CHAPTER-III

CONSUMER LAW RELATING TO HEALTH LAWS AND EDUCATION IN INDIA
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3.1. Introduction

Consumer law relating to health Laws and Education focuses on the
nexus between law, public health and the legal tools applicable to public health
issues. Though there have been consistent interventions to address public health
concerns in the past, there exists a need for a contemporary framework to
appropriately use modern legal tools for complex health challenges. The laws
are designed to prevent businesses that engage in fraud or specified unfair
practices from gaining an advantage over competitors and may provide
additional protection for the weak and those unable to take care of themselves.
Consumer protection laws are a form of government regulation which aims to
protect the rights of consumers. For example, a government may require
businesses to disclose detailed information about products particularly in areas
where safety or public health is an issue, such as food. Consumer protection is
linked to the idea of "consumer rights", and to the formation of consumer
organizations, which help consumers make better choices in the marketplace
and get help with consumer complaints.

The moral or legal duty of States to protect the health of citizens is the
foundation of public health law. This duty is recognized in the Preamble to the
Constitution of the World Health Organisation.1 In most countries, the right to
life, and the right to health, are also recognized in national constitutions. To
fulfill their duty, governments need laws that set out their powers to discharge
essential public health functions. These include laws relating to surveillance,
screening, notification, laws relating to sanitation, safe water, safe and
nutritious food, the safety of consumer products, injury prevention, tobacco
reduction, and so on. The core public health functions include:
1. Surveillance/monitoring of health status and risks to health;
2. Public health protection and assurance;
3. Health promotion including education;
4. Financing of public health interventions and health care services;
5. Training and capacity building; and
6. Research and evaluation.

Constitutional provisions, such as the right to health, as well as national public health legislation can empower governments to take action in all of these areas. In this way, law also helps governments to discharge their duty to promote and protect the health of their populations. In practice, public health laws tend to focus on surveillance and monitoring of health risks, and on health protection and assurance.

3.2. Consumer Health Education

Recent events concerning food contamination in China,\textsuperscript{134} the United States,\textsuperscript{135} Canada,\textsuperscript{136} Italy,\textsuperscript{137} and Ireland\textsuperscript{138} have contributed to bringing food safety issues back in the spotlight of public opinion. Some of these events, which have found a wide echo in international media, have triggered a

\textsuperscript{134} In July 2008, due to an increase in the incidence of kidney ailments among Chinese babies, some dairy products were analyzed and found contaminated by melamine. See http://www.who.int/foodsafety/fs_management/infosan_events/en/index.html.

\textsuperscript{135} According to the US Food and Drug Administration (FDA) and the Centre for Disease Control and Prevention (CDC), the sources of the massive outbreak of illnesses of \textit{Salmonella Typhimurium} in the United States in September 2008 were peanut butter and peanut paste produced by Peanut Corporation of America's processing plant in Georgia. See http://www.fda.gov/oc/opacom/hottopics/Salmonellatyph.html.

\textsuperscript{136} In August 2008, the Canadian Food Inspection Agency reported a widespread outbreak of \textit{Lysteria Monocytogenes} in deli meat linked to a Maple Leaf Foods plant in Toronto. caused 20 deaths. http://www.inspection.gc.ca/english/corpaftr/recarapp/recal2e.shtml.

\textsuperscript{137} In March 2008, following the detection of dioxin-positive milk and buffalo mozzarella samples in some areas of the Campania Region, the Italian Ministry of Health identified the 83 agricultural companies which supplied the 25 cheese factories where the contamination was detected and promptly took measures to seize and isolate them. http://www.fas.usda.gov/gainfiles/200804/146294161 .pdf.

\textsuperscript{138} In August 2008, a food poisoning outbreak of \textit{Salmonella Agona} affected the UK and Ireland, and a number of chicken, beef and bacon products from Dawn Farm Foods were withdrawn from sale as a precautionary measure.
worldwide alert that evoked the concerns raised by the high profile "food scares" of the near past (mainly bovine spongiform encephalopathy and avian influenza). As a result, global governance of public health challenges posed by foodborne hazards has been put high again on the international agenda of governmental agencies and international organizations.

Awareness of the significance of food safety has been greatly enhanced in the last two decades, and its impact on health, marketing, and foreign trade are now recognized at different levels. Food safety issues have thus been at the core of extensive scientific and legal literature, with a focus on the most critical aspects of the subject and its intersection with other key legal issues (e.g. consumer protection, biotechnology and safety of genetically modified organisms, application of the precautionary principle, traceability of products, quality standards setting, responses to bioterrorist threats, freedom of trade and legitimacy of restrictions, international cooperation and governance of public health risks). Scientists and legal scholars have paid special attention to the management of foodborne diseases, which are indeed a source of major concern for the whole international community. These diseases encompass a broad spectrum of illnesses causing morbidity and mortality worldwide and their real overall health impact on the world population is yet unknown. Moreover, globalization of trade has led to the rapid and widespread international marketing of food products, demanding that the most careful controls be carried out along the entire food-chain from "farm to fork". Whenever such controls

139 For full coverage of food safety issues see the relevant web pages at http://www.who.int/topics/food_safety/en/.
140 The "farm to fork" approach implies that food hygiene legislation issued both at the national and at the international level apply at every stage of the food chain, including primary production (e.g., farming, fishing and aquaculture), and that official and effective controls under the responsibility of national authorities be carried out from the input level to the front end retail. (see especially the FAO conference document on FAO Veterinary Public Health and Food and Feed Safety Programme: the Safety of Animal Products from Farm to Fork, available at http://www.fao.org/docrep/MEETING/004/AB500E.HTM), http://www.foodsafetyforum.org/global2/index_en.asp). http://ec.europa.eu/food/index_en.htm; http://ec.europa.eu/food/resources/publications_en.htm.
fail and food production and distribution fall short of complying with regulations and standards set either at national or international level the potential likelihood of trans-boundary incidents involving tainted food increases, and global health is hence seriously put at risk. For the reasons stated above, international food safety is perceived as a global challenge. In the wake of a trend towards more efficient food safety policies, the 2007 Beijing Declaration on Food Safety gives voice to the global community’s concern that a comprehensive and integrated approach be adopted, prompting all stakeholders to take cooperative and concerted actions and strengthening links between the different sectors involved.

The Declaration, in fact, recognizes that “integrated food safety systems are best suited to address potential risks across the entire food-chain from production to consumption” and that “oversight of food safety is an essential public health function that protects consumers from health risks”. In this perspective, it mainly urges States to develop transparent regulation to guarantee safety standards; to ensure adequate and effective enforcement of food safety legislation using risk-based methods; to establish procedures, including tracing and recall systems in conjunction with industry; to rapidly identify, investigate and control food safety incidents and to alert the World Health Organization (WHO) of those events falling under the revised International Health Regulations. In short, the Declaration expresses the need to understand food safety as both a national and an international responsibility. Moving from the consideration that food safety issues and the enhancement of health security are of growing international concern, it is interesting to inquire whether the international community is provided with the appropriate legal instruments to face foodborne hazards globally. To this end, this paper will first adopt a human rights-based approach to food safety to make the case for a human right to safe food and to suggest that such a right has progressively emerged as a “derivative” right and could further evolve into a self-standing right; second, it will explore the present state of international law with regard to
food safety regulation and harmonisation in light of the overarching need to prioritize consumer protection over "free trade at all costs"; and third, it will focus on the available means of global management of food safety risks for global public health protection.

Albeit crucial for understanding the multiple facets of food safety governance, all political, economic, social and ethical considerations fall beyond the scope of the present investigation, which is meant to remain faithful to the legal perspective. Therefore, by focusing only on international law norms and obligations, this paper aims to offer a contribution to the current debate on food safety, with the awareness that it represents only a starting point for further analysis and more in-depth reflections on the innovations and developments needed in food safety regulation to achieve the compelling objective of protecting world health.

**A Rights-Based Approach to Food Safety: The “Right to Safe Food” In International Human Rights Law:**

Although emphasis is increasingly being placed on the concept of food safety, legal literature has seldom expanded on the status of a “human right to safe food” in international law. The right to safe food in human rights law is encompassed by both the right to health and the right to food. It is so closely interrelated with these fundamental human rights – being at the same time one of their integral components and an element upon which their realization is

141 On the evolving concept of food safety, see especially Francis Snyder, “Toward an International Law for Adequate Food,” in *La sécurité alimentaire*, 79-163, at 117-121. Professor Snyder asserts that "the idea of risk, the technique of risk analysis and the precautionary principle form the core of the contemporary concept of food safety and how to put it in practice through law" (119).


dependent – that it fits perfectly with the generally accepted idea that all human
rights are universal, indivisible, interrelated, interdependent and mutually
reinforcing. The International Bill of Human Rights provides the basic legal
framework for construing a human right to safe food, and the general comments
elaborated by the United Nations Committee on Economic, Social and Cultural
Rights ("the Committee") offer authoritative guidance for interpretation.
Article 25, paragraph 1, of the Universal Declaration of Human Rights affirms
that "everyone has the right to a standard of living adequate for the health of
himself and of his family, including food, clothing, housing and medical care
and necessary social services", while article 12, paragraph 1, of the
International Covenant on Economic, Social and Cultural Rights enunciates the
right to health as "the right of everyone to the enjoyment of the highest
attainable standard of physical and mental health".

In its General Comment No. 14 on the domestic implementation of
article 12, the Committee "interprets the right to health, as defined in article
12.1, as an inclusive right extending not only to timely and appropriate health
care but also to the underlying determinants of health, such as access to safe
and potable water and ... an adequate supply of safe food." As far as legal
obligations are concerned, the Committee makes it clear that States Parties are
under the obligation to adopt domestic laws aimed to ensure "the underlying
determinants of health, such as nutritiously safe food and potable drinking
water" and to provide for implementation of such legislation. The Committee
further draws attention to the obligation to safeguard all individuals under the
States Parties' jurisdiction from health hazards deriving from the activities of

144 Building on the idea which underpins the formulation of the Universal Declaration of Human
Rights, and after its enunciation in the Vienna Declaration and Programme of Action (World
Conference on Human Rights, Vienna, 25 June 1993, para. 5) adopting the Declaration on the
sixtieth anniversary of the Universal Declaration of Human Rights.
145 Universal Declaration of Human Rights, adopted and proclaimed by General Assembly
Resolution 217 A (III) of December 10, 1948.
146 Committee on Economic, Social and Cultural Rights, General Comment No. 14, The right to the
highest attainable standard of health, UN Doc. E/C.12/2000/4, August 11, 2000, para. 11.
third parties (especially private actors such as individuals, groups or corporations), including the expressly mentioned duty to protect consumers from dangerous practices by food manufacturers. Moreover, the Committee reiterates the view expressed in General Comment No. 12\textsuperscript{147} that guaranteeing "access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone"\textsuperscript{148} is one of the core obligations incumbent upon States Parties to grant satisfaction of minimum essential levels of the right to health.

The Committee's approach is particularly meaningful in this latter respect, since inclusion of the entitlement to safe food in the minimum core content of the right to health demands that States Parties commit themselves to comply with non-derogable obligations of immediate effect (i.e. those which are not dependent upon resource availability, such as respect of the principle of non-discrimination and of the duty to adopt expeditious and effective measures for the progressive realization of the right), and to refrain from invoking unavailability of adequate resources to justify inaction and lack of progress. In this context, obligations of immediate effect would encompass the duty to guarantee that all individuals under the jurisdiction of the State have equal access to safe and nutritious food; the duty to enact food safety and consumer protection legislation, including accountability measures; the duty to take all necessary steps to implement international regulations and standards. Notwithstanding the Committee's approach implicitly acknowledges the crucial role played by food quality and safety in protecting health, and ultimately life, most of human rights relevant documents, backed up by legal scholarship, deal with the right to safe food in the context of the food security discourse. Therefore, although it would be a misconception to equate the right to adequate

\textsuperscript{147} Committee on Economic, Social and Cultural Rights, General Comment No. 12, The right to adequate food, UN Doc. E/C.12/1999/5, May 12, 1999, para. 14.

\textsuperscript{148} Ibid., General Comment No. 14, para. 43 (b); see also General Comment No. 3, The nature of States parties obligations, UN Doc. E/1991/23, December 14, 1990, para. 10.
food with the right to safe food, food safety and food security are considered the two sides of the same coin.\footnote{It would be interesting to further reflect on the question posed by one of the speakers at the latest Dubai Food Safety Conference: “When food is in shortage, can policy makers accept lower food safety standards to protect food security?” available at http://www.dubaifoodsafety.com).}

**Relevance of food safety**

In normative terms, the human right to adequate food is rooted in the above-mentioned article 25, paragraph 1 of the Universal Declaration and further elaborated in article 11, paragraph 2, of the Covenant, which recognizes the fundamental right of every person to be free from hunger, and the duty of States to take, individually and through international cooperation, the measures needed to implement this right by improving the methods of production, conservation and distribution of food. In its general comment on the right to adequate food, the Committee underlines that “the right is indivisibly linked to the inherent dignity of the human person and is indispensable for the fulfilment of other human rights enshrined in the International Bill of Human Rights”. While recognizing that the right to adequate food is crucial for the enjoyment of all rights, the Committee considers that the core content of this right implies “the availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances”. The latter formula is explained as setting “requirements for food safety and for a range of protective measures by both public and private means to prevent contamination of foodstuffs through adulteration and/or through bad environmental hygiene or inappropriate handling at different stages throughout the food chain; care must also be taken to identify and avoid or destroy naturally occurring toxins”.

Moreover, the relevance of food safety to the realization of the right to food both at national and international level is further emphasized by the Committee when it stresses that domestic policies of implementation of article 11 “should address critical issues and measures in regard to all aspects of the
food system, including the production, processing, distribution, marketing and consumption of safe food”, and that States and international organizations have a joint and individual responsibility to ensure that “products included in international food trade or aid programmes be safe”. Within the United Nations, the General Assembly has long adopted the same approach as the Committee: in resolution 63/187 of 18 December 2008 on the right to food, just as it has been doing since 2001, the Assembly “reaffirms the right of everyone to have access to safe, sufficient and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger”. The Human Rights Council has repeated the same formula in its resolution on the right to food of 27 March 2008, the first adopted by the Council so far.

Food safety Comparative Analysis

In different contexts, several international declarations and other soft law instruments have reaffirmed the individual right to *adequate and safe food*. The World Declaration on Nutrition, adopted by the FAO International Conference on Nutrition in December 1992, asserts that “access to nutritionally adequate and safe food is a right of each individual” the 1996 Rome Declaration on World Food Security includes the States’ commitment to “implement policies aimed at eradicating poverty and inequality and improving physical and economic access by all, at all times, to sufficient, nutritionally adequate and safe food and its effective utilization” and the related Plan of Action provides that States “apply measures, in conformity with the Agreement on the Application of Sanitary and Phytosanitary Measures and other relevant international agreements, that ensure the quality and safety of food supply, particularly by strengthening normative and control activities in the areas of

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human, animal and plant health and safety";\textsuperscript{152} the \textbf{Draft Principles on Human Rights and the Environment of} 16 May 1994 state that "all persons have the right to safe and healthy food and water adequate to their well-being" the Declaration adopted at the FAO World Food Summit Five Years Later in June 2002 confirms "the right of everyone to have access to safe and nutritious food" (preamble); and the 2007 Beijing Declaration on Food Safety reiterates the statement of the 1992 Declaration on Nutrition. Moreover, the view that "food safety and food security are inseparable" has been at the basis of the PAHO/WHO Plan of Action for Technical Cooperation in Food Safety, that acknowledges that food safety and security "jointly contribute to progress toward the attainment of the Millennium Development Goals, particularly the reduction of hunger and poverty."\textsuperscript{153} Likewise, the FAO report on Ethical Issues in Food and Agriculture states that "achieving food security requires: i) an abundance of food; ii) access to that food by everyone; iii) nutritional adequacy; and iv) food safety".\textsuperscript{154}

From this legal framework it can be inferred that in the human rights perspective it is generally recognized that every individual is entitled to food that is safe and of good quality, since safe food is functional to achieving freedom from hunger and enjoyment of the best attainable state of health; hence it is crucial for protecting life and human dignity. Clarifying whether this entitlement shapes an autonomous right, separate and distinguishable from the rights to adequate food and to health, and whether it can be considered a fundamental human right, will probably be the subject of further insights by future legal scholarship. It is worth considering, however, that food safety has been already defined "an inalienable right of each individual" by FAO Director-


\textsuperscript{153} FAO/WHO Regional Conference on Food Safety for the Americas and the Caribbean (San José, December 6-9, 2005).

\textsuperscript{154} Available at: http://www.fao.org/docrep/003/X9601E/x9601e00.HTM.
General, Jacques Diouf,\textsuperscript{155} and that the World Health Organization has clearly acknowledged that "the availability of safe food improves the health of people and is a basic human right".\textsuperscript{156} At the moment drawing on the wealth of human rights instruments that approach food safety halfway between enshrining an express legal entitlement to safe food and considering it as an implicit attribute of the rights to adequate food and to health the argument could be made that a "human right to safe food" has progressively taken shape as a "derivative" right and might be on its way to becoming a self-standing right. In this perspective, the evolution of the right to safe food might be compared to the one undergone by the right to safe drinking water, another underlying determinant of the right to health which has achieved over time the status of an autonomous fundamental right.

Making the case for a human right to safe food through a rights-based approach to food safety may offer some advantages in terms of effectiveness and accountability. Of course, recognizing such a right calls for a better definition of the specific legal obligations it imposes, as well as for availability and accessibility of adequate remedies. To meet these needs the Committee could play a fundamental role, either interpreting the right by way of adoption of a general comment or by way of exercise of its new functions under the Optional Protocol to the Covenant.\textsuperscript{157} In fact, once it enters into force, the Protocol will empower the Committee to receive and examine communications by individuals claiming to be the victims of violations by a State Party of any of the rights set forth in the Covenant. It will thus fill a gap in the present state of international law in matter of justiciability of economic, social and cultural


rights, whose effective implementation and full realization have been hampered by lack or scarcity of judicial remedies at the universal level (for inexistence so far of a specifically competent forum), at the regional level (considering, for example, the incompetence ratiocinae materiae of both the European Court of Human Rights and the Inter-American Commission of Human Rights on core rights, like the right to health), and at the national level as well.158 Looked at from this angle, the Optional Protocol and the future interpretive activity of the Committee reveal all their importance for a better comprehension of the human right to safe food. It is thus to be expected that the Committee’s future case law will shed light on the nature and scope of this right and contribute to its interpretation and implementation in accordance with the Covenant.

Prioritizing consumer Protection over Freedom of Trade in the Global Market: The relevance of Food Safety Regulations, International Standards and Precaution:

Global food trade has dramatically increased the risk that contaminated food may pose serious health hazards and spread foodborne diseases worldwide. Consequently, achieving food safety in the global market calls for prioritization of public health interests over freedom of trade. While the realization of the right to safe food beyond the framework of human rights law requires that consumer protection be given precedence over “free trade at all costs”, “the challenge is to work out how the difficult interface between [trade and health] can be managed.”159 The protection of consumers has received ample coverage first and foremost in domestic law. When major environmental and food-related disasters have shifted the attention from the local to the transnational dimension of food safety, consumer protection has also been dealt


with in the regional and international context. Within national legal orders consumer protection is an important part of private law, which is founded on the four basic consumer rights: the right to safety, the right to be informed, the right to choose and the right to be heard. Many States have created national public authorities entrusted with the task of protecting and promoting health, with specific focus on food safety and consumer protection: the U.S. Food and Drug Administration is the most prominent example, although similar agencies have been created all over the world. The national dimension of consumer law and food safety regulation is relevant to the international law viewpoint depending on whether it complies or not with (the rather few) international obligations and (the many) international standards. In the European Union, consumer law has progressively gained recognition and importance after the introduction of article 129a by the 1992 Maastricht Treaty (now article 153 of the EC Treaty). Of course, the reception of European consumer law and the many decisions of the Court of Justice have had substantial consequences on domestic legislation.

In the specific domain of consumers' protection from food-related risks, EC Regulation No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety is of the greatest importance, since it represents the main source of European food safety legislation binding on all Member States. The crucial general principles enunciated in the Regulation concern: a) the general objectives to be pursued by food law, that is a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade; b) resort to risk analysis in food law, with risk assessment being based on the available

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160 See the famous declaration by U.S. President John F. Kennedy in his 1962 message to the Congress.
scientific evidence and undertaken in an independent, objective and transparent manner; c) application of the precautionary principle where the possibility of harmful effects on health have been identified but scientific uncertainty persists; d) protection of the interests of consumers and prevention of fraudulent or deceptive practices, the adulteration of food, and any other misleading practices; e) transparency through public consultation and information.\textsuperscript{163} The Regulation also sets forth the obligations of EU Member States with regard to food trade, general safety requirements of food law and traceability, stating the basic rule that "food shall not be placed on the market if it is unsafe".\textsuperscript{164} It further regulates liability issues, making reference to the responsibility of both States and business operators.\textsuperscript{165} In this latter respect, it is important to take due consideration of the direct effect of the Regulation, which enables European citizens to enforce consumer rights both against Member States before Community Courts (vertical direct effect), and against other individuals and companies in actions before national judges (horizontal direct effect).\textsuperscript{166}

Some provisions of the Regulation also point to another crucial aspect of food safety regulation: the need to strike a fair balance between consumer protection and freedom of trade within the Union and with third countries. In this respect, the Regulation first notes the paramount importance of safety and confidence of consumers, the Community being a major global trader in food and, in this context, a major supporter of the principles of free trade in safe food and of fair and ethical trading practices. It also notes that some Member States have adopted horizontal legislation on food safety imposing a general obligation on economic operators to market only food that is safe; nonetheless,

\textsuperscript{163} Articles 5 to 10
\textsuperscript{164} Article 14, para. 1
\textsuperscript{165} Articles 17 to 21
\textsuperscript{166} Direct effect is a basic principle of Community case law. The concept of direct effect and its further distinction into vertical and horizontal direct effect was mainly elaborated by the Court of Justice in the following landmark cases: NV Algemene Transporten Expeditie Onderneming van Gend en Loos v. Nederlandse Administratie der Belastingen, Case 26/62, Judgment of February 5, 1963, Reports 1963, 1; Defrenne v. Sabena, Case 43/75, Judgment of April 8, 1976, Reports 1976, 455.
it stresses that due to the adoption of different national criteria, and to the lack of legislation in other Member States, barriers to trade in foods are liable to arise, so that it is necessary to establish general requirements to ensure that the internal market functions effectively. The Regulation finally considers that in trade relations with third countries it is necessary to ensure that food exported or re-exported from the Community complies with Community law and that, even where there is agreement of the importing country, food injurious to health is not exported or re-exported. On the basis of these considerations the Regulation states that “food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements” set in the Regulation itself; it adds that risk management measures adopted in application of the precautionary principle should “be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community” and should “be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment”.167

Food safety regulation and health

Food safety regulation and health and trade-related issues in Community law should also be read through the lens of the combined provision of the relevant EC Treaty rules, namely: article 30 allowing “prohibitions or restrictions on imports, exports or goods in transit justified on grounds of ... the protection of health and life of humans”, provided that such prohibitions or restrictions do not “constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”; article 95, paragraph 3, stating that in matters of approximation of laws the Commission’s proposals, aimed to the adoption of a harmonisation measure “concerning health, safety,

167 See article 5, para. 2 and article 7, para. 2, respectively.
environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts”; article 152 on public health, requiring at paragraph 1 that “a high level of human health protection be ensured in the definition and implementation of all Community policies and activities” and that “Community action ... be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health”; article 174 stating that Community policy on the environment must enhance the protection of human health.

The case law of the European Court of Justice has greatly contributed to the interpretation of these provisions while enunciating some important principles of law. The Court has in fact stated that the application of the precautionary principle extends from environmental issues to the common agricultural policy whenever the European institutions deem it necessary to adopt measures for public health protection, this latter objective being an integral part of any Community policy. The Court has thus concluded that the Community can legitimately adopt a restrictive measure any time it foresees a risk for public health and even before the seriousness and gravity of the risk are proved, provided that such a risk is not merely hypothetical but is supported by adequate scientific evidence. The Court has however affirmed that in case of uncertainty as to the existence and extent of the health risk it is necessary that a scientific evaluation be made, in order to guarantee the objectivity and

168 On the application of articles 30 and 95, see especially ECJ, The Queen, on the application of Alliance for Natural Health and Nutri-Link Ltd v. Secretary of State for Health and The Queen, on the application of National Association of Health Stores and Health Food Manufacturers Ltd v. Secretary of State for Health and National Assembly for Wales, Joined cases C-154/04 and C-155/04, Judgment of July 12, 2005, Reports 2005, I-06451; Commission of the European Communities v. Kingdom of Spain, Case C-88/07, Judgment of March 5, 2009, Reports 2009.

169 See also, in the same direction, article 35 of the Charter of Fundamental Rights of the European Union.

correctness of the decisional process within the Community. This approach, which focuses on the procedural aspects of regulation-making, is considered an alternative for implementing the precautionary principle at EU level, and is supposed to guarantee a less intrusive review of national decisions. Moreover, measures of trade restriction adopted under article 30 EC Treaty within the internal market are subject to the scrutiny of the Court, that pronounces on their legitimacy under Community law and according to its settled case law. In this perspective, the trend is distinctively oriented towards recognition of the primacy of the general interest of public health protection over any right of economic operators and other stakeholders.

At the universal level, a major step was taken by the United Nations in the field of consumer protection and food safety regulation when the General Assembly unanimously adopted in 1985 a set of general guidelines that represent an internationally recognized set of minimum objectives, potentially being of particular assistance to developing countries. First and foremost, the Guidelines for Consumer Protection intend to meet the need for the protection of consumers from hazards to their health and safety; this objective is pursued through information and education programmes on foodborne diseases and food adulteration, as well as through promotion of national policies prioritizing areas of essential concern for the health of the consumer (food, water and pharmaceuticals) and maintaining, developing or improving food safety measures (product quality control, adequate and secure distribution facilities, standardized international labelling and information, etc.). Although they are

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not binding on States, the importance of the Guidelines cannot be sidelined, since their adoption reinforces the increasing recognition in recent years that consumer policy issues can no longer be seen as being of purely local concern, but must be considered and faced in an international context.

Further developments in this direction were registered a few years ago, when the FAO Committee on World Food Security elaborated the *Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security*.174 Some of these guidelines are indicative of the trend towards progressive integration, both at the national and international level, among the multiple dimensions of food safety regulation and management. Guideline 4, for example, provides that States should guarantee adequate protection to consumers against fraudulent market practices, misinformation and unsafe food. It adds that national measures of consumers' protection should not constitute unjustified barriers to international trade and should be in conformity with the WTO agreements. Guideline 9, specifically devoted to food safety and consumer protection, urges or encourages States to: 1) take measures to ensure that all food, whether locally produced or imported, freely available or sold on markets, is safe and consistent with national food safety standards; 2) establish comprehensive and rational food-control systems that reduce risk of foodborne disease using risk analysis and supervisory mechanisms to ensure food safety in the entire food chain including animal feed; 3) adopt scientifically based food safety standards, including standards for additives, contaminants, residues of veterinary drugs and pesticides, and microbiological hazards, and to establish standards for the packaging, labelling and advertising of food, taking into consideration internationally accepted food standards (Codex Alimentarius) in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures; 4) adopt measures to

protect consumers from deception and misrepresentation in the packaging, labelling, advertising and sale of food and facilitate consumers’ choice by ensuring appropriate information on marketed food, and provide recourse for any harm caused by unsafe or adulterated food, including food offered by street sellers, in conformity with the WTO agreements; 5) cooperate with all stakeholders, including regional and international consumer organizations, in addressing food safety issues, and consider their participation in national and international fora where policies with impact on food production, processing, distribution, storage and marketing are discussed. As in these Guidelines, reference to the Codex Alimentarius and WTO agreements when discussing of consumer protection and relevant trade implications at the universal level is a must. As a matter of fact, international cooperation in the field of food safety regulation is steadily institutionalized in the Codex Alimentarius Commission (CAC) and its specialised subsidiary bodies since the 1960s, with the World Trade Organization later offering both the normative framework and the judicial forum to settle trade disputes.

The Codex Alimentarius is an ensemble of standards and guidelines regarding food safety and quality, including food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. Although standards and guidelines developed by internationally recognized bodies – such as the CAC or the World Organization for Animal Health (OIE) – are not binding per se, they are generally recognized and have thus become the accepted norms in international trade, which means that where there is no national legislation, these standards can be used directly, in order to ensure the safety of international food and food related aid. In fact, Codex standards are referred to as fundamental reference points in the area of food safety. Albeit voluntary, their application is strongly incentivized because food production that meets these standards is generally viewed as facilitating trade and improving export rates.
GATT and WTO Agreements and Health

The advantages of having universally agreed food standards for the protection of consumers, with a view to facilitating trade, are acknowledged by two important WTO Agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). These Agreements recognize that international standards and technical regulations bring benefits to both producers and consumers; their objective is to facilitate secure and predictable access to markets ensuring that health regulations do not create unnecessary obstacles to trade. In particular, the SPS Agreement provides a multilateral framework of rules applying to all measures which may affect negatively the freedom of international trade, in particular to any trade-related measure taken to protect human life or health from risks arising from additives, contaminants, toxins, veterinary drug and pesticide residues, or other disease-causing organisms in foods or beverages.

Building on the provision of Article XX(b) of the General Agreement on Tariffs and Trade and the terms of its chapeau – which predated the first reference to the precautionary principle by almost 40 years – the SPS Agreement incorporates elements of precaution, setting out the right of Governments to restrict trade to pursue health objectives, provided that the measures adopted be based on scientific evidence or on an appropriate risk assessment and according to the principles of non-discrimination and proportionality. Scientific justification (as provided in Article 2.2 and as backed up by the risk assessment discipline under Article 5) is, in point of fact,

177 General Agreement on Tariffs and Trade (GATT), Geneva, October 30, 1947 (incorporated into GATT 1994), Article XX.
178 Shaw and Schwartz, Trading Precaution, at 6: “As stated in the Preamble, the SPS Agreement is an elaboration of Article XX (b).
the pivot of the Agreement’s management of the health-trade interface.\textsuperscript{179} Hence, while in Article XX of GATT restrictive measures are an exception, in the SPS Agreement “there is a right [under article 5.7], albeit a conditional right, to take provisional measures subject to the requirements for risk assessment laid out in Article 5.1, 5.5 and 5.6”.\textsuperscript{180} Therefore, the Agreement tries to balance two conflicting interests: the sovereign right of Members to determine the level of health protection they deem appropriate, on the one hand, and the need to ensure that a sanitary or phytosanitary requirement does not represent an unnecessary, arbitrary, discriminatory, scientifically unjustifiable or disguised restriction on international trade, on the other. In order to achieve this goal, the SPS Agreement encourages Members to use existing international standards, guidelines and recommendations; it acknowledges the authority of Codex standards by making express reference to them as a privileged basis for internationally harmonised regulation.

The relevance of Codex standards is further confirmed by the case law of the WTO Appellate Body, which considers them as the international benchmarks against which national food measures and regulations are evaluated within the legal parameters of the WTO Agreements. Most important of all, in the disputes concerning the \textit{EC–Sardines}\textsuperscript{181} and the \textit{EC–Hormones}\textsuperscript{182} cases, the Appellate Body Reports pointed to the recognition of Codex standards as “relevant international standards” to be used by States as a basis for their technical regulations, and hinted to the possibility that such standards might be adopted without consensus.\textsuperscript{183} In admitting such possibility the Appellate Body

\textsuperscript{179} Button, \textit{The Power to Protect}, 228.
\textsuperscript{180} Shaw and Schwartz, \textit{Trading Precaution}, at 6.
\textsuperscript{183} See \textit{EC–Hormones}, para. 166; \textit{EC–Sardines}, para. 227: “we uphold the Panel’s conclusion, in paragraph 7.90 of the Panel Report, that the definition of a ‘standard’ in Annex 1.2 to
is said to have sensibly contributed to a greater politicisation of Codex decision processes and standard setting procedures, since adoption of standards without consensus approval implies the possibility that Member States be required to conform to standards they have not supported with their vote. Moreover, the Codex Alimentarius is backed up by the trade sanctions of the WTO, since any non Codex-compliant nation would automatically lose in any food-trade dispute with a Codex compliant country, unless it were in a position to justify a possible ban on food products on the basis of a risk assessment rigorously supported by adequate scientific evidence.

This approach was laid out in both the EC-Asbestos\(^{184}\) and EC-Hormones cases, where the Appellate Body established some basic principles in matter of trade restrictions on products that are likely to pose a health hazard: first and foremost it recognized that public health interests must always take precedence, unless unilateral precautionary measures, not supported by the protection afforded by international standards or risk assessment, disguise protectionist interests; second, it established that the right to fix a higher level of national protection be justified through available, pertinent scientific information, which implies that there exists a rational relationship between the measure and the risk assessment; third, it stressed that States putting in place a measure based on the precautionary principle must continue their scientific research and perform serious reviews of the precautionary measure to show evidence of their good faith. Through this approach, the Appellate Body showed that “the WTO cannot and does not stand for free trade at any cost”; it rather emphasised the importance of international standards for “upholding a rules-based multilateral trading system that ensures secure and predictable

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market access, while respecting health and safety concerns."\textsuperscript{185} Be that as it may, it is necessary to highlight the fact that many global food safety issues still lie beyond the reach of international trade agreements.\textsuperscript{186} Actually, it has been observed that, depending on their focus and characteristics, health regulations may fall under the SPS Agreement, the TBT Agreement or the GATT alone, and that this fragmentary approach is really disadvantageous, especially in view of the need to manage the challenges posed by "the latest frontier[s] of the contested trade-health relationship." This is one of the main reasons why the most important international organizations involved (mainly WHO, WTO and FAO) are steadily improving coordination of their activities and complementing each other's work in the field of health and trade issues. Together with national governments they are also furthering efforts to protect consumers across the globe from threats to food safety due to the most diverse causes.

This international health-trade cooperation is best explained by the WHO and WTO Secretariat: "the usefulness of this link lies in the clarity it bestows on the distinct roles of the two organizations: on the one hand the evidence based nature of WHO's scientific work and, on the other, the more legal trade-related obligations under the WTO. Moreover, the link between the standard-setting work of the Codex and the scientific input from the WHO is important in that it lends some dynamics to the trade rules. While countries negotiate trade rules in the WTO, the WTO is not a scientific body and it does not develop standards. The WHO's active presence at SPS meetings has allowed WHO staff to provide advice on health matters relevant to trade. Examples are WHO's input on the risks of mad cow disease (BSE) to human health, and on the health effects of genetically-modified organisms in food.

\textsuperscript{185} Shaw and Schwartz, Trading Precaution, 11.
\textsuperscript{186} Button, The Power to Protect, 228-229, with special reference to the contested trade of genetically modified organisms. On questions concerning trade of GMOs, see also 107, 230-232;
WHO representatives have also provided expert testimony to WTO dispute settlement panels, for example in the EC-Hormones case.\[187\]

*Managing Global Food Safety Risks in the WHO Network: The International Health Regulations (2005) and Beyond:*

According to the WHO, foodborne diseases are a global public health challenge. Public health emergencies like HIV/AIDS, SARS, avian influenza and the latest pandemic influenza A(H1N1) have marked a watershed in global health governance. The international community has become fully aware that the most challenging health crises need to be fought through effective measures of prevention, control and early response to the outbreak of diseases that can pose a serious threat to human health worldwide. Foodborne diseases, be they caused by bacterial\[188\] or chemical contamination,\[189\] have the potential to impact adversely on the health of wide segments of the world population.

Faced with the menace of new human pandemics, zoonoses and foodborne hazards, the World Health Organization has responded to the general demand for global health security working out a strategy inspired to the principles of timeliness and effectiveness of surveillance, alert and reaction. This strategy is based on updated rules and procedures that can easily adapt to the transmission dynamics of new or emerging diseases (human-to-human or animal-to-human transmission, and transmission via food) and it mainly operates through the sharing of information and of the necessary technical and operational support. Its basic normative source are the International Health


\[188\] According to WHO, the most virulent pathogens causing foodborne diseases are BSE (bovine spongiform encephalopathy), Campylobacter, *Escherichia coli*, *Salmonella*, *Shigella*.

\[189\] "The contamination of food by chemical hazards is a worldwide public health concern and is a leading cause of trade problems internationally. (http://www.who.int/foodsafety/chem/en/index.html).
Regulations (2005), in force from 15 June 2007.\textsuperscript{190} Being the product of WHO's exercise of the quasi-legislative powers conferred on its Assembly, the revised Regulations actually represent an international legal instrument binding on virtually all States of the international community.\textsuperscript{191} As professor Lawrence Gostin stresses, WHO's normative powers are impressive and far-reaching "as states can be bound by health regulations without the requirement to affirmatively sign and ratify".\textsuperscript{192} In fact, according to articles 21 and 22 of the Constitution of WHO, regulations produce compulsory effects for all Member States that do not expressly "opt out" or make reservations to them within a limited deadline. In this specific case, the IHR 2005 can be said to have been substantially agreed by consensus among all WHO member states.

In order to provide the global community with adequate instruments to face acute public health risks that threaten people worldwide, the Regulations try to strike a balance between sovereign rights, human rights, freedom of traffic and trade and shared commitment to protect global health. To this end, they contain a range of innovations including: a broader scope of application which is not limited to specific diseases; States Parties' obligations to develop certain minimum core public health capacities; obligations to notify WHO of events that may constitute a public health emergency of international concern according to defined criteria; provisions authorizing WHO to take into consideration unofficial reports of public health events and ask States for verification; procedures for the determination by the Director-General of a "public health emergency of international concern" and issuance of corresponding temporary recommendations; protection and full respect for the

\textsuperscript{190} World Health Assembly, Fifty-Eighth plenary meeting, May 23, 2005, Resolution WHA58.3, \textit{Revision of the International Health Regulations.}

\textsuperscript{191} At present the IHR 2005 are binding on 194 States, including all WHO Members, of which only two (India and the United States of America) submitted reservations under Article 62 of the Regulations.

dignity, human rights and fundamental freedoms of persons; the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO.\textsuperscript{193} In this perspective, the IHR 2005 define the rights and obligations of States Parties and indicate the proper procedures in order to create a governance system which places at the heart of decision-making and operative activities the interaction among national and international health authorities, thus of State and non-State actors, with a view to sharing responsibilities and fulfilling the duty to cooperate.\textsuperscript{194}

As said before, one of the most important innovations introduced by the revised Regulations is their application to a much broader spectrum of infectious diseases, which require continuous epidemiologic surveillance and compulsory notification to WHO when unusual and unforeseen events of international relevance occur. Widening their field of action also to “emerging” diseases, the Regulations are meant to guarantee an effective response to the new health challenges of a globalized world. As pointed out by professor David Fidler in his early commentaries on the draft Regulations, this innovative approach – which provides for an “open category” encompassing any disease that may seriously and generally put public health at risk – represents the real revolutionary element characterizing the IHR 2005, since they allow a more flexible application with a better management of new health hazards.\textsuperscript{195} It is indeed in this new perspective that the Regulations have become an essential tool for global health protection and a true pillar of international health law. Within the described wider scope of the IHR 2005 fall certain food safety events with international implications – especially bacterial food contamination

\textsuperscript{193} See in particular Articles 2 to 12 of the Regulations.

\textsuperscript{194} Professor Fidler lays special stress on this specific aspect of the revised Regulations, which he deems to be the most relevant: “the new IHR create a strategy and framework for integrated, flexible and forward-looking governance for addressing serious threats to public health.

\textsuperscript{195} David P. Fidler, “Comments on WHO’s Interim Draft of the Revised International Health Regulations,” in Lawrence O. Gostin, ed., \textit{Public Health Law and Ethics: A Reader} (Berkeley: University of California Press 2002);
and foodborne diseases of microbiological origin— that may require action under the legal provisions of the Regulations. In such cases, States Parties are under the obligation to notify to WHO the events detected at national level which meet the conditions laid down in Annex 2: unusualness of the event, emergence of a new disease with significant zoonotic potential, high rate of mortality or morbidity, potential transboundary diffusion, and potential interference with international travel or trade.

Together with the innovations introduced by the IHR 2005, other new initiatives were launched within WHO's network of food safety governance in order to strengthen the surveillance, early warning and reaction system framed by the Regulations. In the first place, WHO established in 2004, and further developed in cooperation with the Food and Agriculture Organization, the International Food Safety Authorities Network (INFOSAN), a joint network whose task is to promote the exchange of food safety information and to improve collaboration among food safety authorities at national and international levels, in particular among WHO and INFOSAN National Focal Points (i.e. national authorities involved across the farm-to-fork chain in food legislation, risk assessment, food control and management, food inspection services, etc.). INFOSAN Emergency a food safety emergency network which is an integral part of INFOSAN facilitates the identification, assessment and management of food safety events under the IHR 2005, complementing and supporting the existing WHO Global Outbreak Alert and Response Network (GOARN).


197 IHR 2005, Annex 2: "Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern."


199 GOARN is a global network launched in 2000 with the aim of combating the international spread of outbreaks, ensuring that appropriate technical assistance reaches affected states rapidly and contributing to long-term epidemic preparedness and capacity building. For further information, see http://www.who.int/csr/outbreaknetwork/en/.
risks is important in order to control ongoing outbreaks and transmission of disease, to detect and remove implicated foods and to prevent future events, WHO has recently developed the *Guidelines for the Investigation and Control of Foodborne Diseases.* The Guidelines are meant to overcome the problem that sometimes these outbreaks go unrecognized, unreported or are not properly investigated, their effects becoming evident only when major health or economic damage has already occurred. In fact, the Guidelines draw on the basic idea that successful identification, investigation and control of foodborne diseases depend on good communication among the most relevant actors and professional groups involved in outbreaks management (governmental health authorities, sanitary and veterinary officials, laboratories, food scientists and consumers), on recourse to validated procedures and protocols, on timely and effective response.

In the third place, WHO has also turned its attention to early warning of outbreaks and early reaction for prevention of spread, which are basic prerequisites for containment and control of zoonotic diseases that can be transmitted indirectly via contaminated food. In this direction, an initiative involving WHO, FAO and OIE gave birth in 2006 to the *Global Early Warning System for Major Animal Diseases, including Zoonoses* (GLEWS), a joint early warning system built on the combination and coordination among the alert mechanisms of the three organizations. GLEWS's task is to detect, analyse and assess each event for its potential international importance according to the risk assessment criteria set forth in the IHR 2005. Together with INFOSAN, GLEWS guarantees extension of international surveillance and response to the entire farm-to-table chain. The two emergency networks share information on events related to food of animal origin, or to contamination of non-animal food products. GLEWS informs INFOSAN Emergency of events where transmission via food is likely and relevant events are in turn notified to WHO's IHR system.

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Fourthly, further innovations concern WHO's attempts to face the problem of under-reporting of data on foodborne diseases, which hinders both accurate determination of the proportion of diseases attributable to contaminated food and realistic estimate of its global burden on health, development and trade. To fill this data gap WHO launched in 2006 an Initiative to Estimate the Global Burden of Foodborne Diseases, again in collaboration with its usual partner organizations, FAO and OIE. The Initiative benefits from the support and expertise of the Foodborne Disease Burden Epidemiology Reference Group (FERG), an advisory board which assembles, analyses and reports data on foodborne diseases, develops models for estimation and appraisal of the overall burden of such diseases and puts such models at the disposal of states for studies at country level.\(^\text{201}\)

Giving birth to these initiatives, WHO has created a network of institutions, programmes and procedures which endeavour to foster international cooperation at the highest degree of quality and effectiveness under the general umbrella of the International Health Regulations. Nonetheless, the IHR 2005 do not include any enforcement mechanism for States which fail to comply with their provisions and do not apply to private entities.\(^\text{202}\) IHR implementation is thus primarily the responsibility of health ministries and the other States authorities involved, and WHO only offers some guidance to Member States indicating preferred areas of work and expected results.\(^\text{203}\) In this respect, the Organization suggests that the process of legislative implementation at national level should start with the general consideration of how the IHR 2005 are to be implemented in the legal and

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\(^{201}\) The task and activities of the Initiative and FERG, together with more detailed information on cooperation with states, are thoroughly described at http://www.who.int/foodsafety/foodborne_disease/ferg/en/index.html.


governance contexts of the State Party concerned; it is then expected to continue with the assessment of existing legislation, regulations and other instruments to determine whether their revision, or adoption of new ones, is appropriate to facilitate the full and efficient implementation of the Regulations. However, failure to comply with the obligations imposed by the IHR 2005 is not complemented by any sanctions regime, and the few relevant reference points on their implementation can be found in Article 3, stating that implementation “shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization”.

The preamble of the WHO Constitution in turn recalls the United Nations Charter, declaring that in conformity with it the principle that “the health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States” is one the fundamental principles which are “basic to the happiness, harmonious relations and security of all peoples”. Translating principles into practice, it could be argued that violations of the obligations to cooperate imposed by the IHR 2005 – which result in hampering a timely and adequate management of health risks of international concern, hence leading to serious challenges to global health – could be reported or denounced to the United Nations Security Council as being a menace to international peace and security, with a call for action under Article 41 of the Charter. This approach may find support in modern thinking and theories on global health security, especially in professor Ilona Kickbusch’s argument that health is a key component of global security.204

The Need to Move Forward

It is generally acknowledged that due to their transboundary dimension and their potential widespread impact on human health, food safety challenges demand close international cooperation and global governance. Following in the wake of a clear trend in international law and practice, we are now

204 For detailed information on professor Kickbusch’s theories and publications see at http://www.ilonakickbusch.com/home/index.shtml.
witnessing the emergence of a general principle on food safety, underpinned by
the progressive affirmation of a human right to safe food, which requires that
international standards and guidelines be voluntarily complied with, legal
obligations be fulfilled in good faith and all stakeholders at different levels play
their proactive role in enhancing the international community's preparedness
and capacity of response to food safety threats. It is in fact common view that
protecting world health from foodborne illnesses and similar hazards is to be
seen as a compelling duty and a primary interest of both States and non-State
actors. This is in tune with the idea that food safety contributes to the
realization of public health in its global dimension, that is to say public health
conceived and theorized in the seminal studies of prominent academics and
experts as a global public good.205

While food safety governance at the global level calls for multi-sectoral
approaches and multi-level cooperation to minimize the effects of food safety-
related public health events, international law can still count on a limited set of
legal instruments. This paper has tried to give evidence for this assertion
showing that, from the viewpoint of both human rights law and international
law, there is a strong need to move forward in order to enhance effectiveness of
the right to safe food, strict compliance with generally accepted international
standards and guidelines, agreement on more stringent and clear international
obligations in matter of food safety regulation at the universal level, and last,
but not least, creation of enforcement mechanisms. In fact, the present state of
international law on food safety regulation still has faults and drawbacks, as
authoritatively confirmed by professor Francis Snyder: "Food supply insecurity
and unsafe food are tolerated, encouraged or even positively promoted by many
aspects of current international law. Serious reform is essential if we want to

in Inge Kaul, Isabelle Grunberg, Marc A. Stern, ed., Global Public Goods: International
Cooperation in the 21st Century (New York: Oxford University Press 1999); Inge Kaul (co-
edited with Pedro Concejiao et al.), Providing Global Public Goods: Managing Globalization
(New York: Oxford University Press 2003); http://www.ilonakickbusch.com/global-health-
govemance/index.shtml;
create an international law for and not just 'of' adequate food".206 The legal framework explored by professor Snyder and his call for reform also lend further support to professor Gostin's general reflections on global health law governance, and especially to his argument that "international law has serious structural problems of application, definition and enforcement" and that "existing legal solutions have deep structural faults".207 Therefore, it is to be hoped that the joint efforts of the major international organizations involved at both the universal and the regional level (WHO, FAO, WTO, UE) – which point towards the prospective enhancement of the degree of cooperation among international actors, State authorities and private stakeholders will succeed in shaping an improved legal framework for food safety governance, which may benefit from the commitment of both international and national institutions.

In such an evolving and interdependent scenario, national initiatives concerning targeted domestic legislation can indeed be welcomed as positive steps forward whenever they substantially contribute to realizing the right to safe food, enhance consumer protection, adopt Codex standards, introduce accountability measures, and strengthen foodborne disease monitoring and surveillance systems. As cases in point, special mention should be made of the recently adopted Chinese Food Safety Law of 28 February 2009208 and of the bills introduced to the United States Congress in 2009, namely the Food Safety Rapid Response Act and the FDA Food Safety Modernization Act,209 which may

206 Snyder, "Toward an International Law for Adequate Food," 162.
208 The Chinese law passed by the National People's Congress Standing Committee, in force as of June 1, 2009, creates a national food safety commission, sets new and stricter standards and aims to tighten supervision and increase penalties for offenders. see Francis Snyder, The European Union and China, 1949-2008: Basic Documents and Commentary (Oxford: Hart Publishing 2008).
209 The Food Safety Rapid Response Act of 2009 [S.1269.IS] was introduced on June 16, 2009, by U.S. Senators Klobuchar and Chambliss and has three main provisions This bill complements the Food Safety Modernization Act of 2009 [S.510.IS], introduced in March, which aims at strengthening the Food and Drug Administration's authority and resources to ensure a safe food supply.
undoubtedly contribute to safeguarding the health of consumers of large sections of the world population (especially in consideration of the fact that these initiatives concern two of the most populated countries in the world), and hence protect global health.

3.2.1. Medical Ethics

Ethical consumerism is buying things that are made ethically by companies that act ethically. "Ethical" can be a subjective term both for companies and consumers, but could be considered to mean without harm to or exploitation of humans, animals or the natural environment. This can take on the following forms:

- Positive buying - favoring ethical products, be they fair trade, organic or cruelty free. This option is arguably the most important since it directly supports progressive companies.
- Moral boycott (Negative purchasing and company-based purchasing)
- Combination of above

Alternative terms for this are Ethical purchasing, moral purchasing or ethical sourcing.

Moral boycott

*Moral boycott* is the practice of avoiding or boycotting products which a consumer believes to be associated with unnecessary exploitation or other unethical behavior. A single product may be the subject of a boycott if it is produced by factory farming, for example, or if it is considered to be harmful to the environment. Similarly, an entire corporation may be boycotted for perceived unethical behavior (such as discriminatory hiring practices), or for investing a portion of its profits in (for example) the arms industry. Such action

http://www.govtrack.us/congress/bill.xpd?bill=s110-3358,
can cause great damage to reputations, not to mention loss of profits, and has, in part, led to the development of the concept of corporate social responsibility. An individual can choose to boycott a product. Alternatively, the decision may be the application of criteria reflective of a morality (or, in the terminology of ethics, a theory of value) to an individual, family, union, or other group's (corporation, university, government) purchasing decisions.

**Spending as morality**

Certain trust criteria, e.g. credit worthiness or implied warranty, are considered to be part of any purchasing or sourcing decision. However, these terms refer to broader systems of guidance that would, ideally, cause any purchasing decision to disqualify offered products or services based on non-price criteria that do not affect the functional, but rather moral, liabilities of the entire production process. Paul Hawken, a proponent of Natural Capitalism, refers to "comprehensive outcomes" of production services as opposed to the "culminative outcomes" of using the product of such services. Often, moral criteria are part of a much broader shift away from commodity markets towards a deeper service economy where all activities, from growing to harvesting to processing to delivery, are considered part of the value chain and for which consumers are "responsible". Some argue that "Shopping is more important than voting", and that the disposition of money is the most basic role we play in any system of economics. Some theorists believe that it is the clearest way that we express our actual moral choices, i.e. if we say we care about something but continue to buy from parties that have a high probability of risk of harm or destruction of that thing, we don't really care about it, we are practicing a form of simple hypocrisy.

**When is "moral" not "ethical"**

Etymologically, morality and ethics are identical ('morality' being derived as a Latin translation of Greek 'ethics'). However, certain English
speakers attempt to draw some distinction between these words in modern usage. Notably, the adjective "ethical" is much more common amongst industry or voluntary groups or non-government organizations, while the adjective "moral" has political or religious overtones, e.g. in the state of Maine, in the United States, in unions (as "moral boycott").

In public administration, "ethics" usually refer to acceptable behavior in professional conditions, while morality refers to judgments of good and evil in all spheres of life. Morals and ethics may clash when a person's work environment operates by deontological guidelines different from his moral perspective. Usually, ethics are governed by laws, regulations, or codes (e.g. the Hippocratic oath) while morals come from a religious or philosophical perspective, and usually do not perfectly overlap with a nation's laws (except for theocratic states, where the two are one and the same). For example, it could be considered unethical but morally acceptable for a soldier to disobey a direct order to kill a civilian, or ethical but morally unacceptable for an obstetrician to perform abortions, if such an operation is permitted by his professional code. Moralism or lacking ability to judge the morality is often based on lacking insight into processes and benefits. For example the transport of beans from Egypt to Europe by airplane may be criticized, as well as the transport of potatoes over the Alps - simply to wash them.

Collective moral choices in business

However, there are many attempts to deliberately systematize the criteria of informing the buyer of what they are involved in, in the entire production process, and these are more commonly referred to as "ethical" endeavors. Dominic A. Tarantino, Chairman of Price Waterhouse World Firm in 1998 described Social Accountability 8000 as "the first ever universal standard for ethical sourcing. SA8000 is an initiative of the Council On Economic Priorities, a New York based research organization. It provides a common framework for ethical sourcing for companies of any size and any
type, anywhere in the world. SA8000 sets out provisions for issues such as trade union rights, the use of child labor, working hours, health and safety at work, and fair pay." However, it does not address broader issues of ecology or bribery or other issues which may require more consumer or executive restraint. Tarantino further argues the need for moral leadership: "Pricing, products and services are no longer the sole arbiters of commercial success... it is business that must take the lead in taming the global frontier. Business must take the lead in establishing rule of law in emerging markets. Business must take the lead in stopping bribery. Business must take the lead in bringing order to cyberspace. Business must take the lead in ensuring that technology does not split the world into haves and have not's."

Collective moral choices in government

Many people would disagree with the view that purchasing should be motivated on personal moral criteria rather than utilitarian grounds. The view argues that a citizen's proper expression of moral choice is via voting for parties and candidates in government. Accordingly, in democratic countries, most people consider themselves to some degree responsible for the decisions governments make about what to buy on the people's behalf, e.g. pacifist nations such as Costa Ricafuse to buy military weapons or equip armies suitable even for self-defense, similar nations such as Japankeep their forces small (notably, in the case of Japan, because of the nation's constitutional restrictions only allowing a 'self-defense force' rather than a full-fledged army), and some, e.g. New Zealand, refuse to allow nuclear ships or weapons into their ports. Furthermore, governments handle various kinds of drugs in very different ways, e.g. buying out a coca or poppy supply for use in medically approved channels, forbidding trade in marijuana and interdicting its movements, all of which involve some degree of purchasing of arms or violent force. By seeking to restrict citizens' spending on drugs, they seek both to prevent the use of these drugs and to keep money from the hands of those whose morals they dislike, e.g. armed "terrorist" groups selling drugs to raise funds to buy arms. An
argument is that governments buy things that the public claims they do not want, but actually do, and so act as collective systems of hypocrisy. Critics of this view argue that the political process, or parties within it, add the hypocrisy for their own benefit, and ignore public will and morality. For example, a comparison of Marijuana and Cocaine: since Marijuana can be grown virtually anywhere many marijuana smokers grow their own supply, eliminating the entire supply chain. By contrast the bulk of the world's supply of cocaine is produced and transported by a relatively small number of cartels, many of which are involved in civil wars and use the profits from cocaine to fund those wars. Despite this fact many governments treat both drugs equally within the law.

Budgeting

On the flipside, governments' budget decisions impact domestic economies in more subtle ways, e.g. by spending more on education, or less on weapons. A particularly key issue is how much government spends on policing and armies. Usually, this is restricted to governments "purchasing" the services of its own citizens, who share some moral code with fellow citizens, and who believe ideologically in what they are doing. It becomes unclear how the politicians' or government's criteria, the people's criteria, and the actual law enforcement or military officer's criteria, interact. These issues are one focus of political economy which establishes what is deemed to be a valid trade good, how its movements are encouraged, discouraged, standardized or otherwise dealt with. The application of United Nations sanctions against nation-states is an increasingly common way for nations to standardize the way they encourage or discourage each other's trade, e.g. preventing nations from purchasing weapons of mass destruction, as in the case of Iraq.
Consumer boycott

Outside state action and the political parties that seek to control states, the best known examples of moral purchasing are in the mass consumer boycott, applied against corporations or states offending public morals in some way. These can often be more effective than public policy measures - and over time can come to be strongly reflected as part of public policy, e.g. consumer boycotts of South Africa over apartheid were mirrored in state policy over time, and contributed to the fall of the white regime. Along with disclosure of ingredients, some mandatory labeling of origins of clothing or food is required in all developed nations. This practice has been extended in some developing nations, e.g. in China where every item of clothing carries the name, phone number and fax number of the factory where it was made so a buyer can inspect its conditions. And, more importantly, to prove that the item was not made by "prison labor", use of which to produce export goods is banned in most developed nations. Experienced ethical consumers will have a good idea of which companies are producing which products and by what means, and their purchasing decisions will reflect what they consider to be acceptable commercial behaviour. By being more selective than most in how they spend their money, ethical consumers hope to use market forces in order to create a fairer, more compassionate world. Magazines and websites are published to keep consumers in touch with current issues, campaigns and boycotts.

Morality as label

There are other such uses of labels to reassure buyers by indicating when goods are "organic", "kosher", "halaal", "vegan", "free-range", contain recycled materials or otherwise morally desirable. In this sense the label serves as a marker or token of some reliable validation process, some instructional capital, much as does a brand name or a nation's flag. It also signals some social capital, or trust, in some community of auditors that must follow those instructions to validate those labels. Theoretically, any such label could be
false, and any such auditor or inspector could be bribed or misled. One inhibitor to wider use of more standard labels is low trust and inability to validate truly global standards for what such labels might mean. Over time, some theorists suggest, the amount of social capital or trust invested in nation-states (or "flags") will continue to decrease, and that placed in corporations (or "brands") will increase. This can only be offset by retrenched national sovereignty to reinforce shared national standards in tax, trade, and tariff laws, and by placing the trust in civil society in such "moral labels". These arguments have been a major focus of the anti-globalization movement, which includes many broader arguments against the amoral nature of markets as such. However, the economic school of Public Choice Theory pioneered by James M. Buchanan has offered counter-arguments based on economic demonstration to this theory of 'amoral markets' versus 'moral governments'.

Global morality

In "The Global Markets As An Ethical System", John Mc. Murtry argues that there is no purchasing decision that does not itself imply some moral choice, and that there is in fact no purchasing that is not ultimately moral in nature. This mirrors older arguments, especially by the Anabaptists, e.g. Mennonites, Amish, that one must accept all personal moral and spiritual liability of all harms done at any distance in space or time to anyone by one's own choices. Accordingly purchasing for vanity or status is abhorred and shunned. This theory is echoed in some modern eco-villages who adopt very similar stances, effectively blocking all goods that do not satisfy their moral criteria at the village gate, and relying on internally produced food and tools as much as possible. A parallel and distinct argument is that for ethical investing, which seeks similarly to impose social or ecological criteria on investing rather than purchasing behavior. This has historically focused on representative boards, disclosure of dealings with possibly-repressive governments, and avoidance of investing in weapons, tobacco, alcohol, or nuclear technology. Usually, the corporations that ethical funds invest in must also agree to some
minimal standards of moral purchasing, i.e. refusing at least to buy or deal in or merge with companies that handle those various dangerous items.

3.2.2. Medical Administration

Consumer protection is a general concept that involves protecting people from buying things and services that are unsafe or fraudulent. The best known consumer protection organization in the United States is the Consumer Product Safety Commission (CPSC). The CPSC is an independent federal regulatory agency created by Congress in 1972. Its charter is to "protect the public against unreasonable risks of injuries and deaths associated with consumer products." The CPSC has jurisdiction over about 15,000 types of products--everything from appliances to toys. It helps manufacturers develop voluntary standards to prevent accident and injury, enforces government determined mandatory standards, issues recalls of unsafe products, does research into potential product hazards, and educates consumers to choose safer products and report accidents and injuries related to consumer products. In addition to the CPSC, in the United States several other agencies are responsible for protecting the public. The U.S. Department of Transportation regulates car, truck, and motorcycle safety.

The U.S. Department of the Treasury regulates alcohol, tobacco, and firearms. The U.S. Food and Drug Administration (FDA) is responsible for the safety and efficacy (whether a product actually does what it says it does) of prescription and over-the-counter drugs, medical devices, cosmetics, and food. In the field of health care, the FDA is the major agency responsible for consumer protection. Keeping food and drugs pure and safe is an old problem. As long ago as 1202, King John of England proclaimed a law that prohibited bread from being adulterated (contaminated) with any ingredients such as ground peas or beans. In 1785, Massachusetts was the first state to pass a food adulteration law. In 1820, a group of well-known physicians met in Washington D.C. to establish the U.S. Pharmacopeia. This was a list of standards (purity
and content) that all drugs had must meet. The U.S. Pharmacopeia is still in existence today. Sometimes on drug labels you will see the letters USP after the drug name. This means that the drug conforms to the standards and formulas of the U.S. Pharmacopeia. Federal regulation of drugs began in 1848 with a law that sought to prohibit the entry of adulterated drugs into the United States. In 1862, President Lincoln established the Bureau of Chemistry, a division of the Department of Agriculture that later to become the Food and Drug Administration. In the first ten years of the twentieth century, Congress passed a series of laws to insure the purity of serums and vaccines, prohibit the interstate transport of adulterated or mislabeled food, drinks, and drugs, and to require federal inspection of meat packers. These laws were passed to eliminate such dangerous practices as using poisonous preservatives and dyes in meat and manufactured foods, and to restrict false claims made for worthless or dangerous patent medicines. Today the FDA's jurisdiction extends to foods, drugs, cosmetics, and medical devices. These products must be proven safe and effective before they can be sold in the United States. Companies wanting to sell a new food product must prove that their manufacturing process destroys harmful bacteria and adds no harmful chemicals to the food. The FDA also regulates the labeling of food and is responsible for the truth of such claims as "low fat" or "cholesterol free" on labels. Currently, naturally occurring herbal supplements do not fall under the control of the FDA. As these supplements become increasingly popular, there is debate in the health care community about whether they should be regulated in a way similar to over-the-counter drugs in order to protect consumers from contaminated products and false claims.

In the area of drugs and medical devices, the FDA requires both animal and human testing before a product can be licensed and sold. Drugs and devices must not only not hurt patients, they must actually do what they claim to do. In other words, if a medicine claims to heal ulcers, the company intending to manufacture it must show through extensive studies that it actually does heal
ulcers in most patients. The FDA also protects people from dangerous medical devices such as x-ray machines by setting standards of operation. It also sets standards for handling blood and other body fluid and tissues that may transmit disease. Because the FDA requires human testing of experimental drugs before they can be licensed and sold to the public, the United States has signed the Declaration of Helsinki, a human rights document that assures that the rights of patients receiving experimental drugs are protected. The FDA enforces that all organizations testing drugs in the United States abide by the conventions of the Declaration of Helsinki. The basic provisions include:

- Drugs should not be tested on people until they have been adequately tested on animals.
- An independent committee, called an Institutional Review Board in the United States, must approve each separate experimental study involving people.
- People conducting the study must be scientifically qualified and approved.
- Every participant in the study has the right to understand the expected goals, risks, benefits, and potential hazards of participating in the study, and may withdraw from the study at any time for any reason. This is called "informed consent."
- The participant's privacy must be maintained in any published information arising from the study.
- The organization performing the study must accept financial responsibility for treating any serious or unexpected problems arising from a person's participation in the study.

The United States food and drug laws provide some of the highest level of consumer protection in the world. In addition to federal regulations, state and local health boards also inspect and enforce laws related to food preparation in restaurants and public places, as well as health risks of public swimming pools,
the disposal of garbage and animal wastes, the sanitary conditions of places like kennels and animal shelters, and a myriad of other health related situations. Another aspect of consumer protection in the health field has come to prominence in the late 1990s. With the popularity of managed health care plans and the rise of for-profit health care organizations, the question has arisen over whether federal legislation is needed to establish a patient's bill rights. Such legislation would seek to strengthen consumer confidence in the health care system by ensuring that the system is fair and responsive to consumers' needs, by reaffirming the importance of the physician-patient relationship, and by setting forth the rights and responsibilities of all Americans in improving their own health. As of 1999, no legislative action had been taken on this issue, however, some health maintenance organizations (HMOs) and insurers had begun voluntarily modifying their regulations to provide consumers with more avenues of appeal in the event treatment was denied. In the absence of federal legislation, laws governing consumer protection in the health arena are implemented on a state-by-state basis. Unfortunately fraud in the health care industry occurs with sufficient frequency that The Food and Drug Administration has prepared a list of the top 10 health frauds. These are: fraudulent arthritis products, spurious cancer clinics, bogus AIDS cures, instant weight-loss schemes, fraudulent sexual aids, quack baldness remedies or appearance modifiers, false nutritional schemes, unproven claims for a muscle stimulators, and so-called cures for Candidiasis hypersensitivity. Dishonest promoters frequently promise quick or painless cures; promote products made from a special or secret formula; present testimonials from satisfied patients, claim their products are effective for a wide variety of ailments; and claim to have the cure for a disease that is not yet understood by medical science. The National Council Against Health Fraud can help the public take legal action against such fraudulent schemes. This organization offers referral to lawyers, a registry of expert witnesses, information on defense witnesses, and maintains a list of unproven, fraudulent, and potentially dangerous treatments.
3.2.3. Medical regulatory authorities

The regulation of medical devices is a vast and rapidly evolving field that is often complicated by legal technicalities. For example, legal terms and their meanings are sometimes non-uniform even within one regulatory system. In an attempt to make this complex subject easier to grasp, this Guide presents a common framework that integrates the regulatory systems of the five countries or regions with the most advanced medical device regulations. Non-technical language, graphics, tables and memory anchors are used to present an overview of medical device safety issues and regulatory philosophy. The Guide begins by explaining how safety is a risk management issue, and how optimum safety and performance require cooperation among all who are involved in the life span of a medical device.

The critical elements of medical device regulations are illustrated using a common framework for regulatory development; as well as the current regulatory tools of the Global Harmonization Task Force (GHTF) and all the key documents it has issued in the past three years. Understanding the different phases in the life span of a medical device and the common framework are first steps to successful harmonization and simplification worldwide. Terms in regulations are legally binding and therefore have restricted meanings. For example, manufacturer, distributor, vendors, retailers all have precise definitions in regulations, and their definitions vary in the regulations of different countries. A regulation normally has an accompanying list of definitions of terms used. A harmonized definition of many important terms such as performance, effectiveness, vigilance and incidents, are still under development. This guideline, however, is written to promote a general understanding of medical device issues and their regulations. IAMRA strives to be responsive to the needs and future direction of medical regulatory authorities worldwide. Communication, participation and interaction by all are deemed paramount to the true success of this international collaboration. IAMRA's
purpose is to encourage best practice among medical regulatory authorities worldwide in the achievement of their mandate to protect, promote and maintain the health and safety of the public by ensuring proper standards for the profession of medicine.

Goals:

- High standards to foster best practices in all aspects of medical regulation (registration and licensure, complaints and resolution, and quality assurance);
- Member support to be aware of the diverse needs of the members; to provide support to one or more members as required, within the human and financial resources of IAMRA;
- Relationship building to reach out to non-member medical regulatory authorities; to work with other international organizations in the spirit of mutually beneficial collaboration; and
- Innovation and dissemination of best practices — to ensure the biennial International Conference on Medical Regulation focuses on best practices developed by, and useful for, all the members.

Recognizing that international medical regulatory authorities receive applications for registration or licensure from physicians with medical credentials from outside their jurisdictions, ECFMG offers the benefits of primary-source verification through EICS. EICS is an application-based process for verification of medical diplomas, medical school transcripts, and certificates of postgraduate medical training and medical registration/licensure. EICS offers confirmation of authenticity of medical education credentials that far exceeds notarization, where a notary or other official declares that a photocopy has been compared to the original document and found to be identical and unaltered. EICS verifies the authenticity of the documents directly with an authorized official of the institution that issued the documents. With the advent of affordable high-resolution scanners, printers, and copiers, and advanced
graphics software, side-by-side comparison of documents is not as reliable as
direct confirmation of the original credential’s authenticity with the originating
institution. EICS customizes its application materials to meet the specific
credential verification requirements of the medical regulatory authority. The
medical regulatory authority controls distribution of the EICS application. EICS
applications can be made available to physicians through the medical regulatory
authorities’ website and/or the EICS website. Under the consumer protection
Act the consumer to whom services has been provided can make a complaint
and in the case in hand the service having been provided to the minor patient.
But at first instance the health care providers should buildup the health care
providers should build up confidence to the consumer in the health care system
by making it easy for consumers to participate actively in their own health care.
So importance of a good health care provider is to be emphasized as it results in
good provider – patient relationship. These should be good and healthy relation
between them. The consumers have an important role in making sure they have
rights and responsibilities with regard to health improvement

Health care providers range from generalists to providers who specialize
in certain areas of the body or disease. Any category of medicine or care such
as cancer or anesthesia can have a specialist, nurses also can specialize in
certain areas of medical care Medical providers are increasingly nervous about
proposals made for the benefit of the patients as consumers. To create
Meaningful health care reform that benefits patients, every stakeholder will
have to rethink their role. As health providers there is a need to shift out
primary focus from providing episodic care for the ill to providing continuing,
preventive, coordinated care that keeps people health. There will always be a
need for treating the ill but that should not be the basis of a health care system.
In reforming the health care by initiating health providers, the concept of shared

210 Bernstein E, Bernstein J. James T. Multi Culturales and care delivery Rosen’s Emergency
responsibility is key. So India has to reform health care system. The health care system in India vehemently displays a promising future. Experts have already suggested countless techniques to reform the health care system in India. And until this day, the government has been successful implementing only a few among them. One must realize that the system is constantly evolving. These were a time when the average life expectancy of an Indian did not cross the 35-year barrier. According to a survey the Indian health care system has been fine-tuned greatly, for the health care system to be and the health care providers to be more effective.

The corporate hospitals in India are providing quality health care delivery system. They believe that the best can be possible only through a honest, sincere and ethical health care practice. Using this philosophy and instituting a support system, it is possible to ensure high quality patient care and to provide smooth and comfortable experience to the patients. The support system in the hospital has patient relations executives who co-ordinate with various departments and patients/relatives of the patients to ensure high level of satisfaction. Clinical coordinators also form as part of the support system that enhances the patient care and their satisfaction levels. Where as in government hospitals which is serving the common people the health care providers begins from village levels. Primary health care centers at the village level and Government hospitals at the district head quarters. Government hospitals some of which are among the best hospitals some of which are among the best hospitals in India, provide treatment at taxpayer expense most essential drugs are offered free of charge in these hospitals Government hospitals provide treatment either free or at minimal charges for example, an outpatient and at AIIMS (one of the best hospitals in India) Costs a onetime fee of rupees 10 (around 20 cents US) and there after outpatient medical advice is free. In hospital treatment costs depend on financial condition of the patients and

facilities utilized by him but are usually much less than the private sector for instance, a patient is waived treatment costs if he is below poverty line. Another patient may seek for an out conditioned room if he is willing to pay extra fee it. The fact is the charges for basic in hospital treatment and investigations are much less compared to the private sector. The cost for these subsidies comes from annual allocations from the central and state governments\textsuperscript{212}. The majority of the Indian population is unable to access high quality health care provided by private players as a result of high costs. Health care today is at cross roads. It is proving beyond the reach of common man especially low and middle income ground.

**Role of Hospitals as Sources of Information**

Meeting on Role of WHO in the Development of Hospital Health Services in the Context of Globalization, Sukabumi, Indonesia, July 1999 In countries like India, Thailand and Indonesia, the commercial pro vision of health care through foreign investment in the form of specialized hospitals, which are commercial enterprises, is attracting many investors.

Hospitals can be classified into four basic categories - the private, income generating hospitals; the charity hospitals run by religious or other NGOs; the industrial/military hospitals and finally, the public hospitals, both large and small. Traditionally, hospitals have been regarded as big institutions, rather awe-inspiring, by the layman, as a place for cure and a place for disease. For health professionals they are centres of technical excellence for both learning and practice. However, hospitals now need to re-think their traditional roles and look at aspects that they did not consider as part of health care. The reason for this is the growing trend of globalization. Globalization is a modern phenomenon, a development of the last few decades of the 20\textsuperscript{th} Century. It is characterized by interdependence and overlapping of all sectors - political,

\textsuperscript{212} Health care in india – Wikipedia
social, economic, military and cultural. Its impact is all-pervasive and encompasses all nations big and small – transforming society world-wide, negating the concept of territorial boundaries. Since ancient times, man has been involved in trading in goods and services. In the twentieth century this has rapidly expanded and is still expanding due to various reasons including modern means of communications and trade liberalization. The driving forces behind this rapid expansion in trade are the new multilateral agreements of the World Trade Organization (WTO). WTO is an international legislative body responsible for handling multi-lateral trade matters between nations. It was created on 1 January 1993, as a successor to the General Agreement on Tariffs and Trade (GATT). WTO currently has 132 members and 34 applicants. Indonesia is a member of WTO. WTO administers and implements the multilateral agreements on trade that become binding on members when they join the Organization. It also conducts multilateral trade negotiations and oversees national trade policies. WTO also has the role of resolving trade disputes between members and can impose trade sanctions against members who do not comply with their obligations under the agreements. WHO, in collaboration with its Member States and other international bodies, has collected, analyzed and disseminated information on the implications on health as a result of these agreements. In this context, national, regional and international debates have been held on this issue.

Of the several trade agreements, four are more relevant to the health sector and could have both positive and negative implications. These agreements are:

- General Agreement on Trade in Services (GATS).
- Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).
- Agreement on Technical Barriers to Trade (TBT).
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).
Of these four agreements, I would specially like to discuss GATS, which will have a profound impact on medical and health services all over the world including Indonesia. Some of you may wonder why I am talking to the hospital administrators about trade and tariffs. Let me explain. GATS is the international trade agreement which covers trade in 'services' in all sectors including health. Services are normally thought to be intangible, non-transferable economic goods. However, under this agreement, trading of services may be done either across borders, or by consumption in other countries, or through foreign direct investment or by movement of personnel serving abroad. No country can treat products, including services differently on account of their origin. Many countries have agreed to open up hospital services as well as medical and dental services to foreign investors. In our Region, only India has included health while providing market access to foreign investors. As many of you know, many Indonesians travel abroad seeking various health services. Most of them go abroad since specific advanced treatment facilities are not available in the country, or if they are available, they are not up to their standards. This results in some countries having a trade surplus in health care. Thus, for example in 1996, the United States had a trade surplus in health services by providing treatment for people from abroad. It is reported that in 1997 the four Mayo clinic's alone in the USA, treated more than 10 000 patients from abroad. Another area of trade is foreign direct investment in the health sector. This is a growing trend in our Region. In countries like India, Thailand and Indonesia, the commercial provision of health care through foreign investment in the form of specialized hospitals, which are commercial enterprises, is attracting many investors. What will be the impact of this? Some feel that this would enhance investment opportunities, increase competition for quality health care and remove the burden on the public sector.

Others feel that the foreign facilities would attract the best people from the public sector and thus lead to internal brain drain. It could also lead to squeezing of the domestic sector, and thus the smaller, less competitive clinics
and hospitals could be edged out. Another related area of globalization is Telemedicine. Trading in medical services can cross borders, using modern means of telecommunications. This is a new area of investment in our Region. This could improve the quality of care and improve skills and knowledge of the professionals but would also need substantial investment. It would also make professional advice available to clients at their homes, through on-line services on the internet, thus affecting the domestic market. The last area of trade in health is the actual movement of personnel who supply health services. Thus there could be an outflow of health personnel creating a situation of surplus or shortages depending on the country. Indonesia could be flooded with service providers from other countries. We are already aware of the large number of medical personnel from South Asian countries working in the UK and the Middle East. All these issues need to be discussed and debated by the health authorities in collaboration with other sectors, professional organizations, and consumers. The goal is to define a consistent set of policy objectives, based on equity and social justice. A number of issues have to be settled, including the qualifications of professionals, accreditation procedures, delimiting professional quotas for employment etc. I would urge you to initiate a dialogue with the trade, commerce and health sectors about how hospital services could promote international trade, while maintaining public health interests. The services of WHO are available as a facilitator to such a dialogue, which could help in a better understanding and preparation for the impact of globalization in health. Globalization is inevitable and desirable.

However, it poses considerable challenges and uncertainties in the provision of health care. If we are not prepared for these changes, they could lead to policy mistakes, which could prove to be costly. Areas that require to be addressed include the opening up of the health sector and moving away from the monopolies that currently exist in this country and introducing competitiveness. Comprehensive health sector reform in medical care would be needed. The needs of the consumers would have to be addressed, making the
system more open and accountable. In addition, it is necessary that the basic services for the poor and under served are not forgotten. It is better to be prepared to face the situation and to be pro-active in devising new strategies and policies. The time for action is now. The system of health care has to be referred to as ‘Consumer driven health care’ because routine claims are paid using a consumer controlled account verses a fixed health Insurance benefit. That own health bridgets. Social health Insurance is where a nation’s centre population is eligible for health care coverage and this coverage and the services provided are regulated. In almost every country, state or municipality with the government health care system a parallel private and usually for profit is allowed to operate. This is sometimes referred as tow-tier health care. The scale, extent and finding of these private systems is variable. In India Health Care facilities and personal increased substantially between the early 1950 and early 1980’s but because of fast population growth, the number of licensed medical practioners per 10,000 individuals had fallen by the late 1980’s to three per 10,000 from the 1981 level of four per 10,000 Approx there were ten hospital beds per 10,000 individuals. In this scenario private hospitals were established to give quality of health service to give quality of health service to the people who can afford to pay for the quality service given by the doctors. But for common people again depended on the Government health centres established only for the common man.

The question arises what type of health service is provided to a common man who approaches a Government clinic for health check. The common man can also be called as a consumer and there are certain rights existing for him as a consumer. The government clinics may be called as primary health centers and they are considered to be the cornerstone of the rural health care system. India had about 22,400 primary health centres, 11,200 hospitals, and 27,000

213 Health care – Wikipedia

214 Health care in India- Indian Health care services & health industry study http://www.Indianchild.com/health_care_in_India.htm
dispensaries (approx). These facilities are part of a tiered health care system that funnels more difficult cases into urban hospitals while attempting to provide routine medical care to the vast majority in the countryside. Primary health centers and sub-centers rely on trained paramedics to meet most of their need. The main problems affecting the success of primary health centers are the predominance of clinical and curative concerns over the intended emphasis on preventive work in rural places. In addition, the integration of health services with family planning programs often causes the local population to perceive the primary health centers as hostile to their traditional preference for large families. Therefore primary health centers often play an adversarial role in local efforts to implement national health policies.

Indigenous or traditional medical practitioners continue to practice throughout the country. The two main forms of traditional medicine practiced are the ayurvedic system which deals with causes, symptoms, diagnoses, and treatment bases on all aspects of well being (mental physical, and spiritual) and unani (so-called Galenic medicine), herbal medical practice. A Vaidya is a practitioner of the ayurvedic tradition and a hakim (Article for a Muslim Physician) is a practitioner of the unani tradition. These professions are frequently hereditary. A variety of intuitions offer training in indigenous medical practice. The Art of health care in India can be traced back nearly 3500 years. From the early days of Indian history the Ayurvedic tradition of medicine has been practiced. During the rule of Emperor Asoka Maurya (3 cen B.C) Schools of learning in healing arts were created many valuable herbs and medicinal combinations were created. Even today many of these have been used. During his reign there is evidence that Emperor Asoka was the first leader in world history to attempt to give health care to all its citizens, thus it was the India of antiquity which was the first state to give its citizens national health care. So the concept of health care was present since times immemorial but

215 Ibid.
the concept of common man as a consumer and his right to health care has emerged recently.

3.3. Consumer Education

Consumer education means to educate the consumers as to what, where, when, how and how much to buy and how to use what they have bought. If we understand the above definition, one will be able to appreciate the relevance of educating people so that they can make correct purchases. Consumers are cheated in the market because they do not get proper "consumer education". The consumers should know the following important aspects of consumerism so as to be protected from exploitation.

- What to buy? We should buy those products that meet your needs and priorities and are of good quality. Before buying, conduct a market survey and collect as much information as possible about the product. Then decide about a particular brand. Brand name is the popular name by which a product is known in the market like Dhara for vegetable oil, HMT for wrist watches etc.

- Where to buy? Purchases can be made at retail shops, cooperative stores, company showrooms, authorized dealers or at wholesale markets.

- When to buy? Some goods such as fruits and vegetables should be bought when they are in season others should be bought during off season or in genuine discount sales such as room coolers, electric heaters, and woolen clothes etc., Visit shops when the shopkeepers are relatively free. Avoid Sundays and evenings as far as possible.

- How much to buy? Buy just the right quantity as per we need, money and storage space available. This prevents spoilage and wastage.
• **How to buy?** Things can be bought either in cash or on credit. You pay less when you pay cash and if you buy on credit you end up paying more than the original price. You may save and buy by paying cash, or buy on credit with installment payments. Analyze the terms and conditions in the case of installment purchases. If it is worthwhile, buy the goods on installments rather than exhausting your savings cash reserves. Choice is yours! Also ask for the guarantee and warranty cards along with the receipt, it is your right.

• **How to use?** Learn about the proper use of any product or service. Read instructions carefully before use and always follow them to avoid any problem we can also ask for a demonstration of usage.

Generally the consumers are benefited if consumers are educated at different levels of the curriculum. It develop the ability to decide and choose things intelligently, demand safe, reliable and good quality products at a reasonable price, be alert, well informed and vigilant against corrupt practices in the market, and to take suitable action when faced with a problem.

### 3.3.1. Problems Faced by Consumers

Consumers normally face the following problems while purchasing the goods from the market. The problems are discussed as hereunder.

**A. Price Variation:** Many times while purchasing products the consumer may notice that the price of the same item is different in different shops within the same market. There are also price variations between markets. Why do prices vary? Sometimes prices vary due to certain genuine reasons and at other times, they vary because the salespersons want to overcharge. Let us understand the reason first: Prices are lower for the same product in wholesale markets as compared to retail markets.
• Prices of packed products are higher than the price for the same product when sold loose. This is due to packaging charges in packed goods.

• Maximum Retail Price inclusive of all taxes, also called MRP, printed on the label of all products includes the commission of the seller. If he is ready to forgo a part of it, he sells the product at a price lower than the MRP to attract consumers and make them regular customers.

• Purchasing power of people varies in different localities. The sellers charge more from people who have the capacity of paying more, for example they claim that they provide the products clean and well packed, showroom is clean, attractive and the customer can move around and select the products, there is also facility of free home delivery.

• Products are sold at a reduced price during the "end-of-season" sales or at a discounted rate during "stock clearance" sales or for early birds.

• Products of better quality cost more than the lower quality ones or those nearing the expiry dates.

B. Adulteration and Poor Quality: Adulteration means addition of certain things or their removal from a product, thereby, lowering its quality. Adulteration can also occur because of the use of poor quality raw materials or poor method of production or inappropriate storage of finished products. Adulteration is usually intentional. Such products may be harmful for the health and safety of consumers. However, all low quality products may not necessarily be adulterated ones. We may have heard of people suffering from diarrhea and vomiting after eating food and sweets from roadside hawkers. This may be due to adulteration of the food with harmful colours, stale ingredients, poor quality cooking oil, etc. These food items may also have been contaminated with germs. Therefore it is important that we
critically evaluate nutritional claims from advertisements and nutrition-related news stories. Cases of people getting electric shocks from poorly designed electric irons and immersion rod may also not be new to you. Many fabrics shrink or the colour fades after the very first wash. Readymade garments that are stitched badly or have loose buttons are the other examples of poor quality products.

C. Non-availability - Hoarding and Black Marketing: There may be occasions when the consumer do not find certain products in the market. This non-availability may be because of any of the following reasons:

- Genuine and unavoidable reasons like off-season, lower production or less supply due to transporters strike or a natural calamity like drought or floods.
- Artificially created reasons by traders to demand a higher price from consumers. This is due to hoarding or hiding of certain products and their sale in black market i.e. at unreasonably high prices to needy consumers. Many times, when the manufacturers want to raise prices, they temporarily withhold the supply of their products from the market, thus causing artificial scarcity. Even in normal periods, when the sellers expect a rise in prices, they hoard products. For example, you may find such a situation for petrol, butter, cooking oil, etc., in the months of January and February, that is, just before the budget and Government announcements of new policies on taxes, duties, etc.

D. Defective Weights and Measures: Shopkeepers use several malpractices while measuring or weighing what the consumer buy. These may be: use of irregular weights like bricks or stones or hollow bottom of iron weights which weigh less than the actual weight,
• Use the weighing balance with a wooden beam that does not remain horizontal when the pans are empty,
• Pointers of weighing scale that do no rest at zero even when no weight is put on the pans,
• Placement of a piece of magnet or cardboard under the pans of a weighing scale,
• Meters at petrol pumps and in auto-rickshaws and taxis not showing zero readings,
• Use of a measure that may be dented or with a false bottom to give less measurements of liquids like milk or oil,
• Use of a short or dented measuring rod, or by stretching the fabric or measuring the fabric on marked table tops to measure less fabric, etc. The shopkeepers' intention all the while is to give you less than the promised quantity without your knowledge, thereby earning higher profits.

E. Deceptive Trade Practices: The consumer may have observed some of the following deceptive trade practices by shopkeepers and manufacturers:

• Packing of small goods in large packets and packing poor quality goods in stylish wrappers that cannot be opened for examining the products inside.
• Use of brand names, labels and packaging similar to good quality popular products for low quality products.
• Offer of attractive free gifts, sales and discounts with some low quality products or offer of cheap free gifts and discounts that are not genuine, etc.
• Selling expired articles at lower prices.
• Polishing and packing second hand articles for selling them at first hand prices. Thus, consumers are deceived and cheated.
F. Poor Consumer Guidance: The consumers have to often rely on the mercy of shopkeepers and manufacturers for information required to make any purchase. But they do not always give us the correct and complete information or they may themselves not have sufficient information. They talk positively about only those brands of products that they stock and get a higher commission. Some salespersons do not pay attention to consumers. They behave rudely and do not show all the items. Thus, the consumers get very little help from these salespersons while making choices. Also there are no standardized consumer booklets available that one can refer to.

G. Lack of Standardized Products: While shopping have the consumer ever noticed that some products bear a quality standard mark like ISI, AGMARK or FPO, along with some numbers? What do they mean to you? Well, these marks are called standardization or certification marks and are issued by the Government. The numbers displayed along with the marks are the numbers of Indian standards corresponding to a product and unique for it. These marks convey that products bearing them are of good quality, correct weight and safe to use. You will read more about these marks later. However, all the products sold in the market including some very popular brands do not bear a standardization mark. For example, when you buy a pressure cooker, you may be not sure and unable to decide whether to buy a popular brand without a standardization mark or to buy a less popular brand with a standardization mark.

3.3.2. Occupational health Laws

The Factories Act, 1948, the Mines Act, 1952, The Dock Workers (Safety, Health and Welfare) Act, 1986 are some of the laws, which contain provisions regulating the health of workers in an establishment. Whereas the Employees State Insurance Act, 1948 and the Workmen’s Compensation Act, 1923 are compensatory in nature.
3.3.3. Health Provisions under the Factories Act, 1948

The Factories Act, 1948 was enacted with the object of protecting workers from subjecting to unduly long hours of bodily strain or manual labour. It lays down that employees should work in healthy and sanitary conditions so far as the manufacturing will allow and that precautions should be taken for their safety and for the prevention of accidents. The Act defines a ‘worker’ as any person employed directly or through any agency (including a contractor), whether for remuneration or not in any manufacturing process or in any work incidental to or connected with the manufacturing process. It is required that work performed should be connected with the product which is produced in the manufacturing process. Section 10 of the Act lays down that a State Government may appoint qualified medical practitioners as ‘certifying surgeons’ to discharge the following duties:

- Examination and certification of young persons and examination of persons engaged in ‘hazardous occupation’.
- Exercising medical supervision where the substances used or new manufacturing processes adopted may result in a likelihood of injury to the workers.
- Exercising medical supervision in case of young persons to be employed in work likely to cause injury.

Chapter IX of the Act lays down in detail the provisions relating to the health, safety and welfare measures, namely, cleanliness, level of ventilation, diversion of dust and fumes, provision of artificial humidification, sanitation, fencing of machinery, among others. There are also provisions that prohibit women and children from working in certain occupations. 27 processes and operations have been identified as dangerous in The Maharashtra Factories Rules, 1963. These Rules lay down detailed instructions regarding preventive measures, protective devices, cautionary notices as well as medical examination of workers. The State Governments have adopted these rules depending on their
local needs. The Act lists 29 occupational diseases and obliges the manager of a factory and medical practitioners to notify the Chief Inspector of Factories if any worker contracts any of the diseases. The Rules are very comprehensive in laying down special provisions with respect to health, safety and welfare of workers including medical examinations, setting up of occupational health centers, etc. The only lapse has been its ineffective implementation since most of the discretionary powers lie in the hands of the Inspectors and occupiers. Although very few cases of occupational diseases are reported in factories, the working conditions in most of the factories handling hazardous chemicals have higher risk potential.

3.3.4. The Employees’ State Insurance (ESI) Act, 1948

It is a social security legislation enacted with the object of ameliorating various risks and contingencies sustained by workers while serving in a factory or establishment. It is designed to provide cash benefit in the case of sickness, maternity and employment injury, payment in the form of pension to the dependents of workers who died of employment injury and medical benefit to workers. It recognizes the contributory principle against such contingencies, provides protection against sickness, replaces lumpsum payments by pension in the case of dependents benefit and places the liability for claims on a statutory organization. The Act does not cover ‘seasonal employments’. It defines ‘employment injury’ as personal injury to employees, caused by accident or occupational diseases, in an insurable employment. The Act lays down provisions to set up an ESI Corporation, to promote measures to improve health and welfare of insured persons and a Medical Benefit Council to advise the Corporation on medical benefits, certification, etc. The Medical Boards have to ascertain the percentage of disability of injured workers before submitting their report to the Corporation in order to grant compensation to the workers. An injured worker has to wait for months before the Medical Board calls him for a
The main source of revenue for the ESI Fund is the Contribution paid by the employers and the employees. The purposes for which the Fund is to be used are numerous. It includes payment of benefits, provision of medical treatment to insured families, meet charges in connection with medical treatment, maintenance of hospitals, dispensaries, etc. In existing conditions there is gross misuse of these funds. The discretionary powers with respect to using the Fund amount lie solely with the Corporation along with the State Governments. According to the Occupational Health and Safety Center, Mumbai, the Corporation has only 4 occupational disease centers for workers. Section 39 of the Act makes the employer primarily liable for the payment of contribution on behalf of himself and his employees towards the ESI Fund. In case of misuse of the contribution by employer, the employee can sue the employer in the Employees' State Insurance Court set up by the respective State Government. Where an employee makes a claim on the grounds of sickness, disablement or maternity, it has to be made against the ESI Corporation and not against the employer. The process involved to obtain the compensation, is tedious. Such a lapse renders the very object of the Act to provide for quick claims as unreal. Under the Workmen's Compensation Act, 1923, there exists a legal obligation on the employer to pay compensation to workmen involved in accidents arising during the course of their employment. The prerequisites for payment of compensation to such workmen are as follows:

- Personal injury must be caused.
- There must be temporary, total or partial disablement due to an accident, which also includes occupational diseases.

The State Government is to appoint a Commissioner to decide the liability of an employer to pay compensation, the amount and duration of compensation, among other issues. An appeal may lie to the High Court in case

the applicant is grieved with the Commissioner's orders. Compensation is decided on the nature of injury caused. Where the injury from an accident results in the death of the workman, the minimum compensation payable is around Rs.50,000 and the maximum may extend to Rs. 3 lakhs. In case of permanent total disablement and permanent partial disablement, compensation may extend to Rs.60,000, depending on its nature. Further the amount of compensation is calculated on the wage-group to which the workman belongs and the time-period for which he has worked. There is no comprehensive law on occupational health, though the Central Government has in its various policies stressed the need to effectively implement the existing laws. A broad insight into the existing occupational health laws in India explicably brings out the verity of non-implementation of such laws, considering the present scenario with respect to the workmen's health conditions. The workmen in dangerous employments are exposed to substances like asbestos, chromium and silica dust and are vulnerable to respiratory diseases and cancer.

There is need to preserve the good health of workmen by ensuring safe and healthy working conditions and provide prompt compensation on account of injury or occupational disease. Consumer law in India recognizes two types of patients, such as paying and non-paying patients. Most of the Government hospitals in India have separate paying wards. The paying wards are mainly designed for affluent patients. However, the general wards are developed for the poor patients, who cannot afford the treatment cost. You can smell it a mile off because they are so badly kept. In fact, they are kept worse than cattle sheds. So many things make it almost poisonous for poor patients to opt for the non paying wards apart from nurses who scream at them and doctors who don't even look their way. Typically, these wards are populated with flies, dirt, and garbage and sometimes even sewage because nobody bothers to clean these wards. An important question in consumer law is that whether a non-paying patient admitted in the general ward, can be considered as a consumer under the Consumer Protection Act, 1986. Consumer Law: Poor Patients cannot be
denied Consumer Protection, Says SC the ambiguity pertaining to the recognition of a non paying patient, as a consumer was discussed in a landmark case, *Indian Medical Association Vs. V.P. Shantha and Others*.[218] In this case, the Supreme Court held that in a Government or Non-Government hospital/health centre/dispensary/nursing home, where the patients in position to pay, are charged and patients who cannot afford to pay, are rendered free services, this falls under the purview of the *Section 2(1)(o)* of the Act. Also, the Court held that free service would also be considered as 'service' and the receiver as 'consumer', under the Act. Further, it is not governed by the fact that whether the service provided was free or charged. Also, the Court held that to rule otherwise, would mean that the Act is applicable to only those who can afford to pay the charges. Patients, who cannot afford to pay, would be deprived of the protection, under the Act. It further, said that such patients need the protection of consumer laws even more. Federal law requires that all individuals receiving home care services be informed of their rights as a patient. Following is a model patient bill of rights the National Association for Home Care (NAHC) has developed, based on the patient rights currently enforced by law.

3.4. Consumer Health Law-National Level

The Government of India has passed certain laws to protect the rights of the consumer. Under these laws any consumer with a genuine grievance can file a formal complaint against a trader and take him to Court. These laws are briefly discussed below.

- Agricultural Produce (Grading and Marking) Act: Under this Act, the AGMARK standardization mark is given by the Government to agricultural or farm produce (e.g. wheat flour, gram flour, honey, spices, ghee, etc). This law ensures that these products are tested for purity, graded according to their quality and packed suitably.

- **Drugs and Cosmetics Act:** It regulates and ensures that only standard quality medicines and cosmetics are sold in the market with a proper cash memo or bill.

- **Prevention of Food Adulteration Act:** This law protects the consumer against adulterated and spoilt food stuff.

- **Essential Commodities Act:** As per this Act, the Government ensures that all the goods and services essential to life are available in the market at a reasonable price. The Government list of essential commodities includes items like cereals, pulses, sugar, raw jute, cotton and woolen textiles, medicines, paper, coal, petrol and petroleum products, iron, steel, cattle fodder, etc.

- **Monopolies and Restrictive Trade Practices (MRTP) Act:** This act protects consumers from being exploited by unfair trade practices like giving false or misleading statement and advertisements, sale of substandard products, hoarding and black marketing. It also prevents traders from conducting any contest or lottery with no intention of giving the promised prizes.

- **Standards of Weights and Measures Act:** This Act prevents the use of non-standard weights and measures. It makes it compulsory for all products to bear a detailed label. You will learn about labels later.

- **Fruit Product Order (FPO):** Under this Act, it is compulsory for all manufacturers of fruit and vegetable products to maintain a certain standard in respect of quality, packing, labeling and sanitary conditions during production, storage and sale. It ensures that safe canned, preserved and processed products like pickles, jams, juices, squashes, frozen vegetables and fruits are sold in the market. All products that meet the FPO specification are given the FPO standardization mark.

- **Consumer Protection Act (CPA/COPRA):** This Act clearly defines consumer rights and responsibilities. It seeks to provide consumers with quick, easy and inexpensive redressal of their genuine
complaints. Under this Act, the consumers can file complaints against goods and services provided by not only private companies but also the Government departments. For the legal settlement of complaints, Courts have been set up at the District, State and National level. Such courts are called Consumer Redressal Forums.

- **Bureau of Indian Standards (BIS) Act**: Under this Act, the quality certification mark ISI is given to those products which meet the specifications and standards set by the Bureau of Indian Standards. The BIS gives specification for products in terms of material used, method of production, labeling, packing, storage and sale. For quality control the BIS conducts surprise checks of the ISI marked products. This Act also prohibits the improper use and misrepresentation of the ISI mark. Examples of products bearing ISI mark are ghee, biscuits, detergent, pressure cooker, electric iron, immersion rod, geyser, LPG cylinders, etc.

**Standardization Marks**:

- A standardization mark is a mark given to a product which meets
- Certain standards with respect to the quality of the product in terms
- Of material used, method of manufacture, labeling, packing, sale and
- Performance”.
- **ISI Mark**: This mark is given by the BIS over specifications and method of testing products. 15000 standards covering a variety of vegetable, fruit and meat products, processed foods, vanaspati, soaps, detergents, paper, paint, nonstick utensils, electrical goods, stoves, LPG cylinders, cement etc. are given ISI marks
- **AGMARK**: So far, standards have been prescribed for about 142 agricultural, horticultural, forest and livestock products, like wheat floor, pure ghee, honey, and spices.
• **FPO**: This mark requires all manufacturers of fruit and vegetable products to acquire a license for their production and sale after meeting the FPO standards. Products like jams, pickles, squashes, juices and ketchups are given FPO mark.

• **Wool Mark**: A standard mark of International Wool Secretariat was established in 1949. It promotes pure wool products. It makes it necessary for manufacturers to mention the amount and identity of other fibers used along with pure woolen the label of wool and woolen garments.

• **ECO Mark**: It has been launched recently by the BIS. It is given to those products which not only meet ISI standards but are also recyclable and save energy; that is, they are environment friendly. Such products help in reducing environmental pollution. Nowadays you might have observed a green or red dot on the label and advertisements of vegetarian and non-vegetarian food products. This mark is given in the form of a dot enclosed in a square. When this symbol is green, it is a vegetarian product, whereas a red symbol indicates the use of non-vegetarian ingredients. This symbol is useful to identify vegetarian and non-vegetarian food products according to your eating habits. This mark is additional information provided by the manufacturers to help the consumers make an informed choice. You can see this symbol on certain medicines also.

The standardization marks discussed above have been laid down by the Government to prevent poor quality, duplicate and unsafe products from coming into the market. Thus, they help you to make wise choices without wasting your time, energy and money.
3.4.1. Possible solutions

The general consumer education should be need-based. It should attempt to teach a value system, which goes beyond acquiring skills, wise use of money and possessions and effective complaining. Such a programme might include care for the environment, duties and obligations as well as rights, concern for the disadvantaged, and an awareness of the finite resources of the economy. This would require motivation on the part of different players: business executives, bureaucrats, planners, teachers, students, consumer organizations etc. The following administrative and legislative measures would be necessary for effective implementation:

- Consumer education programmes through co-operation with other branches of the Government like the Department of Education and the business chambers;

- Specific consumer education resource books, particularly for children and women; pictures and sketches may be incorporated for easier understanding;

- Budgetary provisions and institutional mechanisms to be provided to conduct training on a regular basis; and

- Consumer organizations and other NGOs are to be provided resources to carry this out effectively, besides involving the target beneficiaries in planning and implementing the programmes;

The Department of Consumer Affairs should monitor and evaluate the existing mechanisms, including the present Consumer Information Centers regarding their effectiveness as well as constraints. For this a study could be conducted by an independent agency.
3.5. Other legislative protection Consumers

A number of laws have been passed by the Government of India over the years to protect the interest of consumers. A brief outline of the purpose of these laws in given below.

3.5.1. Agricultural Products (Grading and Marketing) Act, 1937

This Act provides for grading and certifying quality standard of agricultural commodities which are allowed to be stamped with AGMARK seal of the Agricultural marketing department of the Government.

3.5.2. The Agricultural Produce (Grading and Marking) Act, 1937

With a view to provide for the grading and marking of agricultural and other produce, the Agricultural Produce, (Grading and Marking) Act, 1937 was enacted. The Act of fixing a grade designation mark in a manner calculated to cause a person to believe that the goods contained in the receptacle are of definite nature or quality is an offence under the Act. By an amendment of the Act in 1986, a definition of midgrade article has also been incorporated in the definition Section of the Act, providing a penalty for selling midgrade articles.

3.5.3. The Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 was enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. In order to give effect to the recommendations of the Drugs Enquiry Committee insofar as they relate to the matter with which the Central Government was concerned, an Act was passed by the Governor General in 1949. The select committee appointed by legislative assembly was of the opinion that a more comprehensive measure, provided for the uniform control of manufacture and distribution of drugs, as well as of import was desirable.
3.5.4. Industries (Development and Regulation) Act, 1951

This Act provides for control over production and distribution of manufactured goods. According to this Act, the central Government may order investigation of any industry, if it is of the opinion that there has been substantial fall in the volume of production, or a marked decline in the quality of a product, or any unreasonable rise in price. After due investigation, the Government may issue directions to set things right. If the directions are not acted upon, the Government may take over the concerned undertakings.

3.5.5. Prevention of Food Adulteration Act, 1954

This Act provides for severe punishment for adulteration of food articles. In the case of sale of adulterated food which is injurious to health and likely to cause death, life imprisonment with a minimum fine of Rs 3000 may be payable. Food inspectors are appointed and they have powers to lift samples and send them for analysis. Penalties are also provided under the act for offences committed by persons with regard to manufactures, import, storage, sale and distribution of adulterated food articles.

3.5.6. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

This Act has been enacted with a view to control the advertisement of drugs in newspapers or magazines or otherwise relating to alleged cures for venereal diseases, sexual stimulants and alleged cures for diseases and conditions peculiar to women, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities, the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 was enacted. These advertisements had a tendency to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances or to resort
3.5.7. The Prevention of Food Adulteration Act, 1954

To eradicate the evil of adulteration of food which is an antisocial evil and for ensuring purity in the articles of goods, the Prevention of Food Adulteration Act was passed. The Prevention of Food Adulteration Act, 1954 intends to,

- Prevent adulteration and misbranding of food,
- To provide for adequate punishment to food adulterators,
- Secure purity of food to maintain public health,
- Regulate to some extent, the consumer supplier relations,
- Warn producers or manufacturers of food to ensure safety in the realm of food,
- Ensure that food which the public can buy is, inter-alia, prepared, packed and stored under sanitary conditions so as not to be injurious to the health of the people consuming it,
- Forewarn the vendor of adulterated food from continuing to perpetuate the mischief, and
- Protect the lives of innocent persons who without doing wrong to the seller enable the seller of food to make a profit at the expense of consumers' health.

Under the Act, the offence of adulteration is defined so comprehensively that it is impossible for adulterators to escape from the offence. Thus, the broad scheme of Act is to prevent in the interest of the health of the community, the supply of adulterated food stuffs by a person as part of his business activities by prohibiting the same and penalizing violation. It covers a wide range of food articles and defines the standard of quality of a large variety of food stuffs in
the form of various control orders. The penalties provided under the Act are meant to have a deterrent effect on the offenders.

3.5.8. Essential Commodities Act, 1955

Under this Act, the Government has power to declare any commodity as essential in the public interest. Thereby the Government can control the production, supply and distribution of the trading of such commodities. It also provides for action against anti-social activities of profiteers, hoarders and black-marketeters.

3.5.9. The Standards of Weights and Measures Act, 1956

This Act provides for the issue of standard weights and standard measures of length throughout the country. ‘Metre’ has been specified as the primary unit of measuring length, and ‘kilogram’ as the primary unit for measuring weight. Before this act came into force, different system of weights and measures were used in different parts of the country like ‘pound’, ‘Chhatak’ and ‘Seer’ as weights, yard, inch and foot for length, etc. These differences provided opportunities for traders to exploit the consumers.

3.5.10. Monopolies and Restrictive Trade practices Act, 1969

Under the provisions of this Act, as amended in 1983 and 1984, consumers and consumer groups can exercise their right of redressal by filing complaints relating to restrictive and unfair trade practices. The Government has constituted the MRTP commission which is empowered to deal with consumer complaints after due investigation and enquiry. The Commission has power to award compensation for any loss or injury suffered by consumers.
3.5.11. Prevention of Black-marketing and Maintenance of Essential Supplies Act, 1980

The primary objective of this act is to provide for detention of persons with a view to prevention of black-marketing and maintenance of supplies of commodities essential to the community. The maximum detention for persons acting in any manner against the intention of the act can be imprisoned up-to 6 months.

3.5.12. Bureau of India Standards Act, 1986

The bureau of Indian Standards has been set up under this Act, replacing the Indian Standards Institution (ISI), to protect and promote consumer interest. It has two major activities: formulation of quality standards for goods and their certification through the BIS certification marks scheme by which manufacturers are permitted to use the standardization mark (ISI) on their products after due verification of conformity with prescribed quality standards of safety and performance. The Bureau has set up a consumer affairs department to create quality consciousness among ordinary consumers. There is also a public grievances cell to which consumers can make complaint about the quality of products carrying ISI mark.

3.6. Right to Redressal

The socio-political dimension of the issue stems from the fact that in a stratified society (polity) like India, vulnerable sections may not have real access to justice. This right includes the right to receive compensation for misrepresentation of shoddy goods or unsatisfactory services and the availability of acceptable forms of legal aid or redress for small claims wherever necessary.
3.7. Liability under Consumer law in India

The Guidelines provide a framework for Governments to use in elaborating and strengthening consumer protection policies and legislation. One of the major objectives of the Guidelines is that Governments should establish or maintain legal and administrative measures to enable consumers to obtain redress through formal and informal procedures that are expeditious, fair, inexpensive and accessible. Another objective is to encourage all enterprises to resolve consumer disputes including advisory services and through informal complaint handling mechanisms. The third objective is that the information on available redress and other dispute resolution procedures should be made available to the consumers on a regular basis. In India, until the Consumer Protection Act (COPRA) was enacted in 1986, consumers had to rely upon a number of legislations but none provided an effective remedy against violation of their rights. COPRA was designed with the specific purpose of protecting consumers' rights and providing a simple quasi-judicial dispute resolution system for resolution of complaints. The purpose of the Act is to take the system of redressal to the peoples' doorsteps.

Furthermore, COPRA envisages the establishment of Consumer Protection Councils at the Centre and in the states whose main objective is to promote and protect the rights of consumers. These Councils are advisory bodies and meet once a year with a generalized agenda. Under COPRA, three-tier quasi-judicial machinery at the National, State and District levels has been established. Apart from the COPRA, redressal mechanisms are incorporated under the MRTP Act, 1969, Indian Arbitration Act, 1940, and through complaint mechanisms provided by various businesses. However, despite the existence of such a holistic law, the situation in India with respect to consumers' redressal, is constrained with problems like delays in judgment, non-compliance with orders etc. The first and foremost problem is that most State Governments do not evince the requisite enthusiasm and attention in promptly implementing the provisions of COPRA by carrying out their mandatory
obligation of establishing District Forums and State Commissions. Secondly, even with the existence of a justice delivery system, the system is plagued by systemic problems resulting in inordinate delays. Apart from these, consumers are also reluctant to make use of the redressal system. One major reason is the non-availability of proper guidance from voluntary consumer organizations and fear of exploitation by lawyers. Lately the redressal system has become overloaded with inordinate delays in taking decisions, including at the point of admission of a complaint. The consumer Courts are becoming like Civil Courts, with Presidents asking for a more formal approach. Equipment and facilities are also a problem in many cases. Sometimes these forums have even asked complainants to engage lawyers, even when it is not really required. There have been instances when the National Commission has taken more than five years to decide cases. Recently, the National Commission was referring cases for arbitration and the Supreme Court had to intervene to curb this illegitimate practice. All these factors have resulted in frustration among the consumers.

The appointment, of members is another problem. In the past, members were appointed on the basis of their connections rather than merit. Now the system has improved substantially due to an amendment in the law requiring a selection committee to appoint them. Advertisements are also being released for better selection. However, due to very poor compensation packages, good people are not attracted to these positions. In the case of retired judges or civil servants wishing to be appointed, it is not such a problem because the allowances that they get are in addition to their pensions. However, in many cases the appointments of the State Commission Presidents do not last for more than two years on an average.

Role of Non-Governmental Organizations: Non-Governmental Organizations (NGOs) are those associations of people which aim at promoting the welfare of the public without any profit motive. They are voluntary bodies having a Constitution and rules of their own, and are free from Government interference. They depend on donations and partly on Government assistance.
NGOs dealing with consumer problems are known as consumer associations or consumer organizations. The role of NGOs has become increasingly more significant over the last two decades. There are now more than 800 such organizations in India. These organizations are registered under the Societies Registration Act or the companies Act or as Charitable Trusts. NGOs have undertaken various activities as part of the consumer movement. They perform several functions, like:

- Create awareness about consumer rights and educate the general public about consumer problems and remedies through seminars, workshops and training programs
- Provide legal aid to consumers by way, of assistance in seeking legal remedy.
- Undertake advocacy of consumers' point of view as representative members of consumer protection councils and others official boards.
- Arrange comparative testing of consumer products through their own testing apparatus or accredited laboratories so as to evaluate the relative qualities of competing brands and publish the test results for the benefit of consumers to become informed buyers.
- Publish periodicals and journals to disseminate information among readers about consumer problems, legal reporting and other emerging matters of interest. Most of these periodicals do not accept advertisements from business firms.
- Make suggestions and recommend steps which Government authorities should consider in policy making and administrative measures adopted in the interest of consumers.
- Some NGOs have successful used Public Interest Litigation (PIL) to enforce consumer rights in several cases. In other words, NGOs have filed cases in law Courts in the interest of the general public, not for any individual
• **Consumer Institutions for Health Safety:** According to the guidelines issues by the United Nations for the protection of the consumers the following institutions/Councils have been established for the purpose of health safety.

• **Consumer Coordination Council (CCC):** Established in 1993 under the Societies Registration Act 1860, Consumer Coordination Council (CCC) has been a stalwart proponent of good governance. In 1996, CCC launched a national campaign on citizens' charter to implement transparency, accountability, standards of service and a public grievance redressal system at the Government level. CCC has made notable achievements in influencing the making of laws, Governmental policy decisions, and providing administrative infrastructure for protecting consumer interest. It also serves as an umbrella organization for all other consumer NGOs in India.

• **Consumer Guidance Society of India:** Consumer Guidance Society of India (CGSI) was founded in 1966 to eliminate all possible forms of consumer exploitation. It is one of the oldest consumer organizations in the country and has been instrumental in lobbying the Government to pass a Consumer Protection Act, 1986. It has been a member of Consumers International for several years and 70% of the consumer complaints received by it have been resolved. CGSI has been instrumental in promoting consumerism by publishing its flagship monthly periodical "Keemat", performing product testing, providing consumer education at the grass root level such as schools, and giving legal guidance to consumers with grievances. It won the national award for consumer protection in 1991 for its long, dedicated and effective services to consumers.

• **Citizen Consumer and Civic Action Group:** Established on October 7, 1985, Citizen Consumer and Civic Action Group (CAG) has grown out to be one of the country's leading consumer advocacy groups. Instrumental in
running campaigns for greater access to information, improved functioning of public utilities, greater transparency and accountability in Governmental and private sector functioning, and protection of our open spaces and natural environment, CAG plays a vital role in the growth of consumerism in our country. CAG specializes in attending issues that affect the common man's life such as lack of hygiene, pollution of our natural resources, inaccessible healthcare facilities, corruption and lack of accountability for the Government revenue from tax sources. CAG has been a member of Consumers International since 1990.

- **Association for Consumers Action on Safety and Health:** Association for Consumers Action on Safety and Health (ACASH) is a consumer organization that focuses on health-related consumer issues. It has programs aimed at the general public promoting consumer rights and overall dispersion of information regarding consumer safety. Founded by a group of doctors, lawyers and other eminent personalities, ACASH today helps consumers in India through education and awareness, training, developing IEC (Information, Education and Communication) material, networking, advocacy and lobbying and follow-up action. A member of Consumers International since 1990, ACASH is also a member of Global link, International Network of Women Against Tobacco (INWAT), International Baby Food Action Network (IBFAN), International Lactation Consultant Association (ILCA), World Alliance for Breastfeeding Action (WABA), Health Action International (HAI), Breastfeeding Promotion Network of India (BPNI), All India Drug Action Network (AIDAN), Bureau of Indian Standards (BIS) and Voluntary Health Association of India (VHAI).

- **Consumer Education and Research Centre:** Consumer Education and Research Centre (CERC) protects consumer interest in India through consumer research, campaigns through media, creation/monitoring/enforcement of effective consumer laws, consumer
advocacy and information dissemination. An apolitical outfit, CERC has research facilities recognized by the Indian Government, and the United Nations has approved CERC as an NGO. CERC's mission includes environmental protection, creating transparency and accountability in the public and private enterprises and agencies in our country, resolving individual consumer complaints, ensuring consumer safety through product research, consumer education, awareness campaigns and product test results dissemination.

- **Consumer Protection Council:** Not to be confused with the Governmental bodies established as per the Consumer Protection Act 1986, the Consumer Protection Council (CPC) is a consumer organization that is non-affiliated to any statutory agency. Instituted in Ahmadabad, the CPC has been instrumental in undertaking consumer issues such as consumer safety, traffic safety and pedestrian safety. It has effectively and successfully pursued legal battles against Governmental agencies when they neglect or fail to carry out their duties to the tax payers. CPC has been a member of Consumers International since 1986.

- **Consumer Unity and Trust Society:** Consumer Unity and Trust Society (CUTS) originated from a rural background in Rajasthan. It operates five program centers in India, an advocacy center in New Delhi, and resource centers in several international locations. CUTS's consumer work is focused on consumer protection and consumer safety. With about 20,000 square feet office space, 140 employees, and affiliation to / recognition from major national and international consumer agencies, CUTS is truly equipped to be the champion of consumer causes in our country. It publishes a monthly 'Gram Gadar' which has been effective in ensuring justice for oppressed social masses. CUTS has been a member of Consumers International since 1990.

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• **Consumers Association of India:** Consumers Association of India (CAI) was established on the world consumer rights day to be a powerful lobby for the consumer. It has successfully and determinately taken up the mission to spread awareness among consumers, educate them about their responsibilities and rights and to ensure that the consumers' voices can be heard. In the past six years, CAI has successfully settled over 98% of the 7500 complaints it has received through arbitration. For the remaining 2% CAI has supported the consumer in pursuing the complaint through the Indian legal system. CAI has been a member of Consumers International since 2003.

• **Consumers' Forum:** Consumers' Forum is one the consumer organizations that existed in India long before the Consumer Protection Act 1986 was passed. The mission of the organization, at its start, was to promote consumerism by making aware, training and educating the consumers on their rights. This was particularly necessary when there were no stalwart laws in our country to protect the consumers. The forum provides free advice to consumers, conducts brainstorming sessions on matters related to consumer protection and ensures the representation of consumers in national, State and district level consumer Courts and legally mandated consumer protection councils. Consumer Forum has been a member of Consumers International since 1996.

• **Mumbai Grahak Panchayat:** Mumbai Grahak Panchayat (MGP), or Bombay Consumer Forum, started as an agitation against the increase of consumer prices near festival season for fair and free distribution of consumer goods. The distribution system that flourished was registered under the Indian Societies Registration Act 1960 and Indian Public Trust Act 1950 in the name of MGP. MGP promotes consumerism by bringing the consumer to the forefront of the logistics and supply chain of consumer goods as decision makers, executors and monitors. MGP's
primary objectives include organizing the consumers for common causes, educating them and protecting consumer interest through legal and other means.

- **VOICE Society:** Voluntary Organization in Interest of Consumer Education (VOICE) strives to be the voice of and for the consumer that the Governments and other statutory / regulatory bodies of the country seldom hear. The primary focus of this NGO is to establish informed consumers in India. Information dispersed to consumers through VOICE includes corporate negligence / misconduct on issues such as consumer safety or customer satisfaction, your rights as a consumer to get value for your money, and the recourse that can be taken if your consumer rights are defied. Founded by students and teachers of the University of Delhi in 1983, it was registered as charitable public trust in 1986, the same year the Consumer Protection Act, 1986 came into being.

- **Grahak Shakti:** Grahak Shakti works towards creating consumer awareness by organizing various programs, street plays and on shows such as ‘Hello Geleyere’. The organization has undertaken a number of surveys like the one on spurious drugs in coordination with the Drugs Control Department – Government of India. Its campaign on credit cards and effective liaison with the regulator was an effective way to warn the erring bankers to conduct business ethically. It also participated in joint raids in coordination with the Department of Legal Metrology and some oil companies to check malpractices related to weights and measurement, adulteration and pilferage.

3.7.1. Liability under the Consumer Protection Act

In 1995, the Supreme Court decision in *Indian Medical Association Vs. VP Shantha* brought the medical profession within the ambit of a 'service' as
defined in the Consumer Protection Act, 1986\textsuperscript{219}. This defined the relationship between patients and medical professionals as contractual. Patients who had sustained injuries in the course of treatment could now sue doctors in 'procedure-free' consumer protection Courts for compensation. The Court held that even though services rendered by medical practitioners are of a personal nature they cannot be treated as contracts of personal service (which are excluded from the Consumer Protection Act). They are contracts for service, under which a doctor too can be sued in Consumer Protection Courts. A 'contract for service' implies a contract whereby one party undertakes to render services such as professional or technical services to another, in which the service provider is not subjected to a detailed direction and control. The provider exercises professional or technical skill and uses his or her own knowledge and discretion. A 'contract of service' implies a relationship of master and servant and involves an obligation to obey orders in the work to be performed and as to its mode and manner of performance. The 'contract of service' is beyond the ambit of the Consumer Protection Act, 1986, under \textit{Section 2(1)(o)} of the Act. The Consumer Protection Act will not come to the rescue of patients if the service is rendered free of charge, or if they have paid only a nominal registration fee. However, if patients' charges are waived because of their incapacity to pay, they are considered to be consumers and can sue under the Consumer Protection Act.

3.7.2. Liability under tort law

Under civil laws, at a point where the Consumer Protection Act ends, the law of torts takes over and protects the interests of patients. This applies even if medical professionals provide free services. In cases where the services offered by the doctor or hospital do not fall in the ambit of 'service' as defined in the Consumer Protection Act, patients can take recourse to the law relating to negligence under the law of torts and successfully claim compensation. The

\textsuperscript{219} Indian Medical Association Vs. V P Shantha AIR 1996 SC 550: (1995) 6 SCC 651
onus is on the patient to prove that the doctor was negligent and that the injury was a consequence of the doctor's negligence. Such cases of negligence may include transfusion of blood of incorrect blood groups, leaving a mop in the patient's abdomen after operating, unsuccessful sterilization resulting in the birth of a child, removal of organs without taking consent, operating on a patient without giving an anesthesia, administering wrong medicine resulting in injury, etc.

3.7.3. Liability under criminal law

In certain cases, negligence is so blatant that it invites criminal proceedings. A doctor can be punished under Section 304A of the Indian Penal Code (IPC) for causing death by a rash or negligent act, say in a case where death of a patient is caused during operation by a doctor not qualified to operate. According to a recent Supreme Court decision, the standard of negligence required to be proved against a doctor in cases of criminal negligence (especially that under Section 304A of the IPC) should be so high that it can be described as 'gross negligence' or 'recklessness', not merely lack of necessary care. Criminal liability will not be attracted if the patient dies due to error in judgment or accident. Every civil negligence is not criminal negligence, and for civil negligence to become criminal it should be of such a nature that it could be termed as gross negligence. Very rarely can a doctor be prosecuted for murder or attempt to murder as doctors never intend to kill their patients, and hence do not possess the required level of guilty intention. When doctors administer a treatment involving the risk of death, they do so in good faith and for the patient's benefit. A doctor can also be punished for causing hurt or

220 Philips India Ltd. Vs. Kunju Pannu A.I.R. 1975 Bom. 306
221 Kalra Satyanarayana Vs. Lakshmi Nursing Home 1 (2003) CPJ 262
222 Achutrao Haribhao Khodwa Vs. State of Maharashtra (1996) 2 SCC 634
224 Lakshmi Rajan Vs. Malar Hospital III (1998) CPJ 586
226 Spring Meadows Hospital Vs. Harjol Ahluwalia A.I.R. 1998 SC 1801
227 Suresh Gupta (Dr) Vs. Govt. of NCT of Delhi (2004) 6 SCC 422
grievous hurt under the IPC. However, Sections 87, 88, 89 and 92 of the IPC provide immunity from criminal prosecutions to doctors who act in good faith and for the patient's benefit. But the defence must prove that the doctor acted in good faith and for the patient's benefit. For example, a doctor who consciously or knowingly did not use sterilized equipment for an operation cannot be said to have acted in good faith.

3.7.4. Liability under Civil Law

The aggrieved patients can file a case against the doctor for monetary compensation for which the patient to pay Court fees that depends upon the compensation sought. Probably, due to near acceptance of medical negligence as inevitable by the patients and their relatives or local settlements, not many cases have reached the Apex Court of law in the past. The legal remedies are based on the law of Torts, Section 1-A of the Fatal Accidents Act, 1855 and the Section 357 of Cr. P.C., 1973. But to avail it, an aggrieved patient have to wait for years and spend considerable amount of money on litigations. The Civil Court cases take care the route of Sub-Court, District Court, High Court and Supreme Court.

3.7.5. Monopolies and Restrictive Trade Practices Act (MRTP), 1969

This Act is the precursor of Consumer Protection Act, 1986. Before the advent of Consumer Protection Act, 1986, this Act was the only resource to consumers against the unfair trade practices. The commission that looks into the disputes brought under MRTP Act based in New Delhi.

3.7.6. Public Interest Litigation (PIL)

An aggrieved patient can directly approach the High Court or the Supreme Court when his/her grievances was not properly redressed. PILs are usually resorted when public health programmes are not implemented properly.
Some of the landmark judgments on Supreme Court on health are the result of PILs.

3.7.7. The Fatal Accidents Act, 1855

Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such, as would (if death had not ensued) have entitled the party injured to maintain an action and recover damages in respect thereof, the party who would have been liable if death had not ensued shall be liable to an action or suit for damages, notwithstanding the death of the person injured, and although the death shall have been caused under such circumstances as amount in law to felony or other crime. A physician can be charged with criminal negligence when a patient dies from the effects of anesthesia during an operation or other kind of treatment, if it can be proved that the death was the result if malicious intention, or gross negligence. Before the administration of an anesthesia or performance of an operation, the medical man is expected to follow the accepted precautions. In such cases, the physician should be able to prove that he used reasonable and ordinary care in the treatment of his patient to the best of his judgment. He is, however, not liable for an error judgment.

The law expects a duly qualified physician to use that degree of skill and care which an average man of his qualifications ought to have, and does not expect him to bring the highest possible degree of skill in the treatment of his patients, or to be able to guarantee cures. It has long been recognized that criminal liability of a physician may result from a high degree of negligent conduct. What the law calls criminal negligence is largely a matter of degree; it is incapable of a precise definition. To prove whether or not it exists is like chasing a mirage. It requires that any of the following to be established in a case of criminal medical negligence. "Gross Lack of competency or gross inattention, or wanton indifferences to the patient’s safety, which may arise from gross ignorance of the science of medicine and surgery or through gross
negligence, either in the application and selection of remedies, lack of proper skill in the use of instruments and failure to give proper attention to the patient.”

3.8. Conclusion

Every member of society, young or old, rich or poor is a consumer of some goods or services from the time of his/her birth to death. It is therefore necessary that every consumer not only gets a full measure of the value for money he/she spends, but also that his/her interests are fully safeguarded in terms of goods without defects are safe for use and services without any deficiency. It is recognized internationally and nationally that the providers of goods and service whose major aim is to understand their profits, often do so at the cost of consumer either by selling defective or substandard goods or provide services which are not up to expectations but deficient in some way or other. Empowering them implies strengthening them both individually and collectively against malpractices. Also from national and international scenario, consumer, education, health, information, law and rights are interlinked with each other and these concepts are very much essential to build a society of critically aware consumers from patient perspective