PRODUCT LIABILITY ISSUES AND DRUG MANUFACTURERS: IS TORT LAW EFFECTIVE?

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INTRODUCTION

Tort law, the genesis for product liability, is based on the principle that if a product has a manufacturing defect, failure to warn or causes grievous injury, the manufacturer is liable to pay compensation to the injured party.\(^1\) The dominant view for applying the above mentioned principle is for three apparent beneficial effects, (a) improve the safety of the product, (b) provide compensation to the injured party, and (c) acts as a deterrent effect to the manufacturer of the drugs.\(^2\) This article primarily focuses on widely sold pharmaceutical products and argues that product liability is ineffective and socially detrimental in case of pharmaceutical products, considering a cost-benefit analysis of product and its market structure.

This article focuses on the pharmaceutical industry in America, and argues that the fundamental principle of “better safe than sorry” should be applied towards drug manufacturers. Part II of the article assesses whether drug manufacturers are incentivized to make their products safe in the absence of product liability. It is argued that in case of production of drugs, where there are many market players producing similar products, market forces would allow the manufacturers to produce safe products. The competition in the market for many eminent manufacturers would itself act as a regulator and diminish the prevailing view that product liability results in product safety. Additionally, to justify this proposition is that product liability in case of drugs receive a significant attention from the media. Therefore, it would be economically sound for drug manufacturers to produce safe products, since, the sales may drop if they cause harm to consumers. The second reason is that there ought to be safety regulations that
should standardise the quality of the drugs manufactured.


2 Ibid.

Part III of the article assesses the latent costs an injured party incurs during a civil suit. Studies have shown that every dollar received in compensation due to product liability, the latent expenditure on legal system exceeds a dollar. Further, the compensation that is being paid by the manufacturer for the civil suits, manages its way to an addition in the price of the drugs produced by the manufacturer. Part IV of article assesses the widely held notion that product liability in pharmaceutical products allows the drug manufacturer to produce safer products. However, the article argues that tort law remedies are only incremental in production of safety products. Lastly, it is conclusive that tort law is ineffective in product liability.

II. PLACING THE CARROT BEFORE THE WHEEL

The Pharmaceutical industry in the United States has seen a major change in its structure in the recent years. 3 The effects and utility of each drug has been projected on screens, advertisement boards, and movie theatres, in order to incentivise the consumers to purchase it, if they exhibit the concerned symptoms. 4 In order to provide assistance to the “pharmaceutical boom”, 5 a recent study illustrates that health care costs of American consumers formulate sixteen percent (16%) of America’s gross domestic product. 6

In a period where pharmacies have emerged as economic strongholds, it is argued that certain elements, such as market forces, regulatory norms and FDA rules are a guiding factor

3 Victoria E. Shwartz & Liberty Mahshigian, *A Permanent Solution for Product Liability Crises: Uniform*
for pharmaceutical industries to produce risk-free products. Additionally, it examines through a series of empirical data, the costs incurred by victims in course of product liability litigation. Lastly, it analyses whether the tort law regime produces the desirable results in reduction of risks in pharmaceutical products.

A. **Reduction of Risk**

The pharmaceutical industry has seen an increase in the number of market players, which consequently has resulted in increase in production of certain drugs at a more efficient cost.\(^7\)

As a consequence of the current market forces, it is argued that such industries are incentivised to produce risk-free products in order to continue its participation in the concerned market.

In order to lend support to the abovementioned argument, the paper analyses *Chicago Tragedy*,\(^8\) where a series of residents died due to consuming extra-energy Tylenol capsules, which were laced with potassium cyanide.\(^9\) The market share of Tylenol fell from thirty five percent (35%) to five percent (5%).\(^10\) A market analysis frames the economic perspective in an idyllic manner that describes the nature of consumers and incentive of pharmaceutical industries to produce risk-free products:

> “And followed the first rule of these things - never put consumers in a position where they have to make a choice about the risk.”\(^11\)


Dan Fletcher, A Brief History of the Tylenol Poisonings, The Time (February 9, 2009), available at: [http://content.time.com/time/nation/article/0,8599,1878063,00.html](http://content.time.com/time/nation/article/0,8599,1878063,00.html), last seen on 08/11/2015.


Ibid.
It is of common notion that a sale of a product would drastically reduce if the concerned products exhibits certain defects, or with respect to the Chicago Tragedy, where the product lead to a series of deaths, consumers would prefer not to purchase such products.

On the contrary, it is likewise that in the event product manufacturers provide additional information with regard to the safety of the product, consumers would purchase such products, resulting in a rise in demand of the said product. For instance, the market share of Volvo has incurred a rise due to additional information it provides on the safety features such as “crash-test guarantees” of the car.

Additionally, in the event a particular commodity fails and results in largescale damages, it is often seen that media coverage of such instances are widely broadcasted and leads to a dissatisfaction among consumers. For instance, the mass attention the Tylenol Case or the recent Volkswagen Case received, has led to a steady decline in the market share of the concerned manufacturers. In each case, there has been a sharp fall in the market share for each commodity. Based on the above three market elements, it is argued that for pharmaceutical

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12 The concerned defects could be either unknown to the concerned pharmaceutical firms or are purposefully suppressed from the concerns. In either situation, lack of information or detrimental information among consumers with respect to the drug creates a decrease in its demand. As a result of which the overall purchase of that particular commodity reduces, resulting in decrease of market share of the industry.


14 This argument is largely based on the theory that considers actions and inactions of consumers and their willingness to pay additional amount of money for safer products. Ibid, at 15-18.


16 Supra 9.

17 Post the discovery of the harmful pollutants emitted by Volkswagen cars, there has been a steady decline in their market share. In 2015 alone, their sales have decreased by 26%, as a resultant of the bad reputation it caught due to the recent scandal. Additionally, all such information were spread out on thousands of newspapers and television channels, creating a rather ill-image of the car company. This has led a sense of uncertainty towards the consumers, who would now look for alternate or substitutable products for Volkswagen cars.

products which are widely sold, it is of benefit to such industries to manufacture provide risk-free products in order to participate in the relevant market.

B. Regulations of Risk

In the event the market forces fail or are not able to provide required results in order to create risk-free pharmaceutical products, rules and regulations under the Federal Food and Cosmetic Act (FDCA) towards pharmaceutical products are able to cushion the harm or apparent harm from these products. The Food and Drug Administration (FDA) by creating stringent regulations on the quality of pharmaceutical products and penalizing or disapproving products which do not meet the required standard, eliminates the shortfall between product safety and the efficient level of safety.

The regulatory norms prescribed by the FDCA allows consumers to measure by a risk-benefit analysis the utility of the pharmaceutical product. The effect of the regulations are further provided into three basic categories, and it is argued that in the event norms and regulations are strict and manage to regulate the quality of the product, the use of tort law is socially undesirable.

i. Risk Reduction by Labelling: Pharmaceutical industries are required to label potential side-effects, risks and efficacy about the concerned drug on its packaging which is overseen by the FDA. There are series of drug labelling procedures, and provide information the
manner in which the concerned drug operates, dosage limit, risks involved, and other such information.

ii. Clinical Trials: In order to make the concerned drug available to consumers, pharmaceutical product manufacturers require the drug to be tested through a series of clinical trials in order to provide information regarding the safety and efficacy of the drug. In the event the drug succeeds in the clinical trials, the FDA adjudges the matter based on risk-benefit analysis in the process of approving the drug.

iii. Post Labelling Mandates: Every process has its own set of limitations, and all known-side-effects of a particular drug may not be known during the process of manufacture. In the event any such information is discovered, the FDA may require the pharmaceutical company to re-label its products or in extreme cases, withdraw the said product from the market.

The procedural mandated guaranteed by the FDCA and FDA acts as a deterrent factor for pharmaceutical industries to make drugs that pose a threat or a risk towards consumers. Additionally, any substantial violations of the concerned regulations may attract huge fines or in exceptional cases, imprisonment of the defaulting party.

C. Risk Reduction by Application of Product Liability

Whether a case or a series of litigation has reduced the risk of a particular product is a question posed towards the realm of empirical data. In order to substantiate the argument that product liability actually does not reduce risk, due regard has to be provided to a series of data.
collected by Professor Mitchell Polinksy and cited in *The Uneasy Case for Product Liability*.}

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23 Supra 18, at 1441.

24 Supra 20.


26 Supra 16, at 1446.

27 C.F.R. §§ 310.303 (a), 314.80(c) (1993). *See also* Ibid.


29 Supra 15, at 1437.
The article investigates certain products and litigation cases against the said product during a period of time, and analyses whether tort law remedy actually induced the manufacturers to produce safer products. The series of findings are placed as follows:

<table>
<thead>
<tr>
<th>RESEARCH CONDUCTED</th>
<th>PERIOD</th>
<th>SUBJECT OF RESEARCH</th>
<th>CONCLUSION OF RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor John Graham</td>
<td>1950-1988</td>
<td>Whether tort law on motor vehicles fatalities reduce risk in the concerned products.</td>
<td>The data collected showed no such aggressive change in the quality of the products.[^30]</td>
</tr>
<tr>
<td>Andrew Craig and Robert Martin</td>
<td>1970-1980</td>
<td>Whether litigation under tort law claim reduced the risk entailed by general aviation aircraft.</td>
<td>The authors concluded that between the periods where there existed a heightened series of litigation due to aviation fatalities, there was no substantial reduction in risk of the said products.[^31]</td>
</tr>
<tr>
<td>Richard Manning</td>
<td>Late 1970’s – late 1980’s</td>
<td>Effect of Product Liability in reduction of risk in Childhood vaccines (mainly</td>
<td>During a heightened period of product liability towards DPT, litigation against</td>
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diphtheria, pertussis, and tetanus (DPT)).

vaccines manufacturers rose in the latter part of 1980’s. However, according to Professor Manning’s data there was no change in the safety of the concerned product during this period.\(^\text{32}\)

Through a series of illustrations mentioned above, it is seen that product liability cases do not provide way for risk-free products. Its efficacy has been periodically determined in the above example. Therefore, it is argued that market forces and quality regulations posed by the FDA have a larger impact on the pharmaceutical product as opposed to litigation.

**III. WHERE THE LITIGATION COSTS’ THE CONSUMER**

A victim who may have suffered from a defective pharmaceutical product,\(^\text{33}\) would necessarily approach the doors of the Court in order to seek justice. The myriad idea of justice and punitive damages may lure victims to institute tort law claims from these pharmaceutical industries. However, it is argued that such abstract notions are subjects of legislative texts and decisions. There are certain latent expenditures incurred by such parties that are not within its notice, and are subjects of various empirical studies.


See Brooks v Beech Aircraft Corp., 902 P.2d 54 (N.M. 1995).
It is argued that product liability claims are burdensome on consumers on two grounds, first, the consumer does not take into account the litigation expenditure, and second, in the event the pharmaceutical company pays damages to victims, the costs incurred finds its way to the price of the commodity.

A. *Litigation Expenses Incurred by the Consumer*

Litigation expenses incurred in tort law claims are the sum difference between the percentage of money received by the plaintiff as damages and the percentage of expenditures incurred by the consumer, during the course of litigation.\(^\text{34}\) A series of study conducted by eminent researchers, illustrate that the legal expenses incurred by each dollar spent by the consumer, and the amount received for each dollar.\(^\text{35}\) The table below provides a brief analysis of the concerned data:

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</tr>
</thead>
<tbody>
<tr>
<td>Professor Perrin</td>
<td>2003</td>
<td>Nationwide survey of tort law claims and the amount received as compensation. The research analyses the amount received by the victim for each dollar paid by the defendant.</td>
<td>The research concluded by showing that each victim receives $0.47, for each dollar paid by the defendant.(^\text{36})</td>
</tr>
</tbody>
</table>

\(^{34}\) The lesser the percentage difference between both such elements, higher is the legal expenditures incurred by the consumer during the course of litigation. Report of the Legal Costs Working Group, available at: \text{http://www.justice.ie/en/JELR/legalcosts.pdf/Files/legalcosts.pdf}, last seen on 08/11/2015. \text{See also}, Supra 15, at 1469.

\(^{35}\) The studies made by the concerned authors have included court fees, advocate fees, operating costs of a lengthy decision and other such ancillary expenditures. See Ibid.

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<table>
<thead>
<tr>
<th>Professor</th>
<th>Year</th>
<th>Research Description</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Kakalik</td>
<td>1983</td>
<td>The research was conducted on victims of asbestos cases based on tort law claims.</td>
<td>The research concluded that on average each victim received $0.37 for every dollar paid by the defendant.</td>
</tr>
<tr>
<td>Patricia M. Danzon</td>
<td>2000</td>
<td>The research was conducted on the tort law claims based on medical malpractices.</td>
<td>The research concluded that on average each victim received $0.40 for every dollar paid by the defendant.</td>
</tr>
</tbody>
</table>

In light of the above data, it is illustrated that the tort law system is rather expensive rendezvous. A victim may be overwhelmed with the ideas of justice and redemption, however, in course of litigation, very few consider the abovementioned costs. Therefore, it is argued that litigation seems to be a tedious process and the burden of expenditure only weigh’s heavy on the pockets of the consumers.

**B. Inclusion of Incurred Costs in the Product**

In pursuance to the above section, it is argued that the expenses incurred by the pharmaceutical company as damages, is added to the price of the commodity. As a result of

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which, there is an upward-distorted price of the commodity.\textsuperscript{40} It is of common knowledge that if a price of a particular commodity rises, its demand falls.\textsuperscript{41} It may not be that there may be a large drop in the consumption of commodities, especially in the case of medicines. However, it is argued that some individuals may not purchase the concerned drug due to the hike in price. The case of product liability tends to inefficiently discourage certain consumers for purchasing these pharmaceutical products.\textsuperscript{42} Therefore, it is argued that litigation seems to be a tedious process and the burden of expenditure only weigh’s heavy on the pockets of the consumers.

\section*{IV. IS PRODUCT LIABILITY STILL SOCIALLY DESIRABLE}

This part focuses on the desirability product liability and whether both consumers and manufacturers are benefitting from the said tort law claim.

i. Pharmaceutical Companies: It is shown that in a system where market forces and regulatory norms are present, it is for the benefit of the pharmaceutical company to produce drugs which are risk-free.\textsuperscript{43} On the contrary, pharmaceutical products that result in certain damages, such as \textit{Chicago Tragedy Case}, receive widespread media coverage, that inevitably creates a debauched image of the manufacturing company. And as a consequence, the concerned pharmaceutical company has to bear the impact. Therefore, for a pharmaceutical company, it is socially undesirable to neglect market forces and regulatory norms and additionally, product liability claims would result in detriment of the company’s economic interests.

\textsuperscript{40} Ibid.
ii. **Consumers:** Consumers are the disadvantaged group in the event of a product liability, since, they actually take the fall of the drug. At first, tort law claim, may seem socially desirable, however, in light of Part III of this article, it is clearly shown the average a particular victim receives, post the deduction of legal expenses. Additionally, a factor that has not been given due importance, is the time consumed in order to receive a particular judgement in favour of the injury-bearer. Therefore, product liability claims for consumers, are in effect socially undesirable.

V. **CONCLUSION**

The article has focused on an economic perspective of product liability in relation to certain other factors such as market forces, drug regulations, and effectiveness of product liability, litigation expenses and upward-price distortion. As the focus of the article was towards widely sold products, it is argued that product liability claim for pharmaceutical products is ineffective and socially undesirable. Further, through a study of empirical data provided through various sources, it is seen that tort law claims has not in effect reduced the risk of the commodity. In the absence, of any data proving otherwise, it is prudent to conclude that market forces, economic incentive and regulatory norms are more decisive in churning better results in the quality of pharmaceutical products.

Additionally, the compensation provided by the Courts are in effect toothless tigers, for the manufacturers and the consumers. Firstly, manufacturers do not actually incur any punitive damages, since the burden of litigation and compensation costs are channelled into the price of the product. Thus, the intended blow of product liability is cushioned through an upward-price distortion. Secondly, the consumers do not receive any real compensation, since, the Court often
overlook the basic administrative costs incurred by the victim. Therefore, product liability for widely sold pharmaceutical products are ineffective and socially undesirable.