THE SIGNIFICANCE OF COMPETITION ACT 2002 AND CONSUMER PROTECTION ACT 1986 IN CURBING THE ANTI COMPETITIVE PRACTICES
Chapter - V
THE SIGNIFICANCE OF COMPETITION ACT 2002 AND CONSUMER PROTECTION ACT 1986 IN CURBING THE ANTI COMPETITIVE PRACTICES

Competition Act and Consumer Protection Act are complementary and even mutually reinforcing, though their perspectives may differ and they may apply different tools to correct market failures. Competition Act functions primarily at the interface between firms in a sense on a horizontal plane - preventing structural or behavioral patterns that would damage competition, and it tries to restore effective competition in the market. On the other hand, consumer law generally functions at the interface between the enterprises and consumers - in a sense on a vertical plane - trying to address the unequal relationship between the two and ensure that conditions prevail in this relationship that will enable consumer choice to be effectively exercised Cseres\textsuperscript{210} observes that

\textit{“Although the two legal disciplines focus on different market failures and offer different solutions and apply different techniques to correct market failures they are both aimed at keeping the market competitive and try to bring market performance close to the model of perfect competition. These are actually two different approaches to achieve the same goal: a competitive market where consumer sovereignty is safeguarded and welfare is maximized. Competition law and consumer protection are thus mutually reinforcing disciplines”}\textsuperscript{.}

Competition in the market brings for firms the risk of losing customers to rival firms. There is therefore pressure on them to provide the best `value for money' to the consumer in the products or services offered by the firms. A satisfied consumer will bring repeat business and will reduce the marketing costs. Thus, effective competition, when present in the markets, will compel firms to address consumer problems and find market solutions to the same. The OECD paper\textsuperscript{211} cites several examples to support this argument. It refers to the case of "confusopoly”. As competition law can benefit consumers and can reduce the never direct consumer policy interventions, consumer policy can also strengthen competition in markets. Policies that ensure that advertising and product descriptions are honest and informative, that contract terms and the


obligations they involve are understandable and not disproportionate, and that consumers can reasonably expect products to be safe and fit-for-purpose, will both make consumer choice a more effective discipline (thus directly strengthening competition) and will force firms to compete on their merits (rather than on the basis of fraudulent or misleading claims or of unfair contract terms).212

The two policy instruments can be used to advance the goals also pursued by the other; competition policy, by keeping markets effectively competitive, can reduce the work that needs to be done by consumer policy, and consumer policy, by enhancing the ability of consumers to exercise choice, can help make markets more effectively competitive and force firms to compete on their merits, thereby supporting the ends of competition policy. Averett and Lande have observed very insightfully that competition law provides consumers with a choice of competing products and services and consumer protection law allows consumers to exercise that choice free from fraud, coercion, deception, or demonstrably false information.213

Consumer policy protects and strengthens the position of the consumer, the consumer has greater confidence in the markets and is encouraged to participate therein. Being better informed, the consumer will be able to make rational choices amongst the available products and services. In this way, consumer protection will facilitate greater competition between firms. Cseres makes the interesting observation 214 that “Many consumer problems are actually micro-competition problems. A poorly informed consumer who is not aware of alternative choices and who might be subject to the seller’s discrimination is in fact subject to monopoly power. Or a consumer entering a contract with unfair contract terms is subject to the exploitation of market power.”215 Deceit by one group of sellers may lead consumers to

doubt the integrity of an entire industry or to distrust markets generally. Therefore, competition is not simply fundamental to consumer policy but, as the chairman of the OFT remarked much consumer policy is competition policy. Thus competition and consumer policy seem to be truly complementary.

While competition law and consumer protection are complementary in many ways, their interface also creates various challenges due to the tensions that arise between the two disciplines. The above analysis demonstrated that in the implementation of competition law certain trade-offs are involved and this may determine the extent to which competition law serves consumer interest. If the competition agency gives greater weight to total welfare as against consumer welfare or if it gives greater weight to productive efficiency as against allocative efficiency, to that extent it would provide less satisfaction to consumer interest. Similarly, if it gives greater weight to dynamic efficiency as against static efficiency, to that extent it would provide less satisfaction to short-term consumer interest. The opening of previously highly regulated markets to competition may well raise new issues for consumer protection, for example following the liberalization and introduction of greater competition in financial markets, utility markets and professional services. In financial markets, this has exposed consumers to new risks and difficulties in making complex choices; in utility markets (such as electricity and telecommunications) it has created challenges in respect of service, quality, management of customer complaints and of disconnection for non-payment, as well as consumer choice in the face of complex pricing schemes.

The aims of Competition Act and Consumer Protection Act are mutually complementary and reinforcing, but that they have different approaches to similar problems and there are clearly areas of tension between them, the question arises as to how best to maximize the synergies and minimize the tensions. An economics-based approach could smooth the interface between the two disciplines. Competition law is an economic law, with economics providing the theoretical underpinning for the law as well as the analytical tools used in the application of the law. Over the last several decades, the economics of competition law has expanded immensely with enormous research and study enriching the field. On the other hand, the role of

---

economics in the field of consumer law has been much less obvious. Nevertheless, economic insight would facilitate a better analysis of the problems arising from market failures and would also provide a better understanding as to which problems can be addressed by the market itself and which cannot be so addressed and therefore, require the specific tools provided by consumer protection law. This would provide for a more cost-effective approach towards the solution of problems and would avoid unnecessary or excessive intervention in the market through the medium of the consumer law. The OECD paper 217 recommends a tightly coordinated combination of the two disciplines. Consumer policy tools while seeking approaches that effectively protect consumers should not unduly or unnecessarily restrict competition, and competition policy should be brought to bear to ensure that, subject to appropriate consumer protection safeguards being in place, competition should be allowed to work where it can, including by the elimination of any unjustified restriction on entry and on competitive conduct.

While in most countries, separate agencies handle competition law and the generic Consumer Protection Law, in a few countries the same institution is responsible for both laws. Competition law is steeped in economics whereas consumer law could be more ideology driven. The casework of competition law would generally consist of a smaller number of cases, but with each case being large in absolute terms. On the other hand, consumer law casework would generally consist of a large number of smaller cases. Geographical reach may be of critical importance for consumer protection agencies with a view to providing early access to complainants but in the case of a multi city of benches or offices of the competition authority could give rise to the problem of inconsistencies in the orders placed or approaches adopted in similar cases; considering the economy-wide reach of competition law cases, such inconsistencies could lead to considerable uncertainties in the eyes of enterprises. In this respect, therefore, there is a mismatch between the nature of the work involved in the two disciplines and this may not be conducive to their integration into a single agency. On balance, there appears to be little overall advantage in integrating the two agencies, particularly in countries large in terms of size or population.

---

Competition in the markets brings various benefits by enhancing efficiencies, incentivizing innovation and increasing consumer welfare. The consumer also benefits through wider choice, better products and services and more competitive prices. Competition law through promotion and preservation of competition in markets thereby enhances consumer welfare. This is, therefore, one of the aims and justifications for competition law. Accordingly, consumer interest may feature explicitly as one of the goals of competition law, examples of which may be seen in the laws of various jurisdictions. However, the extent to which competition law can serve consumer interest depends upon the efficiency and the welfare standards pursued in its application, and there are certain trade-offs that cannot be avoided.

In the application of the competition law, consumer interest is generally a concealed aspect and it may not figure explicitly in the analysis of individual competition law cases. But its presence does surface in different forms in the application of the law. However, competition law is neither designed to, nor can it, protect all aspects of consumer interest. Competition law has a broader remit and it is part of the institutional framework for the management of the economy. Consumer interest features as just one of the elements in competition law, albeit an important one. Therefore, it would be unrealistic to expect that competition law can protect consumer interest in its entirety. Certain aspects of consumer interest cannot be reached at all by competition law such as safety, health, environment and privacy; there are, therefore, specialized laws in various countries for the protection of these aspects of consumer interest. In addition, to protect consumers against unfair trade practices by producers or suppliers, generic consumer protection laws have come into existence in various countries.

5.1 COMPETITION ACT AND CONSUMER PROTECTION ACT IN INDIA

Competition in a market promotes efficiency, increases consumer welfare, offers wider choice, better products and services, and contributes to the progress of an economy. In an industry where there is intense competition, often, there is a tendency, that the industry would become better and efficient. This happens because competition eliminates the poor performing products or services and leaves only good and outstanding products for the general masses to consume. This particular advantage of competition is more likely to benefit the general population, since they would have better quality products and services for cheaper prices. As there exists competition in
the market, the market players try their best to provide consumers what they need. Consumers need good quality products at lower prices. If there is Competition in the market, the market players in order to survive will be compelled to bow down to the demands of the consumer, i.e. quality products at lower prices. Competition law, therefore, is designed for the regulation of competition, thereby ensuring economic growth. It is commonly believed that competition law is ultimately concerned with the interest of the consumers. The kind of protection accorded to consumers under the Competition Act and the Consumer Protection Act can be inferred from the definition of the word ‘consumer’ under the two statutes.

The definition of ‘consumer’ under the Consumer Protection Act, 1986, includes any buyer or user of goods or services but does not include a person who obtains such goods for resale or for any commercial purpose. However, the definition under the Competition Act, 2002, recognizes a person who buys or uses goods or services for commercial purpose or for resale, as a consumer. In this way, the Competition Act aims to protect the larger public interest from anticompetitive practices. Consumers have been recognized as an important component of the economy, and protecting them from exploitation and ensuring their rights has become a vital feature of government legislations and policies. Apart from the legislation enacted for consumer protection, a number of other laws provide for the protection of consumer interests.

The Consumer Protection Act, 1986 (COPRA) provides a three-tier, simple, quasi-judicial machinery, at the National, State and District levels, for the protection of consumers. The preamble of the Act states its objective, i.e., to provide for better protection of the interests of consumers and for that purpose to make provision for the establishment of consumer councils and other authorities for the settlement of consumers' disputes. The Act establishes Consumer Councils at the National, State and District level, the object of which, under Sec. 6, is to promote and protect the rights of the consumers such as, redressal against unfair trade practices, consumer education, protection against hazardous goods, right to be heard, right to be informed etc. A recent amendment of the COPRA among other things deals with rights of complaint, monetary jurisdiction and enforcement. The amended Act provides for attachment and subsequent sale of the property of a person not complying with an order. Proceeds from such sales may go to pay the damages of the aggrieved consumer.
Thus, COPRA is a comprehensive piece of legislation, dealing with all the aspects of consumer protection in India, and ensuring consumer rights in the best possible way.218 Under the Consumer Protection Act, any person who hires or avails any service for a consideration is a consumer. Secondly, shareholders under the Companies Act, have limited liability, unlike the owners, who have an unlimited liability. Therefore, shareholders cannot be considered as owners, and thus can be considered as consumers. The suggestion for setting a ‘consumer ombudsman’ has often been voiced by consumer activists. A ‘consumer ombudsman’ or a state level competition and regulatory agency, could be helpful in dealing with local-level monopolies and collusive practices which a consumer often encounters. A consumer ombudsman will also take the pressure off consumer courts and formalize and strengthen the prevalent practice of out-of-court settlements mediated through consumer groups. The banking and insurance sectors, as mentioned above, already have such a system.

Effective competition regime provides necessary conditions for maximizing the interests of the consumers. The protection of consumer interests runs through the Competition Act. The Preamble of the Act and subsequent provisions like Sec 18, 19 etc. expressly provide for protection of consumer interests. Sec. 2(f) defines ‘consumer’ which, as earlier mentioned, is much wider than the definition given under the Consumer Protection Act, 1986. Further, under the chapter on Duties, Powers and Functions of Commission, it is provided that the Commission shall, while determining the "relevant geographic market" and "relevant product market", have due regard to consumer preferences. The National Competition Policy, 2011 also stated that the fundamental role of competition policy is to guarantee consumer welfare by encouraging optimal allocation of resources and granting economic agents appropriate incentives to pursue productive efficiency, quality and innovation. The consumer protection has become an important aspect of various legislations, and same is the case with competition law. The legislators are realizing the vulnerability of consumers, and are trying to incorporate the relevant provisions in the legislations of the sectors which are more likely to affect the consumers.

Competition law has multiple goals, which include: Ensuring an effective competitive process

---

• Promoting consumer welfare.
• Enhancing efficiency.
• Ensuring economic freedom.
• Ensuring a level playing field for small and mid-sized enterprises.
• Promoting fairness and equality.
• Achieving market integration.
• Facilitating privatization and market liberalization and
• Promoting competitiveness in international market

Consumer welfare is therefore, one of the goals of competition law. Competition law aims to protect competition in the market as a means of enhancing consumer welfare and ensuring the efficient allocation of resources. Consumer welfare also known as consumer surplus refers to the difference between what consumers are willing to pay and what they actually pay. The level of consumer surplus is shown by the area under the demand curve and above the ruling market price. Competition is now universally acknowledged as the best means of ensuring that consumers, even more so the aam adami or common man, have access to the broadest range of services at the most competitive prices. At this stage, a brief discussion on the difference between consumer interest and public interest may be necessary to help appreciate the analysis. The Report of the High Level Committee on Competition Policy and Law popularly known as the Raghavan Committee, explains that often consumer interest and public interest are considered synonymous, but they are not and need to be distinguished. In the name of public interest, many Governmental policies are formulated which are either anticompetitive in nature or which manifest themselves in anti-competitive behaviour. If the consumer is at the fulcrum, consumer interest and consumer welfare should have primacy in all Governmental policy formulations. Consumer is a member of a broad class of people who purchase, use, maintain and dispose of products and services. Consumers are affected by pricing policies, financing practices, quality of goods and services and various trade practices. They are clearly distinguishable from

219  2007 ICN Report
manufacturers, who produce goods and wholesalers or retailers, who sell goods. Public interest, on the other hand, is something in which society as a whole has some interest, not fully captured, by a competitive market. It is an externality.

The core of this lays enhancement and maintenance of competitiveness. Consumer protection policy is part of the strategy that emanates from the first approach, while competition policy is an integral part of the second approach though there are significant overlaps. However, it may be noted here that the two approaches do not mean two alternatives, but rather two instruments that must be used simultaneously. Competition law concentrates in maintaining the process of competition between enterprises and tries to remedy behavioral or structural problems in order to re-establish effective competition in the market. The consequence of this is higher economic efficiency, greater innovation and enhancement of consumer welfare. Thereby the consumer experiences wider choices and greater availability of goods at affordable prices. On the other hand, the consumer protection policy and law are primarily concerned with the nature of consumer transactions, trying to improve market conditions for effective exercises of consumer choice. Thus, the two disciplines focus on different market failures and offer different remedies, but are both aimed at maintaining well functioning, competitive markets that promote consumer welfare.

The two disciplines are mutually re-enforcing.\textsuperscript{222} The relationship between competition policy and consumer welfare is governed by three fundamental principles:

Principle 1. Competition policy exists within the realms of consumer welfare and not the other way around.

Principle 2. Competition policy should encourage only conduct which promotes consumer welfare.

Principle 3. Competition policy imposes an obligation on consumers, not only on merchant.

Competition law protects consumers directly and indirectly. The substantive provisions of competition legislation are grouped under two broad headings:

\textsuperscript{222} \textit{Consumer Protection and Competition Policy}, available at http://planningcommission.nic.in/plans/planrel/fiveyr/11th/11v1/11v1\_ch11.pdf, accessed on 18/10/12

consumer protection and competition protection. The groupings are misleading; however, in the sense that it suggests that consumer protection and competition protection are distinct objectives. In practice, however, both sets of provisions are alternative means of achieving the common goal of promoting consumer welfare. The competition process provides the greatest incentives for merchants to offer consumers the best quality goods and services at the lowest possible prices. The competitive process generates the greatest possible level of public surplus. By protecting the competitive process, therefore, competition protection provisions indirectly promote consumer welfare. While it is apparent that the awareness of consumer interests in the enforcement of competition law is increasing, it is obviously not capable of protecting certain final consumers’ needs. Competition law has inherent limits in that respect. First, the notion of consumer under competition law is broader than under consumer law. This means that competition law might acknowledge certain situations as favourable for consumers while such situations do not benefit the final consumers; only the direct customers of the undertakings. Second, competition law is mostly concerned with the economic interests of consumers and while in a few cases it might take account of wider consumer interests it is definitely not concerned with other significant consumer interests like health and safety issues or information disclosure. Competition policy also has other goals than improving final consumers’ welfare and therefore final consumers cannot and should not become the sole focus of competition laws.223 It is to be noted that even in developed countries, competition policy is not about just promoting maximum competition and hence maximum choice, policy and consumer protection policy may often be complex.

5.2 CONSUMER PROTECTION AT THE INTERNATIONAL PERSPECTIVE:

The competition policies of various countries throughout the world is analyzed here. To what extent is consumer protection guaranteed under different systems of competition law, and whether the primary goal of competition law in these countries is protection of consumer interests, or regulation of competition. Consumers are in most cases the final beneficiaries from strong enforcement of competition rules. They will also be the ultimate losers from any lack of competition since this will mean increased

costs, less choice or lower service quality. Consumers today, are more than simply passive beneficiaries or victims of competition. Informed, educated and active consumers are the real drivers behind a competitive marketplace. Consumers and their representatives are able to bring helpful information about potential market failure to the Commission’s attention. The Hon'ble Supreme Court in the case of *Competition Commission of India v. Steel Authority of India Ltd. & Anr.*224 pronounced on 9th September, 2010 stated that “The main objective of the Competition Law is to promote economic efficiencies using competition as one of the means of assisting the creation of market responsive to consumer preferences.” The Competition Act, 2002, in its Preamble, states protection of the interests of consumers as one of its goal. Further, Section 18 of the Competition Act which defines the duties of the CCI clearly mentions that protection of interests of Consumers is one of the duties of CCI. The consumers or consumer associations are also given the right to complain against any anti-competitive practices in contravention of sections 3(1) and section 4(1) to the CCI under section 19(1) of the Act. Moreover, under section 19(3), the Commission shall, while determining whether an agreement has an appreciable adverse effect on competition under Section 3, have due regard to the following factors, namely

(a) creation of barriers to new entrants in the market;
(b) driving existing competitors out of the market;
(c) foreclosure of competition by hindering entry into the market;
(d) accrual of benefits to consumers;
(e) improvements in production or distribution of goods or provision of services;
(f) promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services. Benefit to consumers is, therefore, one of the factors to be taken into consideration by the Commission. Similar is the provision while determining the dominant position of an enterprise under Sec. 19(4), and while determining the relevant geographical market and relevant product market under clauses (5) and (6) respectively. Further, under Sec. 49(3) the Commission shall take suitable measures for the promotion of competition advocacy, creating awareness and imparting training about competition issues. As a consequence

---

224 *Competition Commission of India v. Steel Authority of India Ltd. & Anr* Civil Appeal No. 7999 of 2010
of the advocacy efforts and enforcement of the Competition Act there has been a perceptible increase in awareness among the business community and consumers, which was reflected in the number of cases that have been filed with the Commission alleging violation of Section 3 and section 4 of the Act.

Consumer awareness is also a goal under the Consumer Protection Act, and under Sec. 6, the right to consumer education is listed as an object of the Consumer Council. It is imperative for the consumer organizations to be aware of the Act and to be with the Commission for achieving the common objective of consumer welfare through competition. In this way, there is a commonality between both the laws. As has been mentioned earlier, the 11th Planning Commission Report states that promotion of consumer welfare is the common goal of consumer protection and competition policy. While some jurists regard consumer welfare as the ultimate object of competition law, others consider it as a consequence of the operation of competition law. In order to clarify the position, the arrangement of the redressal agencies of the two laws may be taken into consideration. Indian law provides for two separate machineries to deal with competition and consumer cases. The CCI addresses only those consumer complaints which involve a competition issue. For all other consumer grievances, there are Consumer dispute redressal agencies. Similarly, individual redressal mechanism while available under the Consumer Protection Act, are not open to address systemic anti-competitive practices, which call for a different approach and redress mechanism. From this kind of arrangement, it can be inferred that consumer protection and competition law, though have a common goal, are different in their approach regarding redressal.

The Competition Act is primarily concerned with ensuring and maintaining free and fair competition in Indian markets and the Act of 1986 is looking after individual consumer grievances against unfair trade practices and deficiencies in goods/services. It was held that in the light of aforesaid discussion, the information filed by the informant does not fall within the four corners of the Act. The Commission finds that no prima facie case is made out against the opposite parties either under section 3 or section 4 of the Act for referring the matter to DG for investigation. It is a fit case for closure under section 26(2) of the Act and is hereby closed.

Sanjeev Pandey v. Mahendra & Mahendra & Ors 225 The Commission observed that the informant has misunderstood the Act and probably confused it with

225 Sanjeev Pandey v. Mahendra & Mahendra & Ors Case No.17/2012
the Consumer Protection Act, 1986. The scope of the Act is primarily aimed to curb the anti-competitive practices having adverse effect on competition and to promote and sustain competition in the relevant markets in India. Whereas the Consumer Protection Act, 1986 is aimed to protect the interest of individual consumers against the unfair practices being widely prevalent in the market. It was held by the Commission that in the instant case, the informant has failed to make out a case under the aegis of the Act as that the main grievance of the informant of allegedly not getting the delivery of the said vehicle from the dealer in time cannot be entertained under the Act.

5.3 MEDICAL PRODUCT LIABILITY IN HEALTH CARE SECTOR

Until the mid-1950s, there are no regulations in the Federal Republic of Germany governing the development, production or sale of medicines. there is no German Drug Law/Medicines Act and no Federal Institute for drugs and Medical Devices (BfArM) or similar agency. 1954 Grunenthal obtains a patent for thalidomide, the active drug substance in the product called Contergan in Germany. October 1, 1957. thalidomide is launched on the West German market and sold under the brand name Contergan. Until withdrawn thalidomide was sold in a total of 46 countries under various brand names. October 1959 First reports suggesting thalidomide might cause nerve damage in the hands and feet (polyneuropathy).

“1961 Grünenthal amends the package leaflet disclosing the side effects and applies for a step-by-step prescription-only status for thalidomide in selected German federal states in May 1961 on account of its potential to cause polyneuropathy

November 15–26, 1961 A Hamburg-based pediatrician, Dr. Widukind Lenz, voices the first suspicion that deformities in unborn children may be associated with thalidomide, first in a telephone conversation and then by letter. on Friday, November 24, 1961, Grünenthal received a letter from the UK-based licensee, Distillers. Distillers said that an Australian gynecologist (later identified as Dr. William McBride) had raised with them his concern about a potential teratogenic effect of thalidomide.

November 27, 1961 Grünenthal withdraws thalidomide from the West German market.

1962 - Scientists succeed for the first time in demonstrating teratogenicity of the active drug substance thalidomide in animal experiments in white New Zealand rabbits.
1964 - An Israeli physician, Jacob Sheskin, discovers thalidomide's effectiveness in treating leprosy.

May 27, 1968 - Legal proceedings are instigated against nine Grünenthal executives and research employees in Alsdorf near Aachen.

April 1970 - While criminal proceedings are still ongoing, Grünenthal begins negotiations with representatives of those affected and voluntarily pledges to pay DM 100 million (approx. EUR 50 million) to thalidomide victims according to an agreed settlement.

December 18, 1970 - the case against Grünenthal is discontinued.

1972 - the West German government enacts a law setting up a public foundation called Disabled Children's Relief Foundation. The government paid DM 100 million (approx. EUR 50 million) into the Foundation and Grunenthal contributed DM 114 million (approx. EUR 58 million). Grunenthal is granted immunity against any other claims.

1990s - Scientists discover that Thalidomide has anti-inflammatory effects on the immune system and inhibits the formation of new blood vessels. The drug is used to treat severe illnesses including AIDS and cancer.

1998 - Prevent other companies distribute thalidomide in order to meet the medical need.

June, 2003 - Grunenthal stops supplying thalidomide. At the request of the World Trade Organisation (WHO), Grunenthal had been supplying thalidomide of a leprosy complication called ENL reaction. Strict conditions applied in order to prevent thalidomide from being given to pregnant women. Grunenthal supplied the drug on a not-for-profit basis.

December 2005 - As thalidomide victims are now adults, the Disabled Children's Relief Foundation is renamed Contregan Foundation for People with Disabilities.

December 2007 - First meeting between Grunenthal and representatives of the German Federal Association of Thalidomide victims.

February 2008 - Grunenthal works with the German government and the German Federal Association of thalidomide Victims towards a collaborative solution to improve the lives of thalidomide victims.
May 2008 - Grunenthal announced that the company intends to voluntarily pay EUR 50 million into German Contergen Foundation to facilitate additional annual payments to those affected. Thalidomide associations value this plan as an important step in the right direction.

July 2009 - Grunenthal transfers the voluntary sum of EUR 50 million to the German Contergen Foundation. As a result, in addition to a monthly pension individuals affected by a thalidomide product from Grunenthal can receive annual payments. The pension and special payments are provided regardless of any other social benefits thalidomide victims receive.

2010 - About EUR 500 million has been paid out to thalidomide victims to date.

June 2011 - Grunenthal started the "hardship initiative". In cases of a hardship, those affected by thalidomide (particularly those affected by a Grunenthal product) can apply for support to fund non-cash benefits focusing on mobility and adaptations of houses and apartments.

August 31, 2012 - Grunenthal CEO, Harald F. Stock PhD., apologized on behalf of the company, its employees and shareholders for the fact that the company has not found the way to reach out to those affected from to person for almost 50 years.

December 2012 - Grunenthal establishes the company-owned Grunenthal Foundation for the support of thalidomide-affected people (Grunenthal foundation).

2013 - Grunenthal organised the first Round Table with representatives of German Thalidomide associations and individuals.

2014 - Since the hardship case initiative was started, the Grunenthal Foundation has approved more than 300 applications. The payments made by the German Contergan Foundation exceed the amount of EUR 600 million.²²⁶

5.3.1 DESIGN DEFECTS AND PHARMACEUTICAL PRODUCTS

Medicinal products may be defective if they are unsafe for their intended or contemplated purpose because of a basic design deficiency. Design defects are most problematic category of defects in medicinal products since the concept of safety is harder to apply to such products, where safety is relative concept²²⁷. While in the US

²²⁶ https://www.contergan.grunenthal.info/grt-ctg/GRT-CTG/Die_Fakten/Chronologie/152700079.jsp
the issue of design defects liability for prescription products seems secondary\(^{228}\), virtually all of the important product liability litigation in the UK concerning medicinal products relates to design defects\(^{229}\).

It is important to understand the true nature of a medicinal product design defect. Helpful guidance is provided by Professor Stapleton who asserts that a design allegation of defect in a medicinal product is necessarily a complaint about the 'chemical effects of the product and can be assessed independently of the state of the art and knowledge at the time of supply\(^{230}\). this has an important consequence in that undiscoverability of the product hazard given the state of the art is no answer to a claim for design defect, since design defect claims are akin to claims of breaches of the warranty of merchantability\(^{231}\). Under a design allegation defect the issue of the level of safety to which there is legal entitlement focuses 'not on the discoverability of the hazard given the state of the art at supply', but merely 'on the impact of the chemical formula as it is now known at trial to have been\(^{232}\). That this is true seems highly likely in that if a medicinal product proves to be unsafe when using the manner apparently intended or according to its normal instructions, it is likely to be found defective\(^{233}\).

Nonetheless, this is not abundantly clear from the legislation since, as has been previously noted, the Directive fails to develop a suitable taxonomy for products, let alone medicinal products.

5.3.2 WARNING AND INSTRUCTION DEFECTS

Notwithstanding the fact that the category of warning about risks and instructions for use is the most significant factor relevant to determining the expectation of safety with medicinal products, the position of warnings under the Product Liability Directive remains uncertain.

\(^{228}\) Professor Owen has noted, the issue of drug design defectiveness is 'a troublesome but largely phantom issue in modern drug litigation': DG Owen, 42 Conneticut Law review 733-750(2010)


it has been submitted that most commentators are correct in viewing warning defects as fault based, and that there is much to Stapleton's analysis of a claim for failure to have warning about a drug's side-effect as being one 'inexorably linked to the reasonable feasibility of warning'. Nonetheless, her argument that in determining whether a warning of a side-effect is necessary, there needs to be a 'scientific consensus of a causal link', formed on the accumulation of enough data to be 'sufficiently scientifically significant' should be viewed with an element of caution. The danger with such an approach is that it might suggest supremacy of statistically significant in determining failure to warn, and that a warning of a suspected side-effect should only be provided when a risk is statistically significant, i.e, where the relative risk of an association is greater than two. Indeed it is clear that there may be a duty to warn of a side-effect even though a casual relationship has not been clearly proved, and this has been recognized both in the US and in recent Vioxx litigation in Australia.

While Stapleton correctly submits that a failure to warn could only be 'impossible' if the risk or hazard in question is 'undiscoverable' or scientifically unknowable in the light of the state of the art of the epidemiological data relating to the drug at the time if it supply, it is perhaps easier to see these issues as matters of foreseeability of risk. This would be consistent not only with the endorsement by the US courts of comment j of Sec 402A of Restatement, that the duty to warn extended only to foreseeable risks, but also with Restatement, Third, Torts 'Product Liability, Sec 6 (d), which limits the responsibility in prescription drug cases to a duty to provide 'reasonable instructions or warnings regarding foreseeable risks of harm'. Although Stapleton correctly concludes that under Article 6 which suspected adverse effects must be warned about and when in order for a drug to provide the safety to which we are legally entitled 'taking on circumstances in to account, is 'a matter of degree and judgment', Newdick's objectification of the foreseeability of risk approach provides greater clarity of guidance as to when an allegation of failure to earn defect became viable than the reasonableness standard of feasibility of warning. Notwithstanding Stapleton's persuasiveness in suggesting that there is no role for Article 7 (e) in failure to warn claims, her elision of state of the art and state of scientific and technical knowledge in so doing is controversial. A better way to think of this issues in terms of the foreseeability of risk. If the injury or risk is unforeseeable, then it might be concluded
that where the claim for a defect on the grounds of failure to warn will fail. The product is simply not defective and the defense would be rendered otiose.

Finally, in the context of drug defects through an alleged failure to warn, the requirement of causation necessitates not only that claimants prove the feasibility of a warning, but also that, had a warning been provided, they would have heeded it, thus avoiding the injury. It is arguable that the amenable approach to causation suggested by Chester v Afshar\textsuperscript{234} could be applied to failure to warn in the context of medicinal products.

5.3.3 USE OF NEGLIGENCE PRINCIPLES

In the United States, failure to provide adequate warnings in case involving prescription drugs is actionable under principles of negligence, strict liability, or warranty or a combination of such actions. A majority of American courts have concluded that failure to warn claims brought under negligence or strict liability are largely indistinguishable\textsuperscript{235} However, in the prescription drug case of Carlin v. Superior Court\textsuperscript{236}, while conceding 'that the knowledge or knowability requirement for failure to warn infuses some negligence concepts into strict liability cases' and that 'in the failure to warn context, strict liability is to some extent a hybrid of traditional strict liability and negligence doctrine', the Californian Supreme Court continued to insist that failure to warn in strict liability 'differs markedly from failure to warn in the negligence context, It concluded the 'in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial' and presented two hypothetical scenarios to support its view:

"Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacture's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of danger that were known to the scientific community at the time it manufactured or distributed the product. Similarly, a manufacturer could not escape liability under strict liability principles merely because

\begin{itemize}
  \item \textsuperscript{234} Chester v. Afshar (2004) 4 All ER - 585
  \item \textsuperscript{235} Gourdine v. Crews 955 A 2d (2008)(claims in negligence and strict liability are morphed together)
  \item \textsuperscript{236} Carlin v. Superior Court 920 P 2d 1347 (Cal 1996)
\end{itemize}
its failure to warn of a known or reasonably scientifically knowable risk conformed to an industrywide practice of failing to provide warning that constituted the standard of reasonable care." Nevertheless, as erstwhile Reporters of the Products Liability Restatement, Professors Henderson and Twerski have reaffirmed that there is little, if any, substantial difference between the failure to warn approached in negligence and strict liability.237

The application of strict liability to unknown and unknowable defects in the context of medicinal product (including diethylstilbestrol) was also rejected by the California Supreme Court in Brown v. Superior Court238 (Abbott Laboratories), where the court held that a drug manufacturer should not be strictly liable for failure to warn of defects inherent in a drug of which it neither knew nor could have known by the application of scientific knowledge available at the time of distribution. A manufacturer of drugs thus has a duty to warn physicians 'about any known or reasonably knowable dangerous side effects'. The same court extended the decision in Brown beyond prescription drugs to produce generally in Anderson v. Owens-Corning Fiberglas Corp239, holding that knowledge or knowability was a component of strict liability for failure to warn. It reaffirmed this position in the context of failure to warn and prescription drugs in Carlin v. Superior Court, holding that '[d]rug manufacturer need only warn of risks that are actually known or scientifically knowable'. In spite of the firm statement of principle in the Sternhagen decision, it seems, as Professor Owen has put it, that 'the tide had sharply turned against a duty to warn of unknowable product risks'. The decision in the higher courts of four other States have supported that there is no duty to warn of unknowable product risks240, two in respect of prescription pharmaceutical products241, and two in respect of products generally242.

5.3.4 STRICT LIABILITY AND NO-FAULT COMPENSATION FOR MEDICAL PRODUCT INJURY

In the case of injury attributable to medical products, German law also offers the possibility of compensation independent of fault. First and most significant, are

---

237 Reporters’- notes to Restatement, Third, Torts: Product Liability Sec 2
238 Brown v. Superior Court (Abbott Laboratories), 751 P 2d 470 (Cal 1988)
239 Anderson v. Owens-Corning Fiberglas Corp 810 P 2d 549
241 Young for Young v. Key Pharmaceutical Inc. 922 P 2d 59 (1996)
242 Owens–Illinois Inc. V. Zenobia 601 A 2d 633 (1992) (no liability for failure to warn if there is insufficient knowledge on the part of the Manufacturer or in the Scientific field involved)
injuries caused by medicinal drugs. Thus in 1976, in the wake of the Thalidomide(Contergan) disaster, the German Parliament enacted the Medicinal Products Act, 2005. This provides in section 84 for liability against pharmaceutical manufacturers in cases where a medicinal product, used a prescribed, causes injury that, in light of the overall level of medical scientific development, may be regarded as unacceptable. In addition, following initiatives at the EC level, injury from non-pharmaceutical medical products is covered within the more general “strict liability” regime for consumer products under the Product Liability Act.

Both the AMG and ProdHaftG regimes are regarded as complex in terms of their scope of application, and are relatively seldom used. One common difficulty has been establishing the causal link between a given product and an injury. In this regard, some reforms were made to the AMG in 2002, easing the patient’s situation. Now, once he shows the medicine was capable of causing the injury he suffered, absent a plausible alternative explanation, the presumption will be that it did so in his case; there is also a right to obtain information from the manufacturer as to the medicine’s known effects. Despite these changes, the pharmaceutical industry reported that between mid-2002 and mid-2005, it received just 220 compensation claim under the Medical Product Liability Act and seventy requests for information.

In the second place, there are two limited pockets of no-fault liability with respect to medicinal product injuries. The first of these covers victims of Thalidomide(Contergan) and was set up in 1971 under the Contergan [Thalidomide Foundation Act]. The relevant scheme provides for compensation (mainly in the form of a fixed monthly pension) from a fund financed by contributions by the federal government and the drug manufacturers. The second German no-fault scheme was established in 1995 to provide compensation to patients infected with HIV as result of receiving contaminated blood. This was introduced by the HIV [HIVHG], inter alia in the light of the difficulties of proof experienced by such patients in bringing a claim under section 84 of the Medical Product Liability Act.

Although no-fault compensation for medical injury thus plays a limited role in modern Germany, it is worth remarking that things were different in the former

---

243 Medical Product Act does not embody strict casual liability.
244 Product Liability Act, 1989
245 Thalidomide Foundation Act, 1971
German Democratic Republic (GDR). There, a partial no fault scheme of “additional support for victims of medical injury” operated, which covered iatrogenic injury, absent fault, if this was severe and in gross disproportion to the seriousness of the condition being treated. A rationale that has been suggested for the scheme was of counterbalancing the duty on GDR citizens to seek treatment to safeguard their economic productivity. Be that as it may, after German reunification, the scheme was no longer seen as socially justified, and it was disbanded in 1994.

A person who alleges an injury caused by a defective product may elect to base his legal cause of action on any of the three principle of products liability theories: negligence, warranty, or strict liability. These may be the criteria in criminal, civil, or consumer case proceeding for product liability in the court of law. However, the proceeding on a negligence theory in a products liability case requires an injured party to show that a specific defendant failed to exercise proper care in designing, testing, manufacturing, or marketing the allegedly defective medical product and that, as a reasonably foreseeable and proximate result of such negligence, the patient suffered the injury. The miraculous extension of life by high technology medical care, organ transplantation, mechanical substitutes, newer antibiotics, anesthetic agent and prosthetic products show the increase in powers of medical care delivery. Developing concurrently with the remarkable achievements of modern medical science and technology has been a similarly profound legal revolution in the body of law commonly known as products liability. Product liability describes the physical agent, which caused the injury in a situation in which a person is under a legal duty to the injured person. The injury or death of the patient may result unexpectedly by faulty, defective or negligently designed medical or surgical instruments or inadequate operating instructions. The manufacturer becomes responsible for injury or death in such case. The patient must prove that the defendant manufacturer departed from standards of due care, with respect to negligent design, manufacture, assembly, packaging, failure to test and inspect for defects or failure to warn or give adequate instructions. If the instrument functioned satisfactorily in previous operations or for several previous years in the hospital’s possession, it is a proof that it was not defective at the time of supplying. If subsequently the instrument develops a defect through ordinary and gradual wear and tear, or if the physician or the hospital misuses the manufacturer’s, medical products, the negligence liability would be imposed on the hospital or physician owner for the
failure to inspect, test and repair such defects. The manufacturer becomes responsible if the patients can prove that the subsequent development of this defect was due to negligent design, structurally inferior component material, or improper assembly. An adequate warning cautions the user to follow directions and may also notify the risk of disregarding directions. This article reviews the theories available to an individual who alleges an injury caused by a defective product and sets forth the elements necessary to establish a cause of action on any of the principal products liability theories and the potential liability of the manufacturer of drug, blood products, medical equipments and various other product used in medical care delivery when something goes wrong due to the use of these product and comment future of product liability.

5.4 THEORIES OF MEDICAL PRODUCTS LIABILITY

Whatever the danger and state of medical knowledge, and however rare the susceptibility of the user, when the drug company positively and specifically represents its product to be free and safe from all dangers, and when the treating physician relies upon that representation, the drug company is liable when the representation proves to be false and harm results. The legal doctrine of negligence may be defined in terms of the duty of the person of “ordinary sense” grounds for products liability case requires an injured party to show that a specific defendant failed to exercise proper care in designing, testing, manufacturing, or marketing the allegedly defective product and that, as a reasonably foreseeable and proximate result of such negligence, the patient suffered injury. Historically, a purchaser of goods has also been able to claim a breach of warranty against the immediate seller on the grounds that the goods were not as they were contracted to be. If a buyer could show that a seller made representations either expressly or impliedly about the quality of the goods that turned out to be inaccurate, the buyer would be allowed to recover appropriate damage without establishing any negligence by the seller. In early common law, the rule of caveat emptor, or “buyer beware”, prevailed. Changing social and economic considerations resulted in warranties, but only in situations where there had been an actual sale contract. “Given the contractual under pinnings of this cause of action, courts were reluctant to expand recovery for breach of warranty against anyone with whom the patient had not directly contracted. The term “privity” was given to the requirement that the parties have had actual dealings among themselves. “As the common law developed, however, certain

---

aspects of tort law were grafted onto warranty law. As a result of this commingling of
tort and contract law with breach of warranty actions, the privity requirement gradually
eroded\textsuperscript{248}. Today, most countries including India allow a suit for breach of warranty
against a seller by the ultimate consumer-under consumer protection act. An injured
party proceeding on a warranty theory of liability need not prove negligence. Instead, it
must be shown that the manufacturer or seller breached an expressed or implied
promise that the product was both free from defects and fit for the ordinary purposes in
which such products are customarily used.

Many countries have evolved basis for liability on the part of the manufacturer
of a defective product. This is known as “strict liability in tort”. The theory behind
strict liability is that is better social policy for manufacturers, rather than injured
consumers, to bear the economic burdens, through products liability insurance or
otherwise, for any injuries caused by defective products. Under the strict liability
theory, an injured party need not prove negligence or any breach of warranty, but rather
must establish only that the product causing the injury was defective when it left the
control of the manufacturer or the seller.

Generally, there are four fundamental types of product defects. The first may be
considered the “manufacturing defect”. An improperly manufactured product is one
that has been incorrectly manufactured or assembled and is thereby different from
similar products manufactured. The second category of defective products is the
defectively designed product. Such a products is identical to similar products
manufactured by the defendant, all of which bear a common design flaw that renders
the product unreasonably dangerous. The third category is a product that is defective
because it has been inadequately tested. The fourth category is a product that is
considered defective because the manufacturer has failed to provide the user with
proper warnings or instructions regarding the product’s use. This type of claimed defect
occurs frequently in cases involving pharmaceutical and medical products.

Under the strict liability theory, potential liability attaches not only to the
product’s manufacturer, but also to its retailer and to any other person in the
distribution chain who is “in the business of selling such a product”. Development in
products liability theories, from negligence through strict liability, has made it easier
for an injured party to establish a viable theory of recovery. Each new theory has

\textsuperscript{248} Consumer Protection Act, 1986.
expanded the law rather than merely replaced its predecessor. This broadening of recovery theories, however, has added new complexities to the products liability field. Depending on the facts of the case and upon the theories advanced, each products liability cause of action will have separate elements, varying burdens of proof, and different potential defenses. The central themes, however—which runs throughout all products liability causes of action in the existence or nonexistence of a product defect at the time the product left the defendant’s control. This theme is essential to products liability and distinguishes it as a separate and unique field of law\textsuperscript{249}.

5.5 THE MANUFACTURER’S LIABILITY

A manufacturer’s liability for its products may be established under the three theories discussed above negligence, warranty, and strict liability. For an injured party patient to establish a successful cause of action in negligence it must be proved that the defendant manufacturer departed from reasonable standards of due care with respect to the design, testing, manufacture, assembly, inspection, packaging, or advertising of the product or failed to warn or give adequate instructions with respect to its use. The manufacturer owes this duty of due care to the ultimate user and not just to the immediate purchaser. A manufacturer’s liability on the theory of breach of warranty is often more closely linked with the contract of sale between the parties involved, specifically the manufacturer and the injured buyer. Privity of contract has been the principal hurdle in breach of warranty actions. Even if privity can be established, traditional warranty theory also requires the patient’s reliance, to his detriment, on an express or implied assertion by the defendant about the nature of the defective product. Without all of these elements, which are often difficult to establish, a warranty action will fail. Strict liability is a more attractive theory for a patient because it eliminates the key requirement of a negligence cause of action – the need for the patient to show that the defendant failed to exercise proper care in the manufacturing or marketing of the product. It also avoids the need for any contractual obligations between the manufacturer and the injured party as requirement for recovery. Under the strict liability theory, a patient needs only to establish that the product in question was so defective as to be unreasonably dangerous and that, as a result, injury was suffered\textsuperscript{250}.

\textsuperscript{249} Bayless v. Stutler, 642 S.W. 2d 586, 588 (1982).
\textsuperscript{250} Adams v. Ison, 294 S.W. 2d 971, 973-974 (ky 1982).
In developing drug theories, the courts have expressly recognized and taken into account the fact that some products are “unavoidably unsafe” given current scientific knowledge. While there are very few decided cases, it would seem that this previously developed liability jurisprudence is directly applicable to artificial medical aid and given the embryonic nature of scientific understanding and experience in this field. To support the analogy of artificial organ liability concepts in terms of established drug liability theories, greater detail of a manufacturer’s duty deserves review. The manufacturer has the duty to warn of complications, side effects, and any potential hazards associated with its products. This duty requires a manufacturer to warn of known hazards as well as those hazards that it has a reasonable basis to suspect might occur. The courts have expressly recognized that prescription drugs are “unavoidably unsafe products” that can be dispensed only under a physician’s authorization. With extraordinary medical devices, there is no question that the manufacturer has the duty to furnish full and complete warnings to any physician considering implanting such a device. The question, which logically and necessarily follows, is whether the manufacturer’s duty to warn also extends to the patient-consumer. Although in the prescription drug context a manufacturer’s duty to warn generally extends only to the medical community, it is unclear at present whether, with respect to extraordinary medical devices, the manufacturer’s duty to warn should also extend to the patient-consumer251.

5.6 LIABILITY OF THE PHYSICIAN

A patient’s suit against a physician for an injury resulting from the physician’s treatment is predicated on professional negligence or malpractice. Malpractice may be defined as “bad or unskillful practice on the part of a physician or a surgeon resulting in injury to a patient. The “failure of a physician to exercise the required degree of care, skill, and diligence,” or “the treatment by a surgeon or a physician in a manner contrary to accepted rules and with injuries resulting to the patient,” are all base upon which malpractice claims may be founded.

To present a cause of action for malpractice successfully against a professional practitioner, the patient must establish four essential elements. First, a cause of action must show that the physician in question owed the patient-patient a particular duty or obligation. This legal duty derives from the physician patient relationship, which

251 Hofstedt v. International Harvester Co. 98 N.W. 2d 808 (Minn. 1959).
requires the physician to act in accordance with specific standards of care established by the profession for the protection of the patient against unreasonable risks. Second, the patient must establish that the physician failed to act in accordance with these standards. An act or omission violating the standard of care owed to the patient is required. Third, the patient-patient must establish that a causal and reasonably foreseeable connection exists between the acts or omissions of the physician and the resulting injury. Fourth, the patient must prove that the physician’s or omissions caused some actual loss or damage. The failure to establish any one of these four elements may defeat a malpractice claim.

Claims for breach of warranty provide an alternative approach for actions by patients against medical practitioners resulting from injuries suffered from medical instruments, drugs, or devices used in treatment. The determinative issue in this instance is whether a sale existed upon which a warranty action could be based. A sale of goods, independent of the medical services provided, is generally the touchstone for warranty recovery. Strict liability, has become a frequent theory upon which attempts to establish a physician’s liability are often premised by a patient injured through the use of any medical instrument or device. However, courts have been hesitant to apply strict liability against physician. Courts analyzing the physician-patient relationship have noted that the primary purpose of this relationship is the performance or rendition of professional medical service, distinguishing this from the sale of medical products. Accordingly, most courts in various country have rejected the application of the strict liability theory to the medical treatment provided by physicians. *Respondeat superior* is a common law doctrine that imputes responsibility for an employee’s acts, carried out during the course of his employment, to the employer as the one who derives advantage from the act and, therefore, must answer for any resultant injury. The two requirements for application of this doctrine are specific. The person charged with liability must be an employer, or someone in direct control of the party who allegedly caused the injury. Further, the person charged with causing the injury must have been acting with the “scope of his employment” at the time the injury resulted. These two requirements have restricted application of this doctrine in the health care context. A doctor is a professional and traditionally was not classified as a

254 *Patterson v. Blair*, 172 S.W.3d 361
hospital employee. Rather, the doctor was viewed as an independent contractor – retained at the expense and will of the patient, not the hospital. Although development in this area has been slow, some jurisdictions have changed the legal status accorded hospitals. Hospitals have an integral role in the patient’s overall treatment, and patients assume that if an error is committed, the hospital will take responsibility. This is based on the “apparent authority” of the hospital to supervise the treatment given, and has become another basis for attributing liability to hospitals. The law is accepted in a majority of jurisdictions. That hospital’s potential liability is to encompass most, if not all, of the hospital’s physicians, specialist, and staff. Another basis adopted by some jurisdictions for hospital liability for negligent treatment is termed corporate negligence. Under this doctrine, established by the USA Supreme Court in the leading case of *Darling v. Charleton Community Memoral Hospital* 256, a hospital has a duty to provide adequate medical care to its patients. This duty charged the hospital with responsibility for all treatment, which takes place within its boundaries, extending liability beyond activities traditionally considered under their direct control and governed by principles of respondents superior and, thus, include liability for acts or omissions of persons, such as physicians, who are not hospital employees. These broad principles of negligence liability on the part of the hospital would seem to be equally applicable in the specialized area of organ transplantation, although it must be recognized that proof of negligence in this evolving scientific area may often be difficult. 257

The manufacturer of medications has a legal duty to use care in research and development of drugs and other medical products. The manufacturer of drug, medical equipment and other surgical product should recommend to the medical professionals prescribing conditions, precautionary measures to be taken and the side effects produced. Injury of a patient due to a drug reaction can result from the negligence or breach of warranty on the part of manufacturer, which is a valid cause of action against a manufacturer. The manufacturer is also liable due to the harm caused by the contamination of a drug. Once the physician has been warned about potential side effects, the manufacturer has no duty to ensure that the warning reaches the patient.

---

255 *State v. Terry*, 325 S.W. 2d 1 (Mo. 1959).
256 *Darling v. Charleton Community Memoral Hospital* 33 Ill.2d 326, 211 N.E.2d 253
257 As a general rule only persons of scientific medical training are regarded as experts who may express opinions upon issues of sanity or insanity. Am. Jur. Evidence 851 (1988).
under normal circumstances. From the information’s received from the manufacturer and other medical sources, the doctor is required to inform the patient of those reasonably foreseeable dangers inherent in the particular circumstances. If the doctor has or should have information, knowledge, or suspicion from any source that a certain medication is likely to produce serious side effects, he may become legally liable for prescribing it, if any substituted drug would have been adequate and satisfactory\textsuperscript{258}. The foregoing overview of products liability theories in the rapidly developing field of high technology and computerized arena of medical care delivery in India discussed several aspects of legal doctrine that surrounds the future and may be standardize by passing health legislation concerned with medical equipment and product safety act in our country which exist in many western country.

5.7 IMPLEMENTATION OF THE REGULATORY MECHANISM BY THE CCI

In a recent judgment \textit{Bengal Chemist and Druggist Association},\textsuperscript{259} the CCI Imposes penalty of Rs. 18.38 crores on Bengal Chemist and Druggist Association (BCDA).\textsuperscript{260}

BCDA, an Association of wholesalers and retail sellers of drugs and affiliated to All India Organization of Chemist and Druggist was engaged in directly or indirectly determining the sale price of drugs and controlling the supply of drugs in a concerted manner and in issuing anti-competitive circulars directing the retailers not to give any discount to the consumers. The CCI after considering the entire material directed the Director General (DG) to cause an investigation into the matter and to submit a report.\textsuperscript{261}

The CCI holds that the attempt of BCDA to justify sale of drugs only on MRP on the basis that the margins have been fixed under the DPCO and accepted in the market is untenable as the issue is not the reasonability or the quantum of trade margins but the concerted action to fix uniform trade margin by an agreement amongst the


\textsuperscript{260} Press Information Bureau, Ministry of Corporate Affairs, Government of India notification available at bib.nic.in/newsite/PrintRelease.aspx?relid=104597.

\textsuperscript{261} This has been done vide a common order in Suo moto Case No. 02 of 2012 and Reference Case No. 01 of 2013 filed by Dr. Chintamoni Ghosh, Director, Directorate of Drugs, West Bengal.
members of the trade association. The CCI found the activities of the BCDA in conflict with the objects of the competition law as they cause restraint of trade, stifle competition and harm the consumers.

The CCI directed the BCDA and its office bearers & executive committee members to seize and desist from indulging in anticompetitive practices found to be anticompetitive in terms of the Act.\(^{262}\) The BCDA has been further directed to file an undertaking within 30 days that the CCI's directions have been complied with. The amount of penalty imposed was directed to be deposited within 60 of the receipt of the order.

In another judgment, \textit{M/s Arora Medical Hall, Ferozepur v. Chemists & Druggists Association, Ferozepur (CDAF)},\(^ {263}\) the CCI ordered another judgment imposing a penalty of Rs.55.42 lakhs on Ferozepur Chemists and Druggists Association.\(^ {264}\)

M/s Arora Medical Hall, Ferozepur informed the CCI that the CDAF made a mandatory rule in 2010 that any chemist/ druggist who wishes to take distributorship for medicines of a company in Ferozepur city to get a NOC and Letter of Credit (LOC) from CDAF by making a payment of Rs. 2100/- per company. The informant alleged that when it objected to the said rule, it was expelled from the primary membership of CDAF and passed a resolution to boycott the informant directing its members to stop purchasing goods from the informant and directed all the wholesalers to stop dealings with the retailers who continued to purchase goods from the informant and thereby, alleged to have violated the provisions of sections 3 and 4 of the Competition Act.

The CCI directed CDAF to cease and desist from indulging in such anti-competitive practices which have been found to be anti-competitive.\(^ {265}\)

The CCI has found the following practices of All India level, State level, District level associations of chemists, druggists, stockiest, wholesalers and manufacturers as anti-competitive:

\(^{262}\) Section 3 of the Competition Act 2002.
\(^{264}\) Press Information Bureau, Ministry of Corporate Affairs, Government of India notification available at pib.nic.in/newsite/PrintRelease.aspx?relid=103171
\(^{265}\) section 3(3)(b) read with Section 3(1) of the Act and imposed penalty accordingly.
1. Issuance of No Objection Certificate or letter of consent by such associations for opening chemist shop/being appointed stockiest/distributor/whole-seller.

2. Compulsory payment of PIS charges by pharmaceutical firms/manufacturers to associations for release of new drug/new formulation.

3. Fixation of trade margins at different levels of sale of drugs/medicines.

4. Issuance of instructions to chemists/druggists/shops/stockiest/whole-sellers/ manufacturers restricting discounts on sale of drugs in retail or wholesale.

5. Issuance of boycott calls by the associations to their members against any enterprise for not following the instructions of associations.  

It is also mentioned in the press release dated 3 February 2014 that penalties have been imposed by the CCI on such trade associations of chemists and druggists for violation of provisions of Competition Act. The CCI had issued cease & desist order against the associations directing them not to indulge in anticompetitive practices and the associations have filed undertakings that they would not indulge in such illegal practices.

It is noteworthy that the CCI's stringency towards the objective of eliminating and regulating against the malpractices from the pharmaceutical market to conclude with, such initiatives by CCI clearly indicate that it intends to bring into its stringent control on the mechanism of the pharmaceutical industry so as to regulate it against all the anti-competitive practices prevailing in the market thereby deterring those players of the market who indulged into such practices for their gain.

It further expected to bring a positive impact on the distribution of medicines in India as well as prices charged to the customers, thus with it, the hope that the Indian pharmaceutical market will move towards being more systematic and organized.

Thus, this has drawn the attention of the Competition Act to penalize and regulate such behaviour, and ensure that all players play by the rules of free and fair competition in the market.

"Patent rights provide the carrot for originators, allowing them exclusivity to produce the patented drug for a limited period. Competition law provides the stick, preventing

---

266 On 3 February 2014, Press Information Bureau, Government of India, Ministry of Corporate Affairs vide press release informed that
originators from abusing their exclusivity and protecting the entry of generics into the market at the expiry of patents.\textsuperscript{267}

With this background, India is gaining in importance as a manufacturer of pharmaceuticals. The pharmaceutical industry is expanding worldwide and it is to be noted that, worldwide and in India that the Pharmaceutical industry is \textit{prima-facie} not functioning in a competitive market framework due to the unique characteristics prevailing in the industry, behaviour of actors and markets characterized by asymmetries in information and structural uniqueness. But many practices in the pharmaceutical supply chain involve concerns of competition.

There exists no established world framework of rules with respect to Competition Law. Countries have considerable discretion in setting their own competition laws increasing globalization. In India we have Independent regulators i.e. Competition Commission with appeal to the Competition Appellate Tribunal\textsuperscript{268}.

With this significant move the present study need to sensitize members of the Competition Commission and the Tribunal to the techniques of modern competition analysis. Further, putting the Competition Advocacy provision to extensive practice is therefore a must. This is a pivotal period in the history of Indian innovation especially in the field of Indian pharmaceutical industry. India stands poised to become a leading hub of global innovation, and Indian pharmaceutical companies are at the center of this process. Providing the right incentives for incremental pharmaceutical innovation can move India forward on this path and encourage the development of drug products that meet the needs of Indian patients. Thus, the pharmaceutical industry is in need of more regulation since there is no sector regulator and thus, the Competition Act 2002 can fill in the essential gap. The relationship between IPR and Competition Act must be further studied with specific emphasis on the pharmaceutical sector.

It is an undeniable fact that access to healthcare is one of the most basic needs and an inviolable right of : every human being.. The right to health has been recognised in a number of international legal instruments. Globally, the drug sector has been


\textsuperscript{268} The Central Government recently put into effect the Competition (Amendment) Act, 2007 which proposes, inter alia, to set up a Competition Appellate Tribunal for hearing appeals from the Competition Commission of India; to rationalize the scheme of penalties; to provide mechanism for mutual consultation between the competition regulators and sectoral regulators etc.
Known for practices thwarting the spirit of competition and regulation. Hence, the role of the competition authority is very crucial in placing appropriate restraints. In India, too there are constitutional commitments, providing access to healthcare.

However, despite tall claims only 35 percent of the people in India have access to essential medicines. Several factors are responsible for such derivation – malpractices in the market as well as anti-competitive conduct in the pharmaceutical industry and the health delivery system.

Given the grim scenario, the overall objectives of the study were to: identify competition concerns in the pharmaceutical sector and health delivery care system; examine the scope of competition policy and law in dealing with such concerns; and suggest an implementation strategy do enhance access to medicines efficiency of health care sector\textsuperscript{269}.

Healthcare is one of the most basic needs and an inviolable right of every human being. The right to health has been recognised in a number of international legal instruments. The health care sector has been known for practises thwarting the spirit of competition and regulation. Hence the role of Competition Act is very crucial in placing appropriate restraints. Healthy and fair competition has proven to be an effective mechanism which enhances economic efficiency\textsuperscript{270}. This led to the need of a strong legislation to dispense justice in health care sector and the Competition Act, 2002 was passed.

The objectives of Competition Act, 2002 include the maximisation of consumer and producer welfare, as well as maximising efficiency in production. The well designed and effective competition laws promote the creation of an enabling business environment, which improves static and dynamic efficiencies and leads to efficient resource allocation and in which the abuse of market power is prevented mainly through competition\textsuperscript{271}. In the above context, the researcher has made an attempt to identify the anti-competition issues in the pharmaceutical industry and the health care sector. These range from being cross-border in nature to those that exist from the local level to international level.

\textsuperscript{269} CUTS International conducted a study in 2005-06 on “Options for Using Competition Act / Policy Tools in Dealing with Anti-competitive Practices in Pharmaceuticals and the Health Delivery System”.


\textsuperscript{271} supra note 3
At present, India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall.\textsuperscript{272} Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value\textsuperscript{273}, and its drug exports have been growing 30 percent annually\textsuperscript{274}. This is because pharmaceutical products are non-homogenous in nature, and there are a large number of “relevant markets” within the pharmaceutical industry.

It is in the absence of effective competition that efficiency of markets is hampered. Different government policies may encourage or adversely affect competition, and hence consumer welfare, particularly in the context of the present globalizing environment\textsuperscript{275}.

Manufacturers of medical equipment of supplies have a clear responsibility towards patients that the equipment is fit for use and medical supplies, drugs and treatments will be as effective as possible whilst giving the least side effects possible. If these responsibilities have been neglected, it can cause serious consequences to patients and families of those concerned.

\textsuperscript{272} IMS Health: IMS Intelligence. 360 Global Pharmaceutical Perspectives, 2004.
\textsuperscript{273} Organization of Pharmaceutical Producers of India, 2004
\textsuperscript{274} Indian Government National Pharmaceuticals Policy, January 2006).
\textsuperscript{275} Towards a Functional Competition Policy for India: An Overview” Pradeep Mehta, (CUTS International)