Chapter 2
Review of Literature

The topic of the study ‘A Study of Legal Regime on Pharmaceuticals in Environment: International and National Perspectives’ is very wide encompassing the aspects concerning pharmaceutical sciences, environmental science and technology, and juridical sciences. The chapter describes the analysis of work already done in the area of PiE in its multi-dimensional perspectives. The researcher has divided the review of literature into two parts - firstly, the literature on scientific and technical aspects of the issue and other part presents the assessment of legal literature pointing out the gaps resulting into sustenance of problem of PiE. The literature available in the form of guides, manuals, articles, research papers, books, notifications reviewed by the researcher.

2.1 Literature on Scientific and Technical Aspect

‘Pollution from Drug Manufacturing’s: Review and Perspectives’ by D.G. Joakim Larsson is pioneering work that portrays causes and methods concerning industrial emissions of pharmaceuticals and the effects associated with exposure to such effluents. It enunciates that risk associated with exposure concentration from manufacturing facilities is wider and different as from the excretion activities. It presents that emission from drug manufacturing as a source of a higher degree of discharges affecting environment and cases have also been reported. The discovery of estrogens in sewage effluents as a cause of the feminization of fish. Discovery of diclofenac residues in cattle carcasses resulting into the decline of vulture population in India and Pakistan sparked the issue of pharmaceuticals in the environment. The studies conducted in the Patancheru-Bolaram region furnishes that concentration of ciprofloxacin reported in PETL is 4500 times higher than reported in Australia.¹ This study does take care of industrial emission generated by manufacturing units. Certain pharmaceuticals like diclofenac, estradiol were recently added to ‘watch list’ within the European Water Framework Directive. Besides, the author has pressed upon the need to develop efficient

wastewater technology which is essential to ensure safe discharge levels from drug manufacturing industries.²

The edited work titled ‘Pharmaceuticals in Environment’ by R.E. Hester and R.M. Harrison with the contribution of David Taylor, Beoit Roig and Vince D’Aco, Sally Gaw, Kevin Thomas and Thomas H. Hutchinson, Daniel J. Caldwell and others chrevolve around the idea that pharmaceuticals undoubtedly perform a vital role in the treatment and prevention of disease in living creatures. The work addresses the concern towards PiE in the form of residues from these pharmaceuticals released into the environment via processes of manufacturing, use and disposal. The contributions of the above authors through various chapters explain in detail how the pharmaceutical residues enter in surface waters, drinking water, sediments and the marine environment.³

C. Visvanathan’s work ‘Hazardous Waste Disposal’ has presented the techno-commercial aspects for disposing of the hazardous waste. Advocating for the importance of the waste disposal, he opines that adequate waste management is vital for industrial growth based on scientific development. He enumerated various importance factor contributing to the success of waste disposal programs such as waste minimization, collection, proper storage, careful transportation, use of incinerators, management of landfill, off-shore, immobilization etc. Visvanathan also worked upon the cost factors for waste disposal method and presented the findings on maintenance cost, technical know-how, capital etc.⁴ The author discusses methods of waste disposal in full depth, however, any specific mention as to waste generated by pharmaceutical industries is not mentioned.

‘Effective Wastewater Treatment in the Pharmaceutical Industry’ by Manfred Martz demonstrates effective implementation of wastewater treatment activities in pharmaceutical industry. Efficient wastewater treatment process is helpful in

² D.G. Joakim Larsson, “Pollution from Drug Manufacturing’s: Review and Perspectives” Biological Sci. (2014); Also available at http://rstb.royalpublishing.org/content/369/1656/20130571 (Visited on November 27, 2016).
reducing the risk of water defilement from activities like R & D, manufacturing of API or final product. Establishment of wastewater treatment plants (WWTPs) is important for the pharmaceutical industry as Municipal WWTPs are not well equipped to remove micro-pollutants altogether and it is very difficult to segregate them if these get mixed with other wastewaters.

The study points out that there are two basic conditions for effective treatment of wastewater from pharmaceutical units. These are the treatment of pharmaceutical wastewater which is an integral part of the manufacturing process and technical expertise required for developing effective, integrated and economical treatment process. The author takes into account case analysis of two pharmaceutical units for the purpose of the study. One unit is engaged in the production of contraceptives containing synthetic hormone and other in the manufacturing of X-ray Contrast Media containing Iodine. The author came to the conclusion that it is the primary responsibility of the industry to ensure environment protection at each and every step of production process. To minimize the adverse environmental impact caused by micro-pollutants, it is required to treat wastewater at the point of generation. The regulation governing manufacturing process should compel the manufacturers before granting them permission to initiate the process. The author advocates 'precautionary approach' in the management of chemical residues. The study examines waste minimization process through adequate wastewater treatment technology and other measures to limit the generation of waste during production process such as adoption of green pharmacy approach, environment risk assessment etc.

Chanti Babu Patneedi and K. Durga Prasadu’s work titled ‘Impacts of Pharmaceutical Wastes on Human Life and Environment’ underscores the toxicity, health hazards and risk assessment of pharmaceutical pollutants. It sensitizes that traditional methods used for the treatment of wastewater are not advanced enough to remove pharmaceutical pollutants completely. Pharmaceutical facilities

generate a huge amount of toxic waste in the form of solids, biodegradable and non-biodegradable wastes, wastewaters etc. and discharge into water channels either without any treatment or partial treatment. The work incorporates the findings of various studies showing the presence of antibiotic compounds in the drinking and groundwater. It is estimated that higher concentrations of antibiotics can result in a change in microbial community structure. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), like ibuprofen, naproxen and diclofenac are used widely. Therefore, amount of these residues is found to be higher in sewage, surface water and groundwater system.\(^7\)

As far as health risks are concerned, it is learned that the long-term exposure of lower concentration of complex pharmaceutical mixtures on stream biota may result in acute and chronic damages\(^8\), behavioral changes,\(^9\) accumulation in tissues\(^10\), reproductive damage and inhibition of cell proliferation.\(^11\) Various studies demonstrated that fish subjected to wastewater effluents can show reproductive abnormalities. Fish exposed to trace levels of birth control pharmaceuticals exhibit dramatic decreases in reproductive rate.\(^12\) Human health and environment are


greatly affected by pharmaceutical effluents especially in the vicinity of pharmaceutical industrial zones. Different classes of pharmaceutical compounds like analgesic, contraceptive, antibiotics, steroids and hormones etc. have been detected in water samples of drug manufacturing units. There is a need for regular monitoring of the concentration of pharmaceutical compounds into drinking water sources.

Adopting as a measure, the United States Environmental Protection Agency has added four pharmaceutical compounds to the most recent Contaminant Candidate List (CCL 3) which includes three birth control substances and one antibiotic. Therefore, there is a need to take into consideration the possible growing effects of different pharmaceuticals manufacturing. Risk assessment of the PiE is essential for detecting inherent hazards at each stage of production process.¹³

‘Impact of Pharmaceutical Industries on Environment, Health and Safety’ by Devesh Kapoor takes note of risk, environmental hazards and toxicity caused by pharmaceutical pollutants. Divergent classes of pharmaceutical compounds are detected in the water samples of various countries. Though the detected concentrations are not very high but are extremely toxic to the whole environment. Waste generated out of pharmaceutical activities is termed as hazardous waste as pharmaceuticals belong to synthesis form of chemicals. Waste is generated in pharmaceutical facilities during activities like manufacturing and formulation process; handling, storage and transportation of hazardous substances; Emission of air pollutants which include Carbon monoxide (CO), Nitrogen dioxide (NO₂), Particulate matter of 10 microns or less (PM10), Total Suspended Particulate Matter (SPM), Sulphur Dioxide (SO₂), and Volatile Organic Compounds (VOCs) and discharge of effluents and wastewater.¹⁴

The study elaborates various methods of treating pharmaceutical wastes depending upon the variety of activities undertaken in pharmaceutical facilities.

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These activities may include preparations, compounding, unused or discontinued pharmaceuticals, partially used vials etc.\textsuperscript{15}

Following are the commonly used methods for treatment of pharmaceutical wastes:

1. Incineration: In this method, solid organic compounds are transformed into residues and gaseous compounds by the use of ignition. It is also called ‘thermal treatment’ because it makes use of very high temperature.

2. Autoclaving: Saturated steam is used in a pressure vessel at high temperature to destroy the pathogens.

3. Microwaving: This method is useful when ultraviolet radiation reaches the hazardous waste. Pollutants are destroyed through conduction method by applying electromagnetic field.

4. Deep Burial: Landfill sites are used for burying the hazardous waste deep into the soil. The site should not be prone to erosion or flood.\textsuperscript{16}

The study suggests that segregation of pharmaceutical waste into hazardous and non-hazardous waste is important for waste management. It can be done either at the time of collection or transportation. Safe handling of pharmaceutical waste is mandatory for environmental management.

The study is quite relevant when the waste is already generated. However, it does not take into account the measures that could be adopted to prevent or minimize the waste generation.

The extensive work by Eric D. Amster, ‘Mitigating Pharmaceutical Waste Exposures: Policy and Program Considerations’ examines policy and program considerations for pharmaceutical waste in Israel. The author submits that dealing with the issue requires a multifaceted approach which includes creating awareness, coordinating disposal system at national level, public participation, research on drug development etc. The author reviewed various programs and policies prevalent in different countries. He holds the view that it is very crucial to


determine which policy is effective and what made it effective. Moreover, there is doubt, whether the policy effective in one country would be equally effective in another country. Therefore, it is better to understand the principles, approach or hypothesis behind a successful policy and adopting the same.\(^\text{17}\)

The work entitled ‘\textit{Analysis of Veterinary Drug Residue Monitoring Results for Commercial Livestock Products in Taiwan Between 2011 and 2015}’ by Hsin Chun Lee, Chi Min Chen \textit{et. al.}\ deals with the issue of veterinary drug residues. The author points out that due to increased demand for proteins, the business of providing livestock food is flourishing. The same has resulted in the emergence of drug-resistant bacteria into animals. The author relies on various studies furnishing evidence as to the presence of antimicrobial resistance of \textit{Salmonella} from pigs at slaughter in Taiwan.

The rates of resistance to the following pharmaceuticals were observed as:

<table>
<thead>
<tr>
<th>Pharmaceutical</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Tetracycline</td>
<td>88.2</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>82.7</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>54.3</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>34.6</td>
</tr>
<tr>
<td>Nalidixic Acid</td>
<td>30.7</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>26.8</td>
</tr>
<tr>
<td>Kanamycin</td>
<td>18.1</td>
</tr>
<tr>
<td>Cephalothin</td>
<td>7.1</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>6.3</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>0.8</td>
</tr>
</tbody>
</table>

\textbf{Table 2.1 Resistance Rate of Pharmaceuticals in Pigs at Slaughter in Taiwan}\(^\text{18}\)


\(^{18}\) Lin Ch., \textit{Prevalence and Antimicrobial Resistance of Salmonella from Pigs at Slaughter in Taiwan} (Unpublished master's theses, Institute of Veterinary Medicine, National Taiwan University).
The present study is based on the samples of mutton, pig organs, pork, beef, cow milk, sheep milk and processed meat. These samples were taken by Taiwan Food and Drug Administration (TFDA). The analysis of these samples reveals these contain a variety of antibiotic residues including residues of chloramphenicol, nitrofurans metabolites, β-agonists, tetracycline, sulfas and quinolone pharmaceuticals, carbadox and its metabolites, betalactams, aminoglycosides, various anti-biotic metabolites, insecticides, diethylstilboestrol and hexestrol, zeranol, 17α-oestradiol and 17β-estradiol, luteal hormone progesterone, and 17α-hydroxyprogestin. The author recommends that the Governments and relevant agencies are required to establish laws and regulations for the use of veterinary pharmaceuticals to ensure safety and hygiene of meat, milk, and eggs from food-producing animals. It requires monitoring the contents of residual pharmaceuticals in livestock products at regular intervals and assessing the effective management of regulations related to food product safety.19

Keshava Balakrishna, Alman Rath et. al.’s work entitled ‘A Review of Occurrence of Pharmaceuticals and Personal Care Products in Indian Water Bodies’ is based on the review of published reports of pharmaceutical occurrence in the aquatic environment in India.20 The studies on which author relies presents that Wastewater Treatment Plants (WWTPs) are the source of pharmaceutical pollution in the aquatic environment.21 Effluents from WWTPs ultimately travels to rivers and lakes and thereby contaminating water channels with pharmaceutical wastes e.g. effluents from PETL are discharged into Nakkawagu and Isakawagu streams that end up in the Godavari river finally. WWTPs in India are not advanced enough to remove micropollutants from the sludge. Their removal efficiency ranges from

12.5% to 100% depending upon the process adopted for treatment, rainfall in the area, the age of sludge, geographical features of particular area etc. The level of pharmaceutical pollutants in the wastewater of WWTPs of pharmaceutical facilities is reported in much higher concentration as compared to WWTPs processing domestic sewage. The Ciprofloxacin is commonly prescribed across the globe for the treatment of seasonal diseases. The WWTPs that treat domestic sewage shows the presence of Carbamazepine which is a psychoactive, antihypertensive, antimicrobials in the form of triclocarban and triclosan, antibacterial, analgesics, ibuprofen and caffeine in higher concentration. Amoxicillin was found in the concentration of 62.5 ng/L in WTP outlet of Vasantkunj in Delhi, whereas ciprofloxacin is found in the WTP outlet of Okhla, Delhi. Its concentration is reported 2.5 times higher than WTP outlets in Australia and 5 times higher than WTP outlets in Italy. Similarly, the concentration of metoprolol


(antihypertensive) in Okhla WTP is 4 times higher than Germany$^{30}$ and 8 times higher than the USA.$^{31}$ The study is based on the presence of parent pharmaceuticals in the aquatic environment, it omits to undertake metabolites into considerations. Cumulative effects of compound mixture concentration are also not included for the purpose of the study.

The article by Szandra Klatyik, Peter Bohus et. al. titled ‘Authorization and Toxicity of veterinary Drugs and Plant Protection Products: Residues of the Active ingredients in Food and Feed and Toxicity Problems Related to Adjuvants’ is in the form of extensive work on the regulation of agrochemicals i.e. veterinary drugs (VDs) and plant protection products (PPPs). The fate of these products is same as human pharmaceuticals. These too end up in food and feed chain. Effective regulation of VDs and PPPs residues in the countries like Germany, UK, Belgium and Italy has considerably reduced the adverse environmental impacts whereas countries like India, China, Brazil and Vietnam are still not able to introduce effective regulation of VDs and PPPs. The work lays stress on the toxicological evaluation of adjuvants e.g. surfactants and other additives and active ingredients in the agrochemical products for effective risk assessment. The work is the comprehensive analysis of EU framework on the production of VDs and PPPs including their registration and authorization processes. It takes into account toxicological effects of agrochemical products by studying environmental incidents across the European countries.$^{32}$ The study is elaborative enough as to the effect of VDs or PPPs on the environment. But the effects of human pharmaceuticals are equally substantial. The authors confined their work on the particular categories of pharmaceuticals.


Kirstie Murdoch’s work entitled ‘Pharmaceutical Pollution in the Environment: Issues for Australia, New Zealand and Pacific Island Countries’ acknowledges the presence of multiple pharmaceutical compounds in treated wastewater, river systems, marine sediments and sewage sludge (biosolids) in Australia, New Zealand and Island countries. In order to minimize the harmful effects of pharmaceutical pollution, norms and their proper implementation is required. For this purpose, adequate disposal system, advanced wastewater treatment plants, technologies for eliminating pharmaceutical pollutants along with policies for quality/rational use of pharmaceuticals that include environmental considerations, quality sewage treatment and binding guidelines for the use of bio-solids and recycled water are needed. The work in hand reveals harmful effects of antibiotics in the environment. Presence of antibiotics in wastewater may promote antibiotic resistance in bacteria used in the wastewater treatment process as well as the bacteria present in the aquatic environment. Acute and chronic effects on various organisms due to the presence of pharmaceutical residues in the environment have been explained. The present study suggests the method of rational use of pharmaceuticals in order to minimize the pharmaceutical pollution. It has been suggested that introduction of environmental considerations into the rational use of pharmaceuticals strategies is the need of the hour and required to be implemented effectively at the country level. It may be useful in reducing pharmaceutical pollution.33

Gwynne Lyons’s report namely, ‘Pharmaceuticals in the Environment: A Growing Threat to Our Tap water and Wild Life’ recommends that pharmaceutical industry must shoulder the responsibility for the life cycle of pharmaceuticals. Endorsing the approach of EU, the report emphasizes the need for global coordination, monitoring, and capacity building, particularly in developing countries under the aegis of UNEP. In addition to ensuring harmony between international environmental law and national environmental law, the report advocates for strengthening better monitoring of the environment against discharge of

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pharmaceutical contaminants, toxicity testing methods and biomarkers of exposure to pharmaceutical contaminants in wildlife, the effect of the antibiotic on the environment.\textsuperscript{34}

The report by Nordea titled ‘Impacts of Pharmaceutical Pollution on Communities and Environment in India’ uncovers the threat posed by pollution caused due to the production of antibiotics in India. The World Health Organisation in its report of 2014 warned that we are at the dawn of ‘post-antibiotic era’. The first ‘State of the World’s Antibiotics’ report published by the Washington-based Centre for Disease Dynamics, Economics and Policy (CDDEP) in 2015\textsuperscript{35} noted that 58,000 new-born babies in India died in 2013 as a result of drug-resistant infections. Major causes of antibiotic resistance are an inappropriate use of antibiotics in humans and pollution resulting from the pharmaceutical manufacturing process itself. A report by the European Agency for Health and Consumers in 2013\textsuperscript{36} notes that “Without any doubt, the development of AMR i.e. Anti-Microbial Resistance is by far the largest risk for humans of having medicinal products residues in the environment”. The report also unfolds consideration of growing trends of Indian pharmaceutical industry, especially in Hyderabad and Visakhapatnam. Where it can't be overlooked that Indian pharmaceutical industry is gaining momentum as a major export-oriented industry, the report presents it as ‘red category’ as it discharges toxic effluents. The report underscores valuable information concerning pollution caused by pharmaceutical industries and its adverse impacts in the Indian scenario. It suggests the need to establish and implement strong environmental standards at each level of the supply chain.\textsuperscript{37} The report focuses only on the single


\textsuperscript{35} Available at http://cddep.org/publications/stateworldsantibiotics_2015#sthash.BmYsUzGz.dpbo (Visited on November 30, 2016).


\textsuperscript{37} Pietro Bruni, Impacts of Pharmaceutical Pollution on Communities and Environment in India (Researched and Prepared for Nordea Asset Management by Changing Markets
aspect of pharmaceutical pollution i.e. AMR. But there are some other implications also e.g. decline of fish population, extinction of certain species etc. The report does not take note of these factors.

The report titled ‘The Environmental Impact of Pharmaceutical Industry and the Way Forward’ describes environmental impact of pharmaceutical pollution. In U.S. medicinal products which are intended to be discarded, are expected to comply with a Federal law and the Resource Conservation and Recovery Act (RCRA). Minnesota Pollution Control Agency prescribes incineration method for destruction of household pharmaceuticals. All active ingredients do not metabolize after consumption. Pharmaceuticals end up in the form of urine, faecal matter and excreted chemicals, flow with sewage to streams and lakes. It is important to mention here that North America represents approximately 38% of the global pharmaceutical market. Therefore, the role of pharmaceuticals in water pollution is a major concern over there. In China, a Pharmaceutical company was subjected to steep fine, when it was found liable for releasing more waste, gases and water in the environment than limits. The work also puts forth suggestive measures to control pharmaceutical pollution. It states that by concentrating more on the ways of proper disposal of wastewater and gases, unused or expired medicinal products, limits can be put to pharmaceutical pollution. In the U.S., health organizations, environmental groups, police, pharmaceutical stores and pharmaceutical manufacturing companies participate in take-back programs. Awareness regarding the regulatory mechanism of disposal system would be of great help to curb the harmful effects of pharmaceutical pollution.38

Executive Agency for Health and Consumers’ Final Report on ‘Study on Environmental Risks of Medicinal Products’ is the executive summary of the environmental risks of medicinal products. The report mentions that due to population explosion, rising production and R & D investment, sale and consumption of medicinal products have increased tremendously. European Union

38 Available at https://www.kwikmed.org/environmental-impact-pharmaceutical-industry/ (Visited on December 5, 2016).
is considered to be the second bigger consumer of medicinal products throughout the World, as the first position is occupied by the USA. The report presents that 30%-90% of the orally administered dose is excreted as active substance in the urine of animals and humans. Besides, manufacturing and waste disposal of pharmaceutical residues hold importance in environment perspective. After entering into the environment, pharmaceutical compounds are transformed into various other sources resulting in the exposure of biota and causing damage to ecosystems. The study incorporates various legislative and non-legislative factors regulating the presence of medicinal products in the environment. The process of market authorization, environment risk assessment, Industrial emission Directive, Water Frame Directive etc. have been covered under the statutory framework while consumption, improper dosage, ineffective prescription strategies are non-legislative measures to control the pollution by pharmaceuticals. The report identifies various policy options in the EU to ameliorate legislative and non-legislative factors concerning the issue.39

‘Eco-Pharmaco-Stewardship Programme’ takes into consideration increased concerns raised by stakeholders regarding the presence of pharmaceuticals, as micro-pollutants in the environment specifically in water. Association of the European Self-Medication Industry, the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the European Generic and Biosimilar Medicines Association (EGA) jointly developed Eco-Pharmaco-Stewardship (EPS). The initiative is based on the concept of product stewardship which means product-centric approach to environmental protection.40 The EPS initiative is supported by three ‘pillars’. These are as follows: Pillar 1 – IMI PiE project: The identification of the potential environmental risks of existing and new active pharmaceutical ingredients (API) through intelligent and targeted assessment strategies; Pillar 2 – Manufacturing Effluents Management: The compilation of best industry practices enabling manufacturers to minimize risks to the environment and Pillar 3 –Extended ERA: The refinement of the existing environmental risk

assessment process for medicinal products to ensure that they remain up-to-date and relevant. ⁴¹

USEPA’s Guides to Pollution Prevention, ‘The Pharmaceutical Industry’ is the guidance document. It is in the form of advisory to the manufacturers of pharmaceutical products. It underlines the duty of pharmaceutical manufacturers to comply with environmental, occupational, health and safety standards. The guide spells out the way and mechanism for proper utilization of raw material, minimizing the waste, reducing the requirement of raw material and cost of disposal and performing the liabilities associated with hazardous waste management. The document elaborates various operations and processes applicable in pharmaceutical units. It also illustrates the available options for waste minimization by nipping the bud at the source of generation and advocates for recycling through case studies. Waste minimization policy of U.S. Environmental Protection Agency has also been elaborated in detail. Enlightening about various manufacturing processes and the generation of waste in these processes, the guide presents useful worksheets for the assessment of waste minimization depending upon the specific processes or operations undertaken in particular manufacturing unit. ⁴² However, it is important to point out here that the guide covers entry of PiE only through the industrial process while disposal of expired or unused pharmaceuticals, rinse off from bathing, discharge through excretion activities are not the part of the study.

2.2 Literature on Enviro-Legal Aspect

The masterpiece work of Daniel Bodansky’s ‘The Art and Craft of International Environmental Law’ relies on a pragmatic approach. The author places reliance on the international environmental law as a whole taking into account treaty design, policy implementation, social norms etc. It presents that international environmental law is not concerned about legal norms rather it is multidisciplinary in approach. This is clearly reflected in the range of issues that author took up from


various walks of life. Before finding a way out to solve environmental problems, the author goes deep down to locate causation of such issues. The author explains it with examples, as global warming is the result of excessive emission of gaseous substances in the atmosphere causing enormous heat. The efforts should be made to emit less or there should be a substitute for these gaseous substances. In the same way, extinction of various species is the result of damage caused to biological resources. Among various factors, improper use of increased technological capabilities has resulted in the deterioration of the environment. The issue of Persistent Organic Pollutants (POPs) is the outcome of the development of chemicals like DDT and dioxin. Accumulation of chemicals in the food web causes consequential environmental problems like reproductive disorder, retardation of immune system etc. Environmental problems are not to be viewed only from the scientific or technological perspective, but behavioral approaches are required for proper understanding of the issues. As it is observed that global warming is the outcome of increased demand for products generating heat like a refrigerator, air conditioners. The author focused on economic, cultural, ethical and above all political perspectives for handling environmental issues. Coming to the concept of international environmental norms, the author states that environmental norms are prescriptive in nature i.e. related to evaluative standards. These standards influence behavior pattern. Exporting hazardous waste to the countries having given prior informed consent is the example of the environmental norm. It influences the behavior of States while making the transboundary movement of hazardous waste.

‘Climate Change and Future Justice- Precaution, Compensation and Triage’ by Catriona McKinnon serves some important clues to resolve paradoxes arising out of the production of medicine for treatment of disease and right to health in contradiction with the right to clean and healthy environment of present and future generations. The author has addressed the key concern of delivering justice to future generations- as a pre-requisite of fairness and impartiality. He inter-relates Rawls’ principle of just savings principle with the principle of inter-generational


44 Ibid.
justice. Catriona elaborates that concept of justice and reminds present generation of its obligation to save resources for subsequent generations. Priority to basic liberties rather than goods should be the hallmark of the development policies. Thus, the author suggests formulating the development policies by integrating the precautionary principle despite its weakness yet searching out for certainty to avoid harm to the environment. According to the author, the policy makers and implementing mechanism is compelled to act in the face of strong uncertainty even though their action may later prove to be an unnecessary precaution against a non-existent or vanishingly unlikely, harm. Such actions and apprehensions may be expansive and costly, disruptive and unpopular yet in public interest. The author has also presented his views on cost-benefit analysis based on playing safe argument. The detailed discussion has been made on the corrective justice underscoring the victim's right to be compensated for the injury. Holding the present generation duty bound and liable to provide the funds adequate to just claims for compensation that many of their successors will have against them. Referring the work of many contemporary scholars on corrective justice, Ripstein's 'principle of liability to assess the putative wrong', Coleman's 'correlativity doctrine-injurer's duty of repairing the damage', Schroder's 'interpretation of responsibility' have been examined in detail to assess the liability of present generation to establish a fund for repairing the damages caused to environment.45

‘International Law and the Environment’ is the seminal work by Patricia Birnie, Alan Boyle, Catherine Redgwell on the international law relating to environmental issues such as climate change, modified organisms and biotechnology and environmental governance etc.46 The work examines various disciplines of international law e.g. human rights laws, trade laws etc as the boosters of environmental laws in the international sphere. The authors have presented an overview of the ongoing trends in the field of international environmental law. The concept and contents of the study are well structured to enlighten the significance and role played by

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international law in the environmental governance. It also outlines the role of legislation in achieving environmental goals.

In ‘Environmental Law and Policy in India’, Shyam Divan and Armin Rosencranz have brought various scattered environmental regulatory measures under one umbrella. The authors have approached every single aspect concerning environment protection. Within the ambit of their work, they have included legislative framework, enforcement and implementation apathy, judicial inclination, environmental policy framework, constitutional provisions, international environmental law, global issues, various projects and case laws with special reference to the Bhopal Gas Leak Disaster etc. Regulations of hazardous substances and toxic chemicals are elaborated with the help of leading case laws.\(^47\) Hazardous waste as the undesired outcome of pharmaceutical industries is latent in the study.

In ‘Environmental Management in Organizations’, by John Brady, Alison Ebbage and Ruth Lunn, the authors present that achievement of better quality of life and achievement of sustainable development is not available only by simply compliance with legislation. It is a cause for concern to be managed in proper perspectives with the strategic economic approach. After assessing the social, economic and environmental effect of a discharge of pollutants, the work suggests to consider economic drivers and burden, cost input and profit output as these have a significant role to shape our environment. The work lucidly explains the key components of the ideal regulatory regime- transparency, accountability, consistency, risk-based assessment or proportionality, and result-oriented strategy. It also specifically enumerates the obligations of the regulatory framework such as setting the target, selection of alternative instruments, monitor compliance, evaluate performance, liberty to take enforcement measures, evaluation of results and communication to the stakeholders. Moving further, the guiding principles for process operators include prevention by minimization of the discharge,

identification of risks and hazards, minimization of the effects, self-monitoring and proper reporting to the public, regulator and other stakeholders.\(^4\)

‘A Guide to EC Environmental Law’ by Dorothy Gillies underscores the initiatives taken by European Community to protect the environment by way of regulatory measures. It discusses existing environmental laws as well as the proposed legislative process. Various environmental measures concerning water, air, noise, chemicals, wastes etc. are elaborated in detail. To achieve environmental goals, it emphasizes the successful implementation of laws relating environment impact assessment, eco-management, environmental audit, integrated pollution prevention and control. EC environmental law ensures waste minimization, disposal and recovery to be safe for human health and environment.\(^5\) Though the study describes various kinds of wastes, waste arising from pharmaceutical activities is not dealt with.

Melanie Leitman in ‘Water Rx - The Problem of Pharmaceuticals in Our Nation’s Waters’ is a very much relevant work concerning PIW in the U.S. Identifying the sources and impacts of PIW, the work explains the regulatory framework in the U.S. covering Federal Food, Drug, and Cosmetic Act, National Environment Policy Act, Clean Water Act, Safe Drinking Water Act, Resource Conservation and Recovery Act, Toxic Substances Control Act and several policy measures handling the problem from source and discharge perspectives.\(^6\)

Elizabeth Fisher, Bettina Lange et. al.’s ‘Environmental Law: Text, Cases and Materials’ is a significant collection of text, cases and legal literature on environmental issues. It provides an extensive source of learning. Each and every aspect of environmental concern is dealt with comprehensively e.g. while analyzing the concept of waste regulation, author included publications of European Commission, Charter presented to UK parliament, review of Government policies

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on the waste management, various case laws dealing with the issue of waste extermination, EU Directive on waste management along with its functional dimensions and fundamental obligations prescribed therein. The work comprehensively draws attention on the emergence of Integrated Pollution Control mechanism. This approach as the name suggests integrates the fragmented approaches applied for the control of pollution. Failure of media-specific approach to curb the pollution levels has given birth to an integrated approach. The media-specific approach supports end-of-pipe regulation which means regulation that controls pollution resulted from industrial or hazardous activities. These regulations seem to be ineffective to promote production techniques, rather these shift the medium of pollution. The author in this context critically examines the EU Integrated Pollution Control mechanism by analyzing the Directive on Industrial Emission (2010/75/EU). This Directive provides compendious rules for integrated pollution prevention and control. The present disquisition stresses upon the shift from environmental government to environmental governance. It contextualizes that shift from public state bodies to private actors by supporting the idea of reflexive modernity as it suggests that scientific knowledge and technological innovations are of limited scope in dealing with environmental upshots. The work introduces the concept of criminal liability for committing an environmental crime. These crimes are the outcome of contravention of statutory environmental provisions entailing punitive sanctions. The behavior that damages the environment is justified to be criminal on the basis of loss it caused to the public health e.g. depletion of resources as environmental damage includes within it ambit economic losses to present and future generations. The study justifies the criminalization of environmentally damaging behavior for the impacts produced by such behavior on lower socio-economic groups.

Stuart Bell and Donald McGillivray’s work titled ‘Environmental Law’ is a landmark work as it deals with the basics of environmental law in comprehensive way elaborating the origin, need and development of environmental law. It provides a synthesis of values, principles and rules forming the body of environmental law in

52 Ibid.
its international and national perspectives. Part II of the work points out that
environment law is made up of more than mere rules that prohibit pollution. The
authors drew their findings on the basis of ground-level realities existing and
applicable in various domestic legal frameworks. The observations of the author
that process of environmental regulation begins before the law are made, when
policies are established that can be translated into laws. The concept of
environmental regulation is not limited only to the statute law, in fact, setting,
applying, enforcing and reviewing the environmental standards are also the law.
The study suggests that implementation of regulations is more important than to
specify what ought or ought not to be done. Standards can be categorized as
Environmental Quality Standards, Emission Standards, Product Standards and
Process Standards. Each type of standard serves different purpose e.g.
environmental quality standards focuses on the effect of a specific pollutant on the
environment. Emission standards rely on what is being emitted as a waste product.
It set the limits of concentration, specific levels etc. Process standards deal with
the technology being applied in the manufacturing of products. Product standards
control characteristics of the product. The author meticulously deals with the
concept of ‘environmental crime’ and suggests application of criminal law theories
for prevention and control of pollution activities. There are various ways of
enforcing criminal law theories in environmental governance e.g. persuasion,
warning letter, issuing a notice, suspension or revocation of licenses, imposing
fines or sentencing imprisonment. Though environmental irregularities generally
end up with civil liability, in case of serious environmental harm, criminal liability is
significant for environmental restoration. Environmental enforcement agencies
must be vigilant enough to locate serious environmental violation and proceed
accordingly.53 Advocating for ‘public participation’, the author points out that access
to information and data on environmental concerns, the participation of the public
in the decision-making process are an integral part of access to justice in
environmental matters.54 Participation of public in environmental issues is very
significant in monitoring and handling the environmental issues. ‘Public hearing’ as

York, 2008).
a part of EIA regulation has also been taken as a positive step in the direction of environmental governance.

Ellen Hey’s ‘Advanced Introduction to International Environmental Law’ approaches the concept of international environmental law in its broader context. The study is founded on the detailed analysis of principles forming the basis of international environmental law. The author elucidates the historical perspective, origin, nature, actors involved in the application and implementation of the international environmental law. Interrelation of international environmental law with other branches of international law such as the law of treaties, human rights, laws on the settlement of disputes are also dealt with. The study makes relevant considerations as to how harmful substances enter the environment. Some pollutants enter the environment accidentally through their use, production or transportation while other enter as by-products. The author considers these by-product pollutants as bigger contributors to environmental deterioration and categorizes them as operational pollutants. The author relies on that carrying capacity of the environment is subject to the condition of the eco-system. In an eco-system, assimilation of synthetic substances presents negative consequences. Prediction as to the carrying capacity of the eco-system is a complicated task because eco-system is affected by multiple pollutants over an exhaustive period of time.\(^5\) Though pollution caused by pharmaceutical residues is not a direct subject of the author, the concept of hazardous waste along with regulatory approaches to deal with such substances, best available technology, banning and phasing out hazardous substances, dumping of waste at sea etc. are the important aspects of the study.

The comprehensive work on the need of new environmental regulation is well crafted by Daniel J. Fiorino in ‘The New Environmental Regulation’. Though the author relies on the importance of old environmental regulation, advocates for the adoption of new regulations for solving environmental problems. Daniel examines U.S. environmental regulations framed in the 1970s and recommends revision and upkeep of statutory framework. New environmental regulation, he advocates,

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should be based on performance rather than on the compliance of standards. The old regulation was based on the administration of rules and standards by regulatory agencies. Governmental coercion ensured compliance with these standards. This model of environmental governance was suitable for past. With the passage of time, a new approach towards environmental regulation is required. The old regulation was concerned with change of behavior while the new one should be based on the performance by supplementing market-based mechanism allowing room for better environmental decision making. The emergence of new and divergent environmental problems requires diversified and multi-pronged approach. The old regulatory model was based on bureaucratic rationality whereas new approach should be based on social, economic, institutional and other behavioral considerations affecting the environment.56

Philippe Sands’ edited work ‘Greening International Law’ is a very contentful collection of contribution from various scholars. Sands contributed under the title ‘Enforcing Environmental Security’ for resolving environmental conflicts with the help of principles of UNCED. Marc Pallemaerts in his article ‘International Environmental Law from Stockholm to Rio: Back to the Future’ emphasizes the need to integrate ecological principles into economic law. Raising the concern for the protection of global commons, Christopher Stone strongly recommended to the establishment of a global commons trust fund for financing the repair of natural resources. Daniel J Dudek, Richard B. Stewart and Jonathan B Wiener in their work titled ‘Technology-Based Approaches Versus Market-Based Approaches’ presents two kinds of tools of environment policy prevailing in U.S. First is ‘Command and Control’ (CAC) approach based on technology and other is market-based approach creating economic incentives for industries to minimize environmental harm. Giving higher significance to market-based approaches, the authors underlined that CAC is static measure as it is based on technology-based standards. It results in increasing compliance cost and hampers the path of innovation and needs comprehensive central planning of economic activities. This approach requires every industry to install technology and to meet same or uniform standards irrespective of their size, growth and infrastructure. On the other hand,

market-based approach is based on ‘No one size fits all’ and it sets environment goals on the basis of performance. It is more flexible and encourages innovation of technology, processes and product designing. Various tools available for this kind of technique may include allowances or permits on the quantum of pollution, taxes or charges on pollution or deposit-refund etc.57

‘Principles of International Environmental Law I: Frameworks, Standards and Implementation’ by Philippe Sands enunciates that environmental law is the indispensable part of the international legal system. International environment law is the branch of Sustainable development, i.e. principal objective that international fraternity thrives to achieve. The author discusses in detail various regulatory perspectives of environmental law in the form of ‘command and control’, ‘integrated pollution prevention and control’, ‘market-based approaches' etc. The work elaborates various legal mechanisms for the implementation of these techniques. Environmental governance can be successfully achieved with the tools like ‘environment impact assessment’, ‘environmental information’, ‘liability and compensation’ etc. The work comprises principles (precautionary, polluter pays) and rules establishing standards for the environmental governance in the areas of environment protection viz. protection of water, air, forests, control of hazardous substances and disposal of wastes.58

‘A Synopsis: Limits to Growth: The 30-Year Update’ by Donella Meadows, Jorgen Randers et. al. phrases out the idea floated by Club of Rome, an international group of businessmen, statesmen, and scientists in their landmark study ‘The Limits to Growth’ in 1972. At that time problem of environmental harm was serious and cautioned that failing to pay attention to sustainable methods of development, environmental problems would rise to the level beyond imagination. Again, the forerunners of environment protection movement raise their concern in updated version ‘Beyond the Limits’. It pointed out that in many areas man had overshoot the limits or expanded his demands on the planet’s resources and sinks beyond


what could be sustained over time. Overshoot, as defined means “to go too far, to grow so large so quickly that limits are exceeded. When an overshoot occurs, it induces stresses that begin to slow and stop growth. The three causes of overshoot are always the same, at any scale from personal to planetary. First, there is growth, acceleration, rapid change. Second, there is some form of limit or barrier, beyond which the moving system may not safely go. Third, there is a delay or mistake in the perceptions and the responses that try to keep the system within its limits. The delays can arise from inattention, faulty data, a false theory about how the system responds, deliberate efforts to mislead, or from the momentum that prevents the system from being stopped quickly."\(^{59}\) Where ‘The Limits to Growth’ elaborated various possible production patterns and underscored environmental outcomes of world’s development over two centuries from 1900 to 2100, the present study warns that “world is in the state of overshoot, we are fetching the resources faster than they can be restored, and releasing wastes and polluters faster than the Earth can absorb. These alarming bells are leading us towards global environmental and economic collapse.”\(^{60}\) The work describes the availability of limited renewable and non-renewable resources, the capacity of the planet to resilient the pollution and waste arising from the human economic activity. Wastes from nuclear are pointed, hazardous activities i.e. human synthesized chemicals and release of greenhouse gases are most crucial. It is very complicated to segregate chemicals from wastewater or detoxify. The politico-economic implications make it extremely difficult to regulate as it affects the interest of the whole nation. The study elaborates that current atmospheric concentrations of carbon dioxide and methane are much higher than ever before. Its results can be seen in the form of melting ice, rising seas, changing currents, greater storms, shifting rainfall, and migrating insects, birds or mammals. It suggests different measures to tackle the issues. These suggestive measures urge a transition to sustainability requiring an active decision to reduce the waste. It stresses that there


are many choices that can be made about numbers of people, living standards, technological investment, and allocations among industrial goods, services, food, and other material needs. The longer the world takes to reduce its ecological footprints and move towards sustainability, the lower, the population and material standard that will be ultimately supportable. The higher, the targets for population and material standard of living are set, the greater the risk of exceeding and eroding its limits. The study also suggests that sustainability can be achieved by extending the planning horizon and relying on the choices among current options much more on the long-term costs and benefits, improving the signals i.e. learning more about the factual welfare of human population and the real impact on the world ecosystem of human activity, speeding up the response time and having watch on the indications that points out when the environment or society is stressed and thereby determining roadmap in advance, minimizing the consumption of non-renewable resources, preventing the gradual destruction of renewable resources and slowing and eventually stopping exponential growth of population.\textsuperscript{61} The study presents a wide range of measures for achieving sustainability under different conditions but whether these measures would be applicable universally i.e. equally successful in developed and developing countries is a matter of concern.

The edited work by Alyson C. Flournoy, David M. Driesen titled ‘Beyond Environmental Law’ with contribution from Sidney Shapiro, Thomas T. Ankersen, Kevin E. Regan, Mark T. Brown, Mary Jane Angelo, Christine Overdevest, Brain Mayer, Walter A. Rosenbaum and other eminent authors proposes third generation environmental regulation. Drawing upon the limitations of first and second generation environmental regulation, it makes proposal and analysis of third generation environment regulation which would be more successful than earlier ones. The work highlighted that aim of first-generation environment law was to protect public health and environment by application of statutory means. These statutes embrace various standards to achieve for environment sustainability. Striking upon the implementation of these standards, the author highlighted that environmental law of the first generation didn’t succeed. The second generation however, achieved some success by relying on Cost-Benefit Analysis (CBA) of

\textsuperscript{61} Ibid.
environmental regulation and market-based mechanisms for technological innovation. However, this approach too has limitations as it put reliance on the precautionary approach. Therefore, the author advocated for third generation environmental law. It proposes 'National Environment Legacy Act' to conserve natural resources and 'Environmental Competition Statute' to motivate eco-technological innovations. The work is based on the idea that purpose of the environmental law is not restricted to the preservation of environment only, in fact, it is meant to construct a better environment for future generation.\(^{62}\)

Barry C. Field, Nancy Olewiler's work on 'Environmental Economics' elaborates the way economic factors influence environmental quality. Economic factors are incorporated into environmental decision making by introducing standards. The author discusses 'command and control' approach i.e. direct regulation in the context of environmental issues. The setting of standards is the primary function of direct regulation. Standards are permitted levels of performance that are backed by law and enforced by regulatory agencies. In the context of environmental governance, three types of standards are enforced. These are ambient standards, emission standards and technology standards. The study exhaustively provides a methodology for arriving at standards and compares between various standards depending upon the industry profile. The author takes account of the problems coming in the way of setting of standards. The problems may be cost-effectiveness and equimarginal utility of these standards. It is pointed out that uniform standards are set out for all sources of particular pollutant which makes marginal abatement cost unequal. For a standard to be cost-effective, it is important that marginal abatement cost should be equalized among various sources.\(^{63}\)

The edited work by Harpal K. Khehra, entitled 'Growth of Law in India: Role of Judiciary' is the comprehensive analyses of the role played by Indian judicial system in the growth of law. The contribution made by Kuljit Kaur, Jaspal Singh, Tarun Arora along with other eminent authors in the present work reveals that environmental law in India, geared up in the wake of pronouncements made by the


judiciary as a response through public interest litigation mechanism. Pollution free environment is termed as an essential element of public interest law and thus made as a fundamental right under Article 21 of the Constitution. Economic development and environmental protection are considered to be conflicting interests and judiciary strives hard to strike balance between them. Application of ‘Precautionary Principle’ and ‘Polluter Pays Principle’ in the environmental governance is the remarkable action of judiciary. The present work has been crafted beautifully concerning the approach adopted Indian judiciary in dealing with every sphere of law. But it is felt that environmental pollution by hazardous waste could have been dealt more elaborately.

Paramjeet S. Jaswal, Nishtha Jaswal and Vibhuti Jaswal’s work ‘Environment Law’ is pioneer discourse concerning environment protection, sustainable development and contribution of the judiciary in the field of environment protection in Indian perspectives. Various aspects related to the prevention of pollution, protection of environment etc. have been covered comprehensively by the authors. An in-depth study is carried out as to Common law, Constitutional provisions, principles of sustainable development with international perspective and implementation of these principles in context of India, water pollution, air pollution, noise pollution, wildlife protection, forest conservation, management of hazardous and solid wastes etc. Role of judiciary in the arena of environmental protection has been dealt with in a comprehensive way with a critical outlook. The authors have traced the long journey of the judiciary in incorporating the principles of international environmental law into Indian environmental jurisprudence. The issues of PIE though have not been touched directly by the authors in their work, however, it is covered implicitly in hazardous waste management theme. The method of evaluation of judicial approach towards the pollution caused by industrial processes in the work served as a guiding mechanism to the researcher to appreciate the role of the judiciary in context of PIE.

P. Leelakrishnan’s work on ‘Environmental Law in India’ portrays that environmental law is multi-dimensional subject. It is the outcome of principles, rules, norms and concepts dealing with different walks of life. It is interrelated with other laws such as the law of torts, administrative law, criminal law, constitutional law etc. It makes a critical analysis of sectoral and framework environmental law. The author has discussed provisions of various environmental laws in detail. He has also analyzed landmark judgments concerning environmental protection. However, the concept of pharmaceutical pollution is not touched by the author but the role of the judiciary in context of environment protection and sustainable development is explained in candid way.

The work of P.B. Sahasranaman in ‘Handbook of Environmental Law’ examines the fundamental issues concerning environmental protection. Drawing attention toward the bitter realities of the present state of things in the form of climate change, deforestation, deterioration in the quality of air and water, extinction of species etc. The author examines various principles of environmental law with special reference to India. The work provides a comparative analysis of international concerns over the environmental issue with those of Indian initiatives. The author in his study takes account of judicial response over protection of the environment by elaborating a number of case laws. For this purpose, he critically examines the principles of environmental law applied by the judiciary.

‘Environmental Law’ by Sukanta K. Nanda deals with social aspects of environmental problems. The concepts of social reality, social justice, the process of planning are the indispensable part of the study. The legal remedies and procedures for environmental damage under various legal mechanisms have been discussed. Various sectoral and framework environment laws with their social dimensions are the part of the study. However, issue related to management of hazardous substances is not dealt with in this work.

66 P. Leelakrishnan, Environmental Law in India (Lexis Nexis, New Delhi, 2005).
In ‘Environmental Jurisprudence: Polluter’s Liability’, Indrajit Dube examines the jurisdicational dimensions of environment laws. The author by considering ‘Law as an instrument of change’ tries to work out the effectiveness of existing legal and judicial framework in the implementation of environmental laws. He outweighs the approach of environmental laws in the terms of infliction of liability upon the polluter. He undertakes various theories of punishment and favours the concept of criminal liability for environmental wrongs. The author explores principles of international environmental law and treaty obligations. He also highlighted the Indian approach especially the judicial concerns over the liability of polluter.

The Dissertation/Thesis entitled ‘Rethinking waste in India: Innovative Initiatives in Waste Management’ by Mariam Abazeri is the elaborative work on solid waste management system in India. The author links the improvement in the waste management with understanding as to the source of generation. The author opines that measures such as government intervention, disposal mechanism, transport process and incineration, policy guidelines etc. are effective with the adoption of decentralized waste management model as there is ‘no one size fits all’. Awareness and participation of all stakeholder in decision-making are important for fostering decentralized waste management. The study is confined to environmental pollution caused by solid wastes. The issue of pollution of environment by hazardous waste is not dealt with by the author.

The enlightened work by Jutta Brunnee titled ‘International Environmental Law’ underscores that international law is the collaboration of legal norms and processes aimed to regulate the environmental harm. The harm resulted from human activities may have regional, territorial, national, international or trans-boundary impacts. The author makes the discussion as to the impediments in the way of implementation of the international environmental law. Regulation of Non-State actors i.e. private parties is a quite complex process. Inter-connection of one issue with others and balance between conflicting interests is another barrier.

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69 Indrajit Dube, Environmental Jurisprudence: Polluter’s Liability (Lexis Nexis, New Delhi, 2007).
70 Abazeri Mariam, Rethinking waste management in India: Innovative Initiatives in Waste Management (Sciences Po, PSIA, 2014).
Moreover, co-operation among developed and developing nations is foremost required. International law has to cater not only to present generation but to consider the interests of future generations also. The work done by the author is of wider connotation. Applying her approach to the global issue of PiE, the international fraternity is expected to develop some solutions.

Cass R. Sunstein’s review essay on ‘Cost-Benefit analysis and the Environment’ compares two environmental techniques i.e. cost-benefit analysis (CBA) of environmental regulation and application of the precautionary approach. For this purpose, the author reviews three different books on the concept and carry out a critical analysis of CBA and taking into account specific incidents. The author pinpoints benefits of CBA subject to certain limitations. These limitations are easy cases versus harder cases, application of maximin principle in catastrophe risks and monetization of human beings on the basis of willingness to pay for environmental regulations. The work reveals that US follows CBA for regulatory process whereas in the EU emphasis is on the precautionary principle. While enacting any environmental regulation in the U.S., it is mandated to carry out CBA and proceed with, if the likely benefits of regulation justify its likely costs. Likely benefits may include factors like reduction in the mortality rate, reduction in morbidity rate, animal welfare, increase in the property value and other socio-economic factors. CBA takes into account likely effects of alternative regulation whereas precautionary approach relies on limited knowledge of scientific uncertainty. If more than one regulation justifies CBA, then the regulation which maximizes ‘net benefits’ is to be adopted. The author considers applicability and success of CBA regime in the context of general environmental regulation. Pharmaceutical residues are the outcome of specifically designed chemicals. These are beneficial as well as detrimental at the same time. CBA of the regulations dealing with compounds of dual nature is not dealt with by the author.

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The approach adopted by Noah M. Sachs in ‘Beyond the Liability Wall: Strengthening Tort Remedies in the International Environmental Law’ towards transboundary environmental damage is based on the futuristic model of tort liability. The work propounds that tort remedies crafted under numerous treaties have failed because of conflicting interests of developed and developing nations, high transaction costs and onerous provisions. Strengthening of tort liability is recommended as it serves as means of deterrence as well as means of compensating the victims of transboundary environmental harm. Tort liability can be strengthened by effective treaty mechanism otherwise ‘liability walls’ are created in the form of procedural impediments and polluter escapes liability under the veil of these liability walls. The author suggests reformation in the process of treaty making and self-reporting by the nations in case of non-ratification of a particular treaty. Tort liability for causing pharmaceutical pollution has its own implications. In mixture concentration, it is a very complicated task to measure which residual compound is responsible for causing damage. Moreover, arriving at the quantum of damage also requires expert technical knowledge.

‘The Emerging Environmental Burden from Pharmaceuticals’, by Geetha Mathew and M.K. Unnikrishnan rightly condemn that pollution in India has never been appreciated by the regulatory mechanism and the government as well unless there is a public outcry. Appreciating the Larsson’s findings, the work indicates that despite the ban of veterinary formulations of diclofenac in 2006, general pharmacies in 11 states continued to sell veterinary formulations of diclofenac. In addition to it, the authors have referred some important observations made by various scientists which have been presented at the relevant places in the later part of this study. Referring Adams’s observation that pharmaceuticals pollute the world twice, first in the bodies of those who take them and secondly, in the rivers and oceans where the toxic residues inevitable accumulate, the work underlines

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that unbridled free market capitalism permitting companies to cut cost at the expense of the environment.\textsuperscript{74}

The study by Joseph A. Gorman entitled *Drugs in Our Water: A Legal Proposal for Responsible Nationwide Pharmaceutical Consumption* examines the presence of pharmaceuticals in the U.S. water channels. The author has crafted the whole study around the regulatory framework, legislative action, drug development techniques, treatment facilities for wastewaters prevalent in the U.S. concerning the issue. The author supports adoption of more aggressive approach in conducting researches over the matter by EPA. The study is divided into three parts. The first part examines the various researches demonstrating the environmental impact of pharmaceutical residues. The second part provides comprehensive information on various source categories. The third part of the study deals with the legislative and regulatory initiative taken by authorities. The work examines relevance of the Drug Free Water Act, 2009 and Universal Pharmaceutical Waste Rule. It also examines the FDA drug approval process and advocates green drug design that aims at the reduction of direct excretion of the parent compound.\textsuperscript{75}

Essay by Rena Steinzor *How Criminal Law Can Help Save the Environment*\textsuperscript{76} deals with philosophical aspects concerning liability in cases of environmental harm. He pointed out that the purpose of the enactment of the environmental law was to plug the loopholes developed in the law of torts and to prevent the injury thereby adhering to the process to nip at the bud instead of compensating it. He recommended that best practice in such cases is to prevent harm than compensating at a later stage.


\textsuperscript{74} Geetha Mathew and M.K. Unnikrishnan, “The Emerging Environmental Burden from Pharmaceuticals” 47(18) *Eco. & Pol.* (2012).


have dealt with the issue of pharmaceutical presence in the environment in a very comprehensive manner. The work highlights each and every minute aspect concerning the issue. The enlightened work is the synthesis of legal, scientific and technical knowledge on the issue. The work critically analyzes the impact of existing GMPs and emission guidelines issued by U.S. Environmental agency on the discharge of pharmaceutical residues into the environment through their life cycle. These guidelines limit the discharge concentration of pharmaceutical compounds during manufacture, use and disposal processes. Scientific knowledge regarding chemical, physical, degradation and sorption properties of pharmaceutical compounds are relevant to determine the net residue levels that could stand in the environment. The work elaborates pathway of pharmaceutical residue. It also dealt with the various techniques of transformation or dilution of pharmaceutical leftovers. These techniques of dilution or degradation may prove to be fruitful in reducing the impact of pharmaceutical residues. The study is silent on the role of collection and take back events on the minimization of environmental impacts of pharmaceutical residues.

The work of Christopher Carrigan, Cary Coglianese on ‘The Politics of Regulation: From New Institutionalism to New Governance’ critically evaluates the implementation of regulations in the light of the concept of institutionalism and governance. The author describes these as ‘new institutionalism’ and ‘new governance’. New institutionalism is concerned with policy-making process and interplay between various regulatory actors. It analyzes activities of regulatory agencies. It concentrates on the relationship between legislators and regulators. New governance is more related to the measures and strategies laying impact on the behavior of persons being governed. It concentrates on the interplay between regulators and entities to be governed. The cohesion of these two paths leads to the construction of new thought regarding politics of regulation, which means regulation is an integrated web of relationships, political entities controlling

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regulatory authorities which in turn controls business entities. The author makes a synthesis of these two approaches and opines that commonalities of these two can prove more fruitful in impacting the behavior of various organs of politics of regulation.

Taking account of the pharmaceutical presence in the waterways and its crucial impacts on the environment, Ryan James Albrecht in ‘Pharmaceuticals in the Environment: Looking to Green Governance for a Remedy’ enjoins shift from traditional regulatory approach to Green-Governance approach. This approach emphasizing upon combining current regulation with economic-based and value-based behavioral approaches. The article recommends public awareness and public participation in limiting the pharmaceutical presence in the environment. It also advocates green pharmacy production techniques on the lines of green chemistry which means designing and manufacturing pharmaceuticals in a way that either reduces their toxicity or increases their biodegradability. The author made recommendations on the basis of analysis of legal and regulatory regime existing in U.S. and EU. It also made a comprehensive study of the applicability of environmental principles. The study stresses on the importance of take-back programs and shared responsibility of producers, consumers and government.

Vikash Batham in ‘Regulatory framework and Challenges in Indian Pharmaceutical Sector’ elaborates status of the pharmaceutical industry in India. It throws light on major regulatory bodies monitoring the Indian pharmaceutical sector, policy measures and mechanism for drug regulations. The Indian pharmaceutical industry is a part of the larger chemicals industry. It consists of about 300 companies, which account for 70% of products on the market. India is emerging as collaborative Research & Development (R&D) bioinformatics, contract research and manufacturing and clinical research destination as a result of growing compliance with internationally harmonized standards such as Good Laboratory Practices.

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(GLP), Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). India is also a signatory to World Trade Organization's Trade-Related Agreement on Intellectual Property Rights (TRIPS), hence it incorporated provisions to provide product patents since January 01, 2005 after making amendments in its Patents Act of 1970. By the year 2020, India is expected to join the league of top 10 global pharmaceutical markets in terms of sales, with the total value reaching US$50bn. The main regulatory body in India is the Central Drug Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare (MoHFW). The CDSCO prescribe standards and measures for ensuring the safety, efficacy and quality of pharmaceuticals, cosmetics, diagnostics and devices in the country and regulates the market authorization of new pharmaceuticals and clinical trials standards. Policy issues associated with the sector are looked upon by Department of Pharmaceuticals (DoP) formed in 2008 under the Ministry of Chemicals and Fertilizers. Drugs and Cosmetics Act, 1940 is the law which regulates the import, manufacture, distribution and sale of pharmaceuticals and cosmetics in this country. The work enlightens as to the regulatory aspect of the pharmaceutical industry. But when comes the matter of pollution control measures, it is silent.

The study by Mark Wu, James Salzman titled ‘The Next Generation of trade and Environment Conflicts: The Rise of Green Industrial Policy’ deals with conflicting interests of international trade and environmental protection. Developed and developing nations are challenging pro-environmental or green industrial policies of each other in the name of violation of international trade rules or missing industrial linkage. Developed countries are implementing green policies, considering themselves to be the leader in environmental protection. Though pro-environmental policies benefit the environment but disturb international trade. The present work approaches the concept of next-generation conflicts regarding renewable energy resources, climate change policies, carbon emissions etc. in an exhaustive manner. The concept is important from Indian perspective as India is a developing country. The work analyzes trade conflicts resulted from the contradiction of ‘green industrial policy’ and norms of international trade. Green

Vikash Batham, Regulatory Framework and Challenges in Indian Pharmaceutical Sector (CUTS Centre for Competition, Investment & Economic Regulation, New Delhi, January 2013).
industrial policies of the nations claim to be creating environmental benefits nonetheless they also create room for protectionism under international trade laws. In next-generation trade conflicts, developing country is blamed to be ‘bad’ actor for its unwillingness to have concern over environmental matters. Developed countries are encouraging unilateral measures in the name of environment protection in return for market access to which developing countries render illegal as being against protectionist international trade law. However, it is for the adjudicators to see, whether concerned policy fulfills the objective which it claims and the restrictions imposed in, are “necessary to protect human, animal or plant life or health”\(^{82}\) or “relating to the conservation of exhaustible natural resources made effective in conjunction with restrictions on domestic production or consumption.”\(^{83}\) Thus author draws attention towards new kind of trade conflicts in the light of guidelines issued in General Agreement on Tariffs and Trade (GATT) and World Trade Organization (WTO).\(^{84}\)

Merita Dauti, Edita Alili-Idriz, et. al.in their pioneer work ‘Legal Regulation and Critical Analysis for an Effectively Treatment of Pharmaceutical Waste’ analyze the practices of pharmaceutical waste management and treatment in European countries along with a review of the legislation and official guidelines concerning the management of pharmaceutical wastes. As per statistical data, total production of wastes from households and industry in 2012 in 27 members of the EU was 2,500 million tons. In order to minimize the impact of such wastes on the environment, regulation 2150/2002 was adopted. This regulation aims at monitoring the implementation of waste policy and principles for a proper disposal of wastes. Along with municipal waste, Health Care Waste (HCW) also poses a potential danger. Health Care Waste means all medical wastes that come from healthcare institutions, research centers and laboratories. According to study, pharmaceuticals and chemicals comprise about 3% of the total amount of Health

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82 Article XX(b) of the General Agreement on Tariffs and Trade (1947).
83 Ibid, Article XX(g).
Care Waste.\textsuperscript{85} For minimizing the effects of dangerous wastes, the Basel Convention on the Control of Trans-Boundary Movements of Hazardous Wastes and their Disposal was held in 1992. The Convention aims to protect human health and the environment against the adverse effects resulting from the generation, management, transboundary movements and disposal of hazardous and other wastes. The author focused on the system of healthcare waste management and legal regulation in Macedonia.\textsuperscript{86} Waste generated in production facilities accounts for various environmental problems such as the proliferation of water, loss of crop, health menace, air pollution etc. All these issues are uncovered in the study.

The study of Shinsuke Tanaka, Wesley Yin, et. al. entitled ‘\textit{Environmental Regulation and Industrial Performance: Evidence from China}’ focuses upon the prominence of environmental regulation on the productivity of industries in the developing countries. It analyzes Two Control Zone (TCZ) policy of China, adopted for the control of emissions from power-intensive firms. For the control of air pollutants, districts and cities are divided into two zones, namely acid rain control zone and SO\textsubscript{2} control zone. Industries located in TCZ area are subjected to more tighter regulations and within the TCZ area pollution, intensive units are to be under rigid controls than non-pollution intensive units. Empirical analysis of the TCZ policy in the developing countries, rebut the neo-classical model of economics that suggests an increase in the financial burden due to environmental regulation and decrease in the industrial performance. Instead, the present study favors environmental regulation as it promotes selection dynamics i.e. it prompts entry of more productive firms and exits of less productive firms. It also incites productivity dynamics as in developing countries industries to adopt low technologies resulting in a high concentration of emission. Environmental regulation creates room for technological innovation in developing countries. The work advocates research in environmental regulation.\textsuperscript{87}

\textsuperscript{85} Available at http://www.who.int/mediacentre/factsheets/fs253/en/index.html (Visited on December 3, 2016).


\textsuperscript{87} Shinsuke Tanaka, Wesley Yin, et. al., “Environmental Regulation and Industrial Performance: Evidence from China” JEL (2014).
Marlene Agerstrand, Cecilia Berg, et. al. in ‘Improving Environmental Risk Assessment of Human Pharmaceuticals’ recommends for the improvement of environmental risk assessment of human pharmaceuticals on the terms of the chemical framework. The authors consider guidelines of European Medicine’s Agency applicable for the authorization of new market products. The work underscores the importance of mixture toxicity assessment of API’s, risk management options, refinement of test proposal, best available scientific methods and streamlining legislation at regular intervals with the improving scientific knowledge. Acceptable limits of concentration set forth by regulations are required to be in consonance with environmental ends. These recommendations suggest ERA for the pharmaceutical products put on the market before the enactment of the guidance document, 2006 as posing risk does not depend upon the date of authorization. Special mention is made in favor of risk assessment of antibiotics to combat antimicrobial resistance. One ERA is recommended per API as the different ERAs may give different results. Other suggestions include the inclusion of ERA in the risk-benefit analysis conducted by pharmaceutical companies, transparency in the process of ERA and reviewing the ERA at regular intervals to make it more effective. The work seems to be the extension of guidelines issued by EMA. It talks about human pharmaceuticals. Any recommendation as to veterinary pharmaceuticals is missing. Moreover, it omits to outline disposal and collection mechanism of unwanted pharmaceuticals.

Zohar Barnett-Itzhaki, Tamar Berman’s work ‘Household Medical Waste Disposal Policy in Israel’, as its title suggests, it, outlines household medical waste disposal policy in Israel. It reveals that presently there is no legislation concerning household medical waste disposal or collection. However, collection programs are run by HMO. There are nations where pharmacies or producers are responsible for funding, for collection and disposal programs on the basis of ‘polluter pays principle’. For Israel, the authors suggest certain measures to improve the situation. These measures include creating awareness as to harmful implications of improper disposal of household medical waste, having an adequate legal mechanism,

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funding of disposal and collection programs.\textsuperscript{89} The paper omits to include household waste arises on account of excretion activities.

‘Global Action Plan on Antimicrobial Resistance’ by World Health Organization earmarks the appellation for an understanding of antimicrobial resistance. Antibiotics are considered to be essential for treatment as they serve as preventive as well as curative measures. But misuse and improper disposal of antibiotics throughout the life cycle is putting the world at serious risk. The plan sought to frame multi-sectoral strategy by World Health Assembly. It accentuates the requirement of ‘one health’ approach to combat the issue by coordinating the actions of various stakeholders. The plan aims to ensure accessibility of quality pharmaceuticals, continuity in successful treatment and prevention of infectious diseases. The plan takes into consideration the objective of ameliorating awareness and understanding regarding the risk posed by antimicrobial resistance, upgrading knowledge concerning the issue through cost-benefit analysis, developing measures for better hygiene, optimizing the consumption of antibiotics and developing a mechanism for Economic Impact Assessment of the socio-economic burden of antimicrobial resistance.\textsuperscript{90}

Guidance Manual on Management of Health Care Waste by World Health Organization entitled ‘Preparation of National Health-Care Waste Management Plans in Sub-Saharan Countries’ is the outcome of joint efforts of Secretariat of the Basel Convention and the World Health Organization. The document advocates for a common approach for the preparation of a national plan for the management of Health Care Waste (HCW). The management of HCW is important from a health and environmental perspectives. The manual comprehensively provides the definition, concepts and fundamental aspects concerning HCW. It necessitates the assessment of the current situation before arriving at any plan for the management of HCW. As a guidance document, it stresses on the application of the holistic approach to address the issue. Plan of implementation is equally important as the plan of management. Collaboration and co-joint efforts among various authorities


from top to bottom level are vital for the successful implementation of the waste management plan. For the preparation and implementation of such a plan, it is necessary that the people involved in the process should be trained and aware of the risk posed by particular kind of a waste. The management of waste is not only to be proper but safe also. Management of HCW means the management of waste generated out of preventive, curative, diagnosis and medicare activities. For this purpose, pharmaceutical waste is categorized as the waste that requires special attention. It is further divided into non-hazardous, potentially hazardous and hazardous categories. Another specialized category is a cytotoxic pharmaceutical waste. The study also emphasizes on the time frame to implement the national action plan. It examines the national legislation and institutional framework for initiating HCW management plan.91

Report of U.S. Environment Agency on ‘Guides to Pollution Prevention: The Pharmaceutical Industry’ provides for waste minimization assessments of pharmaceutical manufacturing plants. Pharmaceutical production processes generate a variety of waste. This cover spent fermentation broths, process liquors, solvents, equipment wash waters, spilled materials, off-spec products,92 and used for processing aids. In America, waste minimization is a policy specifically mandated by the U.S. Congress since 1984. This policy is adopted by the U.S. Environmental Protection Agency (EPA) to ensure that new methods and approaches should be developed for minimizing hazardous waste. Waste minimization consists of two things, source reduction and recycling. For waste minimization, there is a manual known as The Waste Minimization Opportunity Assessment Manual (USEPA 1988). This manual elaborates how to conduct a waste minimization assessment and develop options for reducing hazardous waste generation. It explains the management strategies needed to incorporate waste


92 Off-spec products means the products that do not meet specified or standard requirements.
minimization into company policies and structure, how to establish a company-wide waste minimization program, conduct assessments and implement options.³³

Highlighting the increasing frequency of severe environmental annihilation, Sabina Salim in her doctoral studies guided by Paramjit S. Jaswal, renowned environmental jurist, titled ‘Trans-Boundary Environmental Harm- A Critique of Emerging Liability Principles’³⁴ made a mark by earmarking the difference in the meaning of ‘harm’, ‘damage’, ‘environmental harm’. The work emphasizes upon the consistency in revisiting and re-assessment of traditional principles of environmental law in the light of environmental destruction, whether by way of air/water/soil/marine pollution, land contamination, climatic changes, desertification or loss of biodiversity. If the planet Earth is to survive through sustainable development, the stress has to be on binding laws and not mere guidelines. The trend of entering into treaty instruments and leaving it to the individual signatories to set up a national response mechanism to environmental threats has been the matter of concern by the researcher. Emphasising upon the need to ensure harmony between the fundamental principles of international environmental law, the work appreciates the initiative of Indian Parliament in rendering constitutional status to environment protection and role of the judiciary in evolving the doctrine of absolute liability. The work does cover the issue of Hazardous Waste Management – its generation, effect and causing irreversible damage to the flora and fauna, the liability of the occupier in detail. The work advocates for recognizing and strengthen the concept of strict liability in international law and national law as a supplementary basis for determining the liability and awarding the damages. Identify the vacuum in the area of holding the state liable, the work unfolds the levels of irreparable damage to the environment.

Monika Sharma in her Ph.D. work ‘Legal Control Mechanism for Water Pollution with Special Reference to the State of Punjab’ (2007) with Paramjeet S. Jaswal has emphasized upon the need to update the laws in a way so as to nip the issue


at the bud instead of damage control at subsequent stages. Encouraging the public participation in environmental governance, the researcher appreciated the judicial approach in rewarding the whistle blowers.\textsuperscript{95} Though Monika Sharma has recommended for giving free hand to the officials of State Pollution Control Board and avoid political interference yet it would not be out of place to refer here that such a free hand to the official may result into the promotion of corrupt practice and legal extortion. The gap exists in the study so as to identify more effective suggestions for the proper implementation of the law. The significance of the work lies in its recommendation for the incorporation of the concept of clean-up costs, use of science and technology, strategic industrial development and harmony between principles of international environmental law and national environmental laws.

‘Good Manufacturing Practices for Pharmaceutical Products: Main Principles’ document by World Health Organization presents a detailed overview of the required good manufacturing practices in the manufacture and quality control of pharmaceuticals and pharmaceutical specialties. Its first draft was prepared in 1967, accepted and published in 1968. Thereafter, it has been revised from time to time. This document may be used as a training manual for inspectors, quality control and quality assurance staff in the pharmaceutical manufacturing. To be a part of WHO certification scheme, the status of GMP has to be justified on the terms of this document. This guide is applicable to the production of finished dosages of the pharmaceuticals. It covers a number of aspects related to sanitation, hygiene, production, analysis, self-inspection, quality audit, personnel, training, premises, equipment, material, documentation etc. However, it does not cover environment protection aspect.\textsuperscript{96}

\textsuperscript{95} Monika Sharma, \textit{Legal Control Mechanism for Water Pollution with Special Reference to the State of Punjab} (2007) (Ph.D. thesis, Panjab University, Chandigarh).

'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'\(^97\) are provided under Schedule M of the Drugs and Cosmetics Rules, 1945. These practices do not include environmental considerations. However, numerous other aspects concerning manufacture of pharmaceutical products are covered under these practices e.g. general requirements as to location of building and premises, water system, sanitation system, production area, personnel training, health, clothing of workers, manufacturing operations and various types of control including quality controls, equipment, documentation and records, disposal of wastes which provides that:

1. waste has to be disposed of as per the guidelines of pollution control board;
2. additional precautions are required to be taken for storage and disposal of rejected pharmaceuticals;
3. hazardous and toxic waste is required to be managed as per National and State Legislations.

The researcher has reviewed the literature related to various notifications, orders, guidelines concerning the matter\(^98\), issued by Central Pollution Control Board, Ministry of Environment, Forest and Climate Change from time to time. Data and information on the website of CPCB and MoEF & CC has been used at the relevant places in subsequent chapters.


104 Bosun Banjoko, Pharmacology and Therapeutics (Intech, 2014).
107 Tarun Arora, Environmental Law (Osbert Publishing House, New Delhi, 2006).
108 Telangana State Industrial Infrastructure Corporate Limited, Environment Protection Training and Research Institute, Draft Report Environment Impact Assessment for Proposed Hyderabad Pharma City (January,2018)
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¹²⁰ Christoph Lubbert, Christian Baarset. et. al., “Environmental Pollution with Anti-microbial Agents from Bulk Drug Manufacturing Industries in Hyderabad, South India is Associated with Dissemination of Extended-Spectrum Beta-Lactamase and Carbapenemase-Producing Pathogens” Springer (2017).


The review of the literature reveals that the problem of PiE has been viewed mainly from scientific angles. So far as the attention of regulators and legal academia is

\textsuperscript{130} Holling, C.S., (ed.), \textit{Adaptive Environmental Assessment and Management} (John Wiley & Sons, New York, USA 1978).


concerned, it has not been perceived so serious and appalling. ‘Pharmavision 2020’ sets out the target for the pharmaceutical industry to grow up to $55 billion. The focus of government is also on attracting foreign investment and alluring the Indian masses on the pretext of development. Overlooking the impact of irrational and reckless industrial development, the government and regulatory agencies seem to have in hands in glove with the MNCs.