An Analysis on The Learned Intermediary Doctrine in Pharmaceutical Drugs Liability: A Comparative Study between India and USA

Ms.Golda Sahoo*

Introduction

Global pharmaceutical sales are a multi-trillion dollar industry.But at the same time, dangerous pharmaceutical practices carry significant hazards that could result in serious health problems, birth deformities, or even death. Products liability lawsuits frequently centre on drugs and medications. The most recent Indian pharmaceutical product to draw criticism is eyedrops produced by a company with headquarters in Chennai. Prior to this scores of child fatalities in the last year were recorded in the Gambia and Uzbekistan, purportedly as a result of Indian cough medicines[1].In addition to that serious concerns have been expressed concerning the morality of the marketing methods used by pharmaceutical corporations and according to numerous media outlets, the medicine's manufacturers sent doctors complimentary gifts totalling Rs 1 billion to promote the drug. The petition claimed that paracetamol 650 mg is not recommended in medical texts. To enable a greater price for the medicine, the dosage was increased[2].

* Assistant Professor of Law and Coordinator, Centre of Study on Victimology, Tamil Nadu National Law University Trichy

[1]Firm "Culpable" for Kidney Injuries Linked to Death of 70 Children, Gambia Parliament Probe Says, https://indiankanoon.org/search/?formInput=Firm+%27Culpable%27+for+Kidney+Injuries+Linked+to+Death+of+70+Children%2C+Gambia+Parliament+Probe+Says (last visited Apr 14, 2023).

[2]gifts for doctors: Is the alleged chicanery of prescribing Dolo-650 just another example of doctors trapping you in hunger for freebies? - The Economic Times, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/is-the-alleged-chicanery-of-prescribing-dolo-650-just-another-example-of-doctors-trapping-you-in-hunger-for-freebies/articleshow/93731341.cms?from=mdr (last visited Apr 14, 2023).

2. The concept of Pharmaceutical Drug Liability Claims

Products liability lawsuits frequently centre on drugs and medications. Before releasing these products onto the market, manufacturers of these items have a responsibility to thoroughly examine the drugs and medications. With the exception of over-the-counter medications, practically all medical items include a 'learned intermediary' who stands between the producer and the final consumer. [3]This can be the chemist who fills the prescription or the doctor who writes the prescription for the medicine.[4] A skilled products liability lawyer can assist a plaintiff in determining who may be responsible for any ensuing injuries because the borders of culpability are frequently hazy.There are numerous theories upon which a plaintiff may assert a claim, as well as numerous defences that may bar such an assertion.The following conditions are usually taken into consider for a Pharmaceutical product liability case such as:

2.1 Drugs with dangerous side effects. Pharmaceutical medications that, despite being properly prepared, have potentially harmful side effects under this type of claims. In some instances, the victims may contend that the manufacturer was made aware of the danger but purposefully kept it hidden.[5] Punitive damages will be awarded to the victims if they can successfully prove this.

2.2 Improperly marketed pharmaceutical drugs. The term "marketing" for a pharmaceutical drug refers to any cautions, directions, or suggestions regarding its use. This category frequently includes accidents brought on by

[3] PharmaBoardroom - Product Liability: India, https://pharmaboardroom.com/legal-articles/product-liability-india/ (last visited Apr 14, 2023).
[4] Pharmaceutical Manufacturer Liability Law, BERMAN & SIMMONS, https://www.bermansimmons.com/law-articles/pharmaceutical-manufacturer-liability-law/ (last visited Apr 14, 2023).
[5]PharmaBoardroom - Product Liability: India, *supra* note 3.

a failing to issue sufficient warnings about a risky side effect or a failing to give sufficient instructions for the safe and proper use of the medication.[6] The "poor advice" could have come from the manufacturer, a doctor, a pharmacy, a salesperson, or another medical professional.

2.3 Defectively manufactured pharmaceutical drugs. Caused by pharmaceutical tainted prescription medications are inadequately made.[7] This could be the consequence of a mistake made at the pharmacy where the medicine was produced or bottled, the manufacturing facility where it was made, during shipment, during labelling, or in any other event where a mistake was made between the manufacturer and the location where you received the drug.

3.Pharmaceutical Drug Liability Legislations

3.1. Pharmaceutical Drug Liability in the USA

In the USA,only product liability lawsuits with parties who reside in separate States and who request that the matter be heard in Federal Court are subject to the Federal system.[8] As a result, the theories and standards used to determine a pharmaceutical manufacturer's culpability in cases heard in various jurisdictions may differ. Pharmaceutical liability law nevertheless has certain common aspects despite its complexity. [9]The courts typically establish pharmaceutical product liability in one or two ways, depending on whether

---

[6] *Id.*
[7] Atholl Johnston & David W Holt, *Substandard Drugs: A Potential Crisis for Public Health*, 78 BR J CLIN PHARMACOL 218 (2014).
[8] King, Spalding LLP-Chilton Davis Varner & Madison Kitchens, *Product Liability Litigation in USA*, LEXOLOGY (2019), https://www.lexology.com/library/detail.aspx?g=a28ee9ab-2708-4357-93c7-b5acbb1cbf87 (last visited Sep 21, 2023).
[9]Pharmaceuticals and products liability litigation, https://gabionline.net/generics/research/Pharmaceuticals-and-products-liability-litigation (last visited Apr 14, 2023).

the producer is actually responsible for any damage brought on by the product in question. In the US, drug manufacturers are required to thoroughly test their products following U.S. Food and Drug Administration testing guidelines before releasing them onto the market (FDA)[10]. These requirements are recognised as industry norms but if a drug is found to be otherwise defective, the FDA's valid licensing of the drug has no bearing on the manufacturer's obligation to compensate an injured plaintiff.[11] Certain prescription medications are regarded as 'unavoidably risky' goods which indicates that despite careful manufacturing, they cannot be rendered completely safe.[12] Although these medications may have negative side effects, they may still be helpful to the user. Such medications often cannot be the subject of a fruitful products liability claim if they are properly produced and come with sufficient warnings.As per Section 3 of the Drug Liability Act , 2013 the maker or seller of a drug is not liable for punitive damages if the drug was made and labelled in accordance with relevant and material terms of an approval or licence granted by the 'Federal Food and Drug Administration' under the Public Health Service Act or the Food, Drug and Cosmetic Act and is generally recognised as safe and effective[13]. Section 4 says, "punitive damages may be awarded if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable federal Food and Drug Administration regulations, withheld from or misrepresented

[10]Center for Drug Evaluation and Research, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA (2020), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective (last visited Apr 14, 2023).
[11] *Id.*
[12] Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle over Abortion Medications*, 10 J LAW BIOSCI lsad005 (2023).
[13] Stromenger v. Novartis Pharm. Corp., 941 F. Supp. 2d 1288 | Casetext Search + Citator, https://casetext.com/case/stromenger-v-novartis-pharm-corp (last visited Sep 21, 2023).

to the Administration information known to be material and relevant to the harm which the plaintiff allegedly suffered"[14].

3.2 Pharmaceutical Drug Liability in India

The Indian pharmaceutical market has shown rapid expansion in recent years and is predicted to reach $100 billion by 2025. Around 16.86 billion USD in total foreign direct investment has been attracted to the medications and pharmaceuticals sector between 2000 April to 2020 September, according to data made public by the Directorate for Promotion of Industry and Internal Trade (DPIIT)[15]. The nation is the leading exporter of generic medications in the world, accounting for 20% of all exports. Indian pharmaceutical and medicine exports reached US$24.60 billion in FY22 and US$24.44 billion in FY21[16], respectively. Drug and pharmaceutical exports from India reached $2,196.32 million USD in September 2022[17]. The pharmaceutical industry in India makes a sizable contribution to exports and offers attractive prospects for investors. The World Health Organization (WHO) and the US Food and Drug Administration have established 'Good Manufacturing Practices' (GMP) standards, which are also followed by a substantial number of institutions in India[18]. India is the source of cheap and accessible generic drugs for millions of people worldwide (USFDA). India has long held the top spot among nations that produce drugs. India is anticipated to spend 9–12%

[14] Drug Liability Act, AMERICAN LEGISLATIVE EXCHANGE COUNCIL, https://alec.org/model-policy/drug-liability-act/ (last visited Sep 21, 2023).
[15] Pharmaceutical Companies in India, Indian Pharma Industry- IBEF, https://www.ibef.org/industry/pharmaceutical-india (last visited Apr 14, 2023).
[16]Pharmaceutical Products Distributorship (2023), https://www.takedistributorship.com/2019/11/pharmaceutical-products-distributorship.html (last visited Apr 14, 2023).
[17]Pharmaceutical Companies in India, Indian Pharma Industry- IBEF, *supra* note 16.
[18]Good Manufacturing Practice - an overview | ScienceDirect Topics, https://www.sciencedirect.com/topics/nursing-and-health-professions/good-manufacturing-practice (last visited Apr 14, 2023).

more on healthcare over the next five years[19], placing it among the top 10 nations in the world. The Government of India has implemented a variety of policies to reduce spending and healthcare expenditures. The 2019 Act took the place of the Consumer Protection Act of 1986 which supported rights of consumers and provided a procedure for dealing with grievances regarding subpar goods and services. Anyone who buys a product or service with the aim to resell it or use it for commercial purposes is not included. It includes all business dealings, including teleshopping, multi-level marketing, direct selling, and business dealings conducted both offline and online using technology.Product liability is described as the "responsibility of a product manufacturer or product seller of any product or service to provide compensation for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto" in Section 2(34) of the Act. In India, the Department of Pharmaceutical and the Ministry of Health and Family Welfare[20] serve as the legislative and regulatory bodies that oversee the production of pharmaceuticals, medical devices, and other goods. Although there is no specific law governing pharmaceutical product liability, the following enactments can be used to determine the applicable legal standards:The following are the relevant provisions to deal with pharmaceutical liability.

3.2.1. Indian Penal Code

Section 274-276 deals with offences related to adulteration of drugs.

Section 274 states that- If a drug preparation is adulterated in a way that reduces its effectiveness, changes how it functions, or makes it toxic with the

[19]Pharmaceutical Companies in India, Indian Pharma Industry- IBEF, *supra* note 16.
[20]Section 274 in The Indian Penal Code, https://indiankanoon.org/doc/261128/ (last visited Apr 14, 2023).

intent that it will be sold or used for, or knowing that it is likely to be used for, any medicinal purpose as if it had not been adulterated, it will be punished with either type of imprisonment for a term that may reach six months or with a fine that may reach one thousand rupees.[21].

Section 275 deals with sale of adulterated drugs -. It states that whoever, knowing that a drug or medical preparation has been adulterated in such a way as to reduce its efficacy, change its operation, or render it noxious, sells, offers, or exposes it for sale, or issues it from any dispensary for medicinal purposes as unadulterated, or causes it to be used for medicinal purposes by any person who is unaware of the adulteration, shall be punished with imprisonment of either description for a term that may extend to life imprisonment.[22]

Section 276 of the Act deals with sale of drugs as a different drug or preparation. It states that whoever knowingly sells, offers or exposes for sale, or issues from a dispensary for medicinal purposes any drug or medicinal preparation as a different drug or medical preparation shall be punished with imprisonment of either description for a term up to six months, or a fine up to one thousand taka, or both.[23]

3.2.2. Consumer Protection Act, 2019

Section 83 of the Consumer Protection Act states that a product liability lawsuit can be initiated by filing a complaint against a product manufacturer,

[21] *Id.*
[22] Section 275 in The Indian Penal Code, https://indiankanoon.org/doc/1565155/ (last visited Apr 14, 2023).
[23] Section 276 in The Indian Penal Code, 276, https://indiankanoon.org/doc/1049807/ (last visited Sep 21, 2023).

product service provider, or product seller, depending on the circumstances, for any injury caused to him as a result of a defective product[24].

(1) According to Section 84, A manufacturer of a product will be liable if—
(a) the product is having any built-up defect.

Furthermore section86 speaks about in a product liability action, a product seller who is not a product maker is li able.[25]

3.2.3. The Drugs (Control) Act, 1950

The Act impose liability on each manager, director, agent, secretary or other officer or person who are involved in the management thereof, where a person committing an offence which is punishable under the Act is an association, a company, or a body of persons, whether incorporated or not, shall, except he establishes that the offence has been committed wanting his knowledge.[26]

3.2.4. Drugs and Magic Remedies, 1954

Regulations and Rules were enacted to regulate drug advertising in specific circumstances, to forbid the promotion of treatments that are purported to have magical properties, and to address issues related thereto. It also addresses exaggerated and deceptive claims.DMR forbids the promotion of certain medications for the management of specific illnesses and disorders.

[24]Section 83 Consumer Protection Act 2019, https://www.indianconstitution.in/2021/10/section-83-consumer-protection-act-2019.html (last visited Apr 14, 2023).
[25] India Code: Section Details, https://www.indiacode.nic.in/show-data?actid=AC_CEN_21_44_00007_201935_1596441164903&orderno=87 (last visited Sep 21, 2023).
[26]Drugs (Control) Act, 1950 | Bare Acts | Law Library | AdvocateKhoj, https://www.advocatekhoj.com/library/bareacts/drugscontrol/index.php?Title=Drugs%20(Control)%20Act,%201950 (last visited Apr 14, 2023).

[27]It prohibits anyone from taking part in the publication of any drug advertisements that suggest or encourage use, among other things, for the improvement, diagnosis, treatment, or avoidance of any ailment or condition listed in the DMR Schedule or any other sickness or state that may be listed in that rules prepared under the DMR[28].

3.2.5 Drugs and Cosmetics Act of 1940

The 1940 Medications and Cosmetics Act (often known as the DCA) was passed to regulate the production, importation, distribution, and sale of medications and cosmetics.Both the state and federal governments in the nation regulate the standard of medications.The DCA imposes restrictions on the manufacture, sale, stocking, and exhibition of medications that are, among other things, inferior in quality, adulterated, misbranded, or adulterated.Any violation of the DCA's guidelines is punishable under its regulations.Based on the type and seriousness of the offence, the penalty can be anywhere from a 6-month to a 5-year sentence in prison and a fine ranging from Rs. 500 to Rs.10,000[29].A person who sells a drug solely because it is adulterated, fake, or not of good quality faces a minimum sentence of 10 years in prison and a maximum sentence of life in prison, as well as a minimum fine of Rs. 10,000,000. The maximum fine is three times the value of the drugs that were seized, whichever is greater. The individual who used the contaminated or fake pharmaceuticals mentioned in the relevant section will get compensation in the form of the fine imposed on and released from

[27] Advertisement Of Drugs – Whether Prohibited Or Regulated Under Drug Laws In India - Healthcare - India, https://www.mondaq.com/india/healthcare/1038378/advertisement-of-drugs--whether-prohibited-or-regulated-under-drug-laws-in-india (last visited Sep 21, 2023).
[28] https://www.indiacode.nic.in/handle/123456789/1412?sam_handle=123456789/1362(last visited Apr 14, 2023)
[29]drugs and cosmetic act 1940, https://indiankanoon.org/search/?formInput=drugs%20and%20cosmetic%20act%201940 (last visited Apr 14, 2023).

the individual who was convicted (or, in the case of his death, his relative).[30]If the person is convicted again under the terms of the DCA, they will also be subject to a harsher sentence, ranging from 2 years to life in prison.

3.2.6. Drug (Prices Control) Order, 2013

The Act's main goal is to execute the authority granted by Section 3 of the Essential Commodities Act of 1955 (10 of 1955) and repeal the Drug (Prices Control) Order of 1995[31].

3.2.7. New Drug and Clinical Trial Rules, 2019

The Government of India announced the New Drugs and Clinical Trials Rules 2019 (New regulations) on March 19. In the past, clinical trials were conducted in agreement with Schedule Y of the 1945 Medicines and Cosmetics Regulations. (The D&C Regulations).[32] Yet, There were concerns about patient safety. and paying individuals compensation if they suffered unfavourable side effects as a result of participating in clinical investigations. The ethics committee now operates under clear guidelines (EC). The EC is required to follow the new regulations' requirements and provide a report to the Central Licensing Authority (CLA). In 2012, a patient-focused charity filed a Public Interest Litigation (PIL) alleging improper conduct in the conduct of clinical trials against governmental and non-governmental organisations as well as independent researchers.

[30] *Id.*
[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9329597/ (last visited Apr 14,2023)

[32] Dr V G Somani, *The New Drugs and Clinical Trials Rules, 2019*.

3.2.8. Pharmacy Practice Regulations, 2015.

In agreement with the aforementioned legislation, a licenced chemist may recommend drugs to patients or carers to complement or enhance pharmacological therapy in additionally to distributing prescriptions on a registered medical practitioner's prescription. In view of the aforementioned, it is reiterated that, in accordance with the Pharmacy Act of 1948 and Pharmaceutical Practice Regulations of 2015. a registered pharmacist is never permitted to practise medicine or create clinics that provide medical care.

"The Ministry of Health and Family Welfare" in India is home to the legally recognised organisation known as the Pharmaceutical Council of India (PCI)[33]. As per the Pharmaceutical Act of 1948, it was established. The following are the PCI's goals:

- To oversee pharmacy education across the nation.
- To facilitate the pharmacy act's registration as a chemist.
- To control pharmaceutical practise and profession.

According to the aforementioned legislative initiatives, a variety of rules and regulations were passed between 1945 and 1986 to control the production, sale, and distribution of pharmaceuticals. But there is no law that controls how pharmaceutical companies sell their products.

3.2.9. The Pharmacy Act, 1948

The Act was passed with the preamble which stated - "An Act to control the pharmacy industry. While it is necessary to have Pharmacy Councils to better

[33]Pharmacy Council of India, https://www.pci.nic.in/ (last visited Apr 15, 2023).

regulate the pharmacy profession and practise, better regulations should be put in place ".

3.2.10. The Uniform Code of Pharmaceutical Marketing Practices

The Indian Medical Council's (Professional Conduct, Etiquette and Ethics) 2002 guideline forbade doctors from receiving gifts, travel opportunities, money or other financial benefits, etc., from pharmaceutical corporations. Under it, doctors may occasionally face legal action, but pharmaceutical companies frequently escape punishment. "Yet, there is no regulation that controls how pharmaceutical corporations sell and advertise. As a result, the pharmaceutical industry is becoming authoritarian. Doctors who have business ties to pharmaceutical corporations risk having their licences suspended for negligence. The law is unbalanced, nevertheless, as pharma companies that support misconduct are shielded from its reach.To stop pharmaceutical businesses from engaging in unethical tactics, the government established a Universal Code for 'Pharmaceutical Marketing Practices' (UCPMP) for Pharmaceutical Companies, which went into effect on January 1, 2015[34]. This code regulates how pharmaceutical businesses must behave themselves in their marketing strategies, properly addressing numerous areas including medical representatives, written and visual promotional materials, gifts,samples, etc. The Code also dealt with the relation with healthcare professionals, and it has elaborated the provisions relating to hospitality,travel accommodations, and financial grants to physicians or their families.All of the major associations for pharmaceutical businesses have adopted the Code,

[34]Uniform Code of Pharmaceutical Marketing Practices (UCPMP), https://pib.gov.in/pib.gov.in/Pressreleaseshare.aspx?PRID=1883168 (last visited Apr 15, 2023).

and the Department has on numerous occasions examined how the pharmaceutical associations are putting it into practise. Inspite of all these measures the nexus between pharmaceutical companies and physicians continues to boost drug sales. According to a study, seven major pharmaceutical companies spent a combined Rs. 34,186 crore on marketing over an eight-year period, greatly raising the cost of the drug, the petition said. A further 20% of the cost of the medicine is made up of sales promotions[35]. According to FMRAI's appeal, retail medicines worth Rs 42,000 crore were marketed annually, the majority of which were unethical and hazardous[36]. Despite objections, it claimed that authorities were continuing to engage in these malpractices. Earlier, approval for more than 290 fixed-dose combo medications was revoked. The Central Drugs Standard Control Organization's head of department, the Drugs Controller General of India, authorised the release of more than 100 such combinations back onto the market, according to the plea[37]. After numerous complaints, the government had suggested enacting the 'Uniform Code for Pharmaceutical Marketing Standards' in 2015, which was referred to as voluntary. The Code was to be put into use for a period of six months before becoming a legal requirement. The Supreme Court is currently hearing the case, although this has not yet occurred and drug corporations are not regulating themselves[38]. A case of

[35]James K. Elrod & John L. Fortenberry, *Sales Promotion in Health and Medicine: Using Incentives to Stimulate Patient Interest and Attention*, 20 BMC HEALTH SERVICES RESEARCH 820 (2020).
[36]Dolo controversy revives demand for regulating pharma marketing practices - Frontline, https://frontline.thehindu.com/the-nation/public-health/dolo-controversy-revives-demand-for-regulating-pharma-marketing-practices/article65949470.ece (last visited Apr 15, 2023).
[37]How India got hooked on combination drugs | Reuters, https://www.reuters.com/article/india-medicine-combinations-idUKKBN0TY1SM20151215 (last visited Apr 15, 2023).
[38]Shruti Kakkar, *Supreme Court Seeks Centre's Response On Plea To Regulate Pharma Companies "Bribing" Doctors To Market Drugs*, (2022), https://www.livelaw.in/top-stories/supreme-court-centre-s-stand-framing-uniform-code-pharmaceutical-marketing-practices-regulate-unethical-practices-pharma-companies-197478 (last visited Apr 15, 2023).

Dolo-650 being prescribed incorrectly has previously come to light, but no action was taken.

4. Learned Intermediary Doctrine vis-à-vis Pharmaceutical Drug Liability

The American judicial system employs the learned intermediary defence doctrine. According to this, a product manufacturer must fulfilled its duty to care when it fulfil the required information to a 'learned intermediary' who subsequently communicates with the product's consumer[39]. Pharmaceutical and medical device companies are the main users of this theory to combat tort claims.The phrase "learned intermediary" was originally used in the 1966 Eighth Circuit ruling in the famous of *Sterling Drug v. Cornish*[40], and it is now widely accepted across the majority of American jurisdictions. This hypothesis has recently come under fire due to the increase of direct-to-consumer marketing, in which pharmaceutical corporations pitch their products to consumers rather than medical experts. In *Rimbert v. Eli Lilly & Co.* [41], the District Court argued that the "dramatically increased marketing directed to consumers would persuade the Supreme Court of New Mexico that the justification for the learned-intermediary doctrine is rapidly becoming, if not already the case, outdated."However, in other recent judgments, the so-called "direct-to-consumer advertising" exception to the learned intermediary theory has not been upheld. General product liability laws require manufacturers to alert consumers of flaws or risks associated

[39]James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning It Entirely*, 36 TORT & INSURANCE LAW JOURNAL 119 (2000).
[40]Arizona High Court Reestablishes the "Learned Intermediary" Doctrine, https://www.americanbar.org/groups/litigation/committees/mass-torts/practice/2016/learned-intermediary-doctrine/ (last visited Apr 15, 2023).
[41]Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174 | Casetext Search + Citator, https://casetext.com/case/rimbert-v-eli-lilly-co (last visited Apr 15, 2023).

with using their products that are not visible to or obvious to the intended user. The presumption that makers have the ability to train prospective users through manuals and cautionary literature provided with the product serves as the fundamental foundation for this. Yet, it was acknowledged that with medications, patients rely on their doctors to comprehend the severity of the dangers involved and to weigh the relative benefits and drawbacks of particular drugs. The "learned intermediary" theory, which denied pharmaceutical companies total protection from strict responsibility and design flaw claims that other manufacturers are susceptible to, acknowledged the importance of the doctor-patient relationship. By providing the doctor with knowledge regarding the drug's harmful tendencies, the company fulfilled its obligation to warn the final user[42]. The foundations for the learned intermediary doctrine are eroding as a result of this direct marketing. Even twenty years ago, the doctor-patient interaction was considerably different from what it is today. The choice to take a drug is not solely a medical one because the usage of pharmaceuticals that are subject to advertising is typically voluntary in nature.The learned intermediary theory has some restrictions, according to a recent New Jersey Supreme Court case. In the case of *Perez et al. v. Wyeth Laboratories*[43]plaintiffs sued the company who had sold a prescription contraceptive patch through a significant direct marketing campaign, including television and print advertisements in publications like Glamour, Mademoiselle, and Cosmopolitan. The advertisements made no mention of warnings, instead emphasising simplicity and convenience. Plaintiffs said that the commercials failed to disclose dangerous adverse

[42]Russell G. Thornton, *The Learned Intermediary Doctrine and Its Effects on Prescribing Physicians*, 16 PROC (BAYL UNIV MED CENT) 359 (2003).
[43]Perez v. Wyeth Labs., Inc. | Case Brief for Law School | LexisNexis, https://www.lexisnexis.com/community/casebrief/p/casebrief-perez-v-wyeth-labs-inc (last visited Apr 15, 2023).

effects. Invoking the learned intermediary concept, Wyeth claimed that the prescribing doctors were the only ones who could be held accountable for failing to get informed consent. The trial court agreed and dismissed the manufacturer's claims. The appellate court concurred, stating there was no warning flaw for omitting to warn the users directly if the warnings to the physician were deemed enough under New Jersey law. The learned intermediary theory was not a defence to the plaintiffs' claims, according to the New Jersey Supreme Court, which disagreed. It is one thing to fail to educate a patient about a product's potential side effects; it is quite another to intentionally misinform a patient about such side effects while presenting the product as an effective treatment for a critical medical condition. When the conventional paradigm is still in place, the New Jersey court was unequivocal in upholding the learned intermediary theory. There would have been no cause of action directly against Wyeth on an independent "failure to warn" basis if the pharmaceutical corporation had simply provided information about the medicine to the prescribing physician and avoided advertising directly to the patients.

5. The Way Forward

The biggest barrier to comprehending how product liability affects medication development is the dearth of data on patterns in pharmaceutical liability cases. Due to the fact that the legal system only decides on a small portion of all product liability claims and since there is no national data on court cases. The statistics tell a different tale from the one administrators and politicians in India continue to trumpet as the "pharmacy of the world." Quality assurance and openness are the two pillars on which India's reputation as the "pharmacy of the world" would be built in the future and this is only possible when the learned intermediary doctrine will be strictly applicable in

pharmaceutical drug liability cases. With effect from 1 March 2021, the Drugs and Cosmetics Rules have been changed to hold companies who advertise drugs accountable for the product's quality and regulatory compliance. Any person who adopts a drug produced by another manufacturer for sale and distribution by applying or marking their name to the drug is referred to as a marketer under the Amendment. The firm that markets the drug is not currently held accountable under the Drugs and Cosmetics Rules for any flaws in the drug or for any gaps in compliance with regard to the drug. As a result, a large number of pharmaceutical firms have contracted with outside parties to manufacture their products, leaving the pharmaceutical firm to focus entirely on marketing the drug while the contract manufacturer is solely accountable for the product's quality and other regulatory compliances. The purpose of the Amendment is to encourage pharmaceutical corporations to make sure that contract manufacturers they use adhere to the Drugs and Cosmetics Rules. In recent months, foreign health officials have claimed that Indian medications, ranging from eye drops to cough syrups, have contributed to illness and even death. Such charges run the risk of damaging India's reputation, which otherwise plays a significant part in ensuring the security of the world's supply of drugs and enabling accessible healthcare through its cheaper pharmaceuticals .In this present scenario, the application of Learned Intermediary Doctrine in India will minimise and control product liability cases. Physicians who write prescriptions are already required by law and professional ethics to inform patients of the dangers of taking prescribed medications. They are the only ones with the medical knowledge, the comprehension of the patient's medical history, and the ability to create a specific risk assessment. The idea presupposes that physicians must apply professional judgement to determine whether a medicine is appropriate and to communicate that information to

patients in a way that is understandable.The provisions of the Indian Penal Code, 1860 ("IPC"), which are general in nature and do not particularly address "medical negligence," can be used to establish criminal responsibility. For instance, accidents brought on by reckless or negligent driving of a motor vehicle and cases of medical negligence resulting in patient death are both covered by Section 304A of the Indian Penal Code.In *Dr. Suresh Gupta v. Govt. of NCT Delhi*[44], the Supreme Court raised the bar for criminal responsibility and demanded that medical negligence must be "gross" or "reckless." To establish of a high level of negligence is the requirement for implementing criminal liability as adopted in Dr. Suresh Gupta was recognised in *Jacob Mathew v. State of Punjab*[45] It was also emphasised that in order to establish the existence of criminal rashness or criminal negligence, it must be established that the rashness was of such a degree as to equate to assuming a hazard knowing that injury was most likely forthcoming. In another case, the Supreme Court stated, “Precautions which doctors/hospitals/nursing homes should take:

a. Current practices, paramedical infrastructure, and other staff, hygiene, and sterility must be observed.

b. No prescription should be issued without a physical examination. Except in an emergency, the temptation to prescribe prescriptions over the phone should be avoided.

[44]Dr. Suresh Gupta vs Govt. Of N.C.T. Of Delhi & Anr on 4 August, 2004, https://indiankanoon.org/doc/650550/ (last visited Apr 15, 2023).
[45]Jacob Mathew vs State Of Punjab & Anr on 5 August, 2005, https://indiankanoon.org/doc/871062/ (last visited Apr 15, 2023).

c. A doctor should not depend just on the patient's interpretation of his symptoms, but should additionally do his own analysis, including tests and investigations if needed.

d. A doctor should not experiment unless absolutely essential, and even then, he should obtain written consent from the patient.

e. If in doubt, the doctor should seek the advice of an expert. Thus, in IndraniBhattacharjee (OP No. 233 of 1996 decided on 9-8-2007 [NC]), the patient was diagnosed as having 'mild lateral wall ischemia.' The doctor prescribed medicine for gastroenteritis but he expired. It was held that the doctor was negligent as he should have advised consulting a cardiologist in writing

f. Full record of the diagnosis, treatment, etc., should be maintained."

The discussion above leads to the conclusion that, even though the law fully acknowledges that prescribing excessively high standards may have a chilling effect that is undesirable, it also requires to safeguard the patient's interests to expect a minimum degree of safety and treatment, and to achieve the goal, there should be a Special Law to deal with Pharmaceutical Drug Liability cases where the doctrine of Learned Intermediary can be apply.