INSURMOUNTABLE HURDLES IN THE PROOF OF CAUSATION IN PHARMACEUTICAL PRODUCT LIABILITY IN CAMEROON: PERSPECTIVES FOR REFORM

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ABSTRACT

A very critical issue in almost or all pharmaceutical product liability is deciding who has to be responsible for the injury in which compensation is being claimed. In order to be able to identify the responsible person, a causal link must be established with the product in question. The task seems very challenging for drugs because most often they are taken by ailing patients and establishing the link between the wrongful exposure and injury is a difficult task to go about and therefore undermines compensation. Pharmaceutical product liability often poses the problems of proof of causation. This problem stems from the toxic nature of the products which may be unknown or uncertain. It may be due to a combination of many factors which may cause the plaintiff's injury and finally the injury may only show up many years after the individual must have taken the product. Many people who take action are faced with the problem of proving a breach and the link of causation. This paper, as such, revisits the perennial problem of causation in pharmaceutical liability. It seeks to examine the problems faced by claimants in proving their case due to causal difficulties. It goes further to examine the apparent high levels of scientific proof needed and the claimants' burden of proof. In response to this problem of causation, this article proposes a flexible approach to causation by borrowing best practices from advanced jurisdictions such as Canada, the USA and the United Kingdom. This would assist victims who face difficulties in proving causation. The paper states that causation in Cameroon differs in application depending if the claimant is from the French speaking part of Cameroon which is of the civil law background or from the English speaking part of Cameroon which is of the Common Law background. Ultimately,

harmonizing causation in the two systems would be of great advantage to victims of pharmaceutical products in Cameroon.

KEY WORDS: *Pharmaceutical Products, Causation, Burden of proof, Standard of Proof, Reversal of Burden of Proof, uncertain scientific Causation, Causal inference and market share liability.*

I: INTRODUCTION

In Cameroon, a good number of people get injured or die from drug related injury.[1] This is because of the prevalence of defective drugs on the market. Those injured do not want to take action or when they do, they hardly receive any compensation in case action is taken due to the difficulty of establishing a link between the injury and the product. Causation remains a stumbling block to those who wish to gain compensation in pharmaceutical product liability in Cameroon. Causation is a fundamental concept in all liability issues weather in negligence, contract or strict liability. In both the common law of negligence and the civil law of "responsabilité civile" causation plays an important role in determining liability.[2] Plaintiffs are often confronted with significant obstacles in proving causation against the defendant manufacturers. It is an inherently difficult problem because it requires time consuming analysis of complex scientific evidence.[3] It has to be proven on a balance of probabilities in the English speaking part of Cameroon based on the Common law system and with certainty in the French speaking part of Cameroon based on the civil law system.[4] Other reasons for such difficulty are because of the very nature of pharmaceutical products and the uncertainty about the effects of some medicines. The difficulties of proving causation in this field is actually a big hurdle to plaintiffs who are aware of it and believe that their injury is as a result of the consumption of such products. Harvey Teff and Colin Munzo put it that:

[1] Statistics on drug injury in Cameroon is not readily available but given the prevalence of fake drugs, counterfeit and defective drugs on the market, it is believed many people might likely be injured without understanding the cause of their injury. Also, most of those who are victims do not wish to go through the various hurdles of causation or prefer to stay quiet or go in for out of court negotiations. In fact the ostensible absence of principle and dearth of authority is most likely to contribute to some of the difficulties faced with causation.

[2] Khoury L., *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, p 13.

[3] R. S. Goldberg, "Epidemiological Uncertainty, Causation and Drug Product Liability,"Journal of Technological Innovation and Civil Responsibility, Vol. 59, No.4, (2014), pp777-818, p 778.

[4] Cameroon during the United Nations mandate and the trusteeship systems were handed over to the British and the French and they were given the right to bring in their laws in adaptation to the local conditions. It is the reason we have the common law in the English speaking part of Cameroon and the Civil Law in the French speaking part of Cameroon.

> *…drugs are always potentially dangerous due to their toxicity. They are often taken by people who are already ill and who may be unusually susceptible to further ailments. Unlike many other products, they may cause injury in unpredictable ways, depending on the individual user's constitution. They may not be taken according to the instructions. The user may be allergic to a particular drug. Alternatively, what appears to be an allergy may in fact be a toxic reaction…*[5]

It is very much difficult to prove that one's injuries are due to adverse drug reaction than to prove that the injury have been caused by a faulty machine.[6] The reason for the difficulty in establishing causation stems from the fact drugs have a latency period between the exposure and illness and also the fact that drugs are pruned to multiple and alternate causes of illness which make it difficult to pin-point a particular cause and as such exacerbate the causal problem. Most often the determination of the exact cause is fraught with a lot of difficulties due to the fact that the cause depends mostly on scientific expertise which in the field of pharmaceutical products is still very much lacking behind in Cameroon.[7] These difficulties can either lead to under compensation or no compensation of the pharmaceutical product liability victims. Many victims have to face the insurmountable obstacle of proving causation in pharmaceutical liability especially under circumstances where multiple risk factors are present, for science is often unable to demonstrate the causal link of the exposure of the particular product of the defendant and that such exposure was the "but- for cause" of the injury. More so, even plaintiffs' who have the detail and material information on particular products they have consumed may still find it difficult to meet the burden of establishing causation due to evidentiary requirements and scientific limitations in this field. The proof of a causal link constitutes to the victim an insurmountable task, which is accentuated by the fact that the entire

[5]Goldberg R.S., "Epidemiological Uncertainty, Causation and Drug Product Liability," Journal of Technological Innovation and Civil Responsibility, Vol. 59, No.4, (2014), pp 777-818, p 779, citing Harvey Teff and Colin Munro, *Thalidomide: The legal Aftermath* (Farnborogh: Saxon House), 1976 at 135-36.
[6] Goldberg R.S., "Epidemiological Uncertainty, Causation and Drug Product Liability," Journal of Technological Innovation and Civil Responsibility, Vol. 59, No.4, (2014), pp 777-818, p 779.
[7] Khoury L., "Causation and Health in Medical, Environmental and product Liability", 25 Windsor Year Book, Access to Justice, Lexis Nexis, (2007) pp 135-166, p 136.

manufacturing process is under the control of the defendant which is hardly made known to the plaintiff.[8]

Causation proves to be fatal to plaintiffs' claims for judicial compensation of their personal injuries. In response to such hurdles, many jurisdictions have seen the need to relax some traditional standards of causation. This paper concludes that more flexible judicial approaches and test that have been adopted by other courts such as those of the United Kingdom, Canada, the USA and France to respond to some of the insurmountable hurdles of causation in pharmaceutical product liability can be borrowed by the Cameroonian system. It suggest that the approach used by the courts based on causation in the law or causation in fact as it is practiced in the English part of Cameroon or immediate and certain causation as it is in the French speaking part of Cameroon may be very problematic in some circumstances and that borrowing theories such as causal inference, market share liability, loss of chance that have been tested in the United Kingdom, France, Canada and the USA may go a long way in alleviating some of the causal difficulties.

II: Hurdles in Establishing a Causal Link in Pharmaceutical Product Liability

Various hurdles arise in the establishment of a link between the cause and the injury of a plaintiff who is a victim of a defective pharmaceutical product in Cameroon. They range from scientific uncertainty in the proof of causation, through the burden of proof and standard of proof.

A: Scientific Uncertainty in the Proof of Causation

The first thing for any claimant in a product liability case is to establish a link between the injury and the risk of harm from the product. However, the claimant is always faced with considerable difficulty in establishing that the product in question caused the damage. Proof of causation in pharmaceutical product liability litigation is an inherently difficult problem, which requires time consuming analysis of complex scientific evidence. The problem of causation here is far reaching and necessitates closer attention.

If someone is injured by any ordinary product, there is generally no difficulty in establishing the causal factor and the consequence. In the case of medicines, the causal link is far less clear.

[8] Campbell C., *International Product Liability*, Yorkhill Law Publishing, London 2007, P 250.

Difficulty can arise in establishing the link between a drug and an injurious effect either at the community level or individual level.[9]

i: Difficulty in Establishing a Scientific link

Pharmaceutical products are considered as a double edged knife capable of causing harm as well as preventing it. Scientific difficulties may result from the fact that firstly, most of those who take such products are already ailing and the injuries caused can have alternate or multiple interpretations.[10] So it is very difficult in pharmaceutical liability to point a finger to a particular product for being the real cause of an injury.[11] Public policy tries to balance the benefits of pharmaceutical products and the risk they pose to certain individuals by considering them as unavoidably unsafe products. So the judicial system and victims are always faced with problem of proving causation in a fair, efficient and inexpensive manner. This difficulty stems from the problem of multiple risk of causation and the difficulty of pin pointing the identifiable product that has caused harm or is the possible cause of injury. Persons who experience adverse reactions following the prescription of a variety of different drugs and who cannot identify the specific cause of harm, or where the medicaments have reacted to cause a damaging combination could find themselves in a very difficult position. Causation based on the combined effect of various drugs can be very broad and uncertain.[12]

Assessing causation begins with analyzing one's exposure to the pharmaceutical product. This is done by collecting information on the level of exposure to a particular product, the magnitude, duration and frequencies. The inexactitudes in the way of analyzing such information may lead to substantial uncertainty in the results[13]. Much of the difficulty in drug litigation is due to the insufficient scientific understanding of general causation. Generally the question often asked is to know whether a certain drug has the ability to cause such an injury

[9]Goldberg R. *Medicinal Product Liability and Regulation*, Hart Publishing, Oxford, (2013), p 84.
[10] Galega S.D. "Strict Liability for Defective products? Some Illuminating Lessons from Abroad", Journal of African Law, Vol.48, No.2, pp 239-267, (2004), p 247; Jackson E. *Medical Law Text Cases and Materials*: 2nd ed, Oxford University Press, Oxford, (2009), p 548; Ferguson P.R., *Drug Injury and Pursuit for Compensation*, Sweet and Maxwell, London, U.K, 1996 pp126-133; Goldberg R. *Medicinal Product Liability and Regulation*, Hart Publishing, Oxford, (2013), p 84-113.
[11] The difficulty stems from the fact that pharmaceutical products are always prescribed to be taken in combination with others.
[12] See Ferguson P.R., "Pharmaceutical Product Liability: 30 years of Law Reform?" (1992), Jur. Rev. 226, 231-238; Stapleton J., *Disease and the Compensation Debate*, Oxford, (1986), pp 37-49; Newdick C., "Strict Liability for defective Drugs in the Pharmaceutical industry", (1985), 101 LQR 405, 420-430.
[13]Goldberg R. *Medicinal Product Liability and Regulation*, Hart Publishing, Oxford, (2013), p 84-95.

and if so to what extent? Reliable information regarding the actual effect of a particular drug is rare and most often some of the undesirable effects are yet to be known to science. Animal test, clinical toxicological and epidemiological data can be of great help. However scientists caution that this information cannot always be extrapolated in an accurate and reliable manner to estimate the actual risk. Courts tend to view epidemiological studies which apply statistical techniques to explain variation in disease rates of human populations, as the most persuasive and acceptable type of general causation evidence in drug cases.[14] But the use of such studies creates difficulties. Epidemiological studies establish associations between alleged causes and effects by comparing the drug incidence across exposed and unexposed populations or exposure levels across injured and healthy population. Based on these comparisons, epidemiological studies estimates the risk created by the drug compared to background risk created by all factors. There are however significant limitations to such studies. Such analysis may be unable to detect the increase in risk; they can lack sufficient follow up to discover disease with long latency periods and they may fail to account for unknown factors that affect injury rates. Detailed epidemiological data is available only for relatively few drug injury cases. Similarly where such data is available there may be uncertainty as to the magnitude of the risks involved.[15]

The plaintiff who has to prove the causal nexus is again faced with the problem of plausible scientific evidence available to prove the cause and effect relationship.[16] The evidence to be provided by the plaintiff falls into four categories; the first is the *biochemical evidence* whereby scientific experiments are carried out by scientist to demonstrate a biological or chemical reaction in a test tube. This evidence can provide a theoretical proof of an effect observed in human kind and no more. It can only supplement but not replace other evidence.[17]

The second type of scientific evidence is *animal evidence*, which is equally limited in value in that "laboratory results from animal body systems are so different from those of primates that

[14]Ibid.
[15]Ibid.
[16] See the USA court of Appeal case of *Loveday v Renton (1990) I Med. L.R. 117*, where the plaintiff brought an action for damages in respect of permanent brain damage she suffered from after being administered Diphtheria, tetanus and pertussis vaccine. After considering the complex body of aetiology and epidemiological evidence tendered, the court held she had not proven that the illness was caused by the reaction to the vaccine and to some other unknown cause.
[17]Howells G.G., *Product Liability, Insurance in the Pharmaceutical Industry: An Anglo- American Comparison*, Manchester University Press, 1990, P 27.

it is almost always possible for defendants to argue that for either dose –related or endemic reasons a positive result in animal work cannot be extrapolated to humans. Its main value is that negative results in all animals at all levels of dose may tend to exclude the possibility of a cause and effect relationship in humans."[18] In effect, it has been shown that there is a poor correlation between animal tests and effects experienced in humans.[19]

Epidemiological evidence is a third way of establishing scientific evidence by looking at the number of people who have been exposed to a particular product or products.[20] The plaintiff's problem here stems from the fact that he has no control over the research that has been carried out and therefore is unlikely that the perfectly designed study to test the causal association which he must prove must exist. Furthermore, there are ethical problems in commissioning study once a causal connection between product and condition is suspected. Further still, the science of epidemiology is in its infancy and there are almost no universal approvals of potential expert witnesses' usually on methodological grounds or on the question of comparability between the two groups under scrutiny. Finally the last resort of the defendant is to admit a statistical association but deny that there is any true causal link.[21]It would be noted that epidemiological studies are limited in Cameroon due to lack of financial and human resources.

Despite the short comings, it is likely, in a contested pharmaceutical product liability claim, that it is by reference to epidemiological evidence that the claim falls or stand.[22] The short comings of epidemiological data were seen in the case of *Loveday v Renton* where the defendants prevailed on the issue of general causation.[23] Even armed with epidemiological data, many plaintiffs will still not have sufficient evidence to discharge the burden of proof, because, typically such data cannot be sufficiently focused to eliminate related factors.[24] Also the statistical significance of the number of people needed in order to pick up even quite high

[18] Ibid.
[19] Stapleton J., *Product Liability*, Butterworths, 1994, P 181.
[20] In carrying out the studies, two groups of people are matched as closely as possible and compared with the view of seeing whether the incidence of a medical condition, is higher in the group exposed to the drug in scrutiny than in the group not exposed. The strength of any excess found can be measured in terms of the unlikelihood of its being due to chance. The more the unlikely or confounding factors excluded, the greater the likelihood that a causal connection between product and condition exists.
[21]Howells G. G., *Product Liability, Insurance in the Pharmaceutical Industry: An Anglo- American Comparison,* Manchester University Press, 1990, P 28.
[22] Ibid.
[23] Ibid.
[24]*Loveday v Renton. (1990) I me. L.117.*

rates of adverse reactions is very large and the problem is magnified if the effect is latent.[25] In theory the best way around this massive focused epidemiological study is only feasible for a very few products.

Clinical evidence may come in fourthly to be the bridge between the statistical association and establishment of cause effect. Clinicians will be able to draw upon their clinical experience to say or deny that the epidemiological data accord with patient's history as they hear them and are consistent with generally accepted medical facts and opinions[26]. But clinical trials can involve ethical problems with the denial of protection to the control group where a drug or vaccine protects against a life threatening disease.[27]

The above four ways of evidence in the proof of causation work together in establishing causation and the only way the judge has to approach the problem is that he/she has to get expert evidence from both sides and ask the question whether the weight of evidence given for the plaintiff exceeds, on the balance of probabilities, that for the defendant. It can be said that the contents of epidemiological studies cannot be strictly proven but comprises material evidence of the extent to which an expert may refer in giving his or her opinion.[28]

ii: Consequences of Scientific Uncertainties

The injured consumer in pharmaceutical product litigation has to grapple with various evidences, ranging from biochemical evidence, and animal, epidemiological and clinical evidence irrespective of the legal regime in place. Establishing causation in pharmaceutical product liability especially in cases where non-traumatic injuries resulting from toxic chemical effect is a very big hurdle as is illustrated by the "*Thalidomide case where at one time it was held that it did not cause deformity but instead helped to maintain already deformed foetuses which could have been aborted naturally*"[29] In such cases scientific opinion most often is only guess work.[30] The doctor in such instances has to understand the medical history, life style and dietary habits of that person. This may likely lead to enormous costs on the part of the plaintiff

[25] Stapleton J., Product Liability, Butterworths, 1994, P 281.
[26] Ibid.
[27] Ibid, p 282.
[28] Ibid at P 29
[29]Galega S.D, "Stict Liability for defective products in Cameroon ? Some Illuminating Lessons From Abroad", Journal of African Law, vol.48, No.2, pp239-267, (2004), p 247.
[30] Stapleton J., *Product Liability*, Butterworth's, London, 1994, P 284

and delays in the process that may discourage the plaintiff from continuing with the litigation process.[31]

All the above evidences work together and it is left for the judges to weigh the evidence given by both parties to see if on a balance of probabilities the evidence of one party exceeds the other.[32] Scientific uncertainties can also be seen in the areas of cumulative and alternative causes.

Scientific uncertainty that affects the causal mechanism in pharmaceutical liability may be as a result of a combination of a variety of factors or due to alternative factors that all act together. When an agent has been proven at the general level to have caused an injury, it is not always possible to actually determine which agent actually caused the injury in a specific case.[33] The plaintiff has to proof on a balance of probabilities in common law and with certainty in civil law that the drug was the actual cause of the injury.[34] For an injury can be caused by some other additional conditions. For example lung cancer could be due to exposure to asbestos powder, or may result from a history of smoking as was in the case of *McGhee v National Coal Board.*[35] The issue to be considered results from the question of multiple causes and it is an acute problem that is encountered in the area of pharmaceutical product liability. As such applying the "but for" test might necessarily lead to a wrong decision since a particular defect may simply be one of many causes which are contributing factors to the victims injury.[36]In the case of *McGhee v National Coal Board* the House of Lords established that it is not necessary to proof that a product is the sole cause of the injury, so long as it was the material cause of the injury. In this case the pursuer, a workman employed in emptying pipe kilns at a brick works, developed dermatitis and alleged it had been caused by defenders failure to provide washing

[31]Galega S.D, "Strict Liability for Defective Products in Cameroon, Some Illuminating Lessons From Abroad", Journal of Africa Law, vol. 48, No. 2, 239 267, 2004, p 248, where he states that it "May sometimes involve astronomical costs and delay, such that even the advent of strict liability "May sometimes involve astronomical costs and delay, such that even the advent of strict product liability regime in Cameroon may not turn out to be the magic Wand or the ultimate Panacea to the plight of consumers as may be thought at first sight."

[32] Howells G.G., *Product Liability in the Pharmaceutical Industry: An Anglo-American Comparison*, Manchester University Press, London, 1990, p. 28.

[33]*Wilsher v Essex Area Health Authority, (1988), I, AC, 1074, 1988, I ALL ER 871*.Where the plaintiff suffered from an incurable Retrolinal Fibroplasia (RLF) resulting in near blindness. This condition could have actually been caused by excess oxygen or five other probable causes.

[34]Ibid.

[35] (1973), I ,WLR, I, HL .I.

[36] For example lung cancer may have multiple causes such as environmental pollution, smoking, defective drugs or even the patient's physiognomy; See Galega S.D. "Strict Liability for Defective Products in Cameroon: Some Illuminating Lessons from Abroad.? Journal of Africa Law, vol. 48, No. 2, 239 267, 2004, p 247-249.

facilities at the work place. The defenders admitted negligence for failure to provide these facilities but medical knowledge about the cause of dermatitis was such that it was not possible to say that had washing facilities been provided the pursuer would not have contracted the disease. It was actually impossible to put a figure on the increased risk. It could only be said that the absence of washing facilities had materially increased the risk. The pursuer was held entitled to succeed in the absence of proof by defenders that their breach of duty was non-causative. *Lord Wilberforce* in taking his decision that has been actively criticized by academicians based his motivation on policy and logic. He held that it is a sound principle where a person has by breach of care, created a loss, the loss should be borne by him unless he can show that it had some other cause. Under logical circumstances why should somebody who has suffered injury due to the lack of taking certain precautions by another assume the burden of proving that it was in addition to the risk, caused by the breach of duty which caused or materially contributed to the injury? In many materially contribution cases, it is impossible to prove. This is because medical knowledge cannot distinguish the cause of an illness between compound causes. If the question is asked about which of the parties has to suffer from this evidentiary difficulty? The answer according to policy or justice would normally be that the creator of the risk has to, for, he must have foreseen the possibility of the damage and as such should bear its consequences.[37]

Applying McGhee in the case of defect in pharmaceutical products where the defect materially increased the risk of the plaintiff suffering from personal injury, it would not be necessary in the absence of available scientific evidence to establish that it was more probable than not that the injuries were caused by the defect.[38] This case has the merit that it eases recovery by the claimants, however, it is criticized for abandoning the traditional standards of causation where the defendant has to be proven to be more probable than not the party who caused the plaintiff's damage.

The McGhee principle has not been totally accepted as in the case of *Wilsher v Essex area Health Authority*[39] where a plaintiff who was born prematurely and suffering from oxygen deficiency, succumbed to retinal condition, which led to near blindness. A possible cause of this was excess oxygen caused by a placing the catheter into a vein rather than the artery.

[37] Stapleton J., *Disease and Compensation debate*, Oxford, U.K. (1986), Chapter 3.
[38] Ibid.
[39] *(1987) 2 WLR 425; (1988) AC 1074; (1988) 1 All ER 871 (HL).*

Conflicting medical evidence at the trial identified a number of other possible causes raising causation issues. The Judge placed the onus on the defendant to show that their negligence was probably not the cause of the blindness.[40]This decision was reversed in the House of Lords where it was held that that the plaintiffs injury did not per se give rise to the presumption that it was caused by the defendant. Where a plaintiff's injury is attributed to several possible causes, one of which is the defendant's negligence, the burden of proof is still on the plaintiff to bring out the causal link between the defendants negligence and the injury. In the same vein in *Kay v Ayshire and Arran Health authority*[41] it was that causation is a legal concept and has to be applied bringing out limitation to the McGhee concept..

Further still, pharmaceutical product liability, both sources in aggregate could be the cause of the injury.[42] In this context, competing causes have a specific relevance in the sense that it mostly involves drugs that have the potentiality to cause similar adverse reactions. For example patients who consumed *bendodiazpines* found themselves in a quandary of proving causation for they had consumed some other drugs such as anti-depressants and other substances such as alcohol which made the causal link between *bendoziapines* and the alleged reaction of the drug harder to ascertain.[43]"In fact, the scope for the divergence of opinion as to causation when the reaction could be the result of the combined effect of several drugs might be regarded as potentially as broad and uncertain as to preclude completely the possibility of recovery".[44] Additionally, where injury is due to the peculiarity or idiosyncrasy of the individual the manufacturer cannot be held liable especially in cases where the victim knew but failed to disclose his/her unusual sensitivity.[45]

Another problem linked with scientific uncertainty due to cumulative and alternative causes is that of generic prescribing, where the same drug is marketed by different pharmaceutical companies under various brand names. The consumer in this case can take the same general

[40] The facts in *Wilsher v Essex area Health Authority* were not the same as that of *McGhee*. In *McGhe*e there was no doubt that the defendant's dust caused the dermatitis; what was not certain was whether the defendant's failure to provide washing facilities to remove it was a causative factor. In *Wilsher*, there were at least four factors other than the oxygen administered by the defendants which could have been responsible for the injury. The reason for which the HL disapproved of the decision by Lord Wilberforce in McGhee.

[41] (1987) SLT 577, (1987) 2 All ER 417.

[42] *(1973), I ,WLR, I, HL .I.*

[43] Also find *Ab v John Wyeth and Brother Ltd, No 2, (1944) 5 Med LR 149, AB V Roche Products, (1997), 8 Med, LR 57*

[44]Galega S.D. "Strict Liability for Defective Products in Cameroon? Some Illuminating Lessons from Abroad", Journal of African law, vol 48, No 2, 239-267, 2004, p. 247

[45] For example being allergic to a particular drug.

drug from different pharmaceutical companies with different brand names. In the case of an injury, it is extremely difficult and complex to hold liable a particular brand responsible for the harm.[46]

B: PROOF OF CAUSATION

The biggest barrier to be surmounted in pharmaceutical product liability is that of causation where the plaintiff must establish two types of causation. First of all, there is factual causation which is proving on a balance of probabilities that the product is actually capable of causing such an injury and that it is due to the defendants tortuous conduct that the damage occurred.[47] If the plaintiff can proof that the damage would have not occurred but for the fault of the defendant then the fault is in fact the cause of the damage. However, if it can be stated that the injury would have occurred with or without the fault then the fault is not the cause of the damage and it would be of very little assistance in this area. It would be noted that factual causation which is based on the traditional but-for-test is of very little assistance in pharmaceutical product liability because many injuries can occur without any particular causal factor or even understood by science.[48]

Secondly the plaintiff must also prove causation through specific causation by indicating that the substance in question is in fact what actually caused the injury among all other complex causes. It requires that the victim should proof that injury suffered from was proximately caused by the defect in the product. [49] In the Cameroonian context it would be noticed that the But-for-test and causation in the law are practiced in the English speaking part of Cameroon meanwhile in the French speaking part of Cameroon there is no clear distinction between factual and legal causation. Causation needs to be direct certain and immediate.[50] Causation here seems to be straight forward since it is direct and immediate. However problems might arise when it has to deal with many competing factors.

[46] The Canadian case of *Snell v Farell (1990) , 72, DLR, (4th) 289, 1990, 2 SCR 311*, American case of *Sindell v Abott Laboratories, 26, Cal 3d 588, 607, P 2d 924, 163 Cal RPR 132, Cert. Denied 499 U.S. 912 (1980)* is an illustration of the problem involved with proof of causation when it comes to generic prescribing.
[47] Lord Dennings statement in *Cork v Kirby Maclean Ltd*, 1952, 2 All ER 402.
[48] This difficulty would lead to the need for experts to evaluate the clinical , epidemiologic and toxicological data to be sure, which, again is not all that easy; See Galega S.D. "Strict Liability for Defective Products in Cameroon: Some Illuminating Lessons from Abroad", Journal of African law, vol 48, No 2, 239-267, 2004, p. 247.
[49]Geistfeld M.A., *Principles of Product Liability*, Foundation Press, New York, (2006), p 193.
[50] See Article 1151 of the Civil Code.

Injury resulting because of the intake of a particular drug can be easy; however there are multiple causes for which causation seems to be very difficult.[51] Separating the roles played by each of the potential causal agents, which may interact in complex ways, is often problematic, if not impossible. There is usually no evidence that a particular product caused the injury. The problem of causation is further seen in cases of generic prescribing where a generic product could be marketed under various brand names. Generic prescription makes causation much more complex[52].

Furthermore, the causal problem in drug injury is more complicated based on the fact that the 'but for test' that is normally applied in other product liability actions " is of little help here because in disease aetiology, many illnesses occur without a particular causal factor being established or even known by science."[53]

i: Hurdles Based on Burden of Proof of Causation

The plaintiff who suffers from an injury due to the defective nature of pharmaceutical products must have to prove that but for the defective product, he would not have suffered the loss.[54] The onerous burden of prove lies on the plaintiff,[55] and at times on the defendant in the case of reversal of burden of proof.[56] Proving that damage is as a result of a defect in a product is a severe task on the claimant especially when such proof turns out to be technically complicated and expensive due to the requirement of expert opinion.[57] It should also be noted that the existence of a defect and the causal nexus between the defect and damage suffered, is a very big task for the plaintiff because in most cases, there is usually a lack of balance between the defect and the damage in respect of information needed, as it is the producer that has knowledge

[51]*MCGhee v The National Coal Board 1973, WLR I.*
[52]Galega S.D., "Strict Liability for Defective Products in Cameroon? Some Illuminating Lessons from Abroad, Journal of African Law, Vol. 48, No.12, (2004), PP 239-167, P 247.
[53]Ibid.
[54] See *Suit N° BM/35/95-96 of the Bamenda High Court unreported, between Elise Elange Ndua v Brasserie du Cameroon* where the victim was to prove on a balance of probabilities through laboratory analysis and other scientific test, that what she consumed was the actual cause of her ailment. (Unreported). Though not a pharmaceutical product liability case, it exemplifies some of the difficulties that are faced in product liability which are applicable to pharmaceutical product liability.
[55] Burden of prove is generally considered as the "Legal obligation imposed on the party to persuade the tribunal of fact, to the required standard of prove and on the whole evidence of the truth of every essential fact at issue."
[56]Article 28 of the Law on the Legal Framework on Consumer Protection in Cameroon, Law no 012 of 6th May 2011.
[57] Commission Green paper: Liability for defective products, Brussels, Com 1999 396 (28 July 1999), summary P 2.

of the information and is in a better position to explain how the injury occurs.[58] Difficulties in causation also arise when it comes to products that are "ingested or no longer available".[59]

Other insurmountable problems of proving causation are that the victim may be unable to locate the manufacturer due to the fact that the product was given to him by someone else. He may also not know the manufacturer or supplier; least to mention forgetting all the information that was given on the product and worst of all, the identification and product could have also come from abroad as it is the case with most pharmaceutical products in Cameroon. So reaching the defendants in case of injury is not only an expensive task to the average Cameroonian but also a near impossibility taking into consideration the actual per capital income in the country.

ii: Hurdles Based on the Standard of proof of Causation

In simple terms the standard of proof is the degree to which proof must be established by the party that is legally obliged or on whom the burden of proof rests.[60] In order to be successful in any pharmaceutical product liability action, the plaintiff must establish on a balance of probabilities in the English part of Cameroon that the defect in the product manufacture, design or warnings was as a matter of fact, casually connected to the plaintiff's injury and in the French part of Cameroon it has to be done with certainty. In other words, this is to say that there must be some link or connection between the wrong act and the loss that is complained of. The cause-in-fact tries to inquire or find out whether the product in question actually caused the injury or damage.[61] This involves mainly factual inquiry resolved by the production of evidence and the drawing of inferences or conclusions from the evidence[62]. The idea of a factual inquiry aims at identifying the causally relevant factors but acts only as a preliminary step which is not very determinative of liability.[63] A choice has to be made between the various identified causes in order to find out how to attribute liability. Factual causation is based on theories such as the But-for-test, substantial factor rule and material contribution to damage.

According to traditional principles in the law of tort, the plaintiff must prove, on a balance of probabilities that "but for" the defendants tortuous conduct, the plaintiff would not have

[58]Ibid PP 20-21.
[59]Ibid.
[60]Khoury L., *Uncertain Causation in Medical Liability*, Hart publishing, Oxford, 2006, P 34.
[61]Allee J.S., *Product Liability*, Law Journal Seminar Press, New York, 1995, Para 7. 02.
[62]Khoury L, *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, P. 17.
[63]Ibid.

sustained the injury or damage.[64] If a plaintiff can hold that the damage would not have happened but for a particular fault, then that fault is in fact the cause of the damage; but if the plaintiff can say the injury would have occurred just the same, fault or no fault, then the fault is not the cause of the damage.[65]This traditional approach of causation considered in the pharmaceutical context is of limited assistance because many diseases occur without the presence of the particular causal factor having been previously established, or even known to science[66]. The question to bear in mind is the link between the plaintiff's injury and the product that has caused it. In such instances, two principal inquiries have to be taken into consideration, evaluating the clinical toxicological and epidemiological data for a product in order to be sure if the coming into contact with it is associated with a specific illness, reaction or condition.[67] Secondly, its properties have to be investigated into in order to know if the exposure of a particular individual to a product or combination of products has, or will result in such an illness.[68] Even with these findings, there are no guarantees that they are accurate, for to in order to understand the exact causal nexus, the doctor may still need to understand the patient's background, medical history, life style or dietary habits.[69] The carrying out of such investigations could be very costly and impossible and actually difficult for an average Cameroonian to afford such large amounts needed for proof of causation and thereby discouraging litigation and so the victim or most victims would be deprived of legal relief.[70] It should be understood that the "But-for-test" does not assign culpability but seeks to tie together an act and the resulting harm from the act.[71]

Specific proof here requires both foreseeability and proximity of the product as a source of the injury and that the exposure caused the particular effect. Causation in law tries to determine if the act or omission of the defendant is a "sufficient legally effective" cause amongst all other

[64] Lord Dennings statement in *Cork v Kirby Maclean Ltd, 1952, 2 All ER 402.*
[65]*Ibid.*
[66] *McGhee v National Coal Board, 1973 WLR 1.*
[67]Galega S. D., "Strict Liability for Defective Products in Cameroon? Some Illuminating Lessons from Abroad", Journal of African Law, 48, 2, (2004), PP 239- 267, P. 247.
[68]Ibid.
[69]See difficulties in *Lovedayv Renton (1990) Med. L. R., 117, CA.* Intersecting the probabilistic standard of law which is based on a preponderance of evidence of 50% and that of scientific evidence where the rules of epidemiology requires evidential proof of a balance of probabilities of at least 95% is very difficult . The claimants did not recover from the brain damage of the pertussis vaccine because scientific evidence did not establish on a balance of probabilities a causal link between the pertussis vaccine and the children.
[70]Galega S.D., "Strict Liability for Defective Products in Cameroon: Some Illuminating Lessons from Abroad", Journal of African Law, 48, 2, (2004), PP 239- 267, p. 247
[71] Ibid.

complex causes.[72] It is meant to limit the potential scope or extent of the manufacturer's liability. The law of tort normally requires that the plaintiff should prove that injury suffered was proximately caused by the defect in the product[73]. The question in this context is to know if the manufacturer has to be held liable for the injury suffered by the plaintiff.[74] In legal causation, it is value, fairness and legal policy that are taken into consideration[75] rather than the factual existence of a causal link. It addresses and takes into consideration the liability of the defendant who has breached a duty of care. It defines the circumstances that break the chain of causation between the defendant's act and the plaintiff's harm. Therefore causation is viewed as the chain of events, leading to the defendant's conduct on the one hand and the plaintiff's harm on the other hand. "The link in the chain connects the defendant's conduct with the plaintiff's harm"[76]. If the defendant is to be held liable for the resulting harm, then each of the links must be foreseeable to the defendant. The test for causation is therefore based on foreseeability.

Reasonable forseeability is seen as the standard for defining proximate cause (cause in law).[77] It can be defined as what is "objectively reasonable to expect, not what might conceivably occur".[78] Differences most often arise as to the standard of reasonably foreseeable when applying such a theory and so it can be said that such a theory is an abstract concept in law.[79] What is researched in this notion is whether the claimant's injury should be within the scope of the defendant's liability?[80] Given the reason why law has recognised this cause of action in question[81] there is therefore a need for the law to limit the causally related losses for which a defendant can be held liable and proximate causation which is therefore seen as the limit to liability of this nature.[82] It is held that the precise manner in which harm does occur is not supposed to be foreseeable and that instead it should be the foreseeability of the use that establishes the limit of proximate cause.[83] If the foreseeability of use is literally applied in such

[72]Khoury L., *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, P 17.
[73]Geistfeld M.A., *Principles of Product liability*, Foundation Press, New York, 2006, p 193
[74]Khoury L.,*Uncertain Causation in Medical Liability*, Hart publishing, Oxford 2006, P.17.
[75]Ibid.
[76]Abood R.R, *Pharmacy Practice and the Law*, Jones and Barlett Publishers International, London UK, 2008, P 351.
[77]Allee J.S, *Production Liability*, Law Journal Seminar Press, New York 1995. P 7-33.
[78] Ibid, p 7-34.
[79] Ibid, p 7-33.
[80] Miller C.J; Goldberg R.S., *Product Liability*, Oxford University Press, London, 2004, P. 731.
[81] Ibid.
[82] Ibid.
[83]Allee J.S., *Product Liability*, Law Journal Seminars – Press, New York 1995, P. 7-35

instances, it can lead to "Freakish and bizarre accidents"[84] for the extent of injuries need not be foreseen. At times, superseding causes such as abnormal use, substantial alteration, and knowledge of danger from the defect can relieve the manufacturer based on unforeseeability. Abnormal use, extra-ordinary use or something else may interrupt the natural sequence of events.[85]With such limits of causation brought by the doctrine of reasonable forseeability, it is but normal that most victims will go uncompensated.

The severity of the standard of proof needed in proving liability brings out a choice as to who should bear the evidential uncertainties and the risk of error in the adjudication process. Risk allocation depends primarily on the burden and standard of proof.[86] The law has to make a choice as to which party bears the risk of insufficient or absence of evidence. Admitting the proof of a fact in the absence of certain and sure evidence will lead to error in passing judgement.[87] It is believed that:

> *...the dramatic difference in treatment of situations that are identical except for* ***trivial*** *differences in statistical probability is due to unexamined assumptions that the usual "preponderance of evidence" or "balance of probabilities" burden of persuasion in civil laws cases merely requires proof of 50% statistical probability. It is held to be inconsistent and incoherent treatment of normative and descriptively analogous types of situations even in erroneous denial of proof of causation in some situations in which tortuous causation clearly exist...*[88]

The difference between the standard of causation between the English speaking part of Cameroon and the French speaking part of Cameroon lies in the fact that, in the English

[84]Ibid.

[85] See the American case of Speer v United States, 512, I, Supp 670 (N.D, Tex 1981) where the superseding cause doctrine was discussed. Following both new prescriptions and refills of *Etrafon* 4-25 which had been dispensed to a patient at frequencies more than what the patient should have needed. The patient was stock piling the excess quantity of the medication, with which he subsequently committed suicide. The deceased's spouse sued the pharmacy for being negligent. The court held that although the pharmacists were negligent, they did not foresee that the patient would use the drug to commit suicide. The ingestion of overdose by the patient broke the link between the negligent refilling of *Etrafon* prescription and patient's death.

[86]Khoury L., *Uncertain Causation n Medical Liability*, Hart Publishing, Oxford, 2006, P 38

[87]Ibid.

[88]Wright R.W. "Proving Facts in the Common Law and the Civil Law. Radical Different Standards of Persuasion" Re-Quoting Clermont L.M, Sherwin E, A Comparative Standard of Proof, American Journal of Comparative Law (Ajcl), 50, 2002, 243, 249, www. works.bepress.com (Richard_wright)/38, Accessed on the 1st of May 2012.

speaking part of Cameroon on the one hand standard of proof is considered on the basis of balance of probability. The judge weighs the evidence given by the experts on behalf of each party and then tries to find out whether the evidence given by the plaintiff out weighs on a balance of probability that of the defendant.[89] Despite the fact the judge uses his discretion to determine the balance of probability, there are certain guidelines to be respected such as: the magnitude of the risk which is that of finding out the likelihood that the injury will occur and the seriousness of the risk. A second condition is that the risk has to be balanced against the consequences of not taking it and lastly, the practicability of the precaution has to be taken into consideration where the risk is balanced against the measure necessary to eliminate it. Such standards are not absolutely a mathematical certainty. The probability standard here has to be above 50% that the defendant caused the injury.[90] It should be stated that judges do not make calculations when evaluating when evaluating the threshold to be considered. The judge uses his discretion and policy considerations. Balance of probability can be termed an "all or nothing Rule" for it is based on the fact that once causation has been proven to exist on a balance of probability full compensation is granted and when the balance of probability is not met, then there is no compensation granted to the victim even when there is the possibility that injury is a result of defendants conduct.[91]

In the civil law Jurisdiction of Cameroon on the other hand, taking from its French background of the "Code Civile", there is the need for certainty of the causal relationship between the fault and damage.[92]The civil jurisdictions apply the "in time conviction" so the judges need to be sure before upholding the burden of parties proof. It should be stated that absolute certainty is impossible and as such affects the outcome of the legal action.

With such high standards, it is difficult for victims whether from the French part or English part of Cameroon to be able to link an injury to a drug. As such there is the need for a reform on the law of causation with the introduction of flexible measures of causation which would go a long way to harmonize the differences in the two parts of Cameroon.

[89]Howells G. G., *Product Liability Insurance and The Pharmaceutical Industry: An Anglo American Comparison* , Manchester University Press, London, 1990, p 28.
[90] Khoury L. *Uncertain Causation in Medical Liability*, Hart publishing, Oxford, 2006, p 34.
[91] See *Wilsher v Essex Area Authority 1988, 3 All ER. 80l.*
[92] J. Carbonnier., *Droit Civil 4 les Obligations,* 22nd ed, Paris Puf, 2000, p 391.

V: Possible Measures to Facilitate Causation

Nowadays, society faces increasing risk of injuries flowing from the consumption of pharmaceutical products. But the problem that arises is that when injuries result in connection with such products, the determination of the exact cause which depends essentially on evidence for scientific expertise is often flawed with difficulties due to incomplete scientific knowledge and controversies, cumulative and alternative causes.[93] The particular problem of causation in pharmaceutical liability is unique due to the complex nature in which such products interact with the human body. This has been accentuated with generic prescription by doctors. It is equally not an easy task for plaintiffs to establish causation when faced with the complexity of aetiology and epidemiological evidence by pharmaceutical companies. These difficulties have led many jurisdictions to bring out exceptional rules to avoid unacceptable outcomes that plaintiffs have to suffer from. The reasons for which there is need for the facilitation of causation is based on the fact that the defendant should not rely upon another's wrongful conduct in order to avoid liability to pay damages which it has as effect of depriving a person whose injury would not have occurred had no one behaved wrongfully in relation to that person.[94] Also, causation needs to be facilitated based on the fact that an injured claimant should be able to recover damages even if he is unable to establish that the person wrongfully caused the injury.[95] The question is how, can this problem of causation be resolved in order to give plaintiff the means to get compensation. As noted above, causation is a legal theory and must be handled as such rather than dealing without it. As such the experiences of other jurisdictions such as the USA, France, the United Kingdom and Canada with theories such as the market share liability and material contribution for multiple and indeterminate causal problems, loss of chance doctrine, causal inference based on lowering the standard of proof and the reversal of burden of proof. These methods would considerably ease causal problems for victims of pharmaceutical products.

A: Reversal of Burden of proof

[93]Khoury L., " Causation and Health in Medical, Environmental and Product Liability", Lexis Nexis, Windsor Yearbook of access to justice, 25, PP 135-166, P 136

[94] Wrongful conduct principle; See S. Steel, *Proof of Causation in Tort Law*, Cambridge University Press, U.K, 2015 p 4.

[95] Prevented Claim Principle; See S. Steel, *Proof of Causation in Tort Law*, Cambridge University Press, U.K, 2015 p 4.

Since the duty of the law is to protect the weak from the injustices of the strong and maintaining a balance between them, there is the need for a reversal of burden of proof. The reversal of burden of proof is equal to the shift of the risk of not being able to prove a certain fact unto someone else. Shifting the burden of proof may result in someone wining a case that would otherwise have been lost due to evidential difficulties. Reversal of burden of proof is a means of protection of the position of the victim because in pharmaceutical liability, the victim is put under unreasonable difficulties due to, for instance, the technical and organizational complexity of the defendant's activities and as a result making the facts difficult to prove. Another reason for the reversal of the burden of proof is on the fact that he who benefits from an activity should also bear the extra burden related to that activity.[96]

There is also the need of channeling liability in a certain direction, the idea of promoting the preventive effects of habits, the need to prevent fundamental rights at stake, the wish to decrease the dependence of one party, the need to decrease the imbalance in information between the litigants.[97] The Cameroonian law on the legal framework has actually stipulated something on the reversal of burden of proof but has not specified its operation.[98] This is a gap in the law that would need to be corrected for without the manner of operation of such a theory there would be practical difficulties in its application and causal difficulties would still remain. This theory needs to be put into practice. A Law must not only exist in principle but it has to be pragmatic.

B: Considering material Contribution theory and Market share Liability

[96] Profit theory.

[97] *See McGhee v National Coal Board (1973) I WLRI* where Lord Wilberforce stated *"…it is sound principle that where a person has breached a duty of care , created a risk and injury occurs within the area of that risk, the loss should be borne by him unless he shows that it had some other cause… If one asks which of the parties should suffer from the inherent difficulty, the answer as a matter of policy or justice should be that it is the creator of the risk who, ex hypthesi, must be taken to have foreseen the possibility of the damage who must bear the consequences"*

[98] Section 28 of the Legal Framework on Consumer protection of LAW N° 2011/012 OF 06 MAY 2011 provides that " During any trial proceedings concerning consumer protection, the burden of evidence to the contrary of the allegations shall lie with the vendor, supplier or service provider."

If more than one person has caused harm by a jointly committed tort then each of them should be responsible for the harm.[99] It would also apply to circumstances where it cannot be established which of the several persons involved caused the harm.[100]

Material contribution can be considered in other ways as risk contribution or alternative liability. France has circumvented the difficulty of providing causation in the case of alternative defendants by adopting the principle of attribution of responsibility for the acts of another person on the basis of common activity.[101] Another area of material contribution that is considered in France is that of collective guardianship of things (garde Collective) in respect to which strict liability is often considered.[102] This is exemplified in the classic hunter's case which is based on the reasoning that hunters have the collective control of the guns and bullets from which the bullet came.[103] However, this rule despite its importance has the shortcoming based on that of proximity of the tortfeasors. The fact that tortfeasors can be standing apart needs to be considered.

The market share liability is of the American experience[104] which is concerned with the attribution of liability for damage caused by defective pharmaceutical products. Market share liability has been developed to deal with factual uncertainty which is the impossibility of identifying the author of the damage and as such there is the necessity to adapt the rules of causation and liability. This is in the case where liability is found against several manufacturers since the plaintiff cannot identify which of the manufacturers have marketed the product that caused him injury. As such each manufacturer is to be held in proportion to its market share unless he has proof to show that it did not cause it. Not only is liability allocated proportionally

[99] Joint tortfeasors

[100] Alternative defendants where each number of the wrong doer acted tortuously and there is no doubt that at least one of them caused the claimants harm but it cannot be established which of them singly or jointly caused the harm.

[101] For example children playing together and throwing stones have been found to be jointly engaged in a dangerous activity causing injury and held to be jointly and severally liable even though it could not be shown whose stone struck the victim; Cass 2e Civ., Mar. 8 1968, Bull. Civ.,II, No. 78.

[102] Article 1384 Code Civil; G. Viney & P. Jourdain, *Traite de Droit Civil : Les Conditions de la Responsabilité*, 2nd ed. 2003, p 366.

[103] *Cass. 2eme. Civ., Mar.13, 1975, Bull-Civ. II. no. 88.*

[104] The American Experience was brought out in the *Sindell v Abott Laboratories* (1980), which concerned a defect in Diethylstibestrol (DES), a drug which expectant mothers took during pregnancy to prevent miscarriage. the children suffered as a result of the drug from a type of cancer as well as other conditions. The condition was not discovered until puberty. By the time they became aware of the damage, it was impossible to identify the precise manufacturer of the drug their mother ingested. A claim was brought against all the companies involved in the manufacture, distribution and marketing of the drug.

to each defendant's causative chance of having been the cause of the injury but the burden of disapproving causation is automatically shifted to the defendant. Each manufacturer who fails to prove this is liable to pay a percentage of the compensation awarded to the plaintiff and this percentage is dependent on the share of the market for which the drug company was responsible at the relevant time. A defendant who is faced with such liability can decide to bring in other co-defenders. Cameroon has integrated the reversal of burden of proof in its legal framework on consumer protection, so it would be necessary to consider market share liability for policy reasons in other to avoid certain injustices that are suffered by consumers due to causal hurdles.

It would be submitted that Cameroon needs to copy some of these good practices in the area in reducing some of the difficulties faced by victims in proving causation in the case of alternative defendants. Actually the "Code Civile" is applicable in French Cameroon which therefore means that to a limited extent, the difficulties of uncertain causation in French Cameroon has been surmounted to a certain level due to the application of article 1384. However, it would be necessary that despite its limitations it should be applicable to the totality of Cameroon so as to make victims of the same country to benefit from the same treatment.

C/ Loss of Chance

The loss of chance doctrine that is mostly applicable in medical liability in other jurisdictions[105] needs to be applied to pharmaceutical product liability in Cameroon due to the fact that pharmaceutical product liability is faced with the some uncertain difficulties of proof of causation in the same light as medical liability cases.[106] Loss of chance allows one to assess the plaintiff's hypothetical damage by calculating not only the value of the end result expected but also that of the plaintiff's chance of achieving that end result, gain the advantage or avoid the loss. He/she must show that there was a reasonable chance or a real and serious chance that the damage would have been avoided. According to French commentators, the chance must be

[105] The French jurisdictions have accepted the Loss of Chance Doctrine in medical liability cases. As early as the 14 of December 1965, the Cour de Cassation granted a claim for loss of chance to an 8 year- old- boy who was diagnosed by the defendant doctor with a fracture of the Humerus. Following the defendants treatment, the child was still suffering when moving his elbow; other physicians consulted later found a dislocation of the elbow. Damages were claimed against the first doctor based on the doubts about timely treatment. The court of Appeal and later the Cour de Cassation granted the claim based on the fact that serious, precise and concordant presumptions showed that the boys damage was the direct consequence of the defendants fault and that the defendants fault deprived the child of total recovery and as such they granted compensation. Bull. civ 1965.i.541, para707; d 1966.jur453; JCP1966.G.II.14753 (note Savatier), (1967) Revue Trimestrielle de Droit Civil 181.

[106] This are cases involving death, sickness and disability and the doctor's fault is uncertain or controversial.

capable of being assessed as objectively independent of the value hoped for the benefit.[107] Loss of chance must be causally related to the defendants fault.[108] This concept is useful when even causation cannot be established between the defendants fault and the plaintiff's damage based on the traditional standards of proof, it allows the plaintiff the possibility to plead that before the act, he had a chance of survival which the defendants fault destroyed. Hence the loss of chance of recovery is considered a legal damage in its own right independent of the final outcome suffered by the victim. The plaintiff is not required to demonstrate the final outcome. In pharmaceutical liability, the loss of chance doctrine can be applied in the case where the plaintiff would have been better off without taking the drugs and in the case where it is difficult to determine if it is the drug that actually caused the injury and also when it is difficult to determine which drug caused the injury. Despite the fact that the doctrine of loss of chance is controversial in nature, based on the fact that it is considered as an all or nothing rule flowing from the balance of probability criterion, it can be used as one of the best techniques to deal with some of the hurdles that victims of pharmaceutical product liability face due to various uncertainties. This technique has been used by the French courts based on the fact that the injury should constitute a type of injury that is independent from the final injury suffered by the plaintiff.[109]This is mostly in cases where there is causal uncertainty as to the causal link between the fault and the injury.

The Cameroonian judiciary should think of using the loss of chance doctrine in compensating victims of pharmaceutical liability because it gives the courts some flexibility to act and it achieves apparent fairness to both parties since damages are calculated according to the probability that the defendant caused the plaintiff's damage. Also it allows victims to obtain damages despite the causal uncertainties. Again, on the part of the defendant it does not impose an unfair burden since it holds him liable only to the extent that he has proven to have caused

[107] Khoury L. *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, p 95, citing Conte P and Maitres de Chambon P., La Responsabilite Civile Delictuelle, 2nd ed. Grenoble, Presses Universitaires de Grenoble, 2000, 43-45.

[108]In contractual and extra-contractual reasoning, loss of chance involves either attempting to define what would be i.e the present if the past was different.

[109] Couturier, *Note under Cass.Civ. 1st, 7 June 1989, D. 1991 Jur.158, 159*; J Bore, Indemnisation Pour Les Chances Perdues : « Une Forme d'Appréciation Quantitative de la Fait d'un fait dommageable » JCP 1974, I. 2620 paras 2 ; Phillipe Le Tourneau & Loic Cadiet, Droit de la Responsabilité Civile (paris ; Dalloz, (1998), para 876.

the damage. However, it should be used only in cases of causal uncertainty, difficulties and not as a means to abandon or put aside causation.

D/ CAUSAL INFERENCE

Causal inference is lowering the standard of proof by drawing inferences from the evidence. The law of evidence grants much to plaintiffs who are faced with causal uncertainties. Circumstantial and indirect evidence allows the plaintiff to bridge gaps in the evidence by attempting to convince the judge to draw a reasonable inference from the facts that are demonstrated.[110]The flexibility afforded in the standard for the burden of proof of factual causation would enable the courts to give a decision when the plaintiff has made a plausible, if ambiguous and circumstantial case of causation. It is the lack of flexibility in the standard of proof that makes it necessary for the application of causal inference. The Canadian courts in dealing with causative uncertainties in medical liability cases have favoured this evidential means of causal inference.[111] This inference is as a result of the fact that evidence in case of uncertainties like that of pharmaceutical products often offers little information on which to infer causation as such courts have had to devise certain justifications on which inferences can be validly considered. Causal inference is mostly applied when the causal link between the defendant's fault and the plaintiff's damage is uncertain and cannot be demonstrated by the traditional rules of evidence.[112] Causal inference is mostly considered when the causal link between the defendants fault and the plaintiff's damage is uncertain and cannot be demonstrated by the traditional means of evidence like in the case of *McGhee v the National Coal Board.*[113]Inference is based on the common sense of the judges even in the absence of positive or scientific proof of causation. This has to be done through the careful assessment of the available evidence in order to determine whether the factual, statistical and expert evidence demonstrates on the balance of probabilities the existence of serious, precise and concordant presumptions of causation instead of causation being proven with exactitude and certainty.

Causal inference is justifiable based on the fact that scientific uncertainty, the available lay evidence may provide little information on which to rest even an indirect proof of causation. Additionally, expert evidence most often is inconclusive or at best contradictory and is

[110] Khoury L. *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford 2006, p 39.
[111] In *Snell v farrell (1990) 72 DLR (4th) 222, (1990) 2 SCR 311, 330.*
[112]Khoury L., *Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, p 134.
[113] 1973 WLR 1

consequently of little support to draw presumptions. Inferences here is the courts willingness to go above the various difficulties by devising conceptual justifications on the basis of which they consider it permissive to draw causative inference in the presence of scarce evidence.[114] The main justification that is afforded is based on the concept of material contribution of risk of damage.[115] Canadian courts have used it based on the fact that the information about causation lies within the particular knowledge of the defendant and the defendant has negligently undermined the plaintiff's means of proving causation. As such in surmounting the hurdles created by the insufficiency of evidence, courts have to rely on the notions of increase of risk and creation of danger.

It would be submitted that the Cameroonian courts should borrow this notion of inference from the Canadian courts, so as to help plaintiffs who cannot directly link their injury to the pharmaceutical products of the defendant due to lack of scientific and expert knowledge. By so doing the rigidity of certainty of the causal link is relaxed and more people in Cameroon would be compensated if they take action.[116] Hence, if direct evidence adduced at trial leads the judge to find that there is no causation between the fault and the damage, the court should not ignore the result but draw inference of causation. Causal inference has mostly been used in medical negligence cases but if applied to pharmaceutical liability it can serve the purpose. If applied to the Cameroonian situation it would greatly surmount the hurdles of causation and benefit victims of pharmaceutical product liability.

III Conclusion

Causation has overlooked the problem of pharmaceutical industry despite the fact that pharmaceutical products causes significant problems of fatalities and serious illnesses. Claimants have to prove on a balance of probability or with certainty that their injury was caused by the ingested drugs which is not so easy to fulfill. This is further compounded by the

[114] Khoury L.,*Uncertain Causation in Medical Liability*, Hart Publishing, Oxford, 2006, p 147.

[115] Ibid; Risk is relied on based on the argument that: the defendants fault created the risk of damage for the plaintiff; increased the risk to which the plaintiff was already exposed before intervention; or subjected the plaintiff to a danger by creating substantial risk of damage or substantially increasing and existing risk. material increase of risk is based on the fact of adapting the case of material contribution to damage to the needs of cases including uncertain causation. This is useful when the cause of damage comes from two or more contributive sources including the defendant's wrong doing and cannot be attributed to one or the other. It simply means the defendant's negligence materially contributed in producing the damage even though his act alone was not sufficient to create it.

[116] It would be noted that victims of drug injury in Cameroon hardly take action and prefer negotiating out of court due to the fear of the unknown and the outcome.

fact that the very nature of drugs makes them to be associated with adverse effects which vary in timing of relevant exposure and manifestation. The legal Framework on consumer protection has failed to address the issue of causation and so it remains a hurdle to victims. The Cameroonian framework law on consumer protection has introduced the reversal of burden of proof to facilitate causation. However, this does not actually solve the problem of causation since the manufacturing process is in the hands of the manufacturer who can easily rebut any fault on his part. The coherent development of the law in the area of causation in pharmaceutical product liability is indispensible so as to serve even handed the ends of justice. Borrowing good practices from other jurisdictions such as Canada, France, the United Kingdom and the USA where they have taken up with the loss of chance doctrine, market share liability, material contribution of risk and causal inference would actually help enhance the law in an area where human life is in danger. Without a clear cut means of causation, it can prejudice access to justice because most of those injured would not want to go through such difficult hurdles and as such would not take action. The lessening of the burden of proof may likely spur more people to take action and be compensated rather than going in for out of court negotiations for smaller amounts. Introducing such theories would certainly not facilitate all the hurdles of causation but it is submitted that its impact would be significant for the compensation of victims of defective pharmaceutical product.

It would also be submitted that for these theories to be beneficial to the Cameroonian system, the law on burden of proof and standard of proof has to be harmonized. This is based on the fact that while the English part of Cameroon that was colonized by the British is using factual and legal causation to proof causation, its French counterpart that was colonized by French do not make any clear distinction of the terms and only needs that causation should be certain, direct and immediate. Also, for the standard of proof it is a probability standard that is applicable in the English part of Cameroon while for the French part of Cameroon it is based on certainty. Harmonization would make citizens of the same country to get the same justice.