Revisiting Factor VIII Cases: Is It Time for an Agency Adjudication System?

Yi-Chen Su
Revisiting Factor VIII Cases: Is It Time for an Agency Adjudication System?

YI-CHEN SU, DVM, MS, JD*

I. INTRODUCTION

It has been extensively argued that an agency adjudication system to supplant state tort claims is preferable in a plaintiff’s winning case, based on the presumption that a jury would only see the injury caused by the medical product and ignore the benefit brought about by the same product.1 The view is best reflected by the Supreme Court’s opinion in *Riegel v. Medtronic, Inc.*2 The *Riegel* Court expressly stated its disfavor of juries in a medical-device context. The Court advanced a policy argument that “tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.”3 Nevertheless, there are cases that never have a chance to reach the jury. They are the plaintiffs’ losing cases.

Factor VIII cases are the plaintiff’s losing case. They are a class of cases sharing the same or similar factual context: hemophiliacs who contracted AIDS by using HIV-infected blood products in the early 1980s. They represent a class of cases that tort law cannot resolve. Contrary to a plaintiff’s winning case, Factor VIII cases may help to illustrate why an agency adjudication system is favorable even in a plaintiff’s losing situation.

The dissent’s major concern in *Riegel* was that an outright preemption of state common-law suits would “remove all means of judicial recourse.”4 Even though the *Riegel* holding only applies to medical devices that are subject to FDA’s premarket approval, FDA’s regulation of drugs and food additives provided the model for its regulation of medical devices.5 Therefore the Supreme Court did not exclude extending preemption to FDA approved drugs and additives.6 Whether or not preemption would eventually extend to FDA approved drugs, an agency adjudication system to supplant common-law suits may be preferable or favorable in most, if not all, medical-product-liability contexts.

An agency adjudication system is generally exercised by appointed experts, rather than lay jurors. As the *Riegel* Court has stated in the dicta, “[a] state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”7

---

1 See *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1008 (2008); see also *Struve*, infra note 59, at 607.
2 *Riegel*, 128 S.Ct. at 1008.
3 *Id.*
4 *Id.* at 1015 (Ginsburg, J., dissenting).
5 *Id.* at 1016 (Ginsburg, J., dissenting).
6 *Id.* at 1009.
7 *Id.* at 1008.

---

* Mr. Su is a 2009 LL.M, IP, candidate at the George Washington University Law School. He received his J.D. degree from the City University of New York Law School in 2008.

The author thanks Professor Paula Berg at the City University of New York Law School, and two anonymous reviewers’ valuable comments on earlier drafts of this article. The author also thanks the assistance of Professor Yi-Ming Arthur Chen at the National Yang-Ming University, Taiwan, in collecting information regarding the past and current situation of HIV positive hemophiliacs in Taiwan.

---

* Mr. Su is a 2009 LL.M, IP, candidate at the George Washington University Law School. He received his J.D. degree from the City University of New York Law School in 2008.
acknowledged that “while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”8 Adopting an agency adjudication system on a no-fault basis to supplant common-law suits in a medical-product-liability context would provide recourse to the victims without contradicting with the Riegel Court’s concern.

This article employs Factor VIII cases as an example to illustrate that an agency adjudication system is preferable, not only in a plaintiff’s winning case, but also in a plaintiff’s losing case. In addition, the article argues that an agency adjudication approach supplemented with long-term medical care is a preferable model for resolving Factor VIII cases compared to the American tort approach. Part II of this article briefly introduces the background and history of Factor VIII cases in the United States and Taiwan. Part III explores the obstacles in the American tort system that impedes HIV positive hemophiliacs from seeking compensation. Part IV examines the agency adjudication approach in Taiwan and its supplemental measures supporting the victims’ long-term medical need. Part V explains how the Supreme Court, the executive branch and Congress have taken steps limiting or tending to eventually abolish juries in medical-related suits, and toward the direction of establishing an agency adjudication system. In this light, the article offers a solution, based on the principle and example of agency adjudication, to the problem of HIV positive hemophiliacs’ compensation, as well as the defective medical-device victims’ recourse in the wake of Riegel.

II. BACKGROUND

Some have estimated that more than ten thousand hemophiliacs in the United States, and thousands in other countries, contracted HIV in the 1980s by using blood products contaminated with the virus. Biopharmaceutical companies have manufactured Factor VIII concentrates for use by hemophiliacs since the 1970s.9 The manufacturers processed the pooled blood plasma of thousands of donors to produce Factor VIII concentrate. Portions of the plasma collected to prepare Factor VIII concentrate became contaminated with HIV in the early 1980s as the virus appeared in the donor population prior to routine screening for risk factors and testing. Hemophiliacs using the product were infected with the virus as a result.10

Four pharmaceutical companies based in the United States that manufactured Factor VIII concentrates were listed as defendants in various lawsuits brought by hemophiliacs who had contracted HIV by injecting those products.11 The Multiple District Litigation Panel labeled claims filed by American citizens since the 1980s as the “first generation” cases to be distinguished from those filed by foreign nationals since 2004.12

In 1993, the parents of a hemophiliac who died from AIDS were awarded $2,000,000 by the jury in an action brought in Florida.13 It was believed to be the first jury verdict in favor of a hemophiliac infected with HIV via Factor VIII con-

8 Id.
10 Id.
12 In re Factor VIII or IX Concentrate Blood Prods. LIAB. LITIG., 408 F. Supp.2d 569, 571 (N.D. Ill. (2006)).
centrate blood product in the United States. However, later cases did not follow this decision.

In 1997, Judge John Grady of the U.S. District Court approved the settlement of a decertified class action lawsuit by American hemophiliacs with HIV infection. Most of the “first generation” cases were resolved by way of the class settlement of approximately 6000 claims. However, the class settlement did not cover all the victims and it did not address the victims’ long-term medical need, which might be the most critical issue for HIV positive hemophiliacs.

Compared to thousands of hemophiliacs in the United States who contracted HIV by injecting Factor VIII concentrate, only 53 victims were reported in Taiwan. The infection rate in Taiwan was approximately 20 percent. It was much lower than the estimated 80-90 percent infection rate in the United States. An American company, Cutter Biological, accounted for 95 percent of the market share of Factor VIII concentrate sold in Taiwan during that period. Another American company, Baxter Healthcare Corporation, accounted for the remaining five percent. No litigation regarding the infection has ever been brought to courts in Taiwan. The Taiwanese government resolved the issue of recovery by adopting an administrative compensation scheme by enacting the Drug Hazard Relief Act in 2000.

Before the enactment of the Drug Hazard Relief Act, the Taiwanese government had rejected HIV positive hemophiliacs’ petition for relief pursuant to the National Reparation Act. The government denied that any public official had acted either “intentionally or negligently” in approving the importation of the products that led to the victims’ infection. However, the government agreed to negotiate with the foreign manufacturers for compensation on behalf of the victims and subsequently enacted the Drug Hazard Relief Act.

---

14 Id.
16 In re Factor VIII or IX Concentrate Blood Prods. LITIG., 159 F.3d 1016, 1018 (7th Cir. (1998)).
17 In re Factor VIII or IX Concentrate Blood Prods. LIA. LITIG., 408 F. Supp.2d 569, 571 (N.D. Ill. (2006)).
18 In Taiwan, according to the Department of Health, 31 out of the 53 hemophiliacs infected with HIV by using Factor VIII products had deceased before 2003. The survival rate of the victims in 2003, since their infection in the early 1980s, was approximately 41.5 percent. See Chao-Chen Lin, Bai erh chih tzu huan zuo chieh shui yu yao ta kua kuo guan szu [Hemophiliacs consider suing Bayer overseas], CHINA TIMES (Taipei), (June 3, 2003), at A9 (Cutter Biological was acquired by Bayer in 1983).
19 Id.
20 Id.
21 Feldman, supra note 15, at 669.
22 Lin, supra note 18.
23 Id.
26 Id.
27 Tzu-Chun Kuo & Cheng-Li Chang, Yiao hai ai tzu jen chiu cheng wei shu shang yia chheng chhiai li shih ia [The Department of Health demanded pharmaceutical companies to offer N.T. 2 million dollars for each victim within one week, otherwise the companies’ drug importation permit would be suspended.] UNITED DAILY NEWS (Taipei), (Feb. 14, 1998), at A6. The article quoted the Minister continued
The Taiwanese administrative compensation scheme not only addressed the victims’ financial need but also supported victims with long-term medical care. Each HIV positive hemophiliac in Taiwan received approximately $60,000 in compensation provided by the pharmaceutical companies. In addition, the Taiwanese government exempted the victims from paying any premium or medical fees under its National Health Insurance system to ensure that the victims received adequate medical care.

Unlike the HIV positive hemophiliacs in Taiwan, the victims in the U.S. fought for their compensation individually in court through a lengthy and painstaking litigation. Even so, most of them did not have a chance to present their cases to a jury.

III. THE AMERICAN APPROACH

Most of the claims filed by American hemophiliacs were unable to survive the defendants’ motion to dismiss and were resolved by settlement as a consequence. Indeed, because of state blood shield statutes, hemophiliacs had to prove negligence of the pharmaceutical companies instead of having to establish mere strict product liability. As many were unable to prove that their infection was caused by a certain company, their claims did not generally prevail, even if the plaintiffs offered sufficient evidence to support their claims of civil conspiracy in some cases. In addition, the trend of recognizing pharmaceutical companies’ regulatory compliance defense would, if adopted, further impede hemophiliacs from seeking recovery through litigation.

One example of this trend was a class action filed on behalf of approximately 9,000 patients in 1993 that was declassified two years later by the Seventh Circuit Court of Appeals which held that the plaintiffs’ claims lacked legal merit. Chief Judge Posner of the Seventh Circuit Court of Appeals granted the manufacturers’ petition for writ of mandamus against the class certified by the District Court. A mass settlement of 6,000 suits followed and was entered into a consent decree of the Department of Health saying that the pharmaceutical companies’ compensation to victims in various countries should not be different. N.T. 2 million dollars were the government’s bottom line; Jing-Mei Wu, Xiao hai ai tsu bai erh pei 200 wan yo jen chieh shou [Some hemophiliacs with AIDS accepted Bayer’s compensation], UNITED DAILY NEWS (Taipei), (May 20, 1998), at A6. The article stated that, in a public hearing, some of the victims refused to accept the amount of compensation offered by Bayer. They asserted that the compensation should be no less than $100,000, the same amount the pharmaceutical companies offered to each victim in the United States. In the same hearing, legislators urged the Taiwanese government to enact the Drug Hazard Relief Act.

28 Infra note 127.
29 Id.
30 State blood shield statutes preclude strict liability claims against donors and preparers of blood or components. The state statutes limit the liability of suppliers of blood components to liability for their own negligence or willful misconduct. Nevertheless, some states restrict the application of the statutes only to blood banks, storage facilities, and hospitals. See e.g., Feldman, supra note 15, at 671; Klein, supra note 9, at 117.
31 Regulatory compliance defense is a concept suggesting that compliance with FDA requirements would establish a defense to negligence claims. Proponents of the defense asserted that certain types of FDA determinations ought to preclude litigation altogether. They argued that FDA’s expert balancing of product risks and benefits leaves no room for disagreement within the tort system. Therefore, there is no reason for judges or juries to second-guess FDA’s judgments. See Struve, infra note 59, at 607-608.
32 Feldman, supra note 15, at 674-675; In the Matter of Rhone-Poulenc Rorer Inc., et al., 51 F.3d 1293, 1304 (7th Cir. (1995)).
Each member of the class who was willing to release the defendants from liability received $100,000. However, many of the plaintiffs lacked adequate health insurance. In addition, many also had to devote a large part of the settlement money to pay for legal fees. Therefore, actual benefits from the settlement could have been much less than the $100,000, and there was no guarantee that they would have access to adequate long-term healthcare.

In the United States, tort actions are the only avenue for HIV positive hemophiliacs seeking compensation in Factor VIII cases. However, many of the Factor VIII cases filed by hemophiliacs were dismissed because the plaintiffs could not meet the high burden of proof under state blood shield statutes.

A. Blood Shield Law

A plaintiff is prohibited from claiming strict product liability against blood suppliers if the state enacted a blood shield law. The states’ primary policy concern in adopting such statutes is to help ensure undisrupted blood supply and recognize the inherent risk that blood products, similar to other organic substances, may carry diseases. By the late 1970s, 48 states had enacted blood shield laws that prohibited product liability lawsuits against blood banks. Some states sought to do this through case law.

In addition to not-for-profit blood banks, blood shield statutes also protect commercial suppliers of blood-derived products from strict liability claims. Under this legal protection, for-profit blood product manufacturers continued to pay people who provided blood plasma.

Because of the blood shield statutes, a plaintiff who has incurred injury from using a blood product is barred from filing claims under strict product liability and has to prove the blood product supplier’s negligence for his claim to proceed. Under a claim of negligence, plaintiffs bear a higher burden of proof. For instance, though blood suppliers are still subject to tort liability in cases of negligence, courts define the standard of care as the relevant custom in the industry and make it difficult for plaintiffs to recover. On the other hand, in New Jersey, a state that did not have a blood shield statute, claimants were able to proceed with their cases under the state’s product liability act and have thus secured more favorable, though confidential, recoveries.

The blood shield laws have allowed the U.S. pharmaceutical industry and companies based in the U.S. to acquire most of the plasma market in the world. The
state blood shield laws offer legal protection to producers of blood products and the whole blood collection system by exempting them from strict product liability suits, but fail to provide substantial oversight of the system.\(^{47}\) Under the system, a for-profit manufacturer may secure its blood supply by paying people who provide blood plasma. Consequently, companies are allowed to compete with the non-commercial blood banks while enjoying exemption from certain liabilities under these blood shield statutes.

B. **Causation**

In a small number of cases, courts have held that Factor VIII manufacturers were not a “bank, storage facility or hospital” under the relevant state statutes. Therefore, the blood shield law did not apply.\(^{48}\) Even so, the plaintiffs still had difficulty proving causation. As a result, their claims still could not survive because plaintiffs failed to name a precise defendant that caused their HIV infection.\(^{49}\)

Hemophiliacs are likely to use more than one brand of Factor VIII concentrate over time. This depends upon which brand the supplier has in stock. Given that the infection is caused by a single contaminated infusion and is not aggravated by subsequent infusions, even if the subsequent infusions contain the virus as well, plaintiffs have extreme difficulties in proving which specific product caused the infection. This problem is further complicated by the fact that the virus may not appear in the blood of the infected person until years after the infusion that caused the infection.\(^{50}\) Additionally, hemophiliacs may use other blood products aside from Factor VIII concentrate.

Plaintiffs in various Factor VIII cases have unsuccessfully argued that market share liability\(^{51}\) or alternative liability\(^{52}\) should apply in their situation. Courts have generally refused to expand causation doctrines and insisted that market share liability and alternative liability could not apply in the Factor VIII context because the plaintiffs could not exclude the possibility that their infection derived from a source other than Factor VIII product, such as locally made cryoprecipitate or their own conduct.\(^{53}\)

However, not all courts agreed that expanded causation doctrines were not applicable in these cases. Some courts have applied market share liability in the Factor VIII context. For instance, in *Smith v. Cutter Biological*, the Court stated that, as the Factor VIII manufacturers were minimal in number, basing liability on each

---

47. *Id.* at 672.
50. *Supra* note 12, at 577.
51. Market share liability is defined as “[e]ach defendant will be held liable for the proportion of the judgment represented by its share of that market unless it demonstrates that it could not have made the product which caused plaintiff’s injuries.” Sindell v. Abbott Lab., 26 Cal.3d 588, 612 (Cal. (1980)). Under this approach, each manufacturer’s liability would approximate its responsibility for the injuries caused by its own products. *Id.*
52. Under the doctrine of alternative liability, where a small number of defendants breach a duty to the plaintiff, but there is uncertainty regarding which one caused the injury, the burden is upon each such actor to prove that he has not caused the harm. Hymowitz v. Eli Lilly Co., 73 N.Y.2d 487, 505 (N.Y. (1989)). Use of the alternative liability doctrine generally requires that the defendants have better access to information than does the plaintiff, and that all possible tort-feasors be before the court. *Id.*
defendant’s share of the national market rather than a more narrow market was the more equitable approach.\(^{54}\) The Court suggested that an appropriately modified theory of market share liability should be adopted to permit the plaintiffs to proceed with their cases based on considerations of equity and fairness even though the theory of alternative liability was not applicable.\(^{55}\)

Similarly, in *Ray v. Cutter Laboratories, Div. of Miles*, the court suggested that the market share theory should apply where there is an inherent inability to identify the manufactured product that caused the injury.\(^{56}\) However, because there was a disputed issue of material fact as to whether the plaintiffs’ infections were caused by infected batches of Factor VIII, rather than by other blood products used by the plaintiffs during the relevant time period, the plaintiffs’ motion for reconsideration was denied.\(^{57}\)

As the Court stated in *Smith v. Cutter Biological*, the plaintiffs should be allowed to proceed with their cases based on considerations of equity and fairness.\(^{58}\) On the other hand, adopting a relaxed theory of market share liability does not seem to be fair to the defendants when there is a possibility that the plaintiffs might have contracted HIV from other sources such as locally made cryoprecipitate, rather than the Factor VIII products manufactured by the defendants. Inability to prove causation continues to be an obstacle for hemophiliacs seeking recovery through litigation, even if some courts have taken equity and fairness into consideration.

C. Regulatory Compliance Defense

Besides the blood shield law and causation restriction, there is a trend in recognizing the manufacturers’ defense based on compliance with FDA regulations. If the regulatory compliance defense is widely recognized, it will erect yet another hurdle for plaintiffs in Factor VIII cases seeking relief in court.

Traditionally, a defense of regulatory compliance is not available. FDA approval was viewed as setting a floor but not a ceiling for product safety.\(^{59}\) A manufacturer might still incur liability if a court later decided that a product was defective or a warning was not adequate after FDA approval and the manufacturer began to market the product.\(^{60}\)

Once a regulatory compliance defense in a medical product liability context is in place, as Catherine Struve has explained, manufacturers of drugs would be shielded from liability by compliance with FDA regulations, including agreed-upon testing protocols, timely submission and complete accurate description of all required information.\(^{61}\) There is no reason for judges or juries to second-guess FDA’s decisions.\(^{62}\)

---

\(^{54}\) *Smith v. Cutter Biological, Inc., Division of Miles Inc.*, 823 P.2d 717, 728 (Haw. (1991)).

\(^{55}\) *Id.*

\(^{56}\) *Ray v. Cutter Biological, Inc., Division of Miles Inc.*, 754 F. Supp. 193, 196 (M.D. Fla. (1991)).

\(^{57}\) *Id.*

\(^{58}\) *Smith*, 823 P.2d 728.


\(^{60}\) *Id.*

\(^{61}\) *Id.* at 608.

\(^{62}\) *Id.*
Consistent with the traditional approach, the Court of Appeals for the Seventh Circuit had found Factor VIII manufacturers’ arguments based on compliance with FDA regulations impermissible.63 In Gruca v. Alpha Therapeutic Corp., a blood products manufacturer argued that FDA’s regulatory actions should protect the defendants from liability for negligence.64 The defendant argued that their ability to improve the safety of Factor VIII concentrate was limited by FDA’s slow response to the onset of AIDS in the early 1980s.65 For instance, the manufacturer claimed that FDA did not require plasma collection centers to screen donors who had a high risk of transmitting HIV, and FDA did not require any warning of the risk of AIDS on the labels of Factor VIII concentrate until December 1983.66

However, the traditional view that regulatory compliance defense is not acceptable has changed in recent years. Some states have enacted legislation designed to limit tort claims against pharmaceutical products by providing an FDA compliance defense.67 If the defense is widely accepted, it will further impede the Factor VIII victims’ chance to seek relief in court.

D. Civil Conspiracy/Concerted Action

Some plaintiffs in Factor VIII cases have raised the claim of civil conspiracy, in addition to negligence and strict product liability. Though recent courts have found that the plaintiffs provided sufficient evidence to support the claims of civil conspiracy, these claims have failed as well because the blood shield law and causation restriction remained.

Under the concerted action or civil conspiracy theory, plaintiffs must show that a tacit agreement existed among defendants to perform a tortious act.68 In Poole v. Alpha Therapeutic Corp., the court held that the plaintiffs’ assertion that defendants committed parallel tortious acts by following an industry standard, which they specifically described as “identical negligent conduct,” was inadequate to support such a theory.69 Accordingly, although the Factor VIII manufacturers likely engaged in parallel practices with respect to testing and marketing, the courts have held that this alone does not rise to the level of concert of action.70

More recent courts have held a different position because of the revelation of new evidence. In Doe v. Baxter Healthcare Corp., the district court found that the plaintiffs’ complaints had set forth with sufficient particularity the alleged conspiratorial acts upon which plaintiffs based their claims.71 Plaintiffs proffered evidence that the defendants agreed to delay FDA implementation of further testing to exclude high-risk donors, and enlisted their trade organization to lobby government officials on the defendants’ positions with regard to AIDS issues.72 Despite the manufacturers’

63 Gruca v. Alpha Therapeutic Corp., 51 F.3d 638, 645 (7th Cir. (1995)).
64 Id. at 644.
65 Id.
66 Id. Contrary to the manufacturer’s argument, the evidence revealed in recent cases suggests that the manufacturers actively participated and played an important role in the shaping of FDA regulations and policy concerning these products. The manufacturers shared certain responsibility with FDA if the latter’s regulations were inadequate. Consequently, compliance with FDA regulation should not be a defense in the Factor VIII context.
67 Noah, supra note 42. “Most States do not treat regulatory compliance as dispositive, but regard it as one factor to be taken into account by the jury.” Riegel, 128 S.Ct. at 1020 (Ginsburg, J., dissenting).
68 Poole v. Alpha Therapeutic Corp., 696 F. Supp. 351, 354 (N.D. Ill. (1988)).
69 Id.
70 Bohannan, supra note 49, at 289.
72 Id. at 1011.
collective decisions to discontinue production of unheated concentrates, defendants continued to market concentrates made with high-risk donor plasma for the duration of its two-year shelf-life. The district court ruled that the plaintiffs had presented sufficient evidence on the claim of civil conspiracy.

On appeal, the Court of Appeals for the Eighth Circuit stated that “the conspiracy alone is not actionable,” even though the district court found that the plaintiffs had presented sufficient evidence of a conspiracy among the defendants. This was because the plaintiffs did not present sufficient evidence that any of the defendants actually caused the plaintiffs to become infected with HIV. Specifically, the manufacturers did not challenge the sufficiency of the plaintiffs’ evidence that there was a conspiracy, but sought to avoid liability of civil conspiracy on the grounds that the plaintiffs could not establish that any single defendant caused the injury.

It is very difficult for the victims in Factor VIII cases to seek justice and relief in U.S. courts because of the concerns stated above. The difficulty of proving negligence and causation has continued to impede plaintiffs from seeking recovery, in addition to the cost in time and money for the litigation, even though recent evidence has shown that some manufacturers engaged in conduct sufficient to sustain a claim of civil conspiracy or concerted action.

IV. THE TAIWANESE APPROACH

As Andrew Klein has suggested, removing difficult causation cases from the tort system and adopting an agency adjudication scheme would promote fairness and efficiency by reducing discovery costs, expert witness fees, and the lost value of time. Taiwan adopted an agency adjudication approach that efficiently resolved the compensation issue for HIV positive hemophiliacs and avoided lengthy litigation with unpredictable outcomes. This section examines the agency adjudication scheme adopted by Taiwan, the mechanism of review, grant of damages under the Drug Hazard Relief Act, and its supplemental healthcare system.

The administrative compensation scheme adopted by Taiwan is an example of agency adjudication approach. As Catherine Struve has explained, an agency adjudication approach of administrative compensation initiates and proceeds with the adjudication of product safety claims within a government agency rather than the court system. Such adjudication can proceed on the government’s initiative or the government could authorize private individuals to file claims.

Responding to the petition of hemophiliacs who had contracted HIV and facing pressure from legislators, the Taiwanese government began to draft its Drug Hazard Relief Act. The statute was enacted in 2000, and it established the legal

---

73 Id. at 1010. Nevertheless, the United States was the first in testing whole blood and in heating blood products. On the other hand, Japan and France delayed the licensing of a U.S. blood test and continued using unheated blood products months after they had been abandoned in the United States. Feldman, supra note 15, at 694. One of the manufacturers, Cutter Biological, introduced its heated blood product in late Feb. 1984. Yet for over a year, the company continued to sell the unheated blood product overseas. Walt Bogdanich & Eric Koli, 2 Paths of Bayer Drug in 80’s: Riskier One Steered Overseas, N.Y. TIMES, (May 22, 2003).
75 Doe v. Baxter Healthcare Corp., 380 F.3d 399, 410 (8th Cir. 2004).
76 Id.
77 Id. at 404.
78 Klein, supra note 9, at 122.
79 Struve, supra note 59, at 614.
80 Id.
81 Wu, supra note 27.
authority of the administrative compensation scheme for providing relief to victims
who suffer from unexpected adverse drug effects, such as the Factor VIII cases.\textsuperscript{82} In
addition, the Taiwanese government has established a system according to which
HIV positive hemophiliacs receive free medical care under the National Health
Insurance System.\textsuperscript{83}

As stipulated in the statute, an important policy consideration for adopting
the system is efficiency.\textsuperscript{84} Efficiency both in time and cost for the victims seeking
compensation are the major concern for adopting such a scheme. Unlike judicial
proceedings, establishing causation between the drug and the injury incurred by
the victim is not necessary under this administrative system. However, one of the
criteria for recovery under the system is that there must be no fault on the part of
manufacturers. The injury must be unforeseeable due to the limitation of science
and technology at the time of injury.\textsuperscript{85}

The Drug Hazard Relief Act authorized the Department of Health to be the
adjudicating agency.\textsuperscript{86} Under the statute, the Department of Health may establish
a relief fund as the financial source of compensation; establish a review committee
in determining claimants’ eligibility; and exercise discretion in the grant of relief
and the amount of compensation.

A. Eligibility for Relief

A drug hazard relief application requires a claimant seeking relief to provide
medical documents necessary for the agency to determine his eligibility. For instance,
the claimant needs to provide relevant records indicating his medical and health
condition before the alleged harm; his medical record after the alleged harm; and
the medical diagnosis certificate issued by a medical institution to prove the harm
alleged by the claimant.\textsuperscript{87}

A claimant who is not familiar with the administrative procedure may entrust a
consumer protection agency or another organization to submit the application.\textsuperscript{88} If
the claimed victim is deceased, the victim’s representative may provide documents
proving his relationship with the deceased victim, in addition to the victim’s medi-
cal record and death certificate.\textsuperscript{89}

The Drug Hazard Relief Act does not open the doors to all victims who suffer
from adverse drug effects. The Act restricts the victims’ eligibility by providing that
there must be no fault on any identified party for the claimant’s injury. For instance,
where the result of drug hazards is the responsibility of the victim, manufacturer

\textsuperscript{82} Drug Hazard Relief Act, supra note 24.
\textsuperscript{83} Chyuan Min Chien Kang Bao Hsien Chung Dah Shang Bing Fan Wei [the scope of serious
diseases covered by the National Health Insurance] available at http://www.nhi.gov.tw/webdata/At-
tachFiles/Attach_1059_2_W0940043268衛署941221公告重大傷病範圍表1.pdf (last visited July 27,
2008).
\textsuperscript{84} Drug Hazard Relief Act, supra note 24, ch. I, art. 1.
\textsuperscript{85} Kuei-Wen Hsueh, Yiao hai chiu ji ji jin yiao chieh tung i jiuan chu cheng li [Pharmaceutical
industry agreed to establish the Drug Hazard Relief Fund], MING SHENG DAILY (Taipei), (May 20,
1998), at 29.
\textsuperscript{86} Drug Hazard Relief Act, supra note 24, ch. I, art. 2.
\textsuperscript{87} Yiao Hai Chiu Ji Shen Chin Ban Fa [Procedure for Drug Hazard Relief Application] (Taiwan),
27, 2008).
\textsuperscript{88} Id.
\textsuperscript{89} Id.
or importer, physician, or other persons, the relief would not be applicable. In other words, only victims who cannot prove causation are eligible for the relief. Those who can identify a culpable manufacturer should be encouraged to remain in the litigation system.

Other provisions under the Act that further restrict the scope of relief include: the adverse reaction caused by the drug should have resulted in death, disability, or serious illness; the damage caused should not be the result of excess-medication during emergency medical care; the damage caused should not be the result of using experimental drugs; the adverse reaction caused by the drug should not be common and foreseeable; the injury sustained should not include conditions caused by mental factors; and the injury caused by using drugs without the directions of medical and pharmaceutical professionals or without following the label or instructions is also excluded. Only a person sustaining injury from the proper usage of approved drugs is eligible to claim relief pursuant to the Drug Hazard Relief Act.

The Taiwanese approach is an example of a narrowly focused administrative compensation scheme. As Andrew Klein has explained, a narrowly focused administrative compensation scheme suggests replacing the litigation system only for those plaintiffs who would rely on expansive causation theories, such as market share liability or alternative liability, due to the difficulty of proving causation. The victims’ eligibility under the administrative compensation scheme adopted by Taiwan is narrowly focused. The Taiwanese Drug Hazard Relief Act enumerates situations where the victims should be excluded from the system.

The most compelling reason for adopting a narrowly focused administrative compensation scheme probably is preventing overlapping functions that the litigation system traditionally serves well. Besides that, a system that restricts its eligibility only to difficult causation cases may better achieve fairness and efficiency by reducing the amount of cases. Also, the government agency does not have to significantly expand its financial budget and personnel to handle a potentially heavy caseload if the administrative compensation scheme is narrowly focused.

For the administrative compensation scheme to work properly, a stable financial source is required. The Taiwanese government devised a mechanism maintaining the relief fund in support of the granted compensation by levying companies in the pharmaceutical industry.

B. Drug Hazards Relief Fund

The Drug Hazard Relief Act authorizes the Department of Health as the adjudicating agency to establish a fund for the purpose of awarding relief to victims suffering from adverse drug effects. Under the Act, drug manufacturers and importers

---

90 Drug Hazard Relief Act, supra note 24, ch. III, art. 13.
91 Id. art. 13(5).
92 Id. art. 13(6).
93 Id. art. 13(7).
94 Id. art. 13(9).
95 Id. ch. I, art. 3(5).
96 Id. art. 3(3).
97 Drug Hazard Relief Act, supra note 24, ch. I, art. 1.
98 Klein, supra note 9, at 129.
99 Drug Hazard Relief Act, supra note 24, ch. III, art. 13.
100 Klein, supra note 9, at 129.
are obliged to pay a levy of a certain ratio in accordance with the sale volume of drugs of the previous year.\textsuperscript{101} Other financial sources of the fund may also include donations, income from subrogation claims if the agency discovers that there exists a party responsible for compensation after relief has been paid to the victim,\textsuperscript{102} and late fees for payments owed by the drug manufacturers and importers.\textsuperscript{103}

The Act further provides the calculation of a levy that manufacturers and importers are obliged to pay per year. The ratio of the levy imposed on drug manufacturers and importers is between 0.02 and 0.2 percent, depending on the sales volume in the previous year.\textsuperscript{104} If the drugs causing the victims' injury were manufactured or imported by a single company, the Department of Health has the discretion to adjust the levy for such drug manufacturers or importers for the next year up to one percent of the sales volume as a penalty to the company.\textsuperscript{105}

In addition, the Act also imposes responsibility on drug manufacturers and importers to declare information regarding estimates of sales volume for the determination of levy.\textsuperscript{106} If relevant information is not attainable from the manufacturers or importers, the Department of Health may request finance and tax organizations, medical care institutions, or other related institutions to provide related sales information.\textsuperscript{107}

A company in the pharmaceutical industry manufacturing or importing drugs is presumed to have agreed to pay the levy unless the company explicitly objects. The Drug Hazard Relief Act does not have an opt-in provision for drug manufacturers and importers. Alternatively, it provides an opt-out mechanism.\textsuperscript{108} The Act provides that a drug manufacturer or importer may process an appeal or litigation if it is unwilling to accept the imposition of levies, late payment penalties, or fines.\textsuperscript{109} However, the Department of Health also retains its right to turn over the company to the court for compulsory execution if it fails to pay the levy, late payment penalty, or fine imposed upon the company under the Act.\textsuperscript{110} As a result, any drug manufacturer or importer that did not exert its right to opt out would be presumed to have accepted its obligation to pay the levy.

From the pharmaceutical industry's perspective, an administrative compensation scheme is preferable because for a predictable levy it shields companies from defending themselves in court for uncertain damages. As stated in a Taiwanese newspaper article, the establishment of the Relief Fund was unanimously supported by the representatives from various pharmaceutical associations and trade organizations that participated in the negotiation with the Taiwanese government concerning the levy before the enactment of the Drug Hazard Relief Act.\textsuperscript{111} Traditionally, even if courts may never impose liability upon the company in a case where the plaintiff cannot prove causation, the mere costs of defending a medical product liability case may significantly outweigh the burden of paying levies. Without an administrative compensation system in place, the astronomical litigation costs may be enough either to drive a certain medication or company out of the market or

\textsuperscript{101} Drug Hazard Relief Act, supra note 24, ch. II, art. 7.
\textsuperscript{102} Id. ch. III, art. 18.
\textsuperscript{103} Id. ch. II, art. 5.
\textsuperscript{104} Id. ch. II, art. 7.
\textsuperscript{105} Id.
\textsuperscript{106} Id. ch. III, art. 9.
\textsuperscript{107} Id. art. 10.
\textsuperscript{108} Id. ch. IV, art. 21.
\textsuperscript{109} Id.
\textsuperscript{110} Id. art. 25.
\textsuperscript{111} Hsueh, supra note 85.
unnecessarily increase the price of the product, regardless of the benefit brought by such product to the society at large.

Because of the highly scientific and complex nature of the issue concerning adverse drug effects, the agency conducting administrative compensation may have to rely on experts outside the agency in making its decisions. For that purpose, the Drug Hazard Relief Act authorizes the Department of Health establish a review committee composed of experts with certain skills and expertise.

C. Review Committee

Under the Act, the Department of Health establishes a review committee for conducting drug hazards adjudication and determining the amount of payments.\textsuperscript{112} The review committee is composed of eleven to seventeen members including medical, pharmaceutical, legal experts and impartial members of society.\textsuperscript{113} Committee members are appointed by the Department of Health and at least one third must be legal experts and impartial members of the society.\textsuperscript{114}

To fulfill the goal of awarding efficient relief for the victims, the Act specifically provides that the review committee should make its determination regarding liability and damages within three months after receiving an application for drug hazards relief.\textsuperscript{115} Extension is allowable only when necessary, but under no circumstances should the extension be longer than one month.\textsuperscript{116} The objective of the system is to provide efficient recovery for the victims.

As Catherine Struve has suggested regarding the selection of committee members, it would be necessary to screen carefully to avoid conflicts of interest and possible bias in the selection of medical experts.\textsuperscript{117} For instance, 44 out of the 53 HIV positive hemophiliacs in Taiwan were treated by the same doctor who was dubbed the “father of hemophilia in Taiwan,” and was a consultant to the Department of Health and drug importers concerning hemophilia treatment and policy.\textsuperscript{118} Under the circumstances, it might be difficult for the Department of Health to seek other medical experts with the same or similar expertise when the most experienced and authoritative hemophilia specialist in the country needs to be excluded.

In 2003, a guideline was promulgated to address the problem by providing that the review committee may entrust a medical center or academic institution in another country for preliminary review if necessary.\textsuperscript{119} Therefore, in the case of hemophilia or other rare diseases, where the patients tend to seek treatment at the same medical institution and there may be only a couple of physicians specialized in the area, the Drug Hazard Review Committee may entrust a foreign institution for preliminary review to avoid bias.

\begin{footnotes}
\item[112] Drug Hazard Relief Act, supra note 24, ch. III, art. 15.
\item[113] Id.
\item[114] Id.
\item[115] Id. art. 16.
\item[116] Id.
\item[117] Struve, supra note 59, at 619.
\item[118] Lin, supra note 18; Ming-Ching Shen, Letter to the Editor, Cheng chih te piao pai [Declaration of sincerity] MING SHENG DAILY (Taipei), (Feb. 23, 1998), at 29. In this letter, Dr. Shen stated that he attended the International Thrombosis and Coagulation Conference held in San Diego in July 1985 and learned that heat treatment would reduce HIV infectivity. After returning to Taiwan, he advised the government to stop the importation of un-heated blood products. The Department of Health soon took action and awarded him a medal for his contribution to the treatment of hemophilia in Taiwan.
\end{footnotes}
D. Determination of Damages

The Drug Hazard Relief Act defines “drug hazard” as death, disability, or any serious illness caused by adverse reactions to drugs. The relief that may be provided is categorized as either death payments, disability payments, or serious illness payments respectively.

All three categories of relief are subject to the restriction of capped amounts. Both death payments and disability payments are subject to a capped amount of no more than N.T. 2 million dollars, which is approximately $60,000. The determination of the N.T. 2 million dollar capped amount was based on the amount awarded by the government in prior cases where victims contracted HIV through blood transfusion. Specifically, serious illness payments would not be granted unless the claimant could provide receipt from medical institutions as proof of the claimant’s medical expenses. The highest amount of serious illness payment awarded should not exceed N.T. 600,000 dollars, which is approximately $18,000.

The capped-amount provisions and a relatively smaller amount of relief granted under the Drug Hazard Relief Act are proper for three reasons. First, the victims’ medical needs are supported by the National Health Insurance System if their health conditions fall in the category of serious illness or injury. Though the one-time payment granted by the Review Committee may relieve the victims’ financial difficulty temporarily, it does not guarantee that the victims have access to adequate long-term medical care, which is what the victims desperately need.

In the Factor VIII context, besides the Drug Hazard Relief Act, HIV positive hemophiliacs’ medical treatments are also supported by other social welfare systems such as the National Health Insurance. In situations where the victim is alive, the award of disability payments may be considered as the victims’ non-pecuniary damages for pain and suffering because the HIV positive hemophiliacs are exempted from paying any medical expenses or premium under the National Health Insurance System.

If an HIV positive hemophiliac is not eligible for the National Health Insurance coverage, he may alternatively seek medical reimbursement for his infection from a...
special project under the Department of Health based on the receipts from medical institutions. Unlike other AIDS patients, there is no capped amount limitation for the HIV positive hemophiliacs who seek medical reimbursement per year.

Second, the provision of a capped award is a measure designed to provide operational efficiency in the determination of relief. Members of the Review Committee are experts in discerning medical, pharmaceutical, and legal issues. However, they are not experts in the determination of damages. Also, experts invited by the Department of Health for each review committee are different, depending on the nature of each case at issue. The capped-amount guarantees the consistency of the relief granted even though the members of each review committee are different.

Third, government agencies are not in a good position to impose punitive damages or large payments in a situation where causation is not clear. Under the Drug Hazard Relief Act, there is no provision concerning the award of punitive damages. The presumption of Taiwan’s adoption of the administrative compensation scheme is that the victims were harmed by pharmaceutical side effects that were not known or preventable by the manufacturers at the time when the drug was approved and marketed. Therefore, its provision concerning recovery did not include the concept of deterrence like the award of punitive damages in the American tort system.

As Christina Bohannan has argued, drugs that cause harmful side effects to some users may also give relief to a great number of others. Therefore, both punitive damages and the awards for pain and suffering should be limited because the possibility of extremely large awards is a primary source of uncertainty for business decision-makers and insurers, which may result in adverse societal consequences.

Factor VIII cases are typical examples where the victims’ injuries are caused by a product that presumably provided relief for an ailment prior to the use of the product. Before the introduction of Factor VIII concentrates, hemophiliacs had to transfuse large quantities of blood or cryoprecipitate collected from local donors to acquire a sufficient amount of blood coagulation factor. It was inconvenient and painful for the hemophilic recipients staying for long hours in a hospital for such transfusions. Factor VIII concentrates simplified the process by a single injection that the patients can even administer themselves. Therefore, the award of damages should be carefully calculated to avoid driving the companies out of the market and causing adverse societal consequences.

Also, as Andrew Klein has suggested, an administrative compensation system may set the amount lower than an average tort award to avoid making the scheme an attractive haven for those who can prove causation in the tort system. The rationale is that if the jury system would impose high uncertainty costs on companies, companies would be willing to opt-in to the administrative compensation scheme, even if the system might broaden the range of situations in which some amount of compensation must be paid.

---

129 Id.
130 Wu, supra note 27.
131 Bohannan, supra note 49, at 296.
132 Id. at 295.
133 Id.
134 Klein, supra note 9, at 126.
135 Struve, supra note 59, at 654.
Therefore, a large sum of monetary relief is not necessary for victims who are seeking administrative compensation if their long-term medical care is covered by National Health Insurance or its equivalents, such as the Medicaid program in the United States. Capped awards are justified for the purpose of efficient relief. Furthermore, a relatively smaller amount of payment under an administrative compensation scheme is adequate when the causation between the claimed adverse drug effect and the harm suffered by the victim is not clear, such as the HIV positive hemophiliacs’ inability to identify a single injection that caused their infection.

The Taiwanese administrative adjudication system followed the observation of painful experiences in other countries. Taiwan adopted the agency adjudication approach to resolve the HIV-contaminated Factor VIII compensation because the government had learned from other major countries that traditional litigation would cause painful consequences to the plaintiffs, the government, and possibly the entire society. The Taiwanese solution was initiated after cases in other major countries had reached mass settlements through lengthy litigation.

It is understandable that the concept of an agency adjudication system would encounter more resistance in a country which has a deep-rooted common law tradition, such as the United States. However, in recent years, the discussion of adopting an agency adjudication system to supplant common-law suits in medical-related contexts has no longer been restricted to academia, mostly because of the disfavor of a lay jury in cases where experts’ evaluation should be heavily relied upon.

V. REACHING CONSENSUS

It appears that the U.S. Supreme Court, the Congress, and the executive branch have taken steps, though the extent varies, toward the same direction in limiting or tending to eventually abolish the role of juries in medical-related suits. The Supreme Court’s disfavor of juries is evident in Riegel. The executive branch’s intention in limiting state tort claims and expanding preemption to drugs can be shown by its amicus brief in Riegel and its position in a later case concerning FDA regulations of prescription drug labeling. Legislators’ efforts to curtail the jury’s role

---

136 Yao-Mao Chang, Hsieh shang pi su song chiu chang geng kuai wei shu ni yiao chiu yiao chang shian ti bo tan bao jin [Negotiation is faster than litigation: The Department of Health will demand the pharmaceutical companies to provide a guarantee fund.] MING SHENG DAIL Y (Taipei), (Feb. 13, 1998), at 29. The article quoted the Minister of the Department of Health saying that it would be faster to reach a result through negotiation with the companies rather than litigation based on the experiences of other countries.


138 Riegel, 128 S.Ct. at 1008.

can be seen in the introduction of the Universal Health Care Choice and Access Act (UHCCAA) to the Congress in 2007, which proposed an agency adjudication approach to resolving medical-malpractice disputes.\textsuperscript{140}  

\textit{Riegel} was a case centered on the preemption clause of the Medical Device Amendments of 1976 (MDA).\textsuperscript{141} 21 U.S.C. § 360k(a) provides that:

\begin{quote}
[No] State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (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 chapter.\textsuperscript{142}
\end{quote}

The \textit{Riegel} Court concluded that state tort law has amounted to a requirement which is different from, or in addition to, FDA premarket approval for medical devices, and therefore is preempted.\textsuperscript{143} As the Court has stated, “while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”\textsuperscript{144} “Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”\textsuperscript{145}

Though the preemption in \textit{Riegel} only applies to Class III\textsuperscript{146} medical devices, which are subject to FDA premarket approval, the executive branch’s intention to expand preemption to drugs can be shown in its amicus brief filed for the same case. By analogizing FDA’s risk-benefit balancing for medical devices with the risk-benefit balancing FDA undertakes pursuant to 21 U.S.C. § 355(d) as part of the approval process for drugs, the executive branch argued that FDA reviews are not merely “minimum standards” of safety and effectiveness.\textsuperscript{147}

Indeed, the Supreme Court did not exclude expanding preemption to drugs and food additives. In \textit{Riegel}, by responding to the dissent, the majority stated that “[i]t has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the [Food, Drug and Cosmetic Act].”\textsuperscript{148}

The \textit{Riegel} Court’s concern regarding state common-law duties did not rest on the remedy itself, but on how the remedy is determined. The Court has expressly stated its disfavor of juries in \textit{Riegel}: “tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.”\textsuperscript{149} On the other hand,
the dissent in *Riegel* worried that an outright preemption would “remove all means of judicial recourse” for consumers injured by devices that receive FDA approval but nevertheless proved unsafe.150 “Regulation cannot protect against all possible injuries that might result from use of a device over time.”151

The disagreement between the majority and the dissent in *Riegel* can be settled by allowing states152 to create their own state agency to adjudicate compensation for victims without employing juries. Though the majority in *Riegel* disfavored juries in a medical-device context, it appeared that the majority may not be oppose to an agency adjudication approach adopted by the state granting compensation to claimants injured by medical products. As the Court has stated in the dicta, “[a] state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”153

Furthermore, an agency adjudication system is not merely a foreign concept or some legal scholars’ fiction,154 as Sen. Thomas Coburn has introduced the UHCCAA in March 2007.155 The Act proposes an agency adjudication approach to resolving medical-malpractice disputes.156 Under the UHCCAA, states would establish an Administrative Health Care Tribunal in resolving medical-malpractice disputes with financial assistance from the federal government.157 A panel of six independent experts would be assigned to review each case before the case goes to the Tribunal.158 These experts would be appointed by the head of the state agency responsible for health-care issues.159 Three of the experts on the panel would be attorneys, and three of them would be medical experts specialized in the type of injury alleged.160

It appears that it is time for states to consider adopting an agency adjudication system to compensate consumers who are injured by FDA-approved medical products with or without the federal government’s assistance. Though the proposal under the UHCCAA would only apply to medical-malpractice disputes, the concept of establishing an agency adjudication system by the state can extend to all medical-related issues, which heavily rely on experts’ evaluation. States have primacy over matters of health and safety.161 Preemption would not preclude a state from

---

150 *Id.* at 1015 (Ginsburg, J., dissenting).
151 *Id.*
152 Unlike an injury caused by vaccine, which is more likely to have a nationwide effect and raises more public health concern, an injury caused by drugs or medical devices may only have local effect. For the efficiency of relief and the ease of collecting information, a state agency which would adjudicate the victims’ relief locally may serve better for the stated purposes.
153 *Id.* at 1008.
154 In addition to the pending legislation, the National Vaccine Injury Compensation Program (VICP) is another example of agency adjudication scheme which is still in effect today. On October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the VICP. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to individuals found to be injured by certain vaccines. Three Federal government offices have a role in the VICP. They are the U.S. Department of Health and Human Services (HHS), the U.S. Department of Justice (DOJ), and the U.S. Court of Federal Claims. The Court of federal Claims decides who should be paid. National Vaccine Injury Compensation Program (VICP), available at [http://www.hrsa.gov/Vaccinecompensation/](http://www.hrsa.gov/Vaccinecompensation/) (last visited Sept. 30, 2008). See also 26 U.S.C. § 9510, 42 U.S.C. § 300aa-10–§ 300aa-34.
155 *Supra* note 140.
156 *Id.* § 399R.
157 *Id.* § 399R (a).
158 *Id.* § 399R (d) (2) (A).
159 *Id.*
160 *Id.* § 399R (d) (2) (B) (ii).
161 See *Riegel*, 128 S.Ct. at 1013 (Ginsburg, J., dissenting).
exercising its traditional function in promoting health and safety, as long as the system adopted by the state does not offend the scope of preemption as interpreted by the Supreme Court.

VI. CONCLUSION

The Factor VIII cases have provided an example showing why an agency adjudication system is not only preferable in a plaintiff’s winning situation. An agency adjudication system is also favorable in a plaintiff’s losing situation where the case did not even reach the jury because of the plaintiff’s inability to prove causation.

A state agency adjudication system may determine the amount of compensation to the claimants on a no-fault basis so as not to impose “additional requirements” in the wake of Riegel.162 A system adjudicating the defendant’s fault and liability, similar to the common-law suits, would amount to “additional requirements” which are subject to preemption, at least in a FDA premarket approved medical-device context.163

The state should be allowed to establish a relief fund as the financial source for awarding compensation to claimants with medical-product manufacturers or sellers required to pay a levy based on their volume of sale. Where the plaintiff alleges that the defendant has violated FDA regulations, the case should be filed in court and be excluded from the agency adjudication system. As the Court has stated in Riegel, 21 U.S.C. § 360k “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations.”164

Finally, the Medicaid system may also play a role in the state agency adjudication system. By providing victims who are seriously injured with free or affordable long-term medical care, the extended Medicaid coverage would prevent such victims from being further jeopardized by rising health insurance premiums. As a consequence, a large one-time payment would not be necessary if the victims’ long-term medical care is being covered.

162 Id. at 1008.
163 Id.
164 Id. at 1011.