COMPENSATION FOR PATIENTS AFFECTED BY DRUG-RELATED INJURIES: LEGAL REMEDIES AND ETHICAL CONSIDERATIONS

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Abstract

Drug-related injuries remain a significant challenge in healthcare systems worldwide, with consequences that are medical, legal, ethical, and economic. This research investigates the multidimensional framework surrounding compensation for patients harmed by adverse drug reactions (ADRs), including the roles of tort law, product liability, and negligence claims. It explores the shortcomings of current legal structures and regulatory bodies in effectively compensating injured patients and proposes ethical and equitable alternatives, such as no-fault compensation schemes, alternative dispute resolution mechanisms, and market-based accountability systems. Through the examination of landmark legal cases and legislative proposals, the paper evaluates the impact of informed consent, patient autonomy, and the burden of proof on victims seeking redress. Ultimately, it underscores the need for comprehensive reform in compensation law to ensure justice, fairness, and protection for patients affected by pharmaceutical harm.

Key words: Adverse drug reactions (ADRs), Tort law, Product liability, Medical negligence, Informed consent, Patient autonomy, Legal compensation, Ethical considerations, Regulatory frameworks, Alternative dispute resolution (ADR)

1. Introduction

Patients suffer serious injuries from medications that affect bodily and psychological functioning. Temporal proximity to the administration of the medicinal/therapeutic substance is a primary factor in establishing a causal link between the drug taken and the adverse result. Evidence should be irrefutable and unwavering, demonstrating that both the consumer's and the manufacturer's/originator's actions did not deviate from the proper standards of behavior until and after the intake of the medication. Additionally, recovery should be proportionate to medical costs, life and day-to-day functioning impairment, and pain and anxiety levels.

However, for substantive, practical, and ethical reasons, victims of drug-related injuries face serious obstacles in getting compensatory damages from originators or drug manufacturers. Drug-related injuries are frequent, costly, and devastating to individuals and society. Therefore, these challenges must be strongly addressed, and effective measures must be implemented to counteract them [1]. The great American tort litigation is theoretically sound, especially when it comes to serious injuries from drugs and medicines, which generate massive compensatory damages based on substantive medical principles. Extensive and needless litigation, to the detriment of all involved parties, is more likely than justice being accomplished.

Additionally, it is illogical to think that formally informed patients of the risks and consequences of medications would have demanded a delayed or, all things considered, a less efficacious treatment. While there is no doubt that the best doctors, hospitals, drugs, and treatments are available, their costly nature makes them the exception rather than the rule. Medical treatment is more likely to be deadly or debilitating than helpful, requiring substantive and philosophical scrutiny. Drug safety, efficacy, and advisability must be today and tomorrow paramount issues for personal and public development [2].

2. Understanding Drug-Related Injuries

Drugs are used on the premises of their beneficent effects without any but isolated exceptions, while the terrible injuries they may inflict have mostly eluded the eye of the law. Concerned only with orthodox use, adopted with the guidance of medical education and of the maternal wisdom of culture, the law leaves drug-related injuries obscure, causation-wise, and all but without legal remedy [3]. Kelsey DeRoche became the plaintiff in a major pharmaceutical controversy concerning a synthetic estrogen, diethylstilbestrol (DES), widely prescribed in the 1940s and 1950s, to avert thenanticipated miscarriage and premature labor, and causing irregularities in the development of the repro-genitalia of many such mothers and of their daughters. But the company that manufactured the version of the drug prescribed to DeRoche was Diasol Chemical Company, which sold the drug through a retailer in New Hampshire to which it had no direct connection, and it was a drug which no doctor today would prescribe. So the court, confronted with a question of encouraging evidence, took mock science from the bench, abstracted it to an untenable image of biological causation in the mind, and awash with biologies, looked to ideology for guidance on the authorize-level. [4][5][6]

The law is a magnificent instrument of social change. Science and ideology grapple with one cultural view, because the fierce sylphipede decries governmental protection of the industry. But the criticisms have dimmed from widely publicized before the court found it could not proceed with the trial, shortly after Daubert's seminal opinion admitting trial court discretion to reject expert testimony deemed unreliable. A decade has passed, by which time the B.A. has turned into a national disgrace. The companies settled for $200 million, putting provisions in the resolution that companies adopt rules by which it is to be defined if research data are turned over to the other side. This way, the discovery path is unclear at best, and has become empowered to go to federal court, which has denied the Durox class of plaintiffs an expanded interpretation of the onerous Cloque that it had deliberately specified and approved.

2.1. Types of Drug-Related Injuries

Drug-related injuries refer to various injuries that patients may suffer as a result of taking drugs. They can be categorized into three types: adverse drug reactions, problems caused by drug vicissitudes, and cases related to medical errors. Adverse drug reactions, which are reactions to drugs that are unexpected to patients and doctors, are often described as an "adverse drug event" or "adverse drug effect" in practice. Due to pharmaceutical companies conducting high-risk experimentations in the face of strict drug administration safety regulation mechanisms for the purpose of development and profit, there are emerging cases in which pharmaceutical products approved by good drug designation systems pose significant health hazards to patients globally [7]. Pharmaceutical companies are thus often mandated with the duty to notify medical authorities and take corrective measures in a timely fashion. The liabilities for adverse drug reactions are contingent on the obligation of pharmaceutical enterprises to take such remedial measures. This class of drug-related injury events can thus be considered as a breach of social administrative obligation.

The former cases often do not incur liability for drug-related injury. They belong to the category of risk events due to drug property vicissitude or risk ignorance at clinical levels. Nevertheless, they can often generate new demands for the pharmaceutical enterprise or the relevant medical organization. The liabilities can thus only be stipulated adroitly and typically involve dilemma-related litigation arguments to avoid such illicit financial losses. On the other hand, adverse drug reactions uncovered after drug marking may widely generate great personal and economic losses in a direct manner. They often bear significant and profound societal implications in the public policy area [8] The correlative liabilities mostly prescribe tortious or quasi-contractual liabilities as required for injuries. In contrast, the liabilities for medical errors are rather straightforward but may generate public concern regarding unfair compensation mechanisms. Drug vicissitudes refer to significant level wording change, indication increase, or serious risk finding in a drug's general usage relation after its market approval. These stricter regulations can be categorized as a breach of social administrative obligation by pharmaceutical authorities or agencies.

2.2. Prevalence and Impact on Patients

Adverse Drug Reactions (ADRs), also referred to as Adverse Drug Events (ADEs) or Drug-Related Injuries, vary in nature from mild to life threatening. Some ADRs, such as anaphylaxis to penicillin, are clear cut and narrowly defined. Others are better termed syndromes, with an array of consequential events extending beyond the drug, drug class or biologic agent that initiated the ADR or event. For example, in some patients, receipt of the antineoplastic chemotherapeutic drug, trastuzumab, can lead to cardiomyopathy, congestive heart failure, and new requirements for heart failure treatment, including vasodilators, diuretics, and cardiac catheters. A qualitative analysis to characterize, describe, and illustrate the syndromes that follow so-called “very serious ADRs” [7] was conducted.

Very serious ADRs are unintended consequences of treatment that are immediately life threatening or involve permanent organ dysfunction. This realm of ADRs is of interest to practitioners, manufacturers, liability insurers, academia, public health officials, and legal scholars. The very serious ADRs considered fall into two broadly defined domains: broad syndromic events (e.g., narrower definitional syndromes) that have an array of consequences extending beyond the drug, drug class or biologic agent that caused the event. Other events, such as aplastic anemia from sales of over-the-counter acetanilid– phenacetin combination analgesics have more narrowly defined initial ADRs leading to premature deaths due to renal cancer and/or database-generated epitheliomatous bladder malignancies. In summary, at the close of this analysis, a very incomplete and nonexhaustive listing of ADRs potentially eligible for consideration is provided.

For decades, arguably the consequence of the most concern has been treatment related deaths (TRD). Because ADRs can be both very serious and very prevalent globally, such ADRs seriously impact public health, clinical care patterns, patient outcomes and final hospital revenue net of expenses and risk. To provide context, patient care at Southern Network on Adverse Reactions (SONAR) is discussed within considerate details: all quality of care measures and outcomes before, during and after very serious ADRs.

3. Legal Framework for Compensation

Compensation for Patients Affected by Drug-Related Injuries: Legal Remedies and Ethical Considerations

I. Basic Differentiation

Compensation for patients affected by drug-related injuries contributes to the health services system as the generator of risk. The injured persons are compensated in the same manner as victims of natural disasters. The financial objectives of this mechanism include the establishment of organizations in charge of expert reviews providing the basis of the expenses, which exceeds €40,000. They generally receive a developer's margin of 1 to 2.5% of services,

which is less than general services. Indemnification based on national solidarity grants a financial margin of 10% of compensation. Medical acts need arrangements based on procedural estimates and forensic accounts.

Two types of procedures exist: outside exclusion procedures for simple claims ranging from €0 to €1,650 and internal exclusion procedures for claims exceeding that threshold, which can be either simple or complex. Most procedures are standard compensation procedures since hazardous methodologies are now outlawed. Internal exclusion procedures have been rendered almost infeasible since major pharmaceutical firms have also encountered basic relevant dosage discrepancies. However, 99% of patent expiration drugs induce renewed safety malfunctions, as none but cyclic regulators are capable of preventing this effect.

II. Acceptance of Vaccination Indemnities

Three levels of safety exist: contraction by refined abuse, by unforeseen negligence, or by medical hazards outside obligations. All three levels of safety are permitted in regard to vaccination recipients and cemeteries storing aqueous elements. Owing to the fast nadir of vaccine validity, the promotion of the narrow vaccine combines a great deal of litigation. Vaccine producers and countless States have withstood claims of national solidarity within their ambit. Preemptively falsification-proof vaccines tumor viroids of vertebrates become the first target on which safety has been extensively clarified. The prepared remedy is economic but needs to be authorized by relevant regulatory agencies, and considerable safety malaise proceeds.

3.1. Overview of Tort Law

A patient who suffers a drug injury from a defective drug or a negligently administered drug may wish to hold the manufacturer, supplier, doctor, or pharmacist legally responsible. Unfortunately, traditional tort law cannot guarantee such recompense. Nevertheless, many patients now hope that they will be compensated for drug injuries when a drug is banned, labelled, or found safe. Some lawyers wonder how a prospective plaintiff can bring suit or, if a suit is brought, whether it will be dismissed without a trial on the merits [9]. It must be remembered that no one can predict the law. Nonetheless, based on recent cases, some general conclusions can be reached.

Tort law has changed but a tort must still be established. A choking on a peanut must still be proved against Peter Pan peanut butter, a seat belt not automatically retracting must still be proved against Ford, and a drug injury must still be proved against the pharmaceutical company. Each participant (drug companies, FDA, doctors, stockholders, or ex-patients) in the drug dilemma must be evaluated on a case by case basis. It is only at that point that a tort, if any, can be established. It is a fact that no new side effects or complications would develop with a single explanation at the time of and as a result of the drug being banned, labelled, safe, etc. The burst of preclusion would be retrosclusive, not prospective, on a tort basis. Just as the national sale of Dalkon Shield was not preclusive of a tort action against the manufacturer, the

suspension of approval or the external mass excision of Norplant would not necessarily be preclusive on a tort basis against the drug company or the rest.

3.2. Product Liability

In the modern world, there is a need to educate consumers who buy prescription medications that they are not perfectly safe and effective just because a physician has prescribed them. Remedies available through the civil tort system satisfy utilitarian, retributive, corrective, and restorative needs. However, because the tort system in the United States does not effectively compensate consumers harmed by dangerous prescription drugs, there is a need for more creative liability standards to bring manufacturers to account when their products harm consumers. The consumer reviewed acceptable safety and effectiveness of the drugs and their design and manufacture. The physician reviewed safety and effectiveness relevant to the patient's condition.

Some of the insights gleaned from analyzing this market are useful in evaluating potential tort remedies. Understanding the goal of the tort remedy is essential. It is disproportionate to expect tort law to provide a panacea to all the ills surrounding prescription medications. Some needs of those harmed by drugs can only be addressed through other mechanisms, such as continued refinement of regulatory approval systems to address problems with inadequate safety and efficacy testing and marketing. Conversely, some issues clearly lie within the dictates of tort and breach of warranty law. Compensating patients harmed by prescription medications is a reasonable goal. However, this task may be better accomplished through a tort-based market assurance system, similar to: pharmaceutical product stewardship insurance (or bonds) that would require sellers to finance a fund to compensate patients for injuries caused by their commercially available prescription medications. The market assurance would fulfill the goals of the current civil tort remedies system while achieving substantially better results.

The analysis offers some features of a tort-based alternative viable mechanism that prevents patient harm while enabling the pharmaceutical industry to thrive. In addition, this analysis can serve as a model for tort systems addressing compensation for consumers injured by the goods and services provided in any industry with vast knowledge gaps between sellers and buyers. Today's tort system is ineffective and inefficient for bringing compensation mechanisms to food, appliances, cosmetics, medical devices, and building materials, among others .

3.3. Negligence Claims

In the event of drug-related injuries, a negligence claim can act as a potent device for victims to seek compensation. Medical negligence may potentially surface in both the pre-administration phase and post-administration phase. As one of the most frequently raised legal issues in drug-related injury cases, the negligence claim confers generic compliance with all qualifying patients' rights to claim compensation to restore relevant property losses by seeking claims against third parties that cause the losses. The negligence claim is raised by the victim him/herself, in which should contain issues such as: the relationship with the patient and

healthcare provider; the specific action/inaction considered negligent; the failure of the duty; the consequences deriving from the failure; and the amount of compensation to be claimed [10].

By focusing on and naming these legal issues, a negligence claim for drug-related injuries can be potentially and effectively raised by the victims, even competent victims to claim negligence against the pharmacist if they procure the injurious drug from the pharmacy directly. Furthermore, as the negligence framework is formulated generically, it may impact and empower victims with wide accessibility to claim compensation. Therefore, besides proposing a negligence claim, attentions should also be directed to the crucial points of predicting whether it can be effectively raised in drug-related injury cases or not, especially when the precise inquiries related to cases are unknown (i.e., whether a negligence claim has been raised against healthcare providers, and the specific healthcare provider(s) be named).

Due to the increasing complexity in medicinal product design and drug delivery technology, it is common for patients to suffer from adverse drug reactions caused by such means, and drug-related injuries have also been embroiled in a medical negligence debate [11]. This indicates that by examining medical negligence in drug-related injuries, the context and the patients' rights to medical services and quality drugs can also be illustrated.

4. Regulatory Bodies and Their Role

To address the increasing demand for drug-related injury compensations, such as those following the use of ozone treatments; health care regulatory bodies need to incorporate a broader range of ethics concerns into their current policies, practices, and enforcement, consider additional forms of compensation and more broadly, appropriate funding sources. More broadly, professional gates need to be re-examined and, if necessary, restaffed to better serve the public, perhaps emphasizing similarly nimble, science-savvy models such as those previously instituted for evaluating drugs at the FDA or the widely discussed but unrealized efforts to better police all food/supplement exposures through a single unified body [12].

A significant place for any professional gate is the legal system. The present system needs to be much more nimble and responsive in its evaluations, able to recognize health care dangers and abuses rather than wait passively for harm to occur. Additionally, a more equitable system or systems for compensations than those currently provided by the non-drug legal system, which typically monopoly firms can afford to exploit and threaten will also need to be elaborated. One possible avenue here might be to expand the staterun tort systems that currently compensate on an ex post basis unexpected disability damages (though again, many complications would likely arise in implementation).

Evolving a range of other, ex ante, compensations might also help better balance the public good.

To openly air the scientific/clinical concerns discussed here with a wider audience, a series of public discussion forums in state capitals might be held to garner public opinions on where the general public feels sufficient harms have happened. Rather than elevating searches by external bodies to admittedly very high levels of scrutiny, sifting through discussions held among the general public in each state might reveal regions where sufficient thought and consideration have not been brought to certain health care applications. More timely yet less ethically heavy-handed evaluations would thus seem more likely to arise from a public set of discussions rather than top-down bureaucratic queries.

4.1. FDA Regulations

Drugs cannot be marketed or sold until after obtaining a New Drug Application ("NDA") approval from the FDA. An NDA must contain information establishing the safety and effectiveness of the drug, together with information on relevant aspects of manufacture, packaging, and labeling. Upon receiving an application, the FDA may take up to 180 days to evaluate it for completeness, safety, and efficacy. If a drug is approved, it can be marketed. However, even after marketing begins, the FDA retains jurisdiction to require additional studies to capture newly emergent risk information. The FDA can also determine withdrawal if the risks outweigh the benefits. Drugs are studied prior to approval in some patients from which the safety and effectiveness information is obtained.

There are several characteristics of drug knowledge and regulation that motivate consideration of purely regulatory compensation schemes: the range of potential defendants and liability designs, the difficulty of incentive-adjustment, and the preference for the guarantee of compensation for some offsets. Where tort liability has existed, it is substantially sidestepped for the reasons mentioned above. In this regard, it should be noted that the FDA routinely makes decisions that affect the risks and benefits of drug use. These decisions are informed by an array of scientific analyses. Consequently, the FDA is a plausible authority whose judgments of risk and benefit could be replaced with strictly regulatory compensation rules [12].

4.2. State Medical Boards

In all states, the State Medical Board is responsible for interpreting the local Medical Practice Act and enforcing it against licensees who violate its provisions. Similar provisions exist for other than MD practitioners. The executive director is usually an attorney, working with staff attorneys and investigators. The board, managing its own investigative process, reviews complaints and determines whether patient care was inappropriate. Board investigators and attorneys can subpoena records and compel testimony. The board can impose a range of administrative sanctions, including revocation, suspension, fines, and restrictions. It can also limit its jurisdiction to monitor compliance with probationary duties assigned to the licensee. State Medical Boards vary in how aggressively they oversee complaints against licensees, and such oversight may vary between license types.

The medical boards' procedures are governed by state administrative procedures acts and are quasi-judicial as opposed to judicial. There are typically provisions for pre-hearing investigations, depositions, interrogatories, and discovery requests for documents. Under some state statutes, the State Medical Board can issue complete immunity to any witness who provides information on licensing compliance or drug abuse. California law allowing such immunity states that only information which contains willful or grossly negligent malpractice is admissible in civil suits [13]. In such cases, the medical board's decision is ordinarily final, although certain upset conditions are statutorily required to be met for a reviewing court to accept it. Such conditions usually involve factors such as whether any competent evidence supports the board's decision, which evidence must be in the record.

Judicial review of quasi-judicial decisions made by non-judicial bodies, such as the State Medical Board, is often limited. Boards may be permitted to find facts within statutory bounds of credibility. They are not required to observe the rules of judicial procedure or statutory construction. Judicial review of quasi-judicial matters is typically only on the basis of whether there is any evidence to support the board's findings. Because of this standard, it's rare for courts to find a state board in error. Protective orders and privileges usually do not protect testimony or documents required to be disclosed to the board to carry out its investigative function.

5. Ethical Considerations in Compensation

No one who has been directly or indirectly affected by the trauma of a personal injury, or a twisted accident, should deny how futile is the attempt of a victim to rationalize or explain what happened. Testimony by the injured person is cogent and often vividly described. Intractable pain not so much as the broken parts, or external scars, weighed in the acceptance of a contingent premium acceptable at common sense [2]. But this fails to take account of a new dimension of injury, again its affective elements. A retrospective survey of patients' experience of compensation law five years post-successful claims can be expanded to partially articulate the meaning of compensation's therapeutic significance. Whence the psychic pathology of money? This, of course, is ultimately unanswerable but, diffusely, some dozen areas of concern enter the equation in different mixes at different times. This may take the form of self-recrimination, for example, in trying to discount PTSD symptoms in terms of whether they are genuine or meet the clinical requirements for recognition. A worry arises that these probably do occur in pain syndromes and thus inappropriately to over-attribute their development to a traumatic accident. Though the claimant may not deny their appearance, his/her sense of having augmented losses and thus worsened eventual damages with esteem is distressing. The negative aspect of a traumatic event, particularly in an assault, is most primary. It is frequently imagined possessing the haunted solitary self watching the offence occur, usually to the utter helplessness and despair of a suddenly confused onlooker. The victorious aggressor intuitively knows all this. Historically and literarily, particular families or clans have often pursued a vendetta of revenge. Then there are the fears of retribution or revenge directed against those feared to provoke retribution from the assailant(s). The ongoing restraint required to avoid land-mines

and traps lays the groundwork for ischemic heart disease. Or, in contrast, professional consultants would enter the equation seeking to orchestrate lengthy and expensive recoveries. The need for honourable reparations thus took on a more complex direction than originally fathomed.

5.1. Justice and Fairness

Justice has been interpreted in many ways - as the virtue of fairness, giving people their due, a set of rules or principles for governing human conduct, a legal system for settlement of disputes, or the provision of structures and arrangements for satisfying rights - but most interpretations agree on two connected concepts: fairness and entitlement [2]. Fairness pertains to a fair rule or principle in dividing out entitlements. Entitlement relates with what is to be divided out. A justice system must have rules to allocate entitlements formally, discover entitlements, and enforce final de facto allocation of entitlements. These three aspects of justice are called fairness, distributive justice, and legal justice, respectively. Drug-related injuries are rising world-wide and yet there are controversies on compensation structures for injured patients. The term "compensation for drug-related injuries" in the title does not concern the provisions of drugs whether they are prescribed by a doctor or dropped down from the air by an aircraft or otherwise. Nor does the structural compensation scheme proposed in this paper to the setting of various compensations concern the private property rights to various compensations for agencies and organizations that are involved in the drug supply and drug market. Only the ethical compensation structures for patients themselves who bear damage and pain caused by drug-related injuries from drugs themselves are considered. Initially, fairness issues for patients affected by drug-related injuries under ordinary tort liability are briefly outlined as background. The reference is a set of ethical criteria to assist the implementation of compensation structures to fairness.

5.2. Informed Consent

Informed consent is an ethical and legal doctrine that requires physicians to provide potential patients with information about medical treatments or procedures to be performed on them. The ultimate aim of the doctrine is to preserve the respect of the patient's autonomy so that the patient would be able to make adequate decisions regarding participation in the proposed medical treatments or procedures. Physicians are obliged to disclose to their patients information that may influence the patients' decision of whether to accept the proffered medical treatment [14]. Given that treating physicians' knowledge of common medical practice and scientific studies largely exceeds their patients', disclosure of medical risks has the practical effect of transferring onto them the burden of deciding the treatment course. On the assumption that patients regard safety and effectiveness as paramount considerations of a treatment course, medical risks undisclosed by the physician might well decide the course of events leading to serious injuries or side effects occurring but not disclosed. Though nationally variations of the doctrine of informed consent abound, similar efforts were developed from common interests that aim at restoring the balance of power in favor of more vulnerable participants of health care services. On the side of patients, protectable interests would encompass the non-injurious,

knowledgeable-patient, informed-consent based, civil-lawprotectable decisions of acceptance of medical treatments that provide adequate riskdisclosure. On the side of the pharmaceutical industry, the purposes of securing investments, protecting business information, scientific findings and reputations, and limiting legal liability should be pursued in a lawful manner and in accordance with world-wide accepted ethical standards.

5.3. Patient Autonomy

Patients have a right to be informed about both the nature and purpose of proposed health care interventions, as well about the risks, benefits, alternatives and costs of those interventions. This right to make an informed decision about a proposed intervention within the existing facts, is the bedrock of the legal accountability of health care interventions. Health care professionals (HCPs) are obliged by laws and regulations to provide adequate information pertaining to a proposed health care intervention. Failure to do so in a way that prejudices their patients' treatment options gives rise to a private right of action against HCPs [15]. Questions arise in cases over the effects of new health care technologies, particularly those technologies that had not been anticipated, pursued or received by patients in any way. Once the hazards of the new technologies are known, and once patients are involved, such cases may contribute to the perverse effects of misinformation. A priori respect for patient autonomy, in these cases, may interfere with the appropriate HCP intervention of health information control. Investigators and regulators, rather than caring for consumers innocently mangled by ordinary nonadherence to statutory duties of care, might instead be ethically culpable of much worse failures. The easy problem of consumerising HCP-Patient interactions can be matched by the hard problem of, after the toppling of their own. The appropriate premises, responsibilities, expertise and actions of HCPs and the courts, protecting patients rather than constructionism's "hear no evil, see no evil, speak no evil," ought to be carefully understood and precisely executed.

6. Case Studies of Drug-Related Injuries

During the late 1970's, studies indicated that a large group of daughters of mothers who had taken DES were developing adenocarcinoma of the vagina. Conducting this research was complicated by the lack of precise medical data for comparison, and it was slow due to the background burgeoning of other health-related studies, i.e., environmental pollution, abandoned dumps, radiation from leaking radon, and so on. It was also complicated by the noticeable lack of the drug for nearly 15 years before the studies. Anyway, the daughters' parents were increasingly becoming involved in the lawsuit against drug manufacturers, aided by health officials who suspected a connection between the mother's prenatal use of DES and the daughter's adenocarcinoma. The first successful lawsuit against a drug manufacturer was entered in Massachusetts in the late 1970's. The case decided several legal principles that had been debated before, including manufacturers' liability despite the lack of fault, exclusive use of a drug for prescription purposes, retroactively bringing into the lawsuit drug companies' subsidiaries who had been only out-of-state manufacturers, allowing drug companies to be liable for a national market share, adoption of the enterprise liability theory, and presumption

of the transferability of the drug in a prescription-only market. These events and the complicated legal principles emerged have been called the DES case and the DES identification problem [3].

A review of the DES reports indicates several limitations on the interpretation of the results. Offspring exposures were based on fairly unspecific interviews; therefore, reliance on memories of mothers who used the drug would likely lead to misclassification of exposure. Most epidemiological studies used clinic patients as the population at risk. This approach introduced considerable bias because it lead to overestimation of the disease probability. Most clinic patients had had complications of DES-exposed pregnancy/delivery, and as a consequence they might not be representative of all women who took DES [16].

6.1. Notable Legal Cases

Patients seeking the compensation they think they deserve from the companies that bring such medicines, vaccines, or medical devices to market often encounter obstacles because of the many legal doctrines that protect government and corporations from lawsuits. This examines these by detailing notable legal cases in this area and law reform proposals designed to make it easier for injured patients or their survivors to recover. Recent highprofile cases against manufacturers of widely used products that are now perceived to have harmed patients with serious side effects highlight this topic's social relevance as well. The cases described here include West v. A & B, a case where the California

Supreme Court affirmed a trial court's decision that the makers of the drug DES could not be held legally liable to a young woman whose overt breast cancer largely arose from her mother using DES while pregnant. Some of the drug case issues raised by this case remain controversial today. This important decision disposed of the case in a very healthy way for the drug makers. Nonetheless, it is clear that everything hinges on what the words "defective product" mean. They are not self-defining legal terms, and their very lack of definition explains their fluidity both in framing action on behalf of injured patients and in achieving success in that action [3]. But this fluidity is exactly what is needed. These regulations are subject to continuous reformulation to reflect unanticipated developments and each invention could be said to define a new era in product liability law. Thus, all that is necessary is a motion for judgment on an overt defect contended to be present in the product at the time of sale. No impression of normalcy should be suborned by arguing that something that was permissible in the commercialization of a product suddenly becomes impermissible when the nature or extent of the pervasive risk attendant to the product changes, or that discovery of the dynamic characteristics of a product after its sale is devoid of legal significance because some state of the art defense victims persuasively matched their own medical or refractory history with "reasonable expectations" and publicly accessible information about the drug's chemistry.

6.2. Outcomes for Patients

Patients affected by drug-related injuries urgently need financial support to relieve their suffering. Following an injury caused by a drug that suffered from post-marketing approval problems, some patients may wish to take actions against the pharmaceutical company. Others may prefer to avoid litigation and receive compensation from a national fund similar to that for vaccine injuries in Sweden. This section examines the ethical issues arising from these two compensation options for patients. It also discusses the potential for these two options influencing pharmaceutical companies to better monitor drugs after marketing approval.

Injury victims can take legal action against and request damages from the company that manufactured the defective drug under tort law. A stricter liability standard applies in this case, but patients must prove four criteria: 1) a drug injury occurred; 2) the drug manufacturer was legally responsible for the injury; 3) the injury was incurred before a specified date; 4) the plaintiff can be traced to the drug manufacturer. Pharmaceutical companies are limited in some cases regarding liability for drug-related injuries incurred after a specific date. A victim can receive at most compensated medical expenses; medical expenses are removed from compensation for a part by applying the rules of contributory negligence [17].

Victims cannot file suits against pharmaceutical companies and receive compensation obligation-free from a national fund. Other than the claim outcomes of tort claims against drug manufacturers, there may be no strict limits on the claim evaluation of state compensation claims. A claim can be rejected if enough evidence of the drug's safety and effectiveness before marketing approval is presented. Victims can also request any damage amounts they wish. The symptoms need not be directly produced by the drug. In the near future, it will be possible to determine the cause of injury and the sufficiency of evidence conveniently based on the differences in medical needs. A state fund can preserve a part of manufacturer sales or profits as a takeoff fund for later compensation. A proportion of this fund can also be used to compensate victims. Since the manufacturer is not completely free of liability, a proportion of compensations paid to victims can be reprised from the manufacturer.

7. Challenges in Seeking Compensation

Prior to introducing a compensation process, it is essential to examine the various types of injuries suffered by those affected by use of the pharmaceutical product that have caused the drug-related inquiry and to review the existing legal forms of compensation that they possess as a result. Thereafter, major ethical issues raised by an introduction of a compensation scheme and a preliminary general assessment of its ethical implications is undertaken.

The starting point of the discussion is an examination of the various types of injury suffered by those affected by the defective, damaging drug that has triggered the inquiry. By definition, patent defect must be severe and pervasive to warrant inquiry. However, the consequences of such a defect hinge on a variety of questions including dosage prescribed, age, co-morbidities,

and more [1]. As a consequence, injury types span broad categories of significant birth and developmental defects (for example, lower limb defects, craniofacial defects, central nervous system defects, death), chronic health impairments (such as renal dysfunction, cognitive impairments, loss of vision, hearing, etc.), complications during pregnancy or birth (e.g. stillbirth, early risk of autism), to less chronic and direct effects on patients and siblings (e.g. mental distress as a consequence of child's disability, impaired health of mother) and more indirect impacts on society and families (loss of income, loss of productivity, inability to work, legal costs, etc.).

Existing legal forms of damage compensation available for those having suffered an injury are then examined. The Steingard Inquiry Rule is similar in intent to existing legislative schemes, with the exception that it is designed for pharmaceutical product safety use. Salt and Hinkley Class Actions provide for transfer of expert and costly damage evidence from claimants to Defendants through one single class period and class actions in Lump Sum Compensation Schemes. While the tort liability aspect of negligence is stipulated within the CWPA Rule, it is not specified whether other forms of tort liability including Pure Mental Hurt or Nuisance might be regarded as eligibility compensatory forms besides direct kind of injuries suffered or cash or indexed bond measure [2].

7.1. Burden of Proof

The plaintiff who has experienced a drug-related injury generally bears the burden of proof regarding all elements of the tort claim. This includes establishing that the drug manufacturer (or another proper defendant) failed to provide adequate warnings or that the sufficiency of the warnings provided was unreasonable. The plaintiff also must establish elements of causation, magnitude of harm, and damages. The general rule of evidentiary law is that the burden of rebutting the prima facie case is on the defendant. As a generalization only the plaintiff would be in possession of evidence regarding baseline risk, warning practices, and variability of drug effects. Access to this evidence is conventionally in a custody chain that leaves the defendant in possession at the beginning of the case. If there is evidence in custody of a plaintiff that is not discoverable by a defendant, the burden of producing the evidence is on the plaintiff. Otherwise, neither party is under a duty to present all evidence in their possession; adversarial litigants are expected to exclude evidence that hurts their positions even if it is not privileged under evidentiary law.

Burden-shifting permissibly alters these common law rules. The burdens of production and persuasion can be allocated to either party, but if the producer of evidence does not produce it the party otherwise having the burden prevails. In American tort law, if two or more defendants create equally plausible but mutually exclusive claims, one must win and one must lose. All-in-third-party lotteries are permitted only the first-choice winner receives either harm or benefit [18]. Just as with the rational basis for Feeser, trial courts possess discretion regarding what evidence is too attenuated from having been the immediate cause of the harm to be relevant. Courts must consider the evidentiary capacities of the parties before allocating a skeptical burden of proof for these reasons as well.

Because food and/or drugs are dropped from buyers' care, damage and risk of injury are not equally distributed. The previous chapter discussed loss distribution and insular expectations. A society's adherence to these expectations reduces damage incentives and thereby enhances efficiency. The latter law and economics literature integrates business and social costs of public health into a cost-benefit calculus [1]. Distributing lost expectations through ex post payment may curtail future trading efficiencies, especially with regards to expense, time, and effort. Spending efforts may both lessen anxiety and protect from unwanted exchanges. Drug and food product cases may be factually dissimilar yet share a common theme for viewing drug manufacturers, food manufacturers, and patients/objectors.

7.2. Insurance Issues

The public health crisis triggered by COVID-19 created a renewed urgency in many countries to develop or improve legislative regimes that assure the production and distribution of COVID-19 vaccines, treatments, and diagnostics. For immune interventions against COVID-19, the over-arching goal of these innovations is to mitigate the harms of COVID-19 disease and/or infection. That same concern guided much of the response to the introduction of immune interventions against HIV, and communication scientists were very much engaged in that process. A brief exploration of how some of the lessons learned from those past efforts could be applied to new efforts commenced in response to the COVID-19 pandemic is presented.

Recent advances in the biomedical sciences have created a host of potential immune interventions to prevent and/or treat COVID-19 disease or infection. The coronavirus that causes COVID-19 is a member of a family of viruses whose entry-initiating spike proteins first bind to a surface-expressed receptor on target cells, then undergo a series of covalent conformational changes leading to its fusion with a trans-membrane protein on the targeted cell. Synthesis of immunobiologicals directed against this spike protein can protect from, or ameliorate, COVID-19 disease (prevention or treatment vaccines, respectively). Neutralization of the spike protein itself, or of a cellular receptor binding pocket/peptide mimic relying on monoclonal antibodies, can also protect against infection (treatment vaccines).

The current COVID-19 vaccines and therapeutics are different than anything that has been used in health and disease before. Essentially, the current vaccine construct is a messenger RNA attached to a lipid nanoparticle. Both are the product of nanobiotechnology research that has matured over the last 25 years. The mRNA strand directs the synthesis of the viral spike protein, which then displays on the outer membrane of the vaccinated cells, whereas the lipid nanoparticle elicits an immune response. All of these vaccine constructs are new and its risk, nature-inspired, effectiveness, and broad public message need to be evaluated. In this era, a public health dilemma existed at the intersection of medical ethics, science, and technology. It outlined the responsibilities of mass vaccination agencies and disseminators in education, research and employability of adaptive risk communication. The elements of the methodology were summarized below. They are not in a particular order and the products are dependent upon the index population.

7.3. Legal Costs

Legal action is another channel whereby patients can receive compensation for losses resulting from drug-related injuries, and patients can take such action against companies as well as professional staff and other individuals. Hence, patients entertain a wide range of prospects when considering such legal actions. In Australia, while patients can sue companies or individual doctors or pharmacists on their own or with the assistance of legal firms which, at least initially, may act on a “no win, no fee” basis, they would not normally do so directly against regulators who would be seen as acting in a public service role. However, in the US scenario, the range of legal options available and their interpretation by the courts is more complex.

To pursue legal action, patients would initially need to manoeuvre through the torture, expense and uncertainty of the legal system. No obvious harm usually arises if this hurdle is surmounted, although there are some widely reported cases where persons have been adversely affected. Patients could seek to either prove fault and pursue damages or argue that some loss had occurred and seek compensation on a non-fault basis. It would be difficult, if not impossible, to provide definitive numbers for the total of legal costs incurred by patients and the legal system on foot of these actions, as patients could incur legal costs of their own as well as those incurred by tribunal hearings. Such costs could be serious, however, as cases proceed over months or years, multiple hearings can occur, or hearings could occur distant from where the injured persons, witnesses and their lawyers reside.

The downside for patients is that they could incur extensive legal costs with no compensation, judgment might go against them, and compensation amounts might be less than the legal costs incurred in pursuing the action [8]. While it is impossible to say with any certainty whether drug companies do safeguard against these costs in their pricing regimes, it is likely that they do take them into account. If however, there is a general public sense that drug companies need better mechanisms for compensating patients, then some attention might need to be given to the process of seeking and awarding compensation.

A broader concern is raised concerning the effects of entrenching fault-based compensation rights on the efficacy of drug regulation. In the absence of a clearer understanding of that relation, a more limited response could be considered, one that confines compensation to situations where drugs have been shown to be unreasonably dangerous or where manufacturers acted unreasonably in their development and distribution. While enjoying some theoretical advantages, this would be implausibly shortsighted. It would threaten to foster a culture of blame that could inhibit formulation (and public acceptance) of broad-based drug regulation policies.

8. Alternative Dispute Resolution

Alternative dispute resolution (ADR) options in civil cases include mediation, collaborative law, and settlement conferences. Each offers its own advantages and disadvantages for different types of cases and litigant needs. Mediation is the most widely used ADR option, and many civil courts provide court-sponsored mediation either as a voluntary or as court-ordered option [19]. Collaborative law is also available in many jurisdictions and, unlike mediation, can prevent a litigant from proceeding with courtbased litigation. Collaborative law requires both parties to obtain new lawyers who agree not to represent the parties in court-based litigation of the dispute. Pleading papers are not filed with the court, and parties who do not settle the case in the collaborative process are precluded from taking the dispute to court. Settlement conferences are generally conducted by judges during which the judge affords the parties substantial time for individual conversations to try to persuade the parties to propose or consider a negotiated resolution to the underlying dispute.

Cost-effective, timely, and satisfaction-gaining resolutions tend to be more accessible through ADR options than through court-based adjudication. Most civil disputes settle before trial through a negotiation or some other out-of-court resolution process. Courts have reason to develop case-processing systems that facilitate settlements, and many courts are making serious investments in such systems [20]. These initiatives are aimed at facilitating communication between the adverse event victim and the physician to prevent lawsuits. The study showed that, with or without involvement of hospital attorneys/redress officers, the proposed disclosure process reduced litigation costs. Disputants may turn to ADR either as a substitute for or a complement to court-based processes. For example, parties may negotiate ADR fairly early on the dispute resolution trajectory to lower costs and increase resolution speed. Some parties may rely on a courtbased system for a long time before exploring other options.

8.1. Mediation

Mediation is a private and confidential process in which an independent third party helps parties to a dispute come together to negotiate a resolution [21]. Mediation is a valuable alternative to litigation and arbitration. While mediation and settlement are core elements of the civil justice systems in the U.S. and elsewhere, they are not yet a regular part of the medical malpractice dispute resolution process. The increasing costs of litigation and the growing dissatisfaction with the civil justice systems generally have led to changing approaches. The mediation process is not always easy to initiate. Institutionalized courtrun mediation programs deflect the burden of providing mediators from the lawyers and parties [20]. Those programs may however lead to few mediations or to mediators failing to understand and, worse, failing to accommodate the particularly sensitive, complex, technical and emotional nature of medical malpractice disputes. Medical malpractice mediations may result in just, fair and economic outcomes. Those mediations avoid the bitterness both sets of clients often feel as a result of discovery and trial. Sometimes, even an apology from the doctor goes a long way toward ameliorating the

hurt feelings of patients and families. Satisfying narratives often emerge. Mediation allows, unlike other forms of dispute resolution, time to develop a more holistic understanding of human relations. The application of mediation to medical malpractice disputes is fraught with potential obstacles, especially adversely affecting patients' perceptions of the fairness of outcomes. The traditional lawyers' perspective of medical malpractice disputes offers a modicum of opportunity within a mine field. Most obviously, lawyers both assess and assert the powerful position of bias on the part of mediators and of opponents. Traditional lawyers' perceptions of medical malpractice mediations' nature also involve questions of materiality and disputes' status as adversarial. Viewing mediation as a facilitative process, traditional lawyers' perspectives both, paradoxically, resist changing perceptions of mediators' roles and solutions' focus and agree that mediators can keep discussions on track.

8.2. Arbitration

Arbitration is the process where one or more experts consider the evidence and make a decision, and that decision is effectively final. There are generally two types of arbitration: voluntary arbitration and mandatory arbitration. Under voluntary arbitration, the parties agree up front to arbitrate future disputes, and under mandatory arbitration, the parties waive their right to court trial in their contracts whether they want to or not. This will focus on pre-treatment mandatory arbitration.

It is important to note that both voluntary and mandatory arbitration can be beneficial to patients and health care practitioners. Arbitration generally results in lower costs of litigation, quicker resolution of disputes, and an opportunity to present the case before an expert in the field. Although preliminary studies suggest that the arbitral proceeding is nearly equal in the treatment of the parties, the differing treatment by panel may be the most decisive distinguishing factor between the two practices [22]. Take for example, a contract with a health plan that states: "You agree that covered services may be performed or administered, without limitation, by any physician or other provider group that has a contract or letter of agreement with us."

Arbitration and triage panels involve far more discretion and leave parties with far fewer recourse or redress. After such proceedings, the parties appear to be treated very differently; clearly, arbitrated contracts may result in overwhelming or total losses compared with court. The initial proceedings governed by contract law could result in different treatment of the claim by the arbitration panel, depending on the contractual provisions of the agreement. The commandeering of patient claims by health plan contracts and the emerging use of mandatory binding arbitration takes medical malpractice claims out of tort law and restricts such claims to contract law.

The complexity of the law and the dueling natures of the claims complicate the resolution of medical malpractice claims to the detriment of the patient. If medical malpractice occurs under the mandates of one of these contracts between the patient and their health plan, the resulting claims must be asserted in a different proceeding than negligence claims against the physician

or other health care provider. In answering a motion to compel arbitration, the court's response was largely cursory, avoiding a greater engagement with the complexity and stacking of the claims. The holding of the court was that the failure to pay medical treatment costs, following in-network treatment, in addition to unreasonably low payment amounts to prosecute that claim was wide enough to include both tort and contract elements.

9. Future Directions in Compensation Law

The foundations for adequate and equitable compensation are rarely assessed from a society-wide viewpoint even though knowing the larger picture is essential to understanding the root of issues or flaws that might adversely impact the health, safety, and welfare of the population at large. This paper looks at compensation systems for patients who have experienced an injury as a result of a drug that a government agency approved. Compensation systems have been set up among patients, pharmaceutical companies, and governments in both industrialized and developing countries over the past 30–35 years. Addressing whether the development of a compensation system is beneficial for either patient or manufacturer in light of socially constructed moral imperatives concerning guilt, blame, and duty is of primary importance. Moral duties stemming from perceptions of guilt and tortious blame and the obligations that result from these perceptions fall into two categories: positive duties to ameliorate and compensate perceived injuries and harms and negative duties not to exacerbate them and not to introduce such harms and injuries in the first place. This body of thought forms the foundation of compensation systems that have been constitutionally created for patients who experience an injury from a drug that a government agency approved (G. Ison, 1986). In order to engage in a practical and meaningful discussion of compensation systems for patients who suffer drug-related injury, it is essential to first characterize the injury, the drug, and the patient. Inherently, drug-related injury is complicated. On one hand, from a patient standpoint, it is an injury that has a debilitating and usually littleknown pathophysiology; on the other hand, from the pharmaceutical standpoint, it is a design, development, and manufacturing decision where the drug officially "stops being a drug and becomes a device." In short, there are criteria that a patient must meet in order to be considered a "patient." An innocent or naïve patient has a drug-related injury; in other words, a patient takes a drug, believes that the drug is safe, takes the drug, and believes that someone must have made the wrong judgment. If a patient has actively attempted to seek a health that causes an injury, a patient has crossed over from the naive to the guilty when seen from the perspective of the manufacturer. Consequently, it is permissible to ask what might happen in the case of the Mukuru drug. If a person knowingly took the Mukuru drug, did he take it because it was inexpensive and already available in most pharmacies although he knew that it was not approved? If he had been so naïve, it would be legitimate to ask who was to blame. Likewise, asking who was to blame for the patient who died of cardiac arrest after refusing a kidney transplant might be simple.

9.1. Legislative Proposals

Legislative proposals were drafted and presented mainly by the Executive, but in some cases, by Members and Councillors in order to cope with the drawbacks of the current situation. The recommendations were: (a) all patients undergoing eligible treatments should be compensated whether or not they prove fault and negligence; (b) patients deemed to suffer due to the malfunctioning of the HCS should be compensated in proportion to the degree of injury; and (c) patients whose health problems were deemed not related to the malfunctioning of the health service should be compensated in proportion to the level of improbability of coincidence between the treatment and their injury.

992 events of damage were claimed and assessed. 542 claims (53.9%) were classified as valid. 450 claims (83% of valid cases) were compensated without entering court. A total redress amount of 27 million Euro was paid assuming medical, morbidity and/or structural costs (31%) and legal costs (65%). 291 court claims were deemed successful. 72 compensation verdicts were notified to HHSs (level of success: 24.8%). 34 outcomes (47% of those deemed successful) were related to the past, while 38 (53%) were futurebased. Court cases take around 53.6 months on average to reach the first instance verdict. Court procedures are lengthy and cumbersome, but this can also be the case in Finland.

The compensation amount determined by the court on the final, legally binding judgement basis is dramatically higher than the compensatory amount determined by the administrative compensation scheme.

Nevertheless, HHSs paid the amount determined by the court regardless of valid reasons to fail appeal. However, geography-related worries could not be considered robust by the researcher. The ethical soundness of the HCS in general, and especially the compensation system were rated. More than 60% of respondents disagreed with the statement asserting the ethical soundness or fairness of the present compensation policy for drug-related injuries. Nevertheless, respondents rated other stakeholders' assessments of the compensation system and the HCS itself higher.

9.2. Advocacy for Patients' Rights

On June 13, 2006, Professor Bernstein's paper was published. It was a thoughtful response to an article written by Professors Berger and Twerski. It raised serious and interesting questions regarding the proper scope of tort liability and the limits of the legal system's ability to protect patients. However, some questions were left unanswered.

Bernstein expressed the right skepticism regarding some calls for more expansive causes of action. He also expressed the rightful concern that the normal means of securing responsiveness in a tort system would not work nearly as well in the prescription drug setting as they would in other cases. Moreover, it was appropriate to warn against some of the proposed judicial remedies. Berger and Twerski had not, in retrospect, devoted sufficient attention to the proper

limits of tort law and the risk that some proposals would do more harm than good to the public health [1].

Nevertheless, it was important to note what Bernstein's views implied for the existing system. What would continue to exist after eliminating all the proposed expansions of liability? What, if anything, would deter drug marketing practices or punish drug companies whose products injure patients? What was it about a tort system that was inherently limited in this area? Why was the case for tort liability different when a negligent act harmed somebody inside or a car or hospital rather than in a public place?

Was it appropriate and wise to abandon the system of law altogether if it was unable to provide all the remedies needed?

Bernstein allowed the courts a great deal of latitude. However, given the present realities, the courts did not seem to have a range of reasonable choices. Courts would either (a) adopt tort liability for this sort of harm, thereby restraining marketing pressure and compensating many patients for their injuries, or (b) do nothing, thereby leaving drug companies to sell drugs with only the side effect information they deemed most essential and permitting any injured patients to become a public burden by virtue of their injuries [2].

10. Conclusion

This analysis reveals the extent of the problem and explores the ethical, legal, economic, and practical aspects of remedies related to drug-related injuries. Social costs and benefits associated with drugs and drug regulations do not fall easily into the category of zerosum games where a benefit to one party is equivalent to a loss to another. Consider an example of prescription drugs [1]. A drug is discovered which can benefit many patients' present and future health, but it means intense testing and significant potential liability for the drug manufacturer. The FDA agrees to allow the drug to be marketed on an experimental basis, subject to unavoidably stringent risk warnings and continuous monitoring. Some patients choose to take the drug as a temporary hedge against uncertain future costs, and their health improves. Other patients, fearing the uncertain risks associated with the drug, choose to forgo it as not worth the risk. Still other patients are unaware of the risks, have no way of knowing about them, and are further unaware of their ignorance. For these patients, the costs of unwanted injury from the drug are enormous, and their state would never have made the informed choice to use the drug had it been subject to required disclosures regarding risk, efficacy, and uncertainty about either. A drug which should be considered a societal benefit has thus become a source of significant societal cost [23]. The question then arises whether there is a way of equitably reallocating this portion of the societal cost. This question is as yet unanswered, but highlighting the profound consequences associated with neglecting ethical responsibility for drugs can provide a basis for consideration of solutions.

One practical solution to the allocation problem would be a tort remedy under which patients who are sufficiently exposed to non-disclosures of risk would have a right to recover this cost from drug manufacturers. Tort has the stated purpose of reallocation of costs from wrongdoing to wrongdoers, and it has traditionally provided remedies for injury by products and other risks traceable to individual wrongdoing. In the case of drugs, many of these strengths are critically undermined, while the availability of the remedy for drug-related injuries remains sorely deficient.

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