns voiced by justice theorists. Moreover, many judges apparently are not persuaded that efficient products liability rules are fair. Judicial opinions in product cases tend to rely on fairness norms when courts perceive a conflict between fairness and efficiency. The debate about the appropriate roles of efficiency and fairness concerns in tort law thus appears to encompass the doctrinal debate pitting the fair, consumer expectations standard of liability in the Restatement (Second) against the efficient, risk-utility test in the Restatement (Third)." Geistfeld, 2011, p. 3.

Professor Geistfeld posits that the study of products liability implicates numerous foundational questions. Is products liability based on well-established tort principles, or has this area of law been largely shaped by political considerations? If there are underlying principles of products liability, are they ones of fairness or efficiency?

ALI promulgated a liability standard for defective drug designs that states in the Restatement of Torts (Third) – Products Liability:

> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonably health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Product liability law was established initially as an outflow of state common law and later some states adopted the model code and sections of the Restatement of Torts (Third) Product Liability in legislation. Except for the Magnuson-Moss Warranty Act contained in 15 USC § 2301-12, and the General Aviation Recovery Act 49 U.S.C.A. § 40101 et seq., for non-commercial aircraft, there is no federal product liability law.

Victor E. Schwartz attempted to promote a federal product liability law. Schwartz was the drafter of the Model Uniform Product Liability Act and is a prolific writer and counsel to the Product Liability Coordinating Committee, which was the principal coalition of the business community on federal product liability reform in the 1990s. He, together with Mark A. Behrens, who was co-counsel to the Product Liability Coordinating Committee, wrote a law review article entitled *The Road to Federal Product Liability Reform*, 55 Maryland L. Rev. 4 (1996) where they outline the political and legislative history of attempting to create a uniform federal product liability law that would have taken into consideration the concerns of plaintiffs and defendant manufacturers. Schwartz and Behrens demonstrated how the movement of goods across state lines in commerce had unfairly subjected business to multiple different bodies of state laws that impeded creativity and greatly added to the costs of operating, which in turn are passed off to the consumers.

The bill (HR 956) which survived the Conference Committee of U.S. House of Representatives and the U.S. Senate, was vetoed by President William J. Clinton at the behest of the American Trial Lawyers Association (ATLA), the predecessor to the American Association for Justice (AAJ), the major plaintiffs' bar group and a large contributor to President Clinton's campaigns. Had House Bill 956 been enacted it would have solved many of the preemption battles that have occupied the Supreme Court in the last decade. A federal product liability law applied to all products manufactured in the United States could be enforceable like many federal laws, such as the Americans with Disabilities Act (ADA), 42 USC § 12101, et seq., in either a federal court or in the state courts. One of the recommendations found in HR 956 was to initiate a non-binding Alternative Dispute Resolution (ADR) program that would dispose of many claims with a minimum of transactional expenses, such as large attorney fees.

To be effective, a federal products liability statute would preempt any state laws that would be in conflict with the federal statute. The result would have been that a uniform national law would have resolved the conflicts between federal and state regulation and state vs. state regulation.

The Learned Intermediary Doctrine

Before a pharmaceutical drug can be legally dispensed to a patient or consumer, a medical doctor must prescribe it based upon a diagnosis and treatment plan. Health care professionals acting in that role are known as "learned intermediaries." Learned intermediaries act between the individual patient and manufacturer of the drug or medical device—to choose from among the various available prescription drugs and medical

devices that have the highest benefit-risk ratio for each particular patient's needs and wants.

The learned intermediary doctrine provides that a drug manufacturer has no duty to warn the patient directly of a known risk. Instead, the manufacturer has a duty to warn that "extends only to the prescribing physician or healthcare provider, who acts as a 'learned intermediary' between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated for the drug." *In re Norplant Contraceptive Prod. Liab. Lit*., 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002). Therefore, adequacy of the warnings is determined from the perspective of what would reasonably be required to be disclosed to a prescribing physician.

The learned intermediary doctrine is a specific application of the more general legal principle that, when a product is supplied to the ultimate consumer through a third person, the supplier's duty to warn may, in some circumstances, be discharged by providing warnings to the third person, regardless of whether or not the warnings reach the ultimate consumer. Restatement of Torts (Second) §388, comments 1.n.

The doctrine first emerged as a legal doctrine in the mid-20th century. The term "learned intermediary" was apparently first used in this context by the U.S. Court of Appeals for the Eighth Circuit in 1966:

> In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that

> injury to the patient can be avoided. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

The doctrine recognizes that the prescribing physician is the appropriate person to evaluate whether the drug's potential benefits for the patient outweigh its risks, considering the individual patient's circumstances.

Exceptions to the learned intermediary doctrine have been recognized in some jurisdictions, but the doctrine has been adopted in some form in every jurisdiction except New Jersey, where direct to consumer advertising has taken place. See *Perez v. Wyeth Laboratories*, 161 N.J. 1 (1999). Professor Aaron Twerski, the former Dean of Hofstra University School of Law and now a professor at Brooklyn Law School, argued in a law review article that notwithstanding the New Jersey Supreme Court ruling in *Perez,* that no other state's high courts has precluded the learned intermediary doctrine to require drug (and device) manufacturers to directly warn consumers of the risks and benefits of a particular drug (or device) that is advertised directly on television, radio, internet and publication to consumers. See, Twerski, A., Liability for Direct Advertising: An Idea Whose Time Has Not Come. *33 Hofstra L. Rev*. 1149 (Summer 2005). In contrast, Kyle T. Fogt has pointed out that after Professor Twerski's article, West Virginia had not adopted the learned intermediary doctrine. See *State ex. Rel. Johnson & Johnson v. Karl*, 648 S.E.2d 899 (W. Va. 2007); Fogt, K.T. The Road Less Traveled: West Virginia's Rejection of the Learned Intermediary Doctrine in the Age of Direct to Consumer Advertising. *34 Iowa J. Corp. L. 587* (2009);

Warnings claims concerning prescription drugs are generally limited to claims for alleged failure to warn the prescribing physician. Where a physician did not read the

warnings, the failure to warn cannot have caused any injury to the patient. *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004). Where the physician testifies that his decision to prescribe the drug would not have been changed by a different or additional warning because he already knew the information the plaintiff claims he or she should have been warned about, the plaintiff's claim may fail for lack of causation. *Plummer v. Lederle Laboratories, et al.*, 819 F.2d 349 (2d Cir.), cert. denied, 484 U.S. 898 (1987).

The growth in recent years of personal injury litigation concerning pharmaceuticals has produced extensive litigation challenging the application of the learned intermediary doctrine, particularly where the prescribing physician has a diminished role in determining that the patient should take the drug. The *Restatement of Torts (Third)—Products Liability* section 6(d)(2), for example, provides that warnings must be provided to "the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instruction or warnings."

The learned intermediary doctor acts as the agent for the patient in their professional selection of drugs and medical devices. Therefore, the warnings given on drugs and medical devices are addressed to the learned intermediaries who arguably have the education, training, skill, experience and knowledge to make beneficial selection of such products for their patients.

If a prescription drug is dispensed under circumstances where a health professional does not render the type of individualized balancing of risks and benefits

contemplated by the learned intermediary doctrine, warnings may have to be provided directly to the patient.

Products liability law has a powerful role to play in compensating persons harmed unnecessarily by defective drugs and medical devices and deterring their sale and promoting safety. Thus, when the rationale for the learned intermediary doctrine falls away, the general rule requiring manufacturers to warn consumers directly reappears. Hutt (2007) 20. Turn on the television for an hour or two and one will see and hear an advertisement for a drug which encourages the public to "ask your doctor for _____," followed by an auctioneer's voice rattling off the possible side effects.

The principles of adequacy applicable to the content of warnings generally apply as well to prescription drugs. All material information on possible risks must be conveyed to the doctor in a comprehensible form to the general practitioner as well as to the specialist. It must also be comprehensible to consumers if the circumstances warrant. An "adequate" drug warning must describe the scope of the danger; the effects of misuse, including the failure to follow instructions, and the physical aspects of the warning, and broader method of conveyance, must be likely to alert recipients to the danger.

Courts rarely have held prescription drug manufacturers liable for design defects. The *Restatement of Torts (Third)—Products Liability* follows this perspective by strictly limiting design liability in § 6(c) to cases where a drug is shown to have no net value for any class of patient. Section 6(d) restates the widely accepted "learned intermediary" doctrine for warnings cases, by which a manufacturer generally is obligated to provide a warning only to the prescribing physician, not directly to the patient.

The Restatement of Torts (Third) delineates liability for drug and device manufacturers as follows:

> § 6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices
>
> (a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
>
> (b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:
>
> (1) contains a manufacturing defect as defined in § 2(a); or
> (2) is not reasonably safe due to defective design as defined in Subsection (c); or
> (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
>
> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.
>
> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

> (e) A retail seller or other distributor or a prescription drug or medical device is subject to liability for harm caused by the drug or device if:
>
> (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or
> (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

This standard leaves a very small window for design defect claims for prescription drugs. Hence, most prescription drug litigation is based on the adequacy of warnings and instructions provided to the doctor about the drug, because the best place to locate a drug manufacturer's responsibility is in the information it provides to the doctors—the learned intermediaries. The information supplied to the doctors should be clear, complete, and properly conveyed. In the great majority of cases, a challenge to a drug's design can easily be reformulated as a defect in a warning or instruction. If a drug's adverse effects are not reasonably foreseeable, the manufacturer should not be responsible for its effects. However, if such adverse effects are reasonably discoverable by a manufacturer properly performing its research and development obligations, then it will have a duty to provide adequate warnings to doctors of those effects.

The FDA is charged with assuring that the products it regulates are safe and truthfully labeled. The agency's current responsibilities encompass a much larger role in the development, testing, introduction, and marketing of products. The FDCA has been amended to transfer the burden of proof from FDA to the regulated industry by requiring premarket approval of products.

The agency's activities have changed from court enforcement of clear-cut statutory prohibitions, to approval of products based upon an administrative choice among closely balanced alternatives in controlling advanced technologies. Hutt, 2007, 5. But FDA regulation leaves no remedy for the injured patient.

The New York Court of Appeals clarified the warnings necessary for prescription drug cases in *Martin v. Hacker*, 83 N.Y.2d 1 (1994). The adequacy of warnings meant for physicians can be decided by the court as a matter of law and it provides detailed guidelines for courts to use in assessing a warning's adequacy. The Court in *Martin* affirmed summary judgment by denying an insufficient warnings claim. The Court concluded:

1. Products liability for prescription drugs is avoided when the drug "is properly prepared, and accompanied by proper directions and warning." Even though side effects may cause injury, a prescribed drug accompanied by adequate warnings is not "defective and unreasonably dangerous." *Where liability is predicated on a failure to warn, New York law views negligence and strict liability claims as equivalent.* Thus, the precise legal theory of the warning claim does not warrant a different standard of assessment or result (emphasis added).
2. Prescription drug warnings are intended for physicians, whose duty includes balancing the risks and benefits of various drugs and treatments in order to prescribe them and supervise their effects. The physician thus acts as a "learned intermediary" between the manufacturer and the patient. Consistent with this premise, the drug manufacturer's warning "must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug."
3. Physicians are advised about dangerous side effects of prescription drugs in a variety of ways, including the *Physicians' Desk Reference* (PDR) and formal warnings in the products' package inserts. The latter must be written in accordance with the Food and Drug Administration's recommendation for proper labeling, which requires the following kinds of information in a designated sequence: description, actions, indications, contraindications,

> warnings, usage in pregnancy, precautions, adverse reactions, dosage and administration, over dosage and how supplied. "Contraindications" must include the "most stringent caveats against use, i.e., a statement of the conditions under which the drug is not to be used." Each succeeding section, especially from "Contraindications" to "Adverse Reactions," sets forth information and admonitions in a "descending order of importance and seriousness of the attendant risks." Hence, the "Warnings" section deals with side effects "of graver consequence" than the "Adverse Reactions" Section.

The test for a warning's legal sufficiency involves the court's examining "not only the meaning and informational content of the language but also its form and manner of expression." The court must bear in mind that the warning is to be read and understood by physicians and must resolve the question of adequacy by examining whether the warning is "accurate, clear, consistent on its fact, and whether it portrays with sufficient intensity the risk involved in taking the drug." *Martin v. Hacker,* 83 N.Y.2d at 10.

These are the same questions that present themselves in courts handling claims by persons injured by FDA approved products, who now find themselves precluded from seeking any compensation for their losses.

Chapter VI

A Brief History of the Food, Drug and Cosmetics Act (FDCA) and the Food and Drug Administration (FDA)

Food and drugs were historically regulated, if at all, by the states. Since the late 1800's the federal government started to entertain regulating food and drugs. Congress considered over 100 bills between 1879 and 1906 that sought to regulate food and drugs. But none of those bills produced meaningful regulation of those sectors of the American economy. However, in 1906 Upton Sinclair's classic muckraking exposé, *The Jungle*, exposed the corruption of the Chicago meat packing industry. The book detailed the unsanitary conditions that existed and spread without government intervention. This proved to be the final impetus needed for the Congress to finally act. President Theodore Roosevelt signed the Food and Drugs Act into law in 1906. The Act was administered by the Bureau of Chemistry, which was part of the Department of Agriculture. But the Bureau of Chemistry was rarely successful in attempting to prove in court that manufacturers of drugs labeled with false therapeutic claims intended to defraud consumers. Nonetheless, the Bureau proceeded to seize misbranded and adulterated drugs throughout the 1920s and 1930s (www. – FDA website last visited on July 5, 2013).

After President Franklin D. Roosevelt sustained several judicial setbacks to this New Deal legislation, which dominated most sectors of the American economy, he was successful in getting the Congress to pass the 1938 Food, Drug and Cosmetics Act

(FDCA). The FDCA was in part a direct response to the mass poisoning deaths of over 100 people from an improperly prepared elixir of sulfanilamide, which caused a public outcry for some control over drugs sold in the marketplace. The new act mandated that drugs must be preapproved before they were allowed to be marketed and manufacturers had to show the drugs were safe. Manufacturers of most consumer products face the prospect of lawsuits by consumers. However, makers of FDA regulated products confront unusually complex demands because their products are subject to extensive federal regulation. The relationship between FDA's regulatory role and the legal principles that govern the liability of sellers of products the agency regulates are sometimes in conflict. Hutt (2007) 1458.

Under the 1906 law, FDA had relatively little influence over the therapeutic claims made for drugs. The FDA exerted its authority only after a drug was on the market, and evidence accumulated that it might not work. The 1938 Act gave the agency a gatekeeper role, which permitted officials to examine and sometimes question a drug's clinical utility. The 1962 Amendments completed the law's reversal of the burden of proof. Since the passage of the Amendments, the FDA has been responsible for evaluating drugs, based on pre-marketing testing conducted by the manufacturer, whether the new drugs are safe and efficacious. This shift in responsibility transformed the way in which drugs are developed, tested, and marketed.

The law makes it unlawful, without proof of intent or demonstration of actual injury or deception, to market drugs in interstate commerce that the agency has not approved. In some sense, the agency becomes a warrantor of manufacturer compliance

with the rules that govern drug development and marketing. But some observers claim that the FDA is exceptionally and, at times inappropriately, over cautious before it allows drugs to reach the market. Merrill, 2006.

The FDCA provides formal procedures for challenging agency decisions, but these administrative safeguards are almost never invoked. Nor are FDA's decisions to grant, withhold, or delay approval commonly challenged in court. Statutory directives do not materially affect the conduct or pace of agency review, nor do they control its evolving requirements to gain marketing approval. In short, the FDA product approval system is free from conventional legal constraint. Merrill, 2006.

Congress provided in 1938 for the criminal prosecution of individuals and firms guilty of prohibited acts, injunction against such acts, and seizure of adulterated or misbranded goods. It also authorized civil penalties for some violations of the FDCA. But the FDA also relies on informal remedies such as publicity, recalls, and warning letters, which now comprise the primary routine enforcement tools of the agency. Hutt, 2007, 14.

In 1962 and again in 1976, the FDCA underwent two major amendments to the basic Act. The 1962 Drug Amendments fundamentally restructured the way in which FDA regulated new medicines. It transformed from premarket notification into individual premarket approval of the safety and effectiveness of every new drug. The FDA also acquired roles in regulating prescription drug promotion and clinical testing of new agents. The regulation of drugs became the largest FDA activity. Hutt, 2007, 15.

Before 1976, medical devices were not regulated by the FDA. In 1976 Congress made fundamental changes in the way that medical devices are regulated under the FDCA. The Medical Device Amendments were the culmination of fifteen years of careful study and debate, not only within Congress and the agency, but also among representatives of clinical medicine, biomedical engineering, device manufacturers, and consumer groups. While the 1976 Amendments did not significantly enlarge FDA's jurisdiction, it transformed its approach to regulation of these products, and substantially enlarged the array of regulatory tools available to it. Hutt, 2007, 15.

To recover for injuries from ingesting food or drink, a plaintiff must establish that the food contained some dangerous element that rendered it unwholesome or "defective." The concept of defectiveness in food and drink cases is basically the same as in other products. If a food or beverage is defective a seller is generally subject to liability in negligence, warranty, and strict liability in tort for selling it, if the food product's condition is dangerous in a manner neither intended by the seller nor expected by the consumer.

The same is generally true for prescription drugs. Prescription drugs with their powerful chemicals and biologics save many millions of humans from suffering and death. Yet, these same chemicals also cause great suffering and death. All prescription drugs possess substantial costs to develop as well as benefits to their users. But most drugs are inherently and unavoidably dangerous.

Consequently, before being allowed onto the market, prescription drugs must undergo rigorous analysis, laboratory testing, and clinical trials, the results of which are closely scrutinized by the FDA, to assure both the safety and efficacy of all new drugs.

The 1976 Medical Device Amendments (MDA) to the FDCA

In the MDA, Congress attempted to define the federal and state roles in the regulation of medical instrumentation. The result is section 521 of the FDCA, which states:

> Sec. 521(a) Except as provided in subsection (b), 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 Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.
>
> (b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if
>
> (1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement
>
> (A) is required by compelling local conditions, and
>
> (b) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

Medical Device Classifications

There are three classes of medical devices:

Class I: Devices that are subject to minimal controls because they pose little or no risk of illness or injury, and are subject only to minimal regulation (21 U.S.C. § 360c(a)(1)(A)). This includes devices such as tongue depressors, elastic bandages and sterile examination gloves.

Class II: Devices that are potentially more harmful. Manufacturers must comply with federal performance standards or specific guidelines known as 'special controls' (21 U.S.C. § 360c (a)(1)(B)). These include devices such as powered wheelchairs and tampons.

Class III: Devices that either "present a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" (21 U.S.C. § 360c(a)(1)(C)). Class III devices include pacemakers, heart valves, prostheses, breast implants, and bone screws.

The Approval Process for Class III Devices

Before a Class III medical device can be marketed, it must be approved by the FDA. The manufacturer must prove to the FDA that 1) the device has been manufactured soundly and, 2) the device is safe and effective. The primary route by which approval is obtained is the PMA or premarket approval. 21 U.S.C. § 360c (d)(2).

1. Premarket Approval (PMA) Process has been described by the Supreme Court as a "rigorous process, under which manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The PMA process requires submission of clinical testing, disclosure of specifications, intended use, manufacturing methods, and proposed labeling.

2. 510(k) Process is an exception to the PMA Process. 21 U.S.C. § 510 allows a manufacturer to sell a device that is "substantially equivalent" to a device that predates the MDA. The manufacturer must notify the FDA of its intent to market the medical device at least 90 days before its introduction to the market and to explain the device's substantial equivalence to a pre-1976 device.

In 1996, the same year it decided *Medtronic, Inc. v. Lohr, Id*., the U.S. Supreme Court denied certiorari to review a case from the Illinois Supreme Court entitled *Haudrich v. Howmedica, Inc*., 169 Ill. 2d 525, 662 N.E.2d 1248, *cert denied*, 591 U.S. 910 (1996), that upheld an award of $1.6 million to the recipient of a defective knee prosthesis. The Illinois state court had rejected the manufacturer's argument that preemption is a jurisdictional matter and thus not subject to waiver, noting that preemption is not a choice-of-forum issue, but an affirmative defense. The Illinois Supreme Court held that if it is not raised at the trial level, is not preserved for appellate review and is thereby waived.

Food and Drug Administration – Structure

The FDA's legal authority is outlined in the FDCA. But the FDA's structure is described in regulations, which are subject to change (21 C.F.R. 5.1100). Although it has a long institutional history, the FDA was a creature of administrative action until it was recognized in legislation in 1988 (102 Stat. 3048, 3120-3122 [1988]). Before 1988, the Commissioner of the FDA was appointed by the Secretary of Health and Human Services (HHS) or its predecessor departments, and thus was not subject to Senate confirmation. Under Section 903(b)(1) of the FDCA, the Commissioner must now be appointed by the President with the advice and consent of the Senate. FDA Commissioners have a direct line to the Secretary of HHS, and sometimes to the White House as well (Hutt, 2007, 17).

The FDA does not have the same independence from presidential control that independent regulatory commissions like the Federal Trade Commission (FTC), Securities and Exchange Commission (SEC), and Consumer Product Safety Commission (CPSC) ostensibly enjoy. A Commissioner of the Food and Drug Administration is subject to direction, and may be removed by the President for any or no reason.

The Directors of the Centers for Food, Drugs, Biologics, Devices, and Veterinary medicine are not political appointees. Therefore, a change in administration does not result in resignations or reassignments among the agency's middle and upper level managers, even though it may abruptly terminate the service of a Commissioner and some Associate Commissioners. Accordingly, for most of its existence, FDA has

operated with considerable decisional independence and enjoyed continuity in the service of employees who hold managerial positions and staff its several field offices. Hutt, 2007, 18.

Throughout the first 70-80 years of FDA's history, regulatory policy was made by the Office of the Commissioner and the Office of the Chief Counsel and carried out through the lower levels of the headquarters staff and the field force. FDA policy is largely made at the lowest levels of FDA rather than at the Commissioner level. There are a number of interrelated reasons for this development. First, the vast bulk of FDA's daily decisions now come in the form of action taken with respect to premarket applications. The Office of the Commissioner almost never reviews these decisions and may not even know about them. It is these decisions that determine FDA policy, not the FDCA or the implementing regulations. Hutt, 2007, 19.

> "The agency has now grown so large that the Office of the Commissioner cannot oversee all of the agency's activities even if it had the resources and desire to do so. For example, more than 2000 informal guidance has been issued in the past decade governing in minute detail thousands of issues relating to new drug regulation alone. It is doubtful that the Office of the Commissioner has the expertise, much less the staff, to review, understand, and comment on even a small fraction of them. Accordingly, the actions of law-level FDA employees almost always prevail within the agency and thus constitute the true agency policy with regard to the matter involved." Hutt, 2007, 20.

> "Approximately 20-25 cents of every consumer retail sales dollar is spent for products within the agency's jurisdiction. FDA's authority over products varies widely, ranging from comprehensive premarket approval responsibility for new drugs, food additives, and life-supporting medical devices, to the policing activities

> applicable to most food products, nonprescription drugs and cosmetics." Hutt, 2007, 20.

The FDA Drugs programs are comprised of three separate areas, Human Drugs, Animal Drugs and Biologics. FDA is responsible for the life cycle of the product, including premarket review and post market surveillance of human, animal and biological products to ensure their safety and efficacy. FDA assures that all drug products used for the prevention, diagnosis and treatment of disease for humans are safe and effective. This includes the review of investigational new drug applications; evaluation of market applications for new and generic drugs, labeling and composition of prescription and over-the-counter drugs; monitoring the quality and safety of products manufactured in, or imported into, the United States; and regulating the advertising and promotion of prescription drugs. Hutt, 2007, 25-26.

The FDA Biologics program assures that blood and blood products, blood test kits, vaccines and therapeutics are pure, potent, safe, effective and properly labeled. FDA's National Center for Toxicological Research in Jefferson, Arkansas, serves as a specialized resource, conducting peer-reviewed scientific research that provides the basis for FDA to make sound science-based regulatory decisions through its premarket review and postmarket surveillance. The research is designed to define and understand the biological mechanisms of action underlying the toxicity of products and developing methods to improve assessment of human exposure, susceptibility and risk of those products regulated by FDA. Hutt, 2007, 26.

FDA Drug Regulation

The determination that a product is a drug or device is often tantamount to a determination that the product cannot be sold at all until FDA approves it for marketing. Section 201(g)(1) of the FDCA defines "drug" as follows:

> The term "drug" means
>
> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) …
>
> Section 201(h) of the FD&C Act defines "device" as follows:
>
> The term "device" … means 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.

One of the reasons that much deference is given to FDA approval is that drug regulation is heavily front-loaded. The FDA spends much time and energy evaluating a proposed drug's safety and efficacy before approving it. But this initial evaluation is inherently constrained by the limited data available from clinical trials conducted before the product enters the marketplace. Ultimately, the FDA makes a judgment based on the limited data available about whether a drug should be approved.

Once a drug receives its initial approval, the FDA generally receded from oversight. In most cases, the agency does not initiate post marketing reviews of a drug's safety. Instead, the FDA left it to the drug manufacturers to alert it when actual use of a product reveals greater hazards. During the Clinton administration, the chief counsel of the agency once wrote: "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."

But the Congress passed the 2007 Food and Drug Administration Amendments Act (FDAAA), which allowed the FDA to perform more comprehensive review of potential new drugs and devices. It also enhanced post approval FDA oversight and reporting requirements and made clinical trials of medicines and devices available on a website at www.clinicaltrials.gov. Ultimately, some of these changes may greatly alter the landscape on post-approval warning changes. Some have even suggested that once the post-approval data collection procedures are fully in place, the Supreme Court might revisit *Wyeth v. Levine*. See Barbara J. Evans, Seven Pillars of a New Evidentiary

Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era, *85 Notre Dame L. Rev. 419* (2010); Ryan Abbot, Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety, *99 Iowa L. Rev. 225* (2013).

For decades, state products liability law and federal regulation of drugs have coexisted. State tort actions against drug companies have been recognized for well over a century. When Congress enacted the Food, Drug, and Cosmetic Act (FDCA) in 1938, it decided not to include a private right of action for damages on the ground that it was unnecessary, because a common law right of action exists.

In recent decades, the FDA repeatedly acknowledged that there was no conflict between these two systems for consumer protection. In the 1979 preamble to an FDA labeling regulation, for example, the agency expressly acknowledged that "it is not the intent of the FDA to influence the civil tort liability of the manufacturer."

Two decades later, when the agency issued a regulation concerning medication guides for prescription drugs, the FDA rejected a drug company suggestion that it preempt "state regulation with respect to civil tort liability claims and other labeling requirements." To the contrary, the FDA said it "does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."

At the end of the Clinton administration, the FDA had proposed some revised drug labeling regulations, with the explicit acknowledgement that they would not preempt state law. But after George W. Bush became president in 2001 this policy

changed dramatically. It started with a series of amicus briefs that the FDA filed in pending tort cases. The Bush FDA began to take the position that certain products liability claims seeking to hold drug manufacturers liable for failure to provide adequate warnings of a drug's dangers conflicted with and were preempted by federal drug labeling regulations. The FDA chose cases in which the agency had already considered the precise warning at issue and decided not to require it. Second, courts consistently rejected the FDA's position.

In January of 2006, the Bush FDA issued the final labeling regulations. The preamble to the final rule took the completely contrary position on preemption, reiterating many of the arguments the agency had advanced in its previously unsuccessful amicus briefs.

The preamble argued that "FDA approval of labeling under the [FDCA] preempts conflicting or contrary state law." It took the position, contrary to explicit FDA regulations, that drug companies were not free to strengthen warnings without FDA approval, because "the determination whether labeling revisions are necessary is, in the end, squarely and solely [the] FDA's under the act."

And, the agency, argued, federal labeling requirements are not "minimum safety standards"; rather, they "establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act." The FDA apparently hoped that, by setting forth its preemption position in a regulatory preamble, it could persuade courts to grant it more deference.

Many drug companies felt empowered by this FDA action. Companies began to file preemption motions in case after case, regardless of whether the facts revealed any conflict between FDA decisions regarding the drug product involved and the plaintiffs' claims.

The preamble led to much confusion in the courts. While some judges continued to recognize that state tort law generally complemented federal drug regulation, others concluded that they must defer to the agency's expertise on this issue and dismiss plaintiffs' claims.

It became clear that the FDA's regulatory preamble raised the stakes and threatened to undermine plaintiffs' rights to redress under state law. The Center for Constitutional Litigation (CCL) and Trial Lawyers for Public Justice (TLPJ) have defended state law in cases in which preemption has been urged – serving as both co-counsel and amici curiae. But it appears they have lost the battle to retain many rights of persons injured by medical devices and generic drugs, which comprise 80 percent of the drug market in the United States. How that battle was lost will be traced in the next chapter covering the U.S. Supreme Court and preemption of FDA approved products.

Under the George W. Bush administration, post-approval enforcement declined. The FDA has used its influence to foster the notion that drug companies ought to avoid state tort liability. The companies argue that state products liability claims and failure to warn about a drug's risks are preempted by federal law and regulations.

The plaintiffs' bar and advocates for drug consumers resisted this movement and won a victory in *Wyeth v. Levine.* But they lost the battles in the Supreme Court in *Riegel, Buckman, PLIVA* and *Mensing*.

Chapter VII

The U.S. Supreme Court on Preemption of FDA Approved Products

In order to demonstrate the Supreme Court's progression in the preemption cases of FDA approved products, the cases are presented in chronological format.

Medtronic, Inc. v. Lora Lohr, 518 U.S. 470 (June 26, 1996)

The Medical Device Amendments of 1976 (MDA or Act) was enacted "to provide for the safety and effectiveness of medical devices intended for human use. The MDA classifies such devices based on the risk that they pose to the public. Class III devices pose the greatest risk and, thus, are subject to a rigorous premarket approval (PMA) process. However, most Class III devices on the market have not been through the PMA process due to two statutory exceptions. Realizing that existing devices could not be withdrawn from the market while the FDA completed PMA analyses, Congress included a provision allowing pre-1976 devices to remain on the market without FDA approval until the requisite PMA is completed. The Act also permits devices that are "substantially equivalent" to preexisting devices to avoid the PMA process until the FDA initiates the process for the underlying device. The FDA uses a "premarket notification" submitted by all manufacturers pursuant to the § 510(k) process to determine substantial equivalence for Class III devices.

Medtronic, Inc.'s pacemaker is a Class III device, which the FDA found was substantially equivalent to other pacemakers under the § 510(k) process. Lora Lohr and

her spouse filed a Florida state court suit alleging both negligence and strict liability claims in the failure of her Medtronic pacemaker. Medtronic removed the case to the Federal District Court. That court ultimately dismissed the complaint as having been preempted by 21 U.S.C. § 360k(a), which provides that "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 (a) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Act]."

The U.S. Court of Appeals for the Eleventh Circuit reversed in part and affirmed in part the trial court's dismissal. The Eleventh Circuit concluded that the Lohrs' negligent design claims were not preempted, but that their negligent manufacturing and failure to warn claims were. Both Medtronic and the Lohrs appealed to the U.S. Supreme Court, which granted certiorari.

Justice Stevens delivered the opinion of the Court with respect to Parts I, II, III, V, and VII of the decision, concluding that the MDA does not preempt the Lohrs' common law claims. Justice Stevens and the majority of the court found that the court need not go beyond § 360 k (a)'s preemptive language to determine whether Congress intended the MDA to preempt at least some state law. It specifically referenced *Cipollone v. Liggett Group, Inc*. (505 U.S. 504, 517 [1996]), quoting "the domain expressly preempted by that language must be identified (*Ibid)*. Justice Stevens asserted that the States' historic police powers cannot be superseded by a federal act unless that is

Congress' clear and manifest purpose (*Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230), and that any understanding of a preemption statute's scope rests primarily on 'a fair understanding of *congressional purpose."*' *Cipollone*, 505 U.S., at 530, n. 27 (emphasis added).

The majority of the court found that the Lohrs' negligent design claims were not preempted. The FDA's "substantially equivalent" determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement that cannot be affected by state law. Since the § 510(k) process is focused on *equivalence*, not safety, substantial equivalence determinations provide little protection to the public. Neither the statutory scheme nor legislative history suggests that the § 510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state law product liability claims.

Moreover, the court held that Section 360k (a) does not preempt state rules that merely duplicate the FDA's rules regulating manufacturing practices and labeling. That state requirements may be narrower than the federal rules does not make them "different" under § 360k. Most importantly, a damages remedy does not amount to an additional or different "requirement;" it merely provides another reason for manufacturers to comply with identical existing federal law "requirements." This view is supported by the regulations of the FDA, to which Congress has delegated authority to implement the MDA.

The Lohrs' manufacturing and labeling claims were also not preempted. While statutory and regulatory language may not preclude "general" federal requirements from ever preempting state requirements, or "general" state requirements from ever being preempted, it is impossible to ignore the overarching concern that preemption occurs only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be "with respect to" medical devices and "different from, or in addition to," federal requirements. They must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Regulations also provide that state requirements of general applicability are preempted only where they have "the effect of establishing a substantive requirement for a specific device." Federal requirements must be "applicable to the device" in question, and, according to the regulations, preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device."

The federal manufacturing and labeling requirements reflect important, but entirely generic concerns about device regulation generally. These were not the sort of concerns regarding a specific device or regulation or statutes which was designed to preclude from potentially contradictory state requirements. Similarly, Florida's common law requirements were not specifically developed "with respect to" medical devices and, thus, are not the kinds of requirements that Congress and the FDA feared would impede implementation and enforcement of specific federal requirements.

Justice Stevens, joined by Justices Kennedy, Souter, and Ginsberg, concluded in Part IV that Medtronic's argument that any common-law cause of action is a

"requirement" under § 360k(a) is implausible, for it would grant complete immunity from design defect liability to an entire industry that, in Congress' judgment, needed more stringent regulation. Justice Stevens explained that it would take language much plainer than § 360k's text to do that. The word "requirement," which appears to presume that the state is imposing a specific duty upon the manufacturer, would be an odd term to use to indicate the sweeping preemption Medtronic urged. *Cipollone*, 505 U.S., at 521-522, was distinguished. The MDA's basic purpose and history entirely support the rejection of such an extreme position of dismissing any common law claims.

Justice Breyer, concurring, concluded that, although the MDA will sometimes preempt a state law tort suit, it did not preempt the claims at issue in *Lohr*. First, since the MDA's preemption division is highly ambiguous, Congress must have intended that courts look elsewhere for help as to which federal requirements preempt specific state requirements, as well as just how they may be accomplished. Second, in the absence of a clear congressional command as to preemption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative action will have preemptive effect. (See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721 (1985).) Third, the FDA's regulations indicate that the FDA does not consider that its requirements preempt the state requirements at issue in *Lohr*. Fourth, ordinary principles of "conflict" and "field" preemption support the conclusion that plaintiffs' tort claims are not preempted.

Five years after *Lohr*, the Supreme Court again visited another FDA approved medical device case in *Buckman Co. v. Plaintiff's Legal Committee,* 531 U.S. 341 (2001) which follows.

***Buckman Co. v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001)**

The Plaintiffs Legal Committee, the respondent, represented numerous plaintiffs claiming injuries caused by the use of orthopedic bone screws in the pedicles of their spines. Petitioner, the Buckman Co., assisted AcroMed Corp., a screw manufacturer, in securing approval for devices from the FDA, which had regulatory authority under the FDCA, to include the Medical Devices Amendments of 1976 (MDA). The orthopedic bone screws in question were classified as Class III medical devices and normally must go through a time-consuming process to receive premarket approval under 21 U.S.C. § 360k. However, the screws were approved under an exception known as the § 510(k) process, for medical devices that were already on the market before 1976 when the MDA was enacted. Section 510(k) also covered devices that are "substantially equivalent" to the devices approved prior to 1976. The § 510(k) application filed by petitioner and the manufacturer sought clearance to market the screws for use in arm and leg bones, but not the spine. The respondents, representing the injured plaintiffs, claimed that the FDA would not have approved the screws had petitioner not made fraudulent representations regarding their intended use in spines. The plaintiffs sought damages under state tort law. The U.S. District Court dismissed these fraud-on-the-FDA claims on the ground that they were preempted by the MDA. The Court of Appeals for the Third Circuit reversed the U.S. District Court's decision. 159 F.3d 817 (3d Cir. 1998).

In the Supreme Court, Chief Justice Rehnquist wrote for the 7-0 unanimous decision, wherein Justices Breyer and Thomas also concurred in the judgment. The court held that the plaintiffs state law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, the FDCA, as amended by the MDA. The court specified that

the relationship between a federal agency and the entity it regulates is inherently federal because it originates from, is governed by, and terminates according to federal law. The petitioner's FDA dealings were prompted by the MDA and were dictated by that statute.

Petitioners did not argue federalism and the historic primacy of state regulation of health and safety matters as did the respondent in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485. Here, there was no presumption against preemption. The conflict surfaced from the fact that the federal statutory scheme has ample powers to punish and deter fraud against the FDA. The FDA uses this authority to achieve a delicate balance of statutory objectives that can be skewed by allowing state law fraud-on-the-FDA claims. The § 510(k) process lacks the PMA review's rigor, but sets forth a comprehensive scheme for determining substantial equivalence with a similar device approved prior to 1976. Other provisions give the FDA enforcement options that allow it to make a measured response to suspected fraud upon the Administration. This flexibility is a critical component of the framework under which the FDA pursues its difficult and often competing objectives of regulating medical device marketing and distribution without intruding upon decisions committed by the FDCA to health care professionals.

State law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. Complying with the FDA's detailed regulatory regime in the shadow of 50 states' tort regimes will dramatically increase the burdens facing potential applicants, who might be deterred from seeking approval of devices with potentially beneficial off-label uses—an accepted medical practice in which a device is used for some other

purpose than that for which the FDA approved it—for fear of being exposed to unpredictable civil liability.

Conversely, applicants fear that their disclosures to the FDA will later be judged insufficient in state court that might lead them to submit information that the Administration neither needs nor wants, thus delaying the comparatively speedy § 510(k) process and, in turn, impeding competition and delaying the prescription of appropriate off-label uses.

The High Court pointed out that that respondent's reliance on *Silkwood v. Kerr-McGee Corp*., 44 U.S. 238, 104 S.Ct. 615, is misplaced. *Silkwood* was based on traditional state tort law principles, not on a fraud-on-the-agency theory. Unlike *Silkwood*, there is clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government. In addition, the MDA's express preemption provision does not bar the ordinary working of conflict preemption principles. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869. *Medtronic, Inc. v. Lohr* can be read to allow certain state law causes of action that "parallel" federal safety requirements, it does not stand for the proposition that any FDCA violation will support a state law claim. Accordingly, the Supreme Court reversed the Third Circuit's decision, 159 F.3d 817 (1998) and reinstated the District Court's dismissal of the action.

***Donna Riegel as Administratrix of the Estate of Charles Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008).**

The Riegels sued Medtronic for damages under New York state law after an FDA-approved Class III balloon catheter lead that was placed into Charles Riegel's coronary artery ruptured. Plaintiffs alleged that the catheter was defective under state law and sued in the U.S. District Court for the Northern District of New York.

When the U.S. District Court was initially faced with a motion to dismiss the plaintiff's complaint based upon federal preemption, it did not dismiss the plaintiff's claims for negligent manufacturing, the loss of consortium derivative of negligent manufacturing and breach of express warranty. Judge Kahn ruled that those claims may proceed to discovery, reasoning that if Medtronic was negligent and did not comply with the FDA approved design and manufacturing specifications when it manufactured the device, there would be no conflict between the state requirement and the federal requirement; and consequently, no federal preemption.

The trial judge also ruled that if express warranties were made based upon express representations, such claims do not interfere or conflict with federal requirements imposed through the FDA, pre-market approval process. See, *Mitchell*, 126 F.3d at 915. Since the negligent manufacturing and express warranty claims were allowed to proceed, it was also not ripe to dismiss the consortium derivative claims. 2002 WL 3423093 (N.D. N.Y.).

At the conclusion of discovery, Medtronic once again moved for summary judgment to dismiss the remaining negligent manufacturing and breach of express warranty claims, along with the derivative consortium claims. However, this time Judge Kahn found that: (1) neither the plaintiffs, nor their agents (the treating physicians-learned intermediaries), relied on any express warranties; and (2) any express warranties were disclaimed. Neither the plaintiffs, nor their doctor, or the hospital as their agents had any knowledge of any warranties when Mr. Riegel underwent the heart procedure. As to the negligent manufacturing claim, the District Court found that the plaintiffs did not possess the actual allegedly defective balloon, and thus did not have any direct evidence of negligent manufacture. Moreover, plaintiffs failed to negate the possibility that causes other than the negligent manufacture may have caused the balloon in the catheter to burst. It was undisputed that the plaintiff's physician exceeded the maximum recommended 8 to 10 atmospheres when inflating the balloon catheter. Moreover, it was contraindicated to use a balloon for Riegel's condition without having used a Rotoblater to remove the heavy calcified spicules. The court concluded from that evidence that no fair minded trier of fact would reasonably conclude that the plaintiff excluded those other causes of the burst. Accordingly, the court dismissed those remaining causes of action along with the consortium claim. *Riegel v. Medtronic, Inc.*, 2003 WL 25556778 (N.D.N.Y.).

The Riegels appealed to the U.S. Court of Appeals for the Second Circuit, which affirmed the U.S. District Court (*Riegel v. Medtronic, Inc.*, 451 F.3d 104 [2nd Cir. 2006]) and held that:

> (1) state requirements applicable to medical devices that have entered the market pursuant to Food and Drug Administration's (FDA) premarket approval (PMA) process are preempted under MDA;
>
> (2) plaintiff's negligence, strict liability, and breach of implied warranty claims were preempted;
>
> (3) *negligent manufacture claims were not preempted*;
>
> (4) *but plaintiff failed to exclude manufacturer's proffered alternate causes for product failure, precluding recovery for negligent manufacture* (emphasis added).

The Medical Device Amendments of 1976 created a scheme of federal safety oversight for medical devices while sweeping back state oversight schemes. The statute provides that a state shall not "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 [federal law] to the device, and . . . (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under" relevant federal law (21 U.S.C. § 360k(a)). The MDA calls for federal oversight of medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the premarket approval process. These devices may enter the market only if the Food and Drug Administration reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of the safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA. But the Riegels appealed, yet again to the U.S. Supreme Court.

Justice Antonin Scalia delivered the 8-1 opinion for the Supreme Court, in which Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer and Alito joined and in which Justice Stevens joined except for Parts III-A and III-B. Justice Stevens filed an opinion concurring in part and concurring in the judgment. Justice Ginsberg filed a dissenting opinion.

The court held that the MDA's preemption clause bars common law design defects and failure to warn claims. Specifically, the court found that the Federal Government has established "requirement[s] applicable . . . to" Medtronic's catheter within the meaning of § 360k (a) (1). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 500-501, the Court interpreted the MDA's preemption provision in a manner "substantially informed" by an FDA regulation (21 CFR § 808.1(d)), which says that state requirements are preempted only when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" under federal law. Premarket approval imposes "specific requirements applicable to a particular device." The FDA requires that a device that has received premarket approval be marketed without significant deviations from the specifications in the device's approval application. If the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness, there should be no deviation from their specifications.

Moreover, petitioner's common law claims are preempted because they are based upon New York "requirement[s]"with respect to Medtronic's catheter that are "different

from, or in addition to" the federal ones, and that relate to safety and effectiveness, § 360k(a).

State common law negligence and strict liability claims impose "requirement[s]" under the ordinary meaning of that term, see, e.g., *Lohr, supra*, at 503-505, 512 116 S.Ct. 2240, 135 L.Ed.2d 700; *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 521-523, 548-549. There is nothing in the MDA that contradicts this normal meaning.

The court distinguished Riegel's contention that the duties underlying her state law tort claims are not preempted because general common law duties are not requirements maintained "with respect to devices." The court held that petitioner's suit depends upon New York State's general tort duties with respect to Medtronic's catheter. Citing to Title 21 CFR § 808.1(d)(1), which states that MDA preemption does not extend to "[s]tate or local requirements of general applicability [whose] purpose. . . relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.".

The Court declined to address petitioner's argument that this lawsuit raises "parallel" claims that are not preempted by § 360k under *Lohr, (supra*, at 495, 513). The Supreme Court affirmed the Second Circuit's opinion.

Executive and Congressional Attempts to Curtail Federal Preemption

It is interesting to note that shortly after President Barrack Obama was inaugurated on May 20, 2009, he issued an Executive Memorandum on preemption. He stated, "[T]hroughout our history, state and local governments have frequently protected

health, safety and the environment more aggressively than has the national government." President Obama directed the heads of Executive Departments and Agencies to review their rules and regulations with respect to federal preemption of state law and to amend such regulations to reflect the President's policy that federal and state law should act concurrently to promote the general welfare. 74 Fed. Reg. 24693, (2009).

Also in 2009, when both houses of the Congress were controlled by the President's Democratic party, Senator Edward Kennedy, a Democrat from Massachusetts and Congressman Henry Waxman, a Democrat from California introduced the Medical Device Safety Act of 2009, H.R. 1346/S. 540 that would have reversed *Riegel v. Medtronic* by adding a provision to the FDCA, which stated that federal approval of a medical device has no effect on liability under state law. The new subsection to 21 U.S.C. § 360k would state:

> (c) No Effect on Liability Under State Law – Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.

Ironically, this bill was not incorporated into the extensive Patient Protection and Affordable Care Act of 2010, commonly known as "Obamacare." That bill has not seen any reported action since the subcommittee hearings in 2009. This may have been a deliberate determination on the part of Congress, rather than a missed opportunity to amend the statute.

The Lore of *Lohr* and "Parallel Claims"

In *Medtronic v. Lohr*, the Supreme Court held that state requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. §360k (a) (1). Thus, § 360k does not prevent a

State from providing a *damages remedy for claims premised on a violation of FDA regulations*; the state duties in such a case "parallel," rather than add to federal requirements (*Lohr*, 518 U.S. at 495) (emphasis added).

While the Supreme Court majority in *Lohr* recognized that the MDA will allow "parallel claims" to be brought under state common law, it does not delineate what "parallel claims" would survive federal preemption. Product liability law is primarily state common law and statutory law. The typical causes of action that are asserted in a product liability case are: negligence, breach of express warranty, breach of implied warranty and strict liability. *Denny v. Ford Motor Co.*, 87 NY2d 248 (1995); *Voss v. Black & Decker Manufacturing Co.*, 59 NY2d 102 (1983). Strict liability includes: design defects, manufacturing defects and inadequate warnings. *Speller ex. rel. Miller v. Sears Roebuck & Co.*, 100 NY2d 38 (2003). Strict liability grew out of judge made law to facilitate recovery for personal injuries caused by defective products. Courts found that manufacturers and sellers implied that their product was merchantable and fit for ordinary purpose. Implied warranties of strict liability eliminated the need for the injured plaintiff to prove negligence by the manufacturer or seller who breached a duty of care owed to all foreseeable users. New York judges instruct jurors in product liability cases that:

> A manufacturer of a product owes a duty to use reasonable care in the manufacture of the product so that it will be reasonably safe for its intended or foreseeable uses. Reasonable care means that degree of care that a reasonably prudent manufacturer of such a product would use in the making, inspecting and testing of the product, and its materials in order to produce a reasonably safe product. See 1NY PJI 3d 2:125 at 774 (2013); *Gebo v. Black Clawson Co.*,

92 NY2d 387 (1998).

Requiring that a manufacturer be careful in the production a product by inspecting it and testing it are the same "requirements" that the FDA imposes upon manufacturers. Yet, Justice Scalia highlights in *Riegel* that "the MDA provides that no state may establish or continue in effect *with respect to a device. . . any requirement*" relating to safety or effectiveness that is different from or in addition to federal requirements §360(a) (emphasis added). *Id*. at 328. He continued 'that the Riegel's suit depends upon New York's continuing in effect general tort duties" with respect to Medtronic's catheter.

While one could well argue that New York product liability law as to manufacturing defect claims parallels and is indistinguishable from the federal requirements of the FDA's current Good Manufacturing Practices and the applicable regulations in the Code of Federal Regulations or the Safe Medical Device Act, the High Court has ruled that medical device manufacturers will not be exposed to damages claims by injured plaintiffs, but will only be subject to enforcement by the FDA who reviews and approves their products.

The FDA Current Good Manufacturing Practice (CGMP) Regulations

The FDA website discloses the purpose of CGMP as follows:

> FDA ensures the quality of drug products by carefully monitoring drug manufacturer's compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe

> for use, and that it has the ingredients and strength it claims to have.
>
> The approval process for new drug and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMP. FDA inspectors determine whether the firm has the necessary facilities, equipment, and skills to manufacture the new drug for which it has applied for approval. Decisions regarding compliance with CGMP regulations are based upon inspection of the facilities, sample analyses, and compliance history of the firm. This information is summarized in reports which represent several years of history of the firms.
>
> FDA can issue a warning letter or initiate other regulatory actions against a company that fails to comply with Current good Manufacturing Practice regulations. Failure to comply can also lead to a decision by FDA not to approve an application to market the drug. (http://www.fda.gov/drugs/developmentalapprovalprocess/manufacturing/ucm090016.htm accessed 7/10/2013)

The FDA established Current Good Manufacturing Practices (CGMP) for processing, packing or marketing of drugs in 21 CFR Part 210 and CGMPs for finished pharmaceuticals in 21 CFR Part 211. The FDA also maintains a Quality System (QS) regulations for good manufacturing practices. The FDA outlines the purpose of the QS-GMP for medical devices as follows:

> The QS regulation embraces the same "umbrella" approach to the CGMP regulation that was the underpinning of the original CGMP regulation. Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

> Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations, 21 CFR 820.5 of the QS regulation. Operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are *safe and effective*, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated (emphasis added).
>
> FDA has identified in the QS regulation the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.

Medical devices are governed by 21 CFR 820. et. seq.

Courts have issued conflicting decisions regarding whether a violation of federally prescribed Current Good Manufacturing Practices (CGMPs) will support a parallel claim. The CGMP standards are FDA regulations setting forth a quality control system governing the methods, facilities and controls used in the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices. They are routinely described as "an umbrella quality system' providing "general objectives." See, e.g., *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009). To comply with the CGMPs, the manufacturer must adopt a variety of procedures and controls relating to quality control. 21 C.F.R. § 820.1 *et seq*. Judges holding that CGMPs do not

support a parallel claim reason that CGMPs are intentionally vague, provide only "general objectives" manufacturers must seek to achieve, and apply broadly to a wide range of medical devices.

Courts may deem a CGMP violation as relevant to a product liability cause of action unless the violation resulted in an actual manufacturing defect which caused the plaintiff's injury. A manufacturing defect claim is the ideal parallel claim. It is both a state law product liability cause of action and results in a product which is adulterated under the FDCA.

The relevant federal regulations concerning product safety are contained in the FDA's Current Good Manufacturing Practice.

The Circuit Courts Rebel

Yet, three U.S. Circuit Courts of Appeal have held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty "parallels" the federal-law duty under the MDA. See, *Hughes v. Boston Scientific Corp*., 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp*., 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 132, S.Ct. 498 (2011); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013).

The Eighth Circuit has also addressed preemption, holding that the MDA preempted the plaintiffs' failure-to-warn claims. See, *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010). First, plaintiff sought to enforce state-law requirements that would have required Medtronic "to give

additional warnings, precisely the type of state requirement that is 'different from or in addition to' the federal requirement." *Id.* at 1205 (quoting *Riegel*, 552 U.S. at 330). Second, the plaintiff sought to bring actions based solely on the MDA rather than on state law, which the court found foreclosed by *Buckman*. At no point did the court address a state-law claim based on a state-law duty that paralleled a federal-law duty. Hence, *Sprint Fidelis* (8th Cir.) is not inconsistent with *Hughes* (5th Cir.), *Bausch* (7th Cir.) or Stengel (9th Cir).

There is no uniformity in the judiciary's interpretation of "parallel claims" that are mentioned in *Lohr*. The *Riegel* Court did not define the term "parallel" because the plaintiffs in the case had waived those claims. Defining the scope of the term "parallel" has since become a hotbed of litigation in both federal and state courts. Clearly, common-law claims that impose liability despite the device manufacturer's compliance with design, manufacturing, or labeling regulations are not parallel. Beyond that, the judiciary has not reached a consensus. A few courts have opted for an extremely narrow approach, under which a claim is "parallel" to a federal requirement only when it provides a cause of action for violation of the federal requirement. Under a more lenient approach, a state law claim that requires more than mere compliance with federal requirements, e.g., that violation of a federal requirement was reckless or unreasonable, is not preempted regardless of whether the claim incorporates additional elements.

As of 2013, not all federal courts of appeals have weighed in on the issue, but the most restrictive approach was rejected by the Seventh Circuit in *Bausch v. Stryker Corp.*, 630 F.3d 546, 552-554 (7th Cir. 2010). The district court had interpreted the term

"parallel claims" as permitting only claims based on state claims that provide damages remedies for violations of FDA regulations, and held that common law claims are "different from or in addition to" federal law and hence preempted. The Seventh Circuit pointed out that the U.S. Supreme Court had rejected precisely that argument in both. Illinois law treats violation of a statute as prima facie evidence of negligence, and the plaintiff's claim that she was injured by defendant's violations of federal law in manufacturing her hip implant did not impose any requirement "different from, or in addition to" any federal requirement. The court concluded that the plaintiff's manufacturing defect claim was not preempted.

The Fifth Circuit handed plaintiffs' bar a much-needed ruling when it issued *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 768-771 (5th Cir. 2011), which concerned a HydroThermAblator. The case arose when the plaintiff sustained second-degree burns from a device her physician was using to treat her uterine bleeding. The plaintiff proceeded on the theory that the manufacturer, rather than reporting incidents of serious injuries as required by MDA regulations (21 U.S.C. § 360k (a) (1); 21 C.F.R. § 803.50(a)), developed an "algorithm" for determining whether a burn incident was one for which it would submit an MDA. While affirming the dismissal of all other claims, the court of appeals held that her failure-to-warn claim was not preempted to the extent it was predicated on the manufacturer's failure to report serious injuries and malfunctions as required by FDA regulations. The court declared that "a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is "parallel" to federal requirements as defined." It found that the plaintiff's failure-to-warn

claim was comparable to the negligent failure-to-warn claim in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 116 S.Ct. 2240, 135 L. Ed. 2d 700 (1996) and to the non-preempted negligent manufacture claim in its pre-case, *Gomez v. St. Jude Med. Diag, Inc*., 442, F.3d 919 (5th Cir. 2006).

The Fifth Circuit also concluded that because the plaintiff's claim was not foreclosed by § 360k of the MDA, she would not be foreclosed from arguing at trial that the doctrine of negligence per se was available to assist her in proving her claims. The defendant has taken the position that the plaintiff could not invoke negligence per se because Mississippi law allows a defendant to argue the reasonableness of its actions to rebut the presumption of negligence, and that this "reasonableness defense" constitutes an impermissible "additional or different duty under § 360k. The Fifth Circuit rejected this argument on the ground that reasonableness is an optional defense, and it is up to the defendant to determine whether to interject it into the case to *narrow* the scope of liability. Thus, "invoking the negligence per se doctrine to support a negligence claim, which is otherwise parallel to federal requirements is not expressly preempted. *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 771-772 (5th Cir. 2011).

The Fifth Circuit quickly disposed of the defense's next contention, e.g., that allowing the jury to determine whether the manufacturer violated FDA reporting requirements would lead to the possible imposition of different or additional state requirements. The gist of the defense argument was the FDA had never made a "formal" finding that the manufacturer failed to comply with the MDA regulations, and that a "formal" action is an implicit condition to a parallel suit. In short, the Firth Circuit did

not find that any such implicit condition exists (*Hughes v. Boston Scientific Corp*. 631, F.3d 762, 772-774 (5th Cir. 2011)) cracked the door open for plaintiffs bringing certain state-law claims involving FDA-approved devices in the Fifth Circuit. *See, e.g., Bush v. Thoratec Corp*. 2011 U.S. Dist. LEXIS 136838, at *10-*16 (E.D. La. Nov. 28, 2011) (granting leave to amend complaint to attempt to state a cognizable claim based on breach of FDA reporting regulations). Indeed, a year later, the Fifth Circuit decided in *Bass v. Stryker Corp.,* 669 F.3d 501, 514 (5th Cir. 2012) which involved the Trident PSL Acetabular Shell where it held that manufacturing defect claims premised on violation of FDA regulations and requirements were not preempted.

Most courts require the plaintiff allege the particular federal requirement that was violated, how the requirement was violated and how the violation resulted in his or her injury. Yet, the Seventh Circuit does not require that the plaintiff specify in detail the basis of their claim before discovery is complete.

The federal courts of appeal began to crystallize their respective requirements for pleading a "parallel claim" under *Riegel* beginning in 2010. Thus far, the Seventh Circuit requires the least amount of pleading specificity. That court pointed out in *Bausch v. Stryker Corp*., 630 F.3d 546, 558-561 (7th Cir. 2010) there are no special pleading requirements for Class III medical device claims in particular. The federal standard of notice pleading applies as long as the plaintiff alleges facts sufficient to meet the "plausibility" standard. However, much of the product-specific information about the manufacturing of medical device needed to fully investigate a defective manufacture claim is confidential under federal law. The court reasoned that formal discovery is

necessary before a plaintiff can be expected to provide a detailed statement of the specific bases for his or her claim, which gave credence to the plaintiff's strategy of seeking additional or early discovery when responding to a motion to dismiss. The original complaint had not specified the precise defect or specific regulations that were allegedly violated, but the court did not view the absence of these details as warranting a Rule 12(b) (6) dismissal.

The Fifth Circuit has now weighed in twice on the issue of pleading a parallel claim. Litigants in that circuit now have an easy-to-follow roadmap as to what will satisfy federal pleading requirements. The complaint in the first case, *Funk v. Stryker Corp*., 631 F.3d 777, 782 (5th Cir. 2011), which deals with the Trident system hip replacement did not meet the mark because it did not specify either the manufacturing defect or the causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the plaintiff's injury. Nor did it explain how the manufacturing process failed or how it deviated from the FDA-approved manufacturing process.

The following year, in *Bass v. Stryker Corp*., 669 F.3d 501, 510 (5th Cir. 2012), a nearly identical claim involving the same device, the court determined that the plaintiff adequately pleaded parallel claims based on manufacturing defects. This was different from the plaintiff who pleaded sufficient facts to find that his injury plausibly resulted from a violation of FDA standards. Specifically, the plaintiff pleaded that he received the hip implant, where the FDA had previously issued a letter warning that the device contained excessive microbial contaminants in violation of federal regulations. The

manufacturer voluntarily recalled the specific shell used in his implant. Plaintiff suffered from a loose shell due to a lack of bony ingrowth, which is a known effect of excessive contamination and manufacturing residuals.

Like the Seventh Circuit, the *Bass* court agreed that the confidentiality that medical device manufacturers enjoy means that plaintiffs are quite literally unable to make more specific allegations regarding defective manufacturing claims before discovery has taken place (669 F.3d 501, 511 (5th Cir. 2012). This provides important guidance to plaintiffs because it outlines the allegations that should be alleged to adequately state a parallel claim.

The Eight Circuit took a stricter approach to the issue in the case *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation,* 623 F.3d 1200, 1207 (8th Cir. 2010). The plaintiffs argued on appeal that the district court's ruling held them to an "impossible pleading standard" because the FDA's specific federal manufacturing requirements were set forth in the agency's files that were accessible only to the defendant and to the FDA without discovery. The court of appeals acknowledged that plaintiffs' argument would have "considerable force" in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements of the premarket approval prior to commencing the lawsuit.

The Eleventh Circuit adopted perhaps the most hard-lined view to the requisite level of pleading specificity in *Wolicki-Gables v. Arrow Int'l, Inc*., 634 F.3d 1296, 1301 (11th Cir. 2011), which involved a spinal pain pump. It emphasized that parallel claims must be specifically stated in the initial pleadings. The court reiterated that plaintiffs

cannot "simply incant the magic words" that a defendant violated FDA regulations to avoid preemption. As many district courts had previously held, the Eleventh Circuit stated that to properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that were violated.

***Stengel v. Medtronic, Inc*., 704 F.3d 1224 (9th Circuit 2013)**

The Stengels sued Medtronic, Inc., the manufacturer of a pain pump in an Arizona state court alleging that the pump rendered Richard Stengel a permanent paraplegic. The case was removed to the U.S. District Court for Arizona. Medtronic moved to dismiss the Stengel's complaint contending that the medical device amendments to the FDCA preempted their state law claims. The Stengels moved to amend their complaint to include a new state law negligence claim. That claim alleged that Medtronic had violated a state law duty of care by failing to report known risks associated with the use of its medical device to the FDA. The MDA required manufacturers to report those risks to the FDA. But Medtronic contended that the MDA also preempted the Stengel's new negligence claim.

After reviewing the U.S. Supreme Court case law in *Medtronic v. Lohr, Buckman Co. v. Plaintiffs' Legal Comm*. and *Riegel v. Medtronic, Inc*., and the aforementioned Circuit Court cases of *Hughes v. Boston Scientific Corp., Bausch v. Stryker Corp*. and *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, the Ninth Circuit held that the MDA did not preempt Stengel's failure to warn claims and found that those are parallel claims which are not preempted under the MDA.

The Ninth Circuit espoused that:

> The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.

While the case was remanded to the U.S. District Court for Arizona, Medtronic sought certiorari from the U.S. Supreme Court, which it is considering. Indeed, on October 7, 2013 the Supreme Court invited the Solicitor General to file a brief expressing the views of the United States on these issues. As of this writing the Supreme Court has not yet granted certiorari. Presumably the Court is awaiting a brief from the Solicitor General on behalf of the United States

Twombly/Iqbal Pleading Standards

Over the past few years the U.S. Supreme Court has re-examined the general pleadings rule of the federal courts that remains the standard in most state courts. Motions for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) are governed by the same standard as motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). *Cleveland v. Caplaw Enters*., 448 F.3d 518, 521 (2d Cir. 2006). A motion to dismiss under 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that the plaintiff has failed to set forth fair notices of what the claim is and the grounds upon which it rests. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

A complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 55 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 570). The plausibility standard requires that "the plaintiff plead factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and demands "more than a sheer possibility that a defendant has acted unlawfully." *Id*. (citing *Twombly*, 550 U.S. at 556). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusion," and "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id*. (citing *Twombly*, 550 U.S. at 555).

The Twombly/Iqbal exacting pleading standards have added yet another hurdle for plaintiffs' counsel who must obtain specific information about a product or manufacturing defect or inadequate warning almost before the discovery process is commenced.

Bucking *Buckman*

Pleading a claim that will survive a court's preemption analysis in the post-*Riegel* landscape is no easy task. To make matters worse, even if one makes it through the court's § 360k(a) express preemption analysis, the court may then find implied preemption under *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 346-348 (2001). In *Buckman*, plaintiffs claimed that a manufacturer had lied to the FDA regarding the intended use of its bone screws, resulting in the devices receiving improper market clearance. The U.S. Supreme court ruled that the "fraud-on-the-FDA" claims

were preempted because allowing a state-law cause of action under the circumstances would interfere with the federal scheme. The Court held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (531 U.S. 341, 350 [2001]).

Buckman is generally plead as a defense fallback position whenever a claim asserts that manufacturer failed to report negative events concerning their product to the FDA in a timely manner or failed not comply with a regulation or the current good manufacturing practices. The argument is that is an FDA enforcement procedure is not a tort, breach of a duty of care, or a breach of the implied warrant of fitness for use or merchantability UCC § 2-314. Therefore, the plaintiff is precluded from maintaining an action because the manufacturer did not comply with FDA regulations that is the province of the FDA to enforce, rather than private persons, to include those seeking compensation for injuries allegedly caused by an FDA approved product.

As has been pointed out in the previous section, federal courts are taking widely divergent views regarding preemption of claims involving PMA-approved devices. A split is developing among the federal circuit courts of appeals as to whether state-law failure-to-warn claims based on the failure to provide disclosures to the FDA are preempted. The Eighth Circuit in *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig*., 623 F.3d 1200, 1205-1206 (8th Cir. 2010) precluded suit. The Fifth Circuit in *Hughes v. Boston Sci. Corp*., 631 F.3d 762, 774-775 (5th Cir. 2011), found no preemption of state failure-to-warn claims based on the manufacturer violation of FDA's reporting regulations was in no way analogous to the "fraud-on-the-FDA." The former was a

recognized state-tort claim, while the latter, according to the Fifth Circuit, was a freestanding federal cause of action.

The Ninth Circuit in *Stengel v. Medtronic, Inc*., 704 F.3d 1224 (9th Cir. 2013) held that the consumer's state law failure-to-warn claims against the manufacturer of a medical pain pump device were not precluded. Hence, some of the federal Circuit Courts of Appeal are bucking the absolute preemption trend of *Buckman*.

Since FDA enforcement does not include damages to those that are injured by FDA approved products, Congress could allow a private right of action to injured parties where there is fraud on the FDA or a violation of the Good Manufacturing Practices approved for the specific device. Such claims would parallel federal law and consequently, would provide an opportunity for injured parties to recover some compensation while policing fraud and malfeasance on the part of the manufacturers.

However, the trend has been in the opposite direction. Manufacturers are exempt from accountability to those who may be seriously injured or die from their products.

Regaling in *Riegel*

After the victory in *Riegel* in February, 2008 the defense bar, which represents pharmaceutical and medical device manufacturers such as Wyeth, Pfizer, Merck, Johnson & Johnson, GlaxoSmithKline (GSK) and Medtronic were regaling in that the Supreme Court decision had reinforced *Buckman.* Defense counsel, together with several academics, were anticipating or at least hoped that the next case dealing with

pharmaceutical brand name drugs approaching the Supreme Court in late 2008 and early 2009—*Wyeth v. Levine*.

Many thought that since *Riegel* preempted state law claims against FDA approved medical devices that now the Supreme Court would also shut the door on state common law claims against FDA approved pharmaceuticals based on an implied conflict preemption or possibly a "field preemption" theory that the FDA dominated the field of pharmaceutical regulation and that under the Supremacy Clause of the U.S. Constitution, where there is a conflict of regulations or requirements, the federal regulations would be the final word on the subject.

Some attorneys representing pharmaceutical drug and medical devices have published articles regaling *Riegel* and wrote on how to defend a medical device action. See Tauber, *A Powerful Tool to Wield Early: How to Argue Medical Device Preemption, For the Defense*, Oct 2012.

In the absence of an express preemption provision from Congress in the FDCA, the FDA has vigorously pursued the implied preemption argument. Indeed, in 2006 during the Bush Administration, the FDA formalized its position in the preamble to a rule that revises drug-labeling requirements by asserting broad preemption of state law: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act…preempts conflicting or contrary state law." The FDA justifies its new position on implied conflict preemption by arguing the policy preference for uniformity, agency expertise, and drug safety, claiming that preemption helps avoid defensive labeling resulting from disparate state liability regimes.

In taking that position, the FDA intended that under the principle of deference to administrative agencies, courts were to respect the FDA position when deciding implied preemption issues. And many did just that. However, the Supreme Court in *Wyeth v. Levine* made an exception for brand name drugs.

Why *Wyeth*?

***Wyeth v. Diana Levine*, 555 U.S. 555 (March 4, 2009)**

Wyeth manufactured Phenergan, an antinausea drug that could be deployed by an intravenous drip method or by an intravenous push method. A physician's-assistant (PA) injected the respondent, Diana Levine, with Phenergan by the intravenous "IV-push" method, whereby the drug was injected directly into her vein. However, the drug entered Levine's artery and she developed gangrene. Unable to save her arm, her doctors amputated her forearm. Levine brought a state law damages action, alleging medical malpractice against the doctor and failure to provide an adequate warning about the significant risks of administering Phenergan by the IV-push method against Wyeth. The medical malpractice cause of action was settled pre-trial and the case against Wyeth continued. A Vermont jury determined that Levine's injury would not have occurred if Phenergan's label included an adequate warning. The jury awarded Levine $5 million dollars in damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician.

The state trial court declined to overturn the verdict and rejected Wyeth's argument that Levine's failure-to-warn claims were preempted by federal law because

Phenergan's labeling had been approved by the FDA. The Vermont Supreme Court affirmed the trial court and Wyeth appealed to the U.S. Supreme Court.

Justice John Paul Stevens, writing for the 6-3 majority, held that federal law does not preempt Levine's claims that Phenergan's label did not contain an adequate warning about the IV-push method of administration.

The majority rejected Wyeth's argument that Levine's state law claims are preempted because it is impossible for Wyeth to comply with both the state law duties underlying those claims and its federal labeling duties. Although a manufacturer generally may change a drug label only after the FDA approves a supplemental application, the agency's "changes being affected" (CBE) regulation permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety. Pursuant to the CBE regulation, Wyeth could have unilaterally added a stronger warning about IV-push administration. There was no evidence that the FDA would have rejected such a labeling change. Wyeth's reading of the CBE regulation and its broad assertion that unilaterally changing the Phenergan label would have violated federal law governing unauthorized distribution and misbranding of drugs was based on a misunderstanding that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. The FDCA and the FDA's regulations mandate that the manufacturer bears responsibility for the content of its label at all times.

Wyeth argued that requiring it to comply with a state law duty to provide a stronger warning interferes with Congress' purpose of entrusting an expert agency with drug labeling decisions was meritless because it relied on an untenable interpretation of

congressional intent and an overbroad view of an agency's authority to preempt state law. The history of the FDCA shows that Congress did not intend to preempt state law failure to warn actions. In advancing the argument that the FDA must be presumed to have established a specific labeling standard that leaves no room for different state law judgments, Wyeth relies not on any statement by Congress, but on the 2006 preamble to FDA regulations declaring that state law failure-to-warn claims threaten the FDA's statutorily prescribed role. Although an agency regulation with the force of law can preempt conflicting state requirements, this case involves no such regulation. It was merely an agency's assertion that state law is an obstacle to achieving its statutory objectives. Where Congress has not authorized a federal agency to preempt state law directly, the weight the court accords the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness. The court cited to *Skidmore v. Swift & Co.,* 323 U.S. 134 (1944) where the court disregarded the policy rulings of an administration of an agency. Under this standard, the FDA's 2006 preamble did not merit deference. It is inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity for comment on the preemption question. Moreover, it is at odds with the available evidence of Congress' purposes; and it reverses the FDA's own longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation.

The very different rulings in *Riegel* and *Wyeth* demonstrate the importance the Court places on statutory express preemption language. While counsel for the manufacturers believe that any FDA approved product ought to be preempted, there

appears to be a victory for the advocates of injured parties, at least as to brand name drugs. While *Riegel v. Medtronic* and *Wyeth v. Levine* were percolating up the appellate pipeline, another drug case was also moving in the same direction, but came to a halt after *Wyeth v. Levine* was issued.

***Colacicco v. Apotex Inc., et al.*, 521 F.3d 253 (3d Cir. 2008)**

While *Wyeth v. Levine* was moving up the appellate pipeline, another drug case out of the Third Circuit was also percolating up to the Supreme Court – *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008). *Colacicco* began as two separate lawsuits against drug manufacturers brought by survivors of individuals who had committed suicide after taking certain antidepressant medications. In one case, a husband sued drug maker GlaxoSmithKline under state common law, alleging that his wife's suicide resulted from the company's failure to warn of the increased risk of suicidal behavior linked to the company Paxil® antidepressant drug. The second case involved a suit brought by a daughter who sued drug maker Pfizer Inc. following her father's suicide after he took that company's Zoloft® antidepressant. She alleged that Pfizer violated state product liability and consumer fraud statutes by selling Zoloft without warnings regarding an increased risk of suicide.

The drug companies moved to dismiss the state claims in both cases, arguing that state remedies were preempted as a result of the FDA's drug-labeling regulatory scheme. Essentially the companies argued that without preemption, drug makers would be subject to considerable liability under various state laws, in direct conflict with Congress's desire for a uniform drug-labeling regulatory system. The defendants claimed that because the

FDA had specifically rejected adding a warning of increased suicide risk in adults to the drugs' labels, it was impossible to comply with both the FDA scheme as well as state laws that permitted a liability action to proceed even when federal labeling laws were satisfied.

Plaintiffs, on the other hand, contended that there exists a presumption against preemption under federal law, that Congress never intended the federal law at issue to preempt state laws permitting individual recoveries for death and injury, and that the drug makers could comply with both federal and state law. Plaintiffs pointed to a federal regulation that permits and encourages manufacturers to strengthen their labels without prior FDA approval.

The two trial courts came to different conclusions: the federal district court in Pennsylvania sided with GlaxoSmithKline and dismissed the plaintiff's complaint based on preemption of state common law claims, while the federal district court in New Jersey denied Pfizer's motion for summary judgment that was based on the same preemption argument. The U.S. Court of Appeals for the Third Circuit consolidated the two cases to address their common question: whether state law claims for injuries arising from regulated pharmaceutical products are preempted as a result of FDA regulatory authority.

In a 2-to-1 opinion, the Third Circuit Court agreed with the drug manufacturers and held that the plaintiffs' state law claims conflicted with federal law and, therefore, should be dismissed. The appeals court relied heavily on the fact that the FDA had, on numerous occasions, publicly rejected adding a warning to the drug labels of these types of antidepressants. In its view, this amounted to conflict preemption, as this regulatory

action could not be reconciled with any attendant state law claims that the label should have been supplemented by additional warnings. The court noted that these legal actions, whether arising under common law or state statutes, stand in the way of achieving federal objectives.

The court's rationale stems from the fact that under the Federal Food, Drug and Cosmetic Act, the FDA has the authority and obligation to prohibit false or misleading labeling—including labels that are considered too alarmist because they restrict potential safe use. Thus, a state law obligation to enhance a drug label regarding risks would directly conflict "with the FDA's oft-repeated conclusion" to the contrary. The court rejected plaintiffs' arguments that anything less than an explicit FDA rejection of a company's request to add a contested warning to the label—which was not the case here—should not be treated as preemptive. Indeed, the FDA itself, in its amicus brief on behalf of the drug companies, stated that the basis for federal conflict preemption was not the federal labeling scheme itself, but rather the agency's repeated public statements that insufficient evidence existed of this association between the drug and suicide. In fact, the court did narrow its holding only to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires. In a similar case, however, the U.S. Supreme Court will decide whether the FDA's mere approval of drug labeling is sufficient to preempt state-based legal claims alleging that the label failed to warn of a given danger.

The majority in *Colacicco* summarily rejected the arguments of the plaintiffs and the dissenting judge, who claimed that a labeling regulation specifically permitting drug

makers to augment and strengthen warnings without prior FDA approval—which the defendants did not utilize—proved that state law should be viewed as complementary to FDA regulations. The dissent claimed that clear congressional intent—that is, express preemption—should be required to preempt "failure-to-warn claims [that] stand near the heart of the states' police powers over matters of health and safety," and argued that even the majority's narrowed holding "threatens the institutional framework we have for balancing safety and efficacy in the pharmaceutical industry while compensating victims of wrongful injuries."

The majority opinion in *Colacicco v. Apotex, Inc.* constituted "silent tort reform" or "backdoor federalization," through the use of the preemption doctrine. For a long time FDA regulatory efforts co-existed with state court injury lawsuits. Indeed, there could have been an indirect benefit of state-based litigation uncovering risks that may not be apparent to the FDA during the drug approval process. The FDA viewed this "feedback loop" as helpful. It enabled the agency to do its job, particularly given the absence of post-marketing oversight resources. Permitting state law remedies allowed federal policy-making to avoid the "harsh implications" of eliminating "judicial recourse for consumers injured by defective" drugs.

Wyeth v. Levine and *Colacicco v. Apotex* came at a time when the public trust in the FDA's ability to adequately protect the public's health was at an all-time low. Indeed, public confidence in the FDA fell from 80% in the 1970s to a mere 36% in 2006. Examples of perceived FDA failures include the withdrawal of Merck & Co.'s Vioxx® drug and the adulteration of the country's supply of heparin, a blood-thinning drug.

Some have argued that the FDA should be restructured or redesign its official mission. While the 2007 FDA Amendments Act provided additional funds for post-approval oversight, the FDA can always use more resources to protect the population from dangers, particularly in the case of drugs that already are on the market.

FDA scientists and doctors agree that problems persist—70% believe that the FDA lacks sufficient resources to protect the public's health, and two-thirds worry that the agency is not adequately monitoring the safety of drugs once they are on the market. The FDA's Office of Drug Safety, which is charged with post-marketing surveillance efforts, has only 100 professional employees to monitor the continued safety of more than 11,000 approved drugs.

This context raises substantial questions about the wisdom of preemption policy. State laws that create remedies for injury may give pharmaceutical manufacturers a monetary incentive to stay abreast of health risks associated with their products and take corrective action. Federal preemption of state failure-to-warn claims effectively removes this incentive. Furthermore, litigation may uncover vital information that exists only within the control of manufacturers and is otherwise unavailable to the FDA. The U.S. Supreme Court has sided with the market forces favoring preemption and has obliterated state public health powers.

However, FDA policy has maintained that its ability to protect the public's health is severely threatened by state tort claims because these state actions could result in label changes not approved by the FDA and thus render drugs misbranded. The agency has advanced this policy in several *amicus* briefs filed in the leading cases discussed herein.

Five days after the Supreme Court decision in *Wyeth v. Levine*, 555 U.S. 555 (March 4, 2009), the Supreme Court granted certiorari to *Colacicco*, but simultaneously remanded it back to the Third Circuit for reconsideration consistent with *Wyeth v. Levine*, 1295 S. Ct. 1578 (March 9, 2009). It is interesting to note that on remand, the U.S. government withdrew its amicus brief and the cases settled.

Chapter VIII

The Vaccine Solution and

The National Childhood Vaccine Injury Act of 1986 (NCVIA)

History

The National Childhood Vaccine Injury Act of 1986 (NCVIA) 42 USC § 360aa-22(b)(1) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflected injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent. The Vaccine Court must resolve the case by a specified deadline. Thereafter, the claimant can decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose.

The Purpose of National Vaccine Injury Compensation Program

The purpose of National Vaccine Injury Compensation Program is to ensure availability of childhood vaccines and to provide fair and simple compensation to those injured by such vaccines. It is not to provide coverage of any vaccine-injured persons, including adults injured by non-childhood vaccines. *Charette v. Secretary of Dept. of Health and Human Services,* 33 Fed. Cl. 488 (1995).

The important federal purpose of the NCVIA was to free manufacturers from the specter of large, uncertain tort liability, which was to keep prices fairly low and to keep manufacturers in the vaccine market. *Schafer v. American Cyanamid Co*., 20 F.3d 1 (1st Circ. 1994). Congress enacted the NCVIA to stabilize the vaccine market and expedite compensation to injured parties after complaints mounted regarding the inefficiencies and costs borne by both injured consumers and vaccine manufacturers under the previous civil tort compensation regime. *See, Sebelius v. Cloer*, 133 S.Ct. 1886 (2013).

The NCVIA limits a manufacturer's liability for design defects regardless of the cause of action. *Bruesewitz v. Wyeth, Inc*., 508 F.Supp.2d 430 (2007), affirmed 561 F.3d 233 (3rd Circ. [PA] 2009), certiorari granted 130 S.Ct. 1734, affirmed 131 S.Ct. 1068 (2011).

The Vaccine Program in the Office of Special Masters

The National Vaccine Injury Compensation Program ("Vaccine Program") comprises Part 2 of the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), See Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified as amended at 42 U.S.C.A. § §300aa-1 through -34. The Vaccine Act became effective October 1, 1988. It establishes the Vaccine Program as a no-fault compensation scheme whereby persons allegedly suffering injury or death as a result of the administration of certain compulsory childhood vaccines may petition the federal government for monetary damages. Congress intended that the Vaccine Program provide individuals a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation.

All vaccine claims are managed and adjudicated by the congressionally-created Office of Special masters, which currently consists of one chief special master and seven associate special masters who are appointed to serve for four year terms. The Office of Special Masters is established within the U.S. Court of Federal Claims, which appoints and removes the special masters and to which the special masters' decisions are appealed. The special master has two primary functions: case management, which involves determining the types of proceedings necessary for presenting the relevant evidence and ultimately weighing the evidence in rendering a final, enforceable decision. In each case, the special master actively and frequently interacts with the parties, generally through counsel representing petitioner and a Department of Justice attorney representing the Secretary of Health and Human Services, to ensure that the case progresses effectively and efficiently. The parties are also given several opportunities early on in the case to ask questions, raise concerns, discuss generally how the system works and, if appropriate, learn the special master's tentative conclusions and findings. Throughout the entire process, the special masters make every effort to balance Congress's vision of streamlined proceedings with the parties' right to a fair opportunity to present their cases. The special masters' rules, orders and Guidelines for Practice Under the National Vaccine Injury Compensation Program provide guidance on how to present claims. www.uscfc.uscourts.gov/vaccine-programoffice-special-masters last visited January 20, 2014.

Bye Bye *Bruesewitz* – *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (Feb. 22, 2011)

Hannah Bruesewitz's parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus and pertussis (DTP) vaccine manufactured by Lederle Laboratories, which was owned by Wyeth at the time of suit. After the Court of Federal Claims denied their claim, they elected to reject the unfavorable judgment and filed suit in the Pennsylvania Court of Common Pleas, alleging that the defective design of the DTP vaccine caused Hannah's disabilities, and that the manufacturer was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth removed the suit to the U.S. District Court for the Eastern District of Pennsylvania. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. § 300aa-22(b)(1)), which provides that "[n]o 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." The Third Circuit affirmed the U.S. District Court, 561 F.3d 233 (3d Cir. Pa 2009). The plaintiffs appealed to the U.S. Supreme Court, which granted certiorari.

Justice Scalia delivered the 6-2 opinion of the court, in which Chief Justice Roberts and Justices Kennedy, Thomas, Breyer and Alito joined. Justice Breyer filed a

concurring opinion. Justice Sotomayor filed a dissenting opinion, in which Justice Ginsberg joined. Justice Kagan took no part in the consideration or decision of the case because she was the Solicitor General, who represented the United States Food and Drug Administration, which had filed an amicus brief in *Bruesewitz.*

Justice Scalia characterized the federal scheme as a *quid pro quo,* where manufacturers enjoy significant tort-liability protections, and injured persons have a source of some compensation. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects. The court held the NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Specifically, it found that Section 300aa-22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would not work.

A vaccine side effect could be avoidable by use of a different vaccine not containing the harmful element. The language of the provision suggests the design is not subject to question in a tort action. The court found that the statute established a complete defense where there are safe manufacturing processes and warnings in regard to the particular design, but nonetheless the harm is unavoidable. This conclusion is supported by the fact that, although products liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only defective manufacture and inadequate warnings. Justice

Scalia reasons that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168.

Justice Scalia interpreted the text of the NCVIA in a discriminating manner. He held that contrary to petitioners' argument, there is no reason to believe that § 300aa-22(b) (1)'s term "unavoidable" is a term of art incorporating the Restatement (Second) of Torts §402A, Comment k, which exempts from strict liability "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment k attach specific significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. He continues that the canon against superfluity does not undermine this court's interpretation because petitioners' competing interpretation has superfluity problems of its own.

The structure of the NCVIA and of vaccine regulation in general reinforces what § 300aa-22(b) (1)'s text suggests. Design defects do not merit a single mention in the Act or in FDA regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandate leads to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two

beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market.

But there was no compensation for Hannah Bruesewitz from either the NCVIA fund or the common law tort system. Both the Court of Federal Claims and the U.S. District Court found that her seizures started shortly after receiving the third dose of the DPT vaccine, at age 18 months. The seizures, which she continued throughout her life, were originally on the Table of Injuries to be compensated, but was removed shortly before her claim was filed. Moreover, after giving the manufacturer the benefit of FDA approval of the vaccine. Bruesewitz was administered the vaccine from the same vaccine lot, which produced 65 adverse events reports to the FDA and CDC, which included 39 emergency room visits, 6 hospitalizations and 2 deaths. Nonetheless, the U.S. District Court found that those adverse events were not conclusively linked to a "hot lot" or highly virulent lot of vaccine, but only that it had the "potential" to be a hot lot (emphasis added).

At the 2011 Association of American Law School Annual Meeting, the Section on Torts and Compensation Schemes held a symposium entitled *Vaccines and Drugs: A Brave New World*. The speaker at the symposium published their remarks and papers in

the Indiana Health Law Review in that same year. Leading the symposium was Professor Catherine M. Sharkey of the New York University School of Law. As one of the nation's leading authorities on federal preemption in the realm of products liability, she outlines how the proliferation of vaccine and pharmaceutical drug-related injuries challenges the conception of how the tort system can best meet its compensatory and regulatory aims in the 21st century.

Congress enacted the National Childhood Vaccine Injury Act (NCVIA) of 1986 by establishing a no-fault compensation scheme for vaccine related injuries. Pub. L. No. 99-660, 100 Stat. 3756 (codified as amended at 42 USC § 300aa-1 to 34 (2013). In 2009 the U.S. Supreme Court held in *Wyeth v. Levine,* 555 U.S. 555 (2009), that failure to warn claims on a brand name drug were not preempted by the FDA's preamble to the 2006 FDCA Amendments. However, the U.S. Supreme Court held in *Bruesewitz v. Wyeth* in 2011 that design defect claims against vaccine manufacturers were preempted due to the express language contained in NCVIA. 131 S.Ct. 1068 (2011).

Professor Robert Rabin of Stanford Law School, in his paper entitled *The Vaccine No-Fault Act: An Overview,* lead off the discussion. His remarks were published at 8 Ind. Health L. Rev. 267 (2011). He began by discussing the most commonly recognized no-fault schemes – workers' compensation programs and automobile no-fault plans, both of which had their origins in what he categorizes as a "proactive industry effort in the 1980s to avoid the perception of unpredictability that had generated considerable criticism of vaccine-related tort claims. *Id*. at 269. Professor Rabin points out that when the NCVIA was enacted in 1986, there was only one manufacturer of the polio vaccine,

one of the MMR (mumps, measles and rubella) vaccine and just two manufacturers for the DTP (diphtheria, tetanus and pertussis) vaccine. He asserts that those manufacturers were threatening to withdraw from the vaccine market due to their exposure to lawsuit judgments from persons who sustained injuries allegedly caused by the vaccines which are mandated for children attending most schools by the health departments of the various states. HR Rep. No. 99-908, reprinted in 1986 USCCAN at 6361.

While the NCVIA does not eliminate all tort claims, it diminishes its appeal. Claimants must now first file with the Vaccine Court, which established schedules or statutory indexes of vaccines and recognized side effects from such vaccines. But no damage awards may be made for "unavoidable injuries" and no punitive damages may be had. If they are successful and receive an award, the claimant may accept or reject the award or appeal the award or rejection to the U.S. Court of Federal Claims and also ultimately to the U.S. Court of Appeals for the Federal Circuit, and potentially to the U.S. Supreme Court.

Claimants who are dismissed or reject the awards of the Vaccine Court may commence a tort action in either state or federal court. Where such suits may be appealed to the appropriate Courts of Appeal in either the state or federal courts and, if granted, certiorari to the U.S. Supreme Court as was done in *Bruesewitz v. Wyeth. Id*. Where the cases are "off-table" no presumption operates.

Professor Mary J. Davis of the University of Kentucky College of Law, presented an article entitled The Case Against Preemption: Vaccines and Uncertainty, *8 Ind. Health Law Rev. 291* (2011). She begins by summarizing the general views of

proponents of federal preemption of state law damages actions that "federal regulatory bodies not common law juries, have the expertise to decide the correct balance of risk and benefit that regulated industries should be permitted to pose to the general public." *Id.* at 293. She continues that "once a federal agency has decided through appropriate regulatory structure that a certain drug is approved or a certain product design is permissible, state juries should not be permitted to second-guess that decision. Federal preemption must operate to defeat the inconsistent actions of state juries because they have neither the expertise to understand complex factors at issue in such a balancing act, nor the ability to see beyond the individual injured plaintiff…" *Id.*

Professor Davis recognizes that if the foregoing reasoning has come to be the mainstream of thought manifested in the recent decisions from the Supreme Court, she then presents the question of whether common law tort doctrines should continue to play a role in the regulatory framework. She concludes that it should and references the historical role that the states have played in regulatory public health and safety.

She points to Judge Guido Calabresi of the U.S. Court of Appeals for the Second Circuit, who is also a prominent torts scholar. He gave his views on this topic in Tort Law in the Shadow of Agency Preemption at a New York University Symposium, *65 N.Y.U. Ann. Surv. Am.L. 435* (2009). Judge Calabresi outlined the core issues in tort law in a world increasingly dominated by administrative regulatory action as follows:

> (1) Does national centralized decision-making, as between safety and accidents – and as to who bears the cost of safety or the cost of accident – work better than local, diverse, and diffuse decision-making?;

> (2) What are the benefits of allowing different local decisions? How often in America do we have and want to have different values, different notions of what life is worthy, of what things are worth?; and
>
> (3) What does the difference between localized and centralize decision-making tell us about who bears the burden of these decisions? *Id.*

Professor Davis follows on by framing the ultimate issue in preemption cases by asking, "[H]ow courts should respond to the evolution of scientific understanding of risk in determining who bears the cost of that risk when assessing congressional intent to preempt traditional state common law." *Id*. at 295. She answers that question by first outlining current preemption doctrine and its interaction between federal regulation and state law as applied to manufacturers. She then demonstrates how that interaction applied to vaccine injury litigation by discussing the Supreme Court's preemption of recovery in *Bruesewitz v. Wyeth*, Inc. She concludes by responding to Judge Calabresi's question by building upon the preemption analysis in *Bruesewitz* to encourage a narrow application of the scope of preemption doctrine, particularly in the case of pharmaceuticals and medical devices." *Id*. at 296.

Professor James R. Copeland is a director of the Center for Legal Policy at the Manhattan Institute. In his presentation Administrative Compensation for Pharmaceutical and Vaccine Related Injuries, *8 Ind. Health L. Rev. 275* (2011), he espouses the benefits of drugs and vaccines. He recommends that since manufacturers spend upwards of one billion dollars to conduct research, development, trials and FDA approvals, those manufacturers should have some type of assurance that once the FDA approves the product for marketing that all their profits should not be spent on defending

lawsuits around the nation and paying out exorbitant jury verdicts. He suggests that once the FDA pharmaceutical and medical devices go to market, an administrative system rather than the tort-jury system should be available to compensate those who are injured by FDA approved products.

Copeland's proposal would create a table of payouts for adverse outcomes categorized by type of injury so that there will be a consistent and predictable measure of value of loss. Under Copeland's proposal known side-effects, which are disclosed in the warning labels provided the prescribing physicians as the learned intermediaries, would not be compensable. He asserts that it is the duty of the physician to disclose those risks to the patient, who can refuse to take the drug or receive the device and the risks associated with it. Physicians would still be liable for misusing the product under typical malpractice causes of actions.

General causation would need to be demonstrated or acknowledged by the administrative court that the product can cause the injury complained of by the claimant. The claimant would then be left to demonstrate that the product did actually cause the plaintiff's injury. I agree that a pure no-fault theory regardless of known risks should not be compensable in general. However, the nature of the warnings should still be considered to ascertain whether there was an adequate warning to the learned intermediaries of the potential side effects, which should be relayed to their patients. Otherwise, all of the risk is left upon the prescribing physician, who could be sued for an inadequate warning label, with no accountability upon the manufacturer or liability upon the fund.

Chapter IX

The Generic Drug Cases

The Hatch-Waxman Act

In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (98 Stat. 1585), popularly known as the "Hatch-Waxman Act." Under Hatch-Waxman, a generic drug may be approved without the same level of clinical testing required for approval of a new brand name drug, provided the generic drug is identical to the already-approved brand name drug in several key respects.

First, the proposed generic drug must be chemically equivalent to the approved brand name drug: it must have the same "active ingredients," "route of administration," "dosage form," and "strength" as its brand name counterpart (21 U.S.C. §§ 355(j)(2)(A)(99) and (iii)). Second, a proposed generic drug must be "bioequivalent" to an approved brand name drug 21 USC § 355(j) (2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand name drug (§ 355(j) (8)(B)). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the brand name drug." § 355(j) (2)(A)(v).

Once a drug—whether generic or brand name—is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the

approved application." 21 CFR § 314.70(b)(2)(i). Generic manufacturers are also prohibited from making any unilateral changes to a drug's label. Approval for a generic drug may be withdrawn if the generic drug's label "is no longer consistent with that for the brand name drug". See 21 CFR §§ 314.94(a)(8)(iii), 314.150(b)(10).

***PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).**

Respondents Gladys Mensing and Julie Demahy were prescribed Reglan in 2001 and 2002, but both received the generic drug from their pharmacists. After taking the drug as prescribed for several years, both developed tardive dyskinesia, a disease characterized by repetitive, involuntary, purposeless movements. In separate state court tort actions, they sued petitioners, the generic drug manufacturers that produced the metoclopramide they took. Each respondent alleged, *inter alia*, that long-term metoclopramide use caused her disorder and that the manufacturers were liable under state tort law for failing to provide adequate warning labels. In both suits, the manufacturers urged that federal statutes and FDA regulations preempted the state tort claims by requiring the same safety and efficacy labeling for generic metoclopramide as was mandated at the time for Reglan. The Fifth and Eighth Circuits rejected these arguments, holding that respondents' claims were not preempted.

Five years after the FDA first approved metoclopramide, a drug commonly used to treat digestive tract problems, under the brand name Reglan, generic manufacturers such as petitioners also began producing the drug. Because of accumulating evidence that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological

disorder, warning labels for the drug have been strengthened and clarified several times, most recently in 2009.

Justice Thomas delivered the 5-4 opinion of the court, except as to Part III-B-2. Chief Justice Roberts and Justices Scalia and Alito joined that opinion in full and Justice Kennedy joined as to all but Part III-B-2. Justice Sotomayor filed a dissenting opinion, in which Justices Ginsburg, Breyer and Kagan joined.

Justice Thomas concluded that federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, these state claims. The court reversed the judgment and remanded the cases to the Fifth and Eighth Circuits respectively. Justice Thomas held that because preemption analysis requires a comparison between federal and state law, the court begins by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers.

Indeed, state tort law requires a manufacturer that is, or should be, aware of its drug's danger to label it in a way that renders it reasonably safe. Respondents pleaded that the manufacturers knew, or should have known, both that the long-term use of their products carried a high risk of tardive dyskinesia and that their labels did not adequately warn of that risk. Taking these allegations as true, the state law duty required the manufacturers to use a different, stronger label than the one they actually used.

On the other hand, federal drug regulations, as interpreted by the FDA, prevented the manufacturers from independently changing their generic drugs' safety labels. A manufacturer seeking federal approval to market a new drug must prove that it is safe and

effective and that the proposed label is accurate and adequate. Although the same rules originally applied to all drugs, the 1984 Hatch-Waxman Amendments allows a generic drug manufacturer to gain FDA approval simply by showing that its drug is equivalent to an already-approved brand name drug, and that the safety and efficacy labeling proposed for its drug is the same as that approved for the brand name drug. Respondents contend that federal law nevertheless provides avenues through which the manufacturers could have altered their metoclopramide labels in time to prevent the injuries here. These include: (1) the FDA's "changes-being-effected" (CBE) process, which permits drug manufacturers, without preapproval, to add or strengthen a warning label; and (2) sending "Dear Doctor" letters providing additional warnings to prescribing physicians and other healthcare professionals.

However, the FDA denies that the manufacturers could have used either of these processes to unilaterally strengthen their warning labels. The Court defers to the FDA's views because they are not plainly erroneous or inconsistent with the regulations, and there is no other reason to doubt that they reflect the FDA's fair and considered judgment, citing to *Auer v. Robbins*, 519 U.S. 452, 461, 462. Assuming, without deciding, that the FDA is correct that federal law nevertheless required the manufacturers to ask for the agency's assistance in convincing the brand name manufacturer to adopt a stronger label, the court turns to the preemption question.

Where state and federal law directly conflict, state law must give way. (See *Wyeth v. Levine*, 555 U.S. 555, 583.) Such a conflict exists where it is "impossible for a

private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

The Court found impossibility in this case. If the manufacturers had independently changed their labels to satisfy their state law duty to attach a safer label to their generic metoclopramide, they would have violated the federal requirements that generic drug labels be the same as the corresponding brand name drug labels. Thus, it was impossible for them to comply with both state and federal law. State law did not require communication with the FDA about the possibility of a safer label.

The Court rejected the argument that the manufacturers' preemption defense fails because they failed to ask the FDA for help in changing the corresponding brand name label. The proper question for "impossibility" analysis is whether the private party could independently do under federal law what state law requires of it. See *Wyeth, supra*, at 573. Accepting respondents' argument would render conflict preemption largely meaningless by making most conflicts between state and federal law illusory. In these cases, it is possible that, had the manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. But it is also possible that they could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them, or persuaded the FDA to rewrite its generic drug regulations entirely, or convinced Congress to amend the Hatch-Waxman Amendments. But it is unclear when, outside of express preemption, the Supremacy Clause of the U.S. Constitution would have any force. The Supremacy Clause read alone does not allow state intervention where federal law speaks expressly or, some would argue impliedly. It

is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes.

The Court held in *Wyeth v. Levine* that a state tort action against a brand name drug manufacturer for failure to provide an adequate warning label was not preempted because it was possible for the manufacturer to comply with both state and federal law under the FDA's CBE regulation. 555 U.S. at 572-573. The federal statutes and regulations that apply to brand name drug manufacturers differ, by Congress' design, from those applicable to generic drug manufacturers. Different federal statutes and regulations may lead to different preemption results. The Supreme Court will not distort the Supremacy Clause in order to create similar preemption across a dissimilar statutory scheme. But the High Court pointed out that Congress and the FDA retain the authority to change the law and regulations if they so desire.

The *Mensing* majority's decision held that state-law claims based on the failure to provide adequate warning labels for generic manufacturers were preempted. Many courts have taken a broad reading of the concept of labeling to find preemption of other generic drug claims, including "negligent continuing to sell" claims; claims alleging negligent concealment of important safety information; negligent failure to test and negligent failure to inspect claims; claims based on the failure to monitor the safety of drugs and report findings to the FDA.

Legislation Proposed in Response to *PLIVA v. Mensing*

After acknowledging the "unfortunate hand" dealt to the *Mensing* plaintiffs, Justice Thomas closed with his observation that "Congress and the FDA retain the authority to change the law and regulations if they so desire." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

Consequently, on April 19, 2012, Representative Chris Van Hollen introduced H.R. 4384, the Patient Safety & Drug Labeling Improvement Act. The bill would allow generic drug manufacturers to independently initiate labeling changes through the Changes Being Effected (CBE) process in the same manner the FDA allows brand name manufacturers to do so. It has not come out of committee and has never been passed by the Congress. Congressman Van Hollen asserted that "it is illogical and unconscionable that a victim of an undisclosed risk associated with a name brand drug has redress to sue, while one injured by that same risk from the same compound in generic form does not."

***Mutual Pharmaceutical Co. v. Karen L. Bartlett*, 133 S.Ct. 2466 (2013)**

In 2013 the Supreme Court revisited the issue of generic drugs in *Mutual Pharmaceuticals Co. v. Bartlett*, 133 S.Ct. 2466 (2013). In 2004, respondent Karen L. Bartlett was prescribed Clinoril, the brand name version of the nonsteroidal anti-inflammatory drug (NSAID) sulindac, for shoulder pain. However, her pharmacist dispensed a generic form of sulindac manufactured by petitioner Mutual Pharmaceutical

Co. Respondent soon developed an acute case of toxic epidermal necrolysis. She is now severely disfigured, has physical disabilities, and is nearly blind.

At the time of the prescription, sulindac's label did not specifically refer to toxic epidermal necrolysis. By 2005, however, the FDA had recommended changing all NSAID labeling to contain a more explicit toxic epidermal necrolysis warning. Respondent sued Mutual in New Hampshire state court, and Mutual removed the case to federal court. A jury found Mutual liable on respondent's design defect claim and awarded her over $21 million. The First Circuit affirmed that judgment. It found that neither the FDCA nor the FDA's regulations preempted respondent's design-defect claim. It distinguished *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), in which the court held that failure-to-warn claims against generic manufacturers are preempted by the FDCA's prohibition on changes to generic drug labels—by arguing that generic manufacturers facing design-defect claims could comply with both federal and state law simply by choosing not to sell the drug at all.

The FDCA requires manufacturers to gain FDA approval before marketing any brand name or generic drug in interstate commerce. 21 U.S.C. § 355(a). Once a drug is approved, a manufacturer is prohibited from making any changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i). Generic manufacturers are also prohibited from making any unilateral changes to a drug's label. See §§ 314.94(a) (8) (iii), 314. 150(b) (10).

Justice Samuel Alito writing for the 5-4 majority held that state law design-defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA v. Mensing,* 131 S. Ct. 2567 (2011). The majority held that under the Supremacy Clause, state laws that conflict with federal law are "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Even in the absence of an express preemption provision, a state law may be impliedly preempted where it is "impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co*., 496 U.S. 72, 79 (1990). Here, it was impossible for Mutual to comply with both its federal law duty not to alter sulindac's label or composition and its state law duty to either strengthen the warnings on sulindac's label or change sulindac's design.

The court specifically found that New Hampshire's design-defect claim of action imposes affirmative duties on manufacturers, including a "duty to design their products reasonably safely for the uses which they can foresee." *Thibault v. Sears, Roebuck & Co*., 395 A.2d 843, 847 (1978). To assess whether a product's design is "unreasonably dangerous to the user" the New Hampshire Supreme Court employs a "risk-utility approach," which asks whether the drug's danger outweighs the product's utility. *Vautour v. Body Masters Sports Industries, Inc*., 784 A.2d 1178, (N.H. 2001) at 1182. The court has repeatedly identified three factors as germane to that inquiry: "the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses." *Id.*

Increasing a drug's "usefulness" or reducing its "risk of danger" would require redesigning the drug, since those factors are direct results of a drug's chemical design and active ingredients. Here, however, redesign was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as its brand name drug equivalent. Second, because of sulindac's simple composition, the drug is chemically incapable of being redesigned. Therefore, because redesign was impossible, Mutual could only ameliorate sulindac's "risk-utility" profile by strengthening its warnings. Thus, New Hampshire's law ultimately required Mutual to change sulindac's labeling.

But *PLIVA* makes clear that federal law prevents generic drug manufacturers from changing their labels. See, 131 S.Ct. 2567. Accordingly, Mutual was prohibited from taking the remedial action required to avoid liability under New Hampshire law.

When federal law forbids an action required by state law, the state law is "without effect." *Maryland, supra*, at 746. Because it was impossible for Mutual to comply with both state and federal law, New Hampshire's warning-based design-defect cause of action is preempted with respect to FDA-approved drugs sold in interstate commerce.

The First Circuit rationale was that Mutual could escape the impossibility of complying with both its federal and state law duties by choosing to stop selling sulindac. That is incompatible with this court's preemption cases, which have presumed that an actor seeking to satisfy both federal and state law obligations is not required to cease acting altogether. Like Justice Thomas in *PLIVA*, Justice Alito recognized the horrible

injuries sustained by Karen Bartlett and once again stated that it was the responsibility of Congress to take corrective action, if it desired to do so.

As a result of the decisions in *Wyeth v. Levine* and *PLIVA v. Mensing*, an individual can bring a product liability action for failure to warn against an NDA holder, but generally not an ANDA holder. Therefore, access to the courts is dependent on whether an individual is dispensed a brand name or generic drug. The *Mensing* decision alters the incentives for generic drug manufacturers to comply with current requirements to conduct robust post marketing surveillance, evaluation, and reporting, and to ensure that the labeling for their drugs is accurate and up to date.

Proposed FDA Regulation Allowing Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

On November 8, 2013, the Director of the FDA's Center for Drug Evaluation and Research issued the following statement with reference to generic drugs:

> FDA is taking a step today that is intended to improve the communication of important drug safety information about generic drugs to both prescribers and patients.
>
> All drug manufacturers are required to keep close tabs on their drugs once they go to market, reviewing all reports of adverse events involving their drug and reporting these findings to FDA.
>
> But currently, only brand name manufacturers are able to independently update and promptly distribute revised drug safety information, also called labeling, and they can distribute that information before FDA has reviewed or approved the change. These updates, which are submitted in changes being effected supplements, ensure that this important safety information gets to the public as quickly as possible.

> Right now generic companies, who are responsible for over 80% of the prescription drugs dispensed to patients, aren't able to revise their drug safety information as quickly as the brand name. They must provide supporting information to FDA, which then determines whether safety information for both the brand and generic drugs should be revised before updates can occur.
>
> Today, FDA is issuing a proposed rule that would allow generic drug manufacturers to independently update and promptly distribute revised product labeling – just like brand name manufacturers – before FDA reviews or approves the change.
>
> Empowering generic drug companies to update their own drug safety information is intended to provide them the incentive to more actively participate with FDA in ensuring the timeliness, accuracy and completeness of this information.
>
> The brand manufacturer would be expected to consider the information provided by the generic drug manufacturer as part of its review and evaluation of adverse drug experience information for its drug.
>
> And to make sure that the drug safety information updates from both generic and brand name companies are readily available to health care professionals and the public, FDA plans to post these updates on its website.
>
> Faster safety updates and easier access to this information should be a win-win for all involved.

On November 13, 2013, the FDA published in *The Federal Register*, the daily journal of the United States government, the proposed rule entitled "Supplement Applications Proposing Labeling Changes for Approved Drugs and Biological Products." The summary stated:

> The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulations to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. The proposed ruled would create parity among application holders

> with respect to such labeling changes by permitting holders of abbreviated new drug applications (ANDAs) to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug (RLD) upon submission to FDA of a "changes being effected" (CBE-0) supplement. The proposed rule describes the process by which information regarding a CBE-0 labeling supplement submitted by a new drug application (NDA) holder, an ANDA holder, or a biologics license application (BLA) holder would be made publicly available during FDA's review of the labeling change and clarifies requirements for all ANDA holders to submit conforming labeling revisions after FDA has taken an action on the NDA or ANDA holder's CBE-0 labeling supplement. The proposed rule also would amend the regulations to allow submission of a CBE-0 labeling supplement for certain changes to the "Highlights of Prescribing information" for drug products with labeling in the "Physician Labeling Rule" (PLR) format.

The FDA's proposed change to the regulations to expressly provide that ANDA holders may distribute revised labeling that differs from the RLD upon submission of a CBE-0 supplement to FDA. FDA's proposed revisions to its regulations would create parity between NDA holders and ANDA holders with respect to submission of CBE-0 supplements for safety-related labeling changes based on newly acquired information. This proposal is also intended to ensure that generic drug companies actively participate with FDA in ensuring the timeliness, accuracy, and completeness of drug safety labeling in accordance with current regulatory requirements. If this proposed regulatory change is adopted, it may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs. Comments on the proposed rule were to be submitted either electronic or in writing by January 13, 2014.

This proposed rule opens the door to requiring generic manufacturers to sit in the same position for labeling purposes and product liability purposes as the brand name drug

manufacturer. The proposed CBE rule will require the generic manufacturer to add or strengthen information about dosage, abuse, dependence, psychological effect, or over dosage, to increase the safe use of the drug product, and to delete false, misleading, or unsupported indications for use or claims for effectiveness. It is precisely these types of claims that the courts have recognized that generic manufacturers cannot make under the current law and which serve as the basis for dismissing thousands of product liability lawsuits.

Under the proposed rule a generic manufacturer must make labeling changes when new information becomes available that causes information in labeling to be inaccurate. A drug is misbranded in violation of the FDCA when its labeling is false or misleading, or does not provide adequate directions for use and adequate warnings.

To implement the new rule, the FDA will now require generic manufacturers to develop written procedures for the surveillance, receipt, evaluation, and reporting of post marketing adverse drug experiences to FDA. Application holders must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers, and comply with applicable reporting and recordkeeping requirement.

The FDA noted that in *PLIVA v. Mensing*, *Id*., the Supreme Court recognized that "Congress and the FDA retain the authority to change the law and regulations if they so

desire." Again, in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, *Id*., the court indicated that Congress' decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings" contributed to the outcome in that case by preempting tort claim against the generic manufacturer.

In *Mensing*, the court correctly noted that Hatch-Waxman struck a balance to provide cheap, not less expensive, lifesaving therapy to patients. In the aftermath of the Supreme Court holding in *Mensing*, Sen. Patrick Leahy of Vermont submitted a draft bill entitled the "Patient Safety and Generic Labeling Improvement Act" to amend the Food, Drug and Cosmetic Act to add to the New Drug provisions under Section 505 (21 U.S.C. Sec. 355) as follows:

> Notwithstanding any other provision of this chapter, the holder of an application approved under subsection (j) [ANDA] may change the 'Warnings' section of the labeling of a drug so approved in the same manner as the holder of an approved new drug application under subsection (b), unless the Secretary prescribes by rule another manner.

That Bill has not yet been approved by the Congress.

Since 1986 when Hatch-Waxman was enacted, Congress has not seen fit to view this dissimilar statutory scheme as being inconsistent with its intent by enacting legislation or to rewrite the formula for generic drug prices. In the Supreme Court opinion in *Bartlett*, the dissent refers to a 'dissimilar statutory scheme" as a "gap" in the federal regulations stating:

> [FDA] "faces significant resource constraints that limit its ability to protect the public from dangerous drugs . . . [t]ort suits can fill the gaps in federal regulation by 'serving as a catalyst to identify previously unknown drug dangers…" [and] "Manufacturers who have greater 'access to information about their drugs' than the FDA retain the ultimate responsibility for the safety of the products they sell."

Whether the statutory authority granted the FDA by the Congress in 21 USC § 371 is sufficient for FDA to create a regulatory solution to fill the "gap" and create tort parity between *Levine* and *Mensing,* remains to be seen.

Since the Congress is mired in gridlock, at least the FDA, to whom Congress has delegated the power to make rules to enforce the FDCA, is now taking the steps to restore the rights of persons harmed by generic drugs by giving them the equal protection of laws as persons injured by brand named drugs - the right to file a claim for inadequate label warnings.

Chapter X

Conclusions and Recommendations

"Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as 'a critical component of the States' traditional ability to protect the health and safety of their citizens'." *Desiano v. Warner-Lambert & Co.*, 467 F. 3d 85 92d Cir. 2006), citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) [Blackmun, J., concurring in part and dissenting in part].

It has long been recognized that it was left to the states to regulate matters of public health and safety. *Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 251 (1984). The Supreme Court has instructed the federal courts that the various police powers of the states are not to be superseded by federal law, unless "that was the clear and manifest purpose of Congress." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). There is a strong presumption against implied preemption with matters traditionally occupied by the states, "particularly those related to health and safety." *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988), citing *Medtronic v. Lohr*, 518 U.S. at 485).

While the FDCA contains a preemption clause relating to medical devices, it does not have a parallel provision governing pharmaceuticals. Congressional silence on state laws related to pharmaceuticals, when Congress has addressed preemption of state laws on medical devices, is not without meaning. "Such reasoning is a variant of the familiar

principle of *expressio unius est exclusio alterius*: Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992).

The bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Up until 2008, Courts have been reluctant to find preemption in such cases without express language of Congressional intent. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 [1996]. "It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct'." Quoting *Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 251, (1984); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

Federal trial courts have also found that Congress would not intentionally remove an injured person's right to sue for damages. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Perry v. Novartis Pharma Corp*., 456 F. Supp. 2d 678, 684 (E.D. Pa. 2006).

It has been mentioned within this paper that Congress may violate the Seventh Amendment of the U.S. Constitution when it preempts the right to a jury trial in the federal courts for persons injured by defective products made and/or distributed by manufacturers or their agents without providing an alternative mechanism to adjudicate injury claims.

While the underpinnings of the Seventh Amendment civil jury trial mandate may not have the strongest historical foundation, many in Congress, as well as several scholars and attorneys, have argued that Congress never intended to preempt the right of an injured party to seek redress for an alleged defective drug or device. They further claim that the majority of the U.S. Supreme Court has misread the Congressional statutes in hyper-technical interpretations to arrive at disparate conclusions.

The proposed Medical Device Safety Act of 2009, introduced by Democratic Congressmen Pallone and Waxman, as well as the late Democratic Senator Edward Kennedy, failed to become law, while Democrats controlled both the House of Representatives and the Senate, with President Barrack Obama, a Democrat in the While House. Now, due to the current configuration of the Congress where Republicans control the House of Representatives and Democrats control the Senate, the prospects for legislative intervention to reverse *Riegel* are even slimmer. It is possible that the U.S. Supreme Court in *Medtronic v. Stengel* will decide to review one of the *Riegel* or *Buckman* issues currently dividing the federal circuits, in whether "failure-to-report" claims are impliedly preempted. In the meantime, plaintiffs may want to argue that the preemption language forming the basis of the *Riegel* decision is vague at best, and that had Congress truly intended to preempt state law causes of action, it could have done so in far more clear and direct language. The prospect of uncovering permissible state-law parallel claims is poor. *Riegel* has made holding manufacturers accountable for defective FDA-approved medical devices very difficult. Accordingly, unless there is a dramatic change in the composition of the Supreme Court, the only means of changing the results

in *Riegel*, *PLIVA*, and *Mutual Pharmaceuticals* is by Congressional action, which is not promising.

But getting a divided Congress to agree to legislatively amend these issues appears to be a herculean task with little prospect of change. However, Congress was successful in crafting the National Childhood Vaccine Injury Act, which did create an alternative means of adjudicating claims against vaccine manufacturers without risking the bankruptcy of the few remaining vaccine manufacturers. For the most part, the non-jury Vaccine Court has proved to be a fair and reasonable alternative to a total preemption of claims and the costly time consuming product liability trials in either state or federal court. While the claimants in the *Bruesewitz* case and others were not satisfied with the results of the Vaccine Court, the Congress did provide a forum where claims could be adjudicated.

Recommendations

Many academics have argued about the virtues of a unified federal regulatory scheme that should not be usurped by an additional layer of state regulation. However, conflicting state regulations and providing a forum to provide compensation to injured users is an entirely different matter. Because tort law and product liability law is based upon state common law and in some instances statutory law, some scholars and currently a majority of the U.S. Supreme Court treat those personal injury lawsuits as an additional requirement which should be preempted by the Supremacy Clause of the U.S. Constitution. Holding manufacturers liable for their express warranties and the implied warranties of the Uniform Commercial Code in producing a product that is merchantable

and fit for ordinary purpose hardly creates an undue burden upon a manufacturer which had its product approved by the FDA for marketing and distribution. Many FDA products, especially drugs and vaccines, are inherently dangerous, but with adequate warnings may be prescribed for appropriate patients in a safe manner by physicians or other authorized health care providers.

Holding manufacturers responsible to stand by their products which underwent extensive trials and approvals is not something that should grant them virtual immunity from the end users of their products. Once a product is approved for distribution to the public, a larger sample of users may uncover risks not anticipated in the studies and trials leading up to approval by the FDA. After widespread use and the collection of adverse events data, manufacturers should be held accountable for the product, which may have had a deleterious effect upon a small number of persons, while benefiting a larger majority of users.

The *quid pro quo* arrangement that Justice Scalia referred to in the *Bruesewitz* vaccine case was never mentioned in the legislation enacting the National Childhood Vaccine Injury Act. The law of "tough luck" should not be the remedy for an innocent child or adult just because the overwhelming majority of users were benefited by a vaccine or a drug. We all have dissimilar reactions to products we ingest. While it is always a risk when people are administered a prescribed drug or vaccine, that risk of harm should not be solely on the users of the product with no accountability upon the manufacturer, who arguably is starting to make a profit after years of expense in the research, development and approval process.

Part of the cost of producing and marketing any product is the cost of defense from the inevitable lawsuits. Automobile manufacturers build that expense into the cost of the product along with the cost of its advertising the product. Drug and device manufacturers can follow that model.

Therefore, producing an FDA approved product that was manufactured defectively and caused harm to its users, who did not abuse the product should not enable a manufacturer to be exempt from accountability for its product. If the approved warnings of a product after use in the marketplace should prove to be inadequate, a manufacturer upon notice of adverse events concerning that product should promptly pass on that information and revise their warnings to those that prescribe their product for use by the public without waiting for FDA approval of their warning. Manufacturers should not be exempt from accountability because the FDA did not timely authorize them to enhance their warnings to the learned intermediary physicians who use and prescribe those products to their patients. Failure to warn of such information that harms an individual user should not be an exemption from accountability because the FDA did not timely approve a change in the warning label.

Congress should prospectively expressly pronounce in enabling legislation whether it intends to preempt state and local law from regulating or governing a particular field or subject matter, and clarify if such preemption precludes the right of injured parties to sue manufacturers of such products.

Congress should also review the areas of law that it regulates and clarify by express legislation whether it intends to occupy the field in its regulation of the specific area or endeavor, or whether it is "saving" rights for the states.

Congress should revisit and enact a federal products liability statute that would establish the general principles that manufacturers of products that it regulates shall be held accountable for the defective products it places into the marketplace. Under no circumstances should a manufacturer be given immunity from claims for injuries sustained as a result of a defective product that caused injury or death to the user, who used such a product in the manner for which it was intended. Such a federal products liability statute should be enforced in either federal or state courts subject to diversity rules. Alternatively, the Congress should create regional administrative courts to adjudicate claims by those injured by FDA approved products.

While it is difficult for a divided Congress to agree on many issues, the Congress did approve the National Vaccine Injury Compensation Program as part of the National Childhood Vaccine Injury Act of 1986 (42 USCA §300aa-1 through 34. Using that statute as a model, the Congress may enact the proposed legislation to preempt all FDA approved products and provide for a similar FDA Pharmaceutical and Medical Device Compensation Act, which would be funded by charging a five percent (5%) increase on each drug and medical device sold, which will be paid as an excise tax to fund the program. The proposed legislation to add justice to preemption is included in Appendix A.

Appendix A – Proposed Legislation

FDA Approved Pharmaceutical and Medical Device Compensation Act

Preamble

Purpose

The purpose of this Act is to provide those persons or their legal representatives a forum in which to file claims for injury or death related to any pharmaceutical drug or Class III Medical Device approved by the U.S. Food and Drug Administration (FDA) (hereinafter FDA approved product).

The Congress has established by this Act exclusive jurisdiction over claims of injury or death related to any pharmaceutical drugs - both brand name drugs and generic drugs and Class III medical devices approved by the FDA. It is the express intent of Congress to preempt under the Commerce Clause and Supremacy Clause of the U.S. Constitution any cause of action filed in any state or federal court, tribunal or agency against any manufacturer for any injury or death related to an FDA approved product as defined above. In order to pay for this program, this Act shall include the levying of an excise tax upon the sale of all FDA approved products, which funds shall be earmarked to compensate injured persons or their legal representatives and to pay for the administration of the fund. Congress may supplement the fund as needed.

The Secretary shall establish in the Department of Health and Human Services a Pharmaceutical and Class III Medical Device Program (hereinafter referred to as an

"FDA approved product") to achieve optimal prevention of human diseases and physical injury, and to achieve optimal prevention against adverse reactions by the ingestion of pharmaceuticals and the use of Class III medical devices approved for marketing to the public by the Food and Drug Administration (FDA). The Program shall be administered by a Director selected by the Secretary.

Establishment of Program

1. Program Established

There is established the FDA approved Pharmaceutical and Class III Medical Device Compensation Act to be administered by the Secretary under which compensation may be paid for pharmaceutical and Class III medical devices related to injury or death.

2. Attorney's Obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to an FDA approved product related injury or death to advise such individual that compensation may be available under the program for such injury or death.

3. Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

General Rule

1. A proceeding for compensation under the Program for an FDA approved product for injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United

States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under this title.

2. (A) No person may bring a civil action for damages against an FDA approved pharmaceutical or Class III medical device manufacturer in a state court or federal district court for damages arising from an FDA approved product related injury or death associated with the administration of an FDA approved product after (effective date).

(B) If a civil action is filed in a state or federal court, that court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by this title, be considered the date the petition was filed if the petition was filed within two years of the date of the dismissal of the civil action.

3. No FDA approved pharmaceutical drug or Class III medical device manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for an injury or death associated with the ingestion of an FDA approved pharmaceutical or Class III medical device after (effective date).

4. If in a civil action brought against a manufacturer before the effective date, damages were denied for an FDA approved product related injury or death, or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

5 (A) A plaintiff who on (the effective date) has pending a civil action for damages for an FDA approved product related injury or death may, at any time within 2 years after

(effective date), or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for an FDA approved product related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

6. If a person brings a civil action after the effective date for damages for an FDA approved product related injury or death associated with the administration of an FDA approved product before (effective date), such person may not file a petition under subsection (b) of this section for such injury or death.

7. If in a civil action brought against a manufacturer for an FDA approved product related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

8. If on (effective date), there was pending an appeal or rehearing with respect to a civil action brought against an administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for an FDA approved product related injury or death, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

9. This subsection applied only to a person who has sustained an FDA approved product related injury or death and who is qualified to file a petition for compensation under the Program.

10. The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for an FDA approved product related injury or death associated with the administration of an FDA approved product on or after (effective date).

Petitioners

1. Any person who has sustained an FDA approved product related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of an FDA approved product may, if the person meets the requirements of subsection (c) (1) of this section, file a petition for compensation under the Program.

2. Only one petition may be filed with respect to each administration of an FDA approved pharmaceutical drug.

3. Only one petition may be filed with respect to each installation of an FDA approved Class III medical device.

Petition Content

A petition for compensation under the Program for an FDA approved product related injury or death shall contain:

An affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died:

(A) Received an FDA approved Class III medical device,

(B) Ingested an FDA approved pharmaceutical drug

(C) Received the FDA approved product in the United States or in its trust territories,

(D) Received the FDA approved product outside the United States or a trust territory and at the time of the ingestion or installation such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen.

(E) Claimant has not previously collected an award or settlement of a civil action for damages for such FDA approved product related injury or death.

(F) A description of the FDA product and the times when the product was prescribed and administered

(G) A list of all health care providers who prescribed or administered the FDA approved product.

(H) A list of all pharmacies where the prescribed FDA approved drug or device was obtained.

Additional Information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the FDA approved product.

Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the FDA approved product.

Court Jurisdiction

(a) General Rule

The United States Court of Federal Claims and the United States court of Federal Claims special masters shall, in accordance with this section, have exclusive jurisdiction over proceedings to determine if a petitioner under this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of Title 28.

(2) Within 30 days after the Secretary receives service of any petitions filed under this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special master which shall consist of not more than 100 special masters, who shall be assigned to Federal Judicial Circuits. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of

whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master and a Deputy Chief Special Master for each Federal Judicial Circuit. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, Title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, Title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa-11 of title and their disposition, the dates on which the FDA approved product related injuries and deaths for which the petitions were filed occurred, the types of amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(7) Deputy Chief Special Master shall have the responsibilities of the Chief Special Master within the Federal Judicial Circuit to which the Deputy Chief Special Master is assigned in coordination with the Chief Special Master.

(d) Special Masters

(1) Following the receipt and filing of a petition under section 300aa-11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of Title 28. Such rules shall:

(A) Provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) Include flexible and informal standards of admissibility of evidence,

(C) Include the opportunity for summary judgment,

(D) Include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) Provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3) (a) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be

provided under the Program and the amount of such compensation. The decision of the special master shall:

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e) of this section.

(b) In conducting a proceeding on a petition a special master:

(i) May require such evidence as may be reasonable and necessary,

(ii) May require the submission of such information as may be reasonable and necessary,

(iii) May require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) Shall afford all interested persons an opportunity to submit relevant written information.

(v) May conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(c) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master

determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information:

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e)Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter:

(A) uphold the finding of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that

the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States Court of Appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals.

(g) Notice

If—

(1) A special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or

(2) The United States Court of Federal Claims fails to enter a judgment under this section on a petition within 120 days (excluding (A) any period of subsection under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under this title or the petitioner may choose to have the petition remain before the special master or court, as the case may be.

Appellate Review

Court of Appeals reviews issues of statutory interpretation under this action that is "not in accordance with law" standard, which is de novo standard of review.

Determination of eligibility and compensation

(a) General Rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole:

(A) That the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition of this title, and

(B) That there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the FDA approved product described in the petition.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the FDA approved product"—

(A) Does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) May, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have not known relation to the FDA approved product involved, but which in the particular case are shown to have

been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record:

(A) Any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) The results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the

evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under this title.

Compensation

(a) **General Rule**

Compensation awarded under the Program to a petitioner under this title for an FDA approved product related injury or death associated with the administration of the product shall include the following:

(1) (A) actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses with the exception of medical, or other remedial care services that are provided for by an approved insurance plan in accordance with the Affordable Health Care Act, which:

(i) result from the FDA approved product related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii) (I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which:

(i) Resulted from the FDA approved product related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of an FDA approved product related death, an award of up to $500,000 for the estate of the deceased, based upon actuarial life expectancy tables.

(3)(A) In the case of any person who has sustained an FDA approved product related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's FDA approved product related injury

for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained an FDA approved product related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's FDA approved product related injury for which compensation is to be awarded and whose related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the FDA approved product related injury, an award not to exceed $500,000.

(b) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a) (1) of this section shall be sufficient to enable the compensated person to remain living at home.

(c) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a) of this section, compensation for other than the health, education, or welfare of the person who suffered the FDA approved product related injury with respect to which the compensation is paid.

(d) Attorneys' fees

(1) In awarding compensation on a petition filed under this title the special master or court shall also award as part of such compensation an amount to cover:

(A) Reasonable attorneys' fees, and

(B) Other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) No attorney may charge any fee for services in connection with a petition filed under this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(e) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made.

(2) (A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Trust Fund established, in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for an FDA approved product related injury or death associated with the administration of an FDA approved product before the effective date of this act, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) of this section in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) of this section are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements

regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Trust Fund established, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(f) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under Title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(g) Liability of health insurance carriers, prepaid health plans, and benefit providers

Payments for hospital, medical, dental, therapeutic, psychiatric or psychological, treatment shall be paid from an insurance policy approved by the Affordable Health Care Act. In the event that the claimant is unable to pay the insurance premiums for such a policy either this Program or Medicaid shall provide such health care coverage. This subsection shall not apply to the provision of services or benefits under Title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.].

(h) Source of compensation

(1) Payment of compensation under the Program to a petitioner for an FDA approved product related injury or death associated with the administration of an FDA approved product before the effective date, shall be made by the Secretary from appropriations under subsection (j) of this section.

(2) Payment of compensation under the Program to a petitioner for an FDA approved product related injury or death associated with the administration of an FDA approved product on or after (effective date), shall be made from the Trust Fund established.

Tax

FICA tax, like federal and state income taxes, shall be deducted in determining lost earnings award under this Act; by specifying objective standard for determining net amount of loss of earnings to be awarded unrelated to what any petitioner might be expected to earn, the Act precluded consideration of petitioner's particular status on question of whether FICA taxes are appropriate to deduct.

Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the FDA approved product related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amount recovered

Amounts recovered under subsection (a) of this section shall be collected on behalf of, and deposited in, the Trust Fund established.

Standards of Responsibility

(a) General Rule

Except as provided in subsections (b), (c), and (e) of this section no State law shall apply to a civil action brought for damages for an FDA approved product related injury or death.

(b) Unavoidable adverse side effects; warnings

No manufacturer shall be liable in a civil action for damages arising from an FDA approved product related to injury or death associated with the administration of the product after the effective date, if the injury or death resulted from side effects that were unavoidable even though the product was properly prepared and manufactured and was accompanied by proper directions and warnings.

For purposes of this paragraph, an FDA approved product shall be presumed to be accompanied by proper directions and warnings if the product manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] (Including regulations issued under such provisions).

(c) Direct warnings

No manufacturer shall be liable in a civil action for damages arising from an FDA approved product related injury or death associated with the administration of an

FDA approved product after the effective date, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the product manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against an FDA approved product manufacturer for a product related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

It is the intent of Congress by this Act to expressly preempt any person or representative of such person who may bring any action in any federal or state court except as provided in the chapter against the United States of America, or any FDA approved manufacturer for any injury or death related to any FDA approved product.

No state may establish or enforce a law which prohibits an individual from bringing a civil action against an FDA approved product manufacturer for damages for an FDA approved product related injury or death.

Bibliography

Books and Journal Articles

Allen, Arthur. (2007). *Vaccine: The Controversial Story of Medicine's Greatest Lifesaver.* New York, NY: W.W. Norton & Company.

American Law Institute. (1998). *Restatement of the Law of Torts (Third)—Products Liability*. St. Paul, MN: American Law Institute Publishers.

American Law Institute (1965). *Restatement of the Law of Torts (Second)* St. Paul, MN: American Law Institute Publishers.

Beck, James M. (2011). *Drug and Medical Device Product Liability Deskbook.* New

York, NY: Law Journal Press.

Bivans, Roger W. (1996). Substantially Equivalent? Federal Preemption of States Common-Law Claims. *74 Tex.L.Rev 1087 (April 1996).*

Brown, Michael K., Lisa M. Baird, Michelle Lyu Cheng and Farah Tabibkhoei. (2012). Medical Device Preemption – Is There Life for Plaintiffs' Claims After Riegel v. Medtronic, Inc.? *Drug and Medical Device Seminar* (May 2012).

Buckman, Deborah F., J.D. (2008). Remedies Available for Violations of Federal Food, Drug, and Cosmetic Act (FDCA). *25 A.L.R. Fed. 2d 431*.

Bullock, Henninger S. and Andrew J. Calica. (2012). Biosimilars: The Next Big Thing? *For The Defense* (Oct 2012).

Buzbee, William W. ed. (2009). *Preemption Choice: The Theory, Law and Reality of Federalism's Core Question.* New York: Cambridge U. Press.

Calabresi, Guido. (1970). *The Costs of Accidents: A Legal and Economic Analysis.* New Haven, CN.: Yale U. Press.

Calabresi, Guido. (2009). Tort Law in the Shadow of Agency Preemption. *65 N.Y.U. Annual Survey of American Law 435*.

Conroy, Alison. (2010-2011). FDA Approval and Federal Preemption After Riegel and Levine. *14 Quinnipiac Health L.J. 285*.

Copland, James R. (2010-2011). Administrative Compensation for Pharmaceutical- and Vaccine-Related Injuries. *8 Ind. Health L. Rev. 275*.

Cupp, Richard L., Jr. (2009). Preemption's Rise (and Bit of a Fall) as products Liability Reform: Wyeth, Riegel, Altria, and the Restatement (Third)'s Prescription Product Design Defect Standard. *74 Brook. L. Rev. 727* (Spring 2009).

Daller, Morton F. ed. (2011). *Product Liability Desk Reference: A Fifty State Compendium.* Aspen Publishers.

Davis, Mary J. (2010). The Case Against Preemption: Vaccines & Uncertainty. *8 Ind. Health L. Rev. 291* (2010-2011).

Dobreff, William. (1990). The National Vaccine Compensation Act. *69 Mich. B.J. 806* (Aug 1990).

Drake, Geoffrey M. and Victoria C. Smith. (2012). Prescription Medication Cases: The Case Against Negligent Design Claims. *For the Defense* (Oct 2012).

Epstein, Richard A. and Michael S. Greve eds. (2007). *Federal Preemption: States' Powers, National Interests*. Washington, DC: The AEI Press.

Fischer, David A., William Powers, Jr., Richard L. Cupp, Jr., Michael D. Green, and Joseph Sanders. (2014). *Products Liability: Cases and Materials, 5th ed.* St. Paul, MN: Thomson/West.

Fogt, Kyle T. (2009). The Road Less Traveled: West Virginia's Rejection of the Learned Intermediary Doctrine in the Age of Direct to Consumer Advertising. *34 Iowa J. Corp. L. 587.*

Frank-Jackson, Demetria D. (2011). The Medical Device Federal preemption Trilogy: Salvaging Due Process for Injured Patients. *35 Southern Illinois Univ. L.J. 453.*

Garner, Bryan A. (2009). *Black's Law Dictionary, 9th ed*. Thomson Reuters/West.

Geistfeld, Mark A. (2011). *Principles of Products Liability, 2d ed*. New York, NY: Foundation Press, Thomson/West.

Goldacre, Ben. (2012). *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients.* New York: Faber & Faber Inc., affil. Farraar, Straws and Giroux.

Goldenberg, Neil A., Esq. and John P. Freedenberg, Esq. ed. (2012). *Products Liability in New York: Strategy and Practice, 2d Ed*. (2 vols.). New York State Bar Association.

Green, Michael D. (1999). Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections. *30 Seton Hall L. Rev. 207.*

Green, Michael D. and William B. Schultz. (2000). Tort Law Deference to FDA Regulation of Medical Devices. *88 Geo. L.J. 2119* (July 2000).

Green, Wilson F. (2011). The Big Story: The U.S. Supremes Dance the Preemption Paso Doble. *72 Ala. Law. 1999* (May 2011).

Hall, Ralph F. (2012). Rethinking Lohr: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both? *13 Minn. J.L. Sci & Tech. 737* (Spring 2012).

Herrmann, Mark, David Booth Alden and Bradley W. Harrison. (2010). The Meaning of the Parallel Requirements Exception Under Lohr and Riegel. *65 N.Y.U. Ann. Surv. Am. L. 545*.

Hutt, Peter Barton, Richard A. Merrill and Lewis A. Grossman. (2007). *Food and Drug Law, 3rd ed.* Foundation Press, Thomson West.

Klein, Kenneth S. (2010). Is Ashcroft v. Iqbal the Death (Finally) of the "Historical Test: For Interpreting the Seventh Amendment? *88 Neb. L. Rev. 467*.

Knauer, Virginia. (1974). The Effectiveness of FDA Medical Device Regulation. 7 *U.C.D. L. Rev. 293*.

Kreindler, Lee S., Blanca I. Rodriguez, David Beekman and David C. Cook. (1997). *New York Law of Torts*. St. Paul, MN: West Group.

Lee, Stacey B. (2012). PLIVA v. Mensing: Generic Consumers' Unfortunate Hand. *Yale Journal of Health Policy, Law and Ethics XII: 2*.

Levy, Richard E. and Robert L. Glickman. (2009). Access to Courts and Preemption of State Remedies in Collective Action Perspective. 4 *Case W. Res. L. Rev. 1-35.*

McGarity, Thomas O. (2013). *Freedom to Harm: The Lasting Legacy of the Laissez Faire Revival*. New Haven, CT: Yale U. Press.

McGarity, Thomas O. (2008). *The Preemption War: When Federal Bureaucracies Trump Local Juries*. New Haven, CT: Yale U. Press.

Meltzer, Daniel J. (2013). Preemption and Textualism. *112 Mich. L. Rev. 1 (Oct, 2013).*

Merrill, Richard A. (1996). The Architecture of Government Regulation of Medical Products. *82 Virginia Law Review 753*.

Mottes, Lisa M. (2011). The Need for Federal Preemption of State Tort Claims in the Context of "New Drugs" and Premarket-Approved Medical Devices. *41 Seton Hall L. Rev. 723*.

Mullenix, Linda S. (2009). Strange Bedfellows: The Politics of Preemption. 59 *Case W. Res. L. Rev.* 837 (Summer 2009).

Mullenix, Linda S. (2009). *Mass Tort Litigation: Cases and Materials 2nd ed*. West.

Nast, Michael G. (2003). Medical Device Preemption – A Plaintiff's Perspective. *12 Widener L.J. 87*.

Neiman, Peter G., Seth B. Orkland and Peter K. Vigeland. (2013). Revisiting 'Off-Label' Drug Promotion Resolutions in Light of 'Caronia.' *New York Law Journal* (February 28, 2013).

Offit, Paul A., M.D. (2005). *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis.* New Haven, CT: Yale U. Press.

Offit, Paul A., M.D. (2007). Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases. New York: HarperCollins Publishers.

O'Reilly, James T. (2006). *Federal Preemption of State and Local Law: Legislation, Regulation and Litigation.* Chicago, IL: ABA Publishing.

Oshinsky, David M. (2005). *Polio: An American Story.* New York, NY: Oxford University Press.

Owen, David G. (2005). *Products Liability Law*. Thomson-West.

Rabin, Robert L. (2010). The Vaccine No-Fault Act: An Overview. *8 Ind. Health L. Rev. 267*.

Rabin, Robert L. (2012). Reflections on Tort and the Administrative State. *61 DePaul L. Rev. 239* (Winter 2012).

Rheingold, Paul D. (2012). *Litigating Mass Tort Cases* (2 vols.) Eagan, MN: Thomson Reuters/West.

Rosen, Jeffrey. (2008). Supreme Court Inc. NY Times Mar 16, 2009 (Magazine) at 38.

Rudin, D. Alan (2005). *Toxic Tort Litigation*. American Bar Association.

Scalia, Antonin and Bryan A. Garner. (2012). *Reading Law: The Interpretation of Legal Texts*. St. Paul, MN: Thomson/West.

Scalia, Antonin. (1989). Originalism: The Lesser Evil. *57 U.Cin.L.Rev. 849*

Schwartz, Victor E., Phil Goldberg and Cary Silverman. (2012). Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects. *81 Fordham L.Rev. 1836*.

Schwartz, Victor E., Behrens, Mark A. (1996). The Road to Federal Product Liability Reform. *55 Md.L.Rev. 1363* (1996).

Schwartz, Victor E., Goldberg, Phil, Silverman, Cary (2013). Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs Has Severe Side Effects. *81 Fordham.L.Rev. 1835* (2013).

Sharkey, Catherine M. (2012). Against Categorical Preemption: Vaccines and the Compensation Piece of the Preemption Puzzle. *61 DePaul L. Rev. 643* (Winter 2012).

Sharkey, Catherine M. (2012). Preemption as a Judicial End-Run Around the Administrative Process. *122 Yale L.J. Online (2012).* http://yalelawjournal.org/2012/04/30sharkey.html

Sharkey, Catherine M. (2011). Inside Agency Preemption. *110 Mich.L.Rev 521.*

Sharkey, Catherine M. (2010). The Association of American Law School 2011 Annual Meeting: Section on Torts and Compensation Schemes Symposium: Vaccines and Drugs: A Brave New Tort World. *8 Ind. Health L. Rev. 259.*

Sharkey, Catherine M. (2009). Federalism Accountability: Agency-Forcing Measures. *58 Duke L.J. 2125* (2009).

Sharkey, Catherine M. (2008). Drug Advertising Claims: Preemption's New Frontier. *41 Loy.L.A.L.Rev. 1625* (2008).

Sharkey, Catherine M. (2008). The Fraud Caveat to Agency Preemption. *102 Nw.U.L.Rev. 841* (2008).

Sharkey, Catherine M. (2008). Products Liability Preemption: An Institutional Approach. *76 Geo.Wash.L.Rev. 449* (2008).

Sharkey, Catherine M. (2007). Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State versus Federal Courts. *15 J.L. & Pol'Y* 1013 (2007).

Sharkey, Catherine M. (2007). Preemption by Preamble: Federal Agencies and the Federalization of Tort Law. *56 Depaul L.Rev. 227* (2007).

Sharkey, Catherine M., Issacharoff, Samuel (2006). Backdoor Federalization. 53 UCLA.L.Rev 1353 (2006).

Stiles, T.J. (2009). *The First Tycoon: The Epic Life of Cornelius Vanderbilt*. NY: Vintage Press.

Sugarman, Stephen D. (2012). Why No Duty? *61 DePaul L. Rev. 669* (Winter 2012).

Tarloff, Elliot Sheppard. (2011). Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations. *NYU L. Rev. 86:1196* (Oct 2011).

Tauber, Andrew, Max Heerman and Brian Wong. (2012). A Powerful Tool to Wield Early: How to Argue Medical Device Preemption. *For the Defense* (October 2012).

Twerski, Aaron. (2005). Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come. *33 Hofstra L. Rev. 1149* (Summer 2005).

Tyler, Ralph S., Thomasina E. Poirot, Andrea S. Andrews and Bruce R. Parker. (2012). Anomalies and Implications: The First Amendment and "Off-Label" Promotion. *For the Defense* (October 2012).

Wartman, Gregory J. (2009). Life After Riegel: A Fresh Look at Medical Device Preemption One Year After Riegel v. Medtronic, Inc. *64 Food & Drug L.J. 291*.

Weiss, Sol. (2009). Dangerous Devices: Consumers Should Be Able to Sue, Keeping Pace With Wyeth. *National Law Journal pg. 35 Vol. 31 No. 37* (May 18, 2009).

Wells, Christina E., William E. Marcantel and Dave Winters. (2011). Preemption of Tort Lawsuits: The Regulatory Paradigm in the Roberts Court. *40 Stetson L. Rev. 793* (Spring 2011).

Wheeler, Malcolm E. (2010). The Case for Preemption: Why the U.S. Supreme Court and the Administration are Wrong to Curtail Implied Conflict Preemption. *8 Ind. Health L. Rev. 317*.

Whitney, Daniel W. (2010). Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices. *65 Food & Drug L.J. 113*.

Wojcicki, Paul E. and Joseph F. Kampherstein, III. (2012). Removal Tactics: Make a Federal Case. *For the Defense* (December 2012).

Zimmerman, Charles S. (2012). *Pharmaceutical and Medical Device Litigation* (2 vols.) Eagan, MN: Thomson West.

Table of Cases

Messner v. Medtronic, Inc., 39 Misc. 3d 1213(a) (Sup. Ct. Richmond Cty. 2013).

Mitaro v. Medtronic, Inc., et al., 73 A.D. 3d 1142 (2010).

Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013).

PLIVA Inc., et al. v. Mensing, et al., 131 S. Ct. 2567 (2011).

Rice v. Sante Fe Elevator Corp., 331 U.S. 218 (1947).

Riegel v. Medtronic, Inc., 2002 WL 34234093 (N.D.N.Y.) (motion to dismiss).

Riegel v. Medtronic, Inc., 2003 WL 25556778 (N.D.N.Y.) (summary judgment).

Riegel v. Medtronic, Inc., 451 F.3d 104 (2d Cir. 2006).

Riegel v. Medtronic, Inc., 2007 WL 2456945 (U.S.) Amicus Brief.

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

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984).

Speller ex. Rel. Miller v. Sears Roebuck & Co., 100 N.Y.2d 38 (2003).

Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013).

Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 809, 395 A.2d 843, 847 (1978).

Vautour v. Body Masters Sports Industries, Inc., 147 N.H. 150; 784 A.2d 1178 (2001).

Voss v. Black & Decker Manufacturing Co., 59 N.Y.2d 102 (1983).

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

Table of Statutes

Table of Executive Orders

Clinton, William J. Executive Order 13132 Federalism (August 4, 1999) (64 Fed. Reg. 153 (1999).

Obama, Barack H. Executive Memorandum on Preemption (May 20, 2009) (74 Fed. Reg. 24693 (2009).