RISK FRAMING IN ASSISTED REPRODUCTIVE TECHNOLOGIES:

A STUDY ON BIOMEDICAL GOVERNANCE IN INDIA

Dissertation submitted to Jawaharlal Nehru University in partial fulfilment of the requirement for the award of the Degree of

MASTER OF PHILOSOPHY

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DECLARATION

I do hereby declare that the dissertation entitled "Risk Framing in Assisted Reproductive Technologies: A Study on Biomedical Governance in India" submitted by me is a bonafide work and that it has not been submitted to any other University for the award of any Degree.

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CONTENTS

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LIST OF TABLES

ABBREVIATIONS

ACT	Assisted Conception Task Force
ART	Assisted Reproductive Technology
BMI	Body Mass Index
ERMA	Environmental Risk Management Authority
EPLF	ESHRE Patient Leaders Forum
ESHRE	European Society for Human Reproduction and Embryology
E U	European Union
GDP	Gross Domestic Product
GIFT	Gamete Intra fallopian Transfer
GMO	Genetically Modified Organisms
GRAEL	Green Alternative European Link
HFEA	Human Fertility and Embryology Authority
hMG	Human Menopausal Gonadotrophin
ICMR	Indian Council for Medical Research
ICSI	Intra Cytoplasmic Sperm Injection
IVF	In Vitro Fertilization
LH	Lieutinizing Hormone
NGO	Non Governmental Organization
NII	National Institute of Immunology
NIH	National Institute of Health
NIVF	Natural In Vitro Fertilization
OECD	Organization for Economic Co-operation and Development
OHSS	Ovarian Hyper Stimulation Syndrome
PGD	Preimplantation genetic Diagnosis
PZD	Partial Zonal Dissection
rFSH	Recombinant Follicle Stimulating Hormone
SUZI	Sub Zonal Insemination
TESE	Testicular Sperm Extraction
uFSH	Urinary follicle Stimulating Hormone
U S	United States of America
WHO	World Health Organization
ZIFT	Zygote Inter fallopian transfer

Chapter - I

INTRODUCTION

> "In the struggle over risks of modernization we are no longer concerned with the specific value of that which appears to us in perception. What becomes the subject of controversy as to its degree of reality is instead what every day consciousness does not see, and cannot perceive".[1]

Ulrich Beck in the above analysis points to the transcendence of the notion of risks of modern technologies in the last quarter of the twentieth century. According to Beck, risk is no more a generalized analysis of self evident events, but a phenomenon that is contextual and overlapping personal, social, cultural, economic and ethical spheres. The importance of the social, cultural and contextual interpretation of risk in the backdrop of technological uncertainty is that it has placed a legitimate claim for public engagement in regulating technologies in the western societies.

The social science scholarship on risk has problemetized the one-dimensional and reductionist analysis of technological risk by experts, which had led to the evolution of inclusive governance mechanisms for risk analysis and decision making in the developed countries. The governance mechanisms are inclusive in the sense that they offer space for different sections of the society to voice their concern on particular technological interventions. Actors and institutions are incorporated into decision making bodies. The shaping of these novel governance mechanisms in decision making related to science and technological issues is interpreted as a shift in the science-society interaction. The interaction characterized by a unidirectional communication style and authoritative decision making process has shifted to a multidirectional communication style and to a participatory decision making process in developed societies.[2] However, the shaping of technology governance mechanisms is seen to be contextual depending on the social and cultural values and democratic practices prevalent in societies. Science-society interaction is also seen to be varying with different fields of science due to the strategic

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1.Beck, Ulrich, *Risk Society: Towards a New Modernity*, (Trans) Mark Ritter, London: Sage, 1992, p. 73.
2.Callon, Michel, "The Role of Lay People in the Production and Dissemination of Knowledge", Science *Technology and Society*, 4, 1999, pp. 81-94.

nature of scientific fields like nuclear energy etc. Hence the implication of the social and cultural interpretation of risk for public engagement in science and technological issues may vary from society to society. How far concerns of different sections of the society are accommodated in regulating technological risks is unclear in the context of developing and underdeveloped countries since the literature is overwhelmingly focused on western societies. It is observed in the case of stem cell research in India and China that the market and science intertwine to shape regulatory regimes where ethical and legal issues are ignored.[3] The observation assumes relevance in the context of the increasing flow of technologies and the research activities especially in the field of biotechnology. It needs to be examined in the light of the above observation whether regulatory policies are shaped by experts and markets or by the interpretation of risk by social actors and cultural values. The study assumes that regulatory policies reflect science-society interaction in the context of particular societies and particular technologies.

The convergence of biotechnology and medicine into biomedicine and ongoing research in biomedical technologies has aroused serious concern in terms of risk among different sections of the society. The development of innovative sectors like tissue engineering and stem cell research has resulted in the commercialization and circulation of human cells, tissues and organs in the global market place and laboratories[4]. The development of new areas in biomedical research involving human embryo and genetic materials have evoked debates about, social, ethical, legal, economic and public health risks involving these technologies. Public health experts have started questioning these technologies on grounds of the public health hazards that technologies like Genetic Screening and Pre-Natal Genetic Diagnosis (PGD) implicate on the professional and personal life of those undergoing these technologies. They have also questioned the technological efficacies of Tissue Engineering, Genetic Engineering and Artificial Reproductive Technology (ART). There are others who question these technologies in terms of the accessibility and

3. Bharadwaj, A., & Glasner, p., (eds.) *Local Cells, Global Science: The Rise of Embryonic Stem Cell Research in India*, London & New York: Routledge, 2009, p.3.
4. Faulkner, Alex *et al.*, "Tissue-Engineered Technologies: Scientific Biomedicine, Frames of Risk and regulatory regime- Building in Europe", *Science as Culture*, 17(2), 2008, p.196.

affordability to the larger public. Sociologists like Nikolas Rose, consider the development of Customized medicine and technologies based on genetic engineering would elevate the existing health inequalities and engender new eugenic possibilities.[5] Religious institutions, especially the Catholic Church have heavily criticized that the assisted reproductive technologies, sperm and ovum banks and that surrogacy would change the basic definition of family.[6] Legal circles are grappling with the issues that have arisen out of research in biomedicine and the circulation of the forms of knowledge and products from these researches. According to a Law Commission of India Report, 'surrogacy involves conflict of various interests and has inscrutable impact on the primary unit of society viz. family.'[7]

The above discussion throws light on the issues grappled by different societal actors and one can see that the concerns are heterogeneous. Usually the concern and the hope over emerging technologies are articulated in terms of their risks. It is important to understand how these risks are played out in policy formulation circle? Do all the actors have equal opportunity, especially in the 'Developing Countries'? What risks are legitimized and given space in governance? Expanding sectors of biomedical research, and the novel and innovative technologies evolving out of laboratories, their risks and uncertainties are challenging the existing regulatory regimes globally. One such emerging sphere of governance in biomedical technologies is the Assisted Reproductive Technologies (ART).[8] In India, Assisted Reproductive Technologies which offer treatment for infertility have remained unregulated for nearly three decades. ARTs' have recently received attention from different sections of the society as a result of the controversies over the development of innovative technologies. Controversies range from surrogacy to health implications for those undergoing treatment and that for donors, stem cell research to

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5.Rose, Nikolas, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the Twenty-First Century*, Princeton: Princeton University Press, 2007, pp. 9-38.

6.The Indian Express, "Kerala church Criticizes surrogacy bill" *The Indian Express*, June 24, 2010. Accessed from http://www.indianexpress.com/news/Kerala-church-criticises-surrogacy-Bill/637771, on 25.06.2010.

7.Law Commission of India Report, number 228. August 2009.

8. Assisted Reproductive Technologies are those technologies which assist couple in conception. They are classified in to in vivo techniques and in vitro techniques depending on place of fertilization of egg. In in vitro the egg is fertilized outside the body of woman and in in vivo the egg is fertilized inside the body of women.

status of the embryo, health tourism to efficacy and affordability of the treatment. The Indian Council for Medical Research has come up with The Assisted Reproductive Technologies (regulation) bill 2008 and the new regulatory regime for the ARTs' is in the shaping. The present bill is contested from different quarters of the society. Women's rights groups have complained that the health implications and range of social and ethical issues raised by the technology has not been duly considered in the bill.[9] The present study explores the implications of the social, cultural and contextual articulation of risk for the regulation of assisted reproductive technologies.

1.1 RATIONALE OF THE STUDY

Regulatory policies not only imply the societal sanction to technologies but also set the rules of the game. Regulatory regimes are instituted to draw the contours of the body of knowledge under question. In the 'Developed' societies, critic of technology is largely based on their inherent risks and ethical issues. In the Global South technologies need not only viewed in terms of their potential risk but through the prism of the historical inequalities that the Global South had been subjected to by these technologies. The 'Digital Divide' is one such example of how technologies can exacerbate inequalities. Technologies can reproduce and reinforce the old inequalities in new forms. The skewed sex-ratio in the Afro-Asian countries caused by female foeticide due to the indiscriminate use of Pre-Natal Diagnostic Technologies is one such example of how technologies can reproduce social, political and cultural inequalities. These are issues which call upon participation from all sections of society in the framing of regulations and governance of technologies

Contemporary Governance of science and technology grapples with the question of narrowing the ever widening gap between scientific Knowledge and the public representation of technologies and ways to engender trust in technologies.[10] Scholars like Sheila Jassanoff argue that the present nature of technological governance is still dominated by the expert framing of risk of technologies. Sheila Jassanoff (2003) calls this

9. SAMA TEAM, "Assisted Reproductive Technologies: For Whose Benefit?", *Economic and Political Weakly*, 44 (18), 2009, pp. 25-31..
10. Jasanoff, Sheila, "Technologies of Humility: Citizen Participation in Governing Science", *Minerva*, 41, 2003, p. 224.

model of governance as 'speaking truth to power'. According to her, this model calls for technical inputs to policy problems to be developed independent of political influences[11]. Some scholars view the engagement of society through public consultations as shift from the 'public deficit' model of science- society interaction, where experts preach the possibilities of science. There is another argument that public consultations have not marked a radical shift from the 'public-deficit' model of engagement because debates on risk and benefits in public consultations take place on the assumption that the scientific knowledge is uncontestable.[12] These are arguments which can only be placed in the context of western societies where public engagement in science and technology issues is sought at least in controversial issues. In the context of third world countries like India, examination of these two arguments should start from exploring the possibilities for public engagement offered in the wake of the social, cultural and contextual articulation. The study is premised on three arguments and examines these arguments in the area of assisted reproductive technologies.

1. Uncertainty on the technological outcomes and the social, cultural and contextual interpretation of risk has led to the emergence of a space for interrogation of science and technology and public engagement in decision making in issues related to regulation of science and technological risks.

2. The lack of consensus among experts on controversial scientific issues places a legitimate claim for public engagement in issues related to science and technology.

3. Public engagement informs regulatory policies with social implications of technologies, which are otherwise ignored or sidelined by the experts, thereby enriching the regulation of technological risks.

These theoretical propositions are examined in the context of the evolving regulatory regime of Assisted Reproductive Technologies in India where participation of all sections of the society in the governance can be contested. Therefore it becomes relevant to study how different actors frame risk of ARTs, which risk frames are legitimized and how are they reflected in the regulatory policy. To understand the implications of risk framing by

11. Ibid, p.225.
12. Ibid.

different actors for the governance of ARTs' the study explores the following questions.

1.2 RESEARCH QUESTIONS

1. How does risk framing by different actors reflect in the regulatory policy of Assisted Reproductive Technologies in India?
2. What are the different Assisted Reproductive technologies and the social, economical, legal and ethical issues raised by these technologies?
3. What are the implications of social, cultural and contextual articulation of risk for the public engagement in regulating assisted reproductive technologies?
4. Who are the actors and what are their interlinkages?
5. What is the nature of public engagement in issues relating to assisted reproductive technologies?

1.3 OBJECTIVES

The study aims to understand the implications of risk framing by different actors on the public engagement in regulating Assisted Reproductive Technologies by studying the risk framed by the different actors and their reflection in the Assisted Reproductive Technologies (Regulation) Bill 2008. The objectives of the study are as follows.

1. To study the implications of social, cultural and contextual articulation of risk for the public engagement in regulating Assisted Reproductive Technology in India.
2. To understand Assisted Reproductive Technologies and identify the debates and actors in the area of social science and reproductive medicine.
3. To analyze the representation of risk frames in the Assisted Reproductive Technologies (regulation) Bill 2008 and draw inferences on public engagement in issues related to assisted reproductive technologies.

1.4 REGULATORY POLICIES IN SHAPING TECHNOLOGIES

Regulatory policies set the rules of the game thereby shaping the technologies and institutions which can be legitimized and can prevent technologies that pose societal

risks.[13] The regulatory regimes as social and political construction reflect whose interests are protected and what kind of risks are recognized. In other words, the study of the political and social process in the construction of regulatory regimes reveals whose interests are sidelined and what risks are delegitimized. The term Governance indicates a change in the behaviour of the state. It connotes to the departure of the state from the traditional way of governing in which decisions on behalf of populations are taken by their elected representatives and implemented by bureaucratic machineries14. Governance, represented as change in the nature of the state, brings in different sectors of the society in to the political space of decision making and implementation. Governance is thus conceptually referred to as the 'Societal Steering' and in action, a process of coordinating different societal actors within networks.[15]

1.5 TECHNOLOGY AND GOVERNANCE

The Discussions on the governance of technologies are commonly centered on their potential benefits and risks. Risks and Benefits are perceived and articulated by different actors and risks are framed according to their interests. Governance of science is expected to converge scientific knowledge and society through regulatory policies and enable technologies to be used for societal good by restraining their deleterious effects on human health and environment. The increasing public consultations on different issues of technology show that role of society in sanctioning technology is increasingly sought by scientists and policymakers. The increasing interest of scientists and policy makers in the governance of innovative biomedical technologies stems from the public responses to these technology and the 'Crisis' of trust in the regulatory regime of biomedical technologies.[16]

1.6 ASSISTED REPRODUCTIVE TECHNOLOGIES

Assisted Reproductive Technologies commonly refers to techniques and therapies used to facilitate reproduction. The technologies can be broadly classified in to In Vitro

13. Faulkner, Alex *et al.*, 2008, op cit., p.198.
14. Treib, Oliver, *et al.*, "Modes of Governance: Towards a Conceptual Clarification", Journal *of European Public Policy*, 14 (1), 2007, p.3.
15. Ibid. originally cited in Jordan, A. and Schout, A. *The Coordination of the European Union: Exploring the Capacities of Networked Governance*, Oxford: Oxford University Press, 2006.
16. Peterson, Alan & Anderson, Alison, "A Question of Balance or Blind Faith? : Scientists and Science Policymakers' Representations of the Benefits and Risk of Nanotechnologies", *NannoEthics*, 1, 2007, p.244.

Fertilization techniques and In Vivo fertilization techniques.[17] World health organization estimates that 13-19 million couples in India are infertile of which 8 per cent of the couples opt for medical intervention involving advanced Artificial Reproductive Technologies (ART). The study has chosen ART for three reasons: 1) the infertility treatment in India had remained highly unregulated for over three decades.[18] Infertility treatment and research on human embryos is devoid of public funds, government scrutiny and insurance coverage and is being carried out in private settings with private funds.[19] 2) The cultural significance attached with motherhood and man's procreativity subjects infertile couples to high psycho-social pressure concomitantly to the painstaking process of ART.[20] 3) It is argued that the recent scientific developments in biomedicine such as stem cell research have a direct impact on Assisted Reproductive Technologies (ART). The ethical dilemmas involved in the commercial transfer of embryonic material, stem cells, etc. are complex, and have yet to be played out in the arena of individual lives, the medical establishment and the market.[21]

1.7 ANALYTICAL FRAME WORK

To understand how the perception of technological risk by different actors shapes the regulatory regime of Assisted Reproductive Technologies, the present study draws on the theory of social construction and risk framing. The scholarship in science and technology studies has unveiled risk from its statistical and cost-benefit analysis models and situated in the complex social and political spaces of human interaction. Risk is not simply an expert calculation to be mitigated by probability analysis, but strongly interwoven into modern human condition and deeply embedded in the notion of progress.[22] Elliot's summary of Beck's risk thesis provides a more meaningful understanding of the conflict between risk and the notion of progress. He suggests that, according to Ulrich Beck, the

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17. Letterie, Gerald, *Surgery, Assisted Reproductive Technology and Infertility: Diagnosis and Management of Problems in Gynecologic Medicine*, Oxon: Taylor and Francis, 2005, p.18.
18 Allahbadia, G. N. & Kaur, K., "Accreditation, Supervision, and Regulation of ART Clinics in India—A Distant Dream?", *Journal of Assisted Reproduction and Genetics*, 20 (7), 2003, p.276.
19. Ibid.
20 Widge, A. & Cleland, J., "Assisted Reproductive Technologies in India: the Views of Practitioners", *Human Fertility*, 12 (3), 2009, p.144.
21 Murthy, *et. al.*, "ICMR Guidelines on Assisted Reproductive Technologies: lacking in vision , wrapped in red tape", *Indian Journal of Medical Ethics*, 4, (3) ,2007.
22 Jasanoff, Sheila, 2003, op cit.

novelty of nuclear, chemical and genetic technologies is that they have dismantled the parameters of calculable risk on which the modern societies have developed a consensus on progress.[23] Another theoretical position on the social construction of risk is by those who argue for a context specific science. Social construction of technological risks does not emerge from vacuum; they are embedded in a context formed by the social and the material.[24] According to this view the risk perception of different actors varies depending on the social and technological context in which they are associated.

According to Faulkner et.al.,(2008), risk framing is interlinked with the building of regulatory jurisdiction, where actors combine or separate risk frames flexibly there by making the social management of risk a space for negotiation between different actors. Faulkner *et al.*, identify three risk frames which the scientific- industrial actors in the tissue engineering zone of EU employed in their study. They are 1) technological safety 2) therapeutic efficacy and 3) economic risk[25]. Risk perception is seen as a collective phenomenon in which every cultural group is seen to accept certain risks and negate other risks.[26] Sheila Jassonoff (2003) offers four focal points around which new technologies of humility can be developed. They are *Framing, Vulnarability, Distribution and learning.* She argues that solutions to problems are influenced by the framing of regulatory issues[27]. Drawing on Faulkner *et al.,* 's concept of risk frames the study employs the notion of framing of risk by different actors to study the implications of social, cultural and contextual interpretation of risk for public engagement in the area of assisted reproductive technologies . The study also employs Callon's (1999) model of public engagement in science and technology and Mikko Rask's (2003) public engagement paradigms in policy making related to science and technological issues to draw inferences on public engagement in the area of assisted reproductive technology.

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23 Elliot, Anthony, "Beck's Sociology of Risk: A Critical Assessment", Sociology, 36 (2), 2002, p.296.

24 Jones, Horlick, "Meaning and Contextualisation in Risk Assessment", *Reliability Engineering and System Safety*, 59, 1998, pp. 79-89.

25 Faulkner, A., *et al.,* 2008, op cit, pp. 216-17.

26 Finucane, M. L., *et al.,* "Psychosocial and Cultural Factors Affecting the Perceived Risk of Genetically Modified Food: An Overview of Literature", *Social Science and Medicine*, 60, 2005, pp. 1603- 1612.

27 Jasanoff, Sheila, 2003, op cit.

1.8 METHODOLOGY

The data for analysis is generated from secondary sources, which is supplemented by data from the interviews conducted among persons who are related to and knowledgeable in assisted reproductive technologies. The study employed case study method for generating primary data. The data was collected through field work among six key respondents. The respondents include a male partner of a couple who has undergone ART, a key policymaker in ICMR, a male and a female scientist from National Institute of Immunology, a female women's rights activist and a male representative of a Non Governmental Organization working on population issues. The secondary data for analysis was generated from a study conducted by an NGO named SAMA and by surveying four websites of ART service providers. The Assisted Reproductive Technologies (regulation) Bill 2008 serves as the primary material of analysis. The key indicator is the risk frames of different actors in the field of assisted reproductive technologies. The risk frames are analyzed as indicators in the bill for understanding public engagement in the issues related assisted reproductive technologies in India.

1.9 CHAPTERISATION

The study is presented in five chapters. The first chapter introduces the study and describes the methodology of the study. The second chapter explores the theoretical perspectives linking the social, cultural and contextual interpretation of science and technological risks and public engagement in the context of biotechnology. The third chapter analyzes the debates on assisted reproductive technologies in reproductive medicine and social science to identify the issues and actors. The fourth chapter presents data from primary and secondary sources to analyze the risk frames of different actors and its representation in the Assisted Reproductive Technologies (regulation) Bill 2008. The fifth chapter presents the findings of the study on representation of risk frames, public engagement in science and technology issues and the paradigm of public engagement in policy making in science and technology.

1.10 LIMITATIONS OF THE STUDY

An important limitation of the study was associated with the collection of primary data.

Limited time period and lack of accessibility to practitioners and individuals/couples who are undergoing or undergone the assisted reproductive treatment was faced through out the study. There were two types of responses from the practitioners either they out rightly denied permission at the first instance or they kept postponing the appointments citing their busy schedule on repeated calls. Problems in identifying the individuals/couples were the limitation with accessing field information.

Chapter – II

PERSPECTIVES ON TECHNOLOGICAL RISKS AND PUBLIC ENGAGEMENT

2.1 INTRODUCTION

This chapter examines how the perception of risks has become a dominant paradigm for questioning of science and technology policy in general and technologies in particular. It analyses the space for questioning technologies facilitated by the transforming views on risk. At the heart of this space are the issues of the lay- expert interface, public engagement, the ideological predilections of institutions and actors and its implications for the regulation of technologies. Focusing on the area of biotechnology, this chapter explores interconnections between actors, institutions, knowledge, values and culture in the discursive space of technology regulation. It examines how these interconnections play out in the shaping of regulatory regimes in different contexts. The analysis is done in the form of a review covering the literature on risk, public engagement with science and technology, regulatory governance and policy making.

The first section of the chapter analyses the changing interpretation of the concept of risk in the risk assessment and management practices with the emergence of the social, cultural and contextual articulation of risk. Secondly the chapter analyses the theoretical positions in framing of risk related to technologies. The third section reviews the different theoretical models of public engagement with science and technology issues which is followed by review of public engagement in formulation of risk management policies. The chapter also analyses the role of institutions and actors in regulatory governance. Finally the chapter contextualises the concept of governance in regulating technologies.

2.2 CONCEPTION OF RISK

The risk communication practice in the 1970's emerged from a world view that separated scientific and social world[1]. The strategies were oriented towards aligning public opinion with expert prescription of technology. The practices that followed resulted in the discounting of the discursive capacity of social factors in the development of effective risk management policies. The separation of science and social issues served the ends of depoliticising the question of risk and completely surrendering it to the techno-managerial discourse of scientific community. The politics built in to such a communication strategy was an enlightenment mission, which would educate the lay public of the possibilities of science and converge the public opinion with expert knowledge on technology and risk to a nodal point, i.e. the cost benefit analysis of risk. The expert mediated governance of risk began to be challenged by the rDNA controversies, which was followed by the Asilomar conference in 1975[2].

According to Nelkin (2001), biotechnology risks presented in the media, which influence the risk perceptions of public, has undergone dramatic change in the past two decades. Starting from a critical response to bioengineering of transgenic animals in the early 1990's, the press reports have not only linked risks to heath but also to ethical, religious, economic inequalities, trade imbalances, concerns on commercially driven science and to the questions of consumer choice[3]. The social context that had brought the risk governance of Genetically Modified Organisms (GMOs) to the centre stage of social and political discourse is two-fold. The articulation of risk invoking ethical, cultural and social values emphasizing the implications to human health and environment and the predilections in the social status of scientific knowledge resulting from the tremendous expansion of demand for specialized knowledge[4]. The deflection in the social status of scientific knowledge is an outcome of the revelation of the subversive role that expert

1. Frewer, Lynn, "The Public and Effective Risk Communication", *Toxicology Letters*, 149, 2004, pp. 391–392.
2. Nelkin, Dorothy, "Beyond Risk: Reporting about Genetics in the Post-Asilomar Press", *Perspectives in Biology and Medicine*, 44 (2), 2001, p. 199.
3. Ibid, p.204.
4. Borras, Susana, "Legitimate Governance of Risk at the EU level? The case of Genetically Modified Organisms", *Technology Forecasting & Social Change*, 73, 2006 p. 63.

knowledge plays in scientific controversies. Controversies both inside the scientific community and in the public became a platform for the application of expert knowledge by protagonists and antagonists creating a demand for expert knowledge but eventually ascribing a mutable status to the scientific knowledge. Increased demand for specialised knowledge and the mutable status of expert knowledge set the stage open for a socio-cultural and political interrogation of risk in the western societies during the turn of last century.

Reflecting on the social and cultural incompatibility in building consensus on risk calculation and mitigation among identical societies like the U. S. and European Union, Jasanoff (2002) argues that 'citizens, experts and policy-makers even in closely similar western societies (the U.S. and E.U.), cannot agree on the nature and severity of technology's risks, let alone on the measures that should be taken to control them' [5]. The European Union – United States feud in World Trade Organisation over the labelling and tracing out of genetically modified crops and food is an example of how social and cultural aspects influence on what should be counted as risk and how it should be mitigated in a given socio-cultural context [6]. In the United States, currently there are no laws requiring the labelling of genetically modified crops and food, on the other hand in the European Union public is apprehensive of the health and environmental hazards of genetically modified organisms which had led to *de-facto moratorium* on the GM crops and food in E U[7]. With regard to biotechnology it is empirically proved that people are not only concerned about the technical risk but also about the implications of the biotechnologies on the uniqueness of human nature and their relationship with other living things and especially among tribal people, who see themselves as located in networks of relations with other living things and physical environment[8]. The transcendental nature of risk from the realm of tangible, i.e. from environmental and

5. Jasanoff, Sheila, "Citizens at Risk: Cultures of Modernity in the US and EU", *Science as Culture*, 11(3), 2002, p. 364.
6. The Financial Express, Monday, 19, May, 2003.
7. Gene Watch, "WTO dispute",*Gene Watch*, (Available at: www.genewatch.org/sub.shtml?als[cid]=538152 accessed on 3.01.2010.)
8. Hindmarsh, Richard and Du Plessis, Rosemary, "GMO Regulation and Civic Participation at The "Edge of the World": The Case of Australia and New Zealand", *New Genetics and Society, 27* (3), 2008, p.192.

health hazards to the intangible, i.e. One affecting the incestuous link of tribal people with nature is not captured by the mathematical models of risk calculation. The encapsulated elements of subjectivity in the nature of risk provide insight in to various complexities of public perception of risk[9].

Empirical studies on the risk perception of BSE (related to beef and beef products), genetic modification of food, high fat diets, pesticide residues in food and Salmonella food poisoning shows that risk perception is multidimensional with its conceptualization ranging from risk to human health to the environment, the economy, animal health and the future generations[10]. Studies analysing perception of risk and benefits suggest that analysing risks associated with technology is easier compared to that of benefits because even hypothetical risks assume relevance in a given social, cultural, economic and political context where as people evaluate benefits that are tangible and concrete[11]. In an attempt to capture the objective elements of risk, what is being missed out by expert oriented risk assessment and management practices is the subjective elements of risk like the aborigine's incestuous link to nature, the ethical and moral questions raised by the technologies, the economic risk and technological exclusion of groups or the risk of technologies in sustaining and reinforcing inequalities.

According to Satterfield *et al.*, (2008) New Zealand case provides a classic example of the tensions that play out when traditional risk based approach tries to incorporate intangible spiritual beliefs. They argue that state and governance institutions get trapped in a dilemma, which reflects on the premises these institutions, are shaped[12]. In New Zealand Maoris', the indigenous population of New Zealand have special constitutional rights. Laws can be constitutional only if they are certified to be complementing the Maori cultural, ethical and spiritual values by the Maori leadership council. Recently the

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9. Slovic, Paul, "Perception of Risk posed by Extreme Events", discussion paper at the conference *Risk Management Strategies in an Uncertain World,* 2002, p. 3. (Available at: http:/ /www2. sfu.ca/ medialab /archive/2004/ 226jan2004/ notes/slovic_wp.pdf, accessed on 10.01.2010.)
10. Miles, Susan and Lynn, F., "Investigating Specific Concerns about Different Food Hazards", *Food Quality and Preference*, 12, 2001, pp. 47-61.
11. Siegrist, Michael, "A Causal Model Explaining the Perception and Acceptance of Gene Technology", *Journal of Applied Social Psychology*, 29 (10), 1999, p. 2094.
12. Satterfield, Terre and Roberts, Mere, "Incommensurate Risk and Regulator's Dilemma: Considering culture in the Governance of Genetically Modified Organisms", *New Genetics and Society*, 27 (3), 2008, pp. 206-207.

controversy on the proposed law for the introduction of genetically modified organism was opposed by the Maori council as it was contradictory to their values and beliefs. These tensions highlight incompetence of traditional risk mitigation practices to incorporate traditional beliefs and values. The dilemma experienced by state and governance institutions stems from the contract between state and science, the basis of which is to advocate techno-managerial solutions to social and political problems. The ideological lenience of institutions and actors are best reflected in the framing of risk associated with particular technologies. Risk frames are useful tools in analysing the conflicting positions of different actors and understanding the diverse meanings ascribed to risk. The following section analyses the theoretical positions on risk frames.

2.3. RISK FRAME WORKS

The cognitive and consequentialist frame work of risk suggests that people take decisions by evaluation of the desirability of possible outcome of choice alternatives and the integration of this information through some calculations of expectations[13]. The studies that emphasize socially grounded evaluation of risk suggest that the evaluative activities of people are influenced by their social contexts and networks in which the development of convenient mental strategies is embedded[14]. Irrespective of the social predispositions of different actors, risk offers a way of ordering life and rendering it in to a calculable form[15].

The literature suggests that the demand for democratization of risk assessment and management is characterised by two conflicting but correlated claims, namely the legitimatory claim and the epistemic claim[16]. According to the legitimatory claim decisions made on risk assessment and risk management can be legitimated only through the effective participation of citizens in the very process of decision making where they

13. Einsiedel, Edna F., and Geransar, Rose, "Framing Genetic Risk: Trust and Credibility Markers in Online Direct-to-Consumer Advertising for Genetic Testing", *New Genetics and Society*, 28 (4), 2009, pp. 344-345.
14. Ibid, p.345
15. Gottweis, Herbret, "Governing Genomics in the 21st Century: Between Risk and Uncertainty", *New Genetics and Society*, 24 (2), 2005, p. 183.
16. Paola Ferretti, Maria, "Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union", Science *as Culture*, 16 (4), 2007, PP. 377-378.

exercise control over the decision makers. According to the epistemic claim risk assessment and management presupposes value judgements, prioritization and interpretation of risk which depends on the value attributed to different options at stake. In order to better prioritize and interpret risk; the value systems of lay-people and experts outside the government structure need to be incorporated in to the process. While the legitimatory claim calls for procedural changes like increasing the participation of people or creating institutions to promote participation. Epistemic claim calls for structural changes like changing the nature of knowledge systems which play a deceive role in decision making.

Even though both these claims call for common ends, but the prism through which they look upon risk is divergent. The legitimatory claim presupposes risk assessment and management as a rational and logical process in which public participation is only up to the point whether the public accepts or rejects the expertise assessment of risk in fear of certain outcomes. The emphasis is on either controlling the decision making process or balancing of interests. The legitimising factor is the collective bargaining power of public. The notion of public connotes to a homogeneous group of people who have common interests, who take up an antagonist role against expert knowledge. The legitimacy of risk assessment and management practices solely depend on the ability of expert to argue and convince the public. Legitimatory claim presupposes that the possible framework for understanding risk assessment and management practices is that of expert frame work and solution lies in placing the lay public world view into the expert frame work. What is subsumed here is the social and cultural values of the public which shape their world view. Here the power of expert knowledge is enforced through convincing the lay public rather than coercion. One can find legitimatory claim enforcing a deficit model of science society interaction.

On the other hand, epistemic claim presupposes that risks are assessed and prioritized on the basis of value systems that different stake holders adhere to. Here participation, for public, is not only a space for analysing expert claims on risk but also a space for articulating their own perception of risk based on their own value system. The expert knowledge is legitimated when it is placed in the world view of the lay public. Epistemic

claim facilitates a convergence of the frame works of the expert and the lay knowledge. The convergence of frame works emerges from a democratic assimilation of different value systems. What is exemplified in the epistemic claim is the recognition of the subjective and objective dimensions of risk as it is played out in the real world. The epistemic claim can be seen to promote a public debate model of science society interaction.

The problemetisation of risk by different streams of thought as discussed above had helped to move the focus of risk assessment and management from the mere contemplation by scientists and statisticians, to the hierarchical nature of science. The contestation is directed towards the nature of knowledge production and its legitimisation. What is being questioned by risk studies is the hierarchical relationship between expert and the lay public and the scope of public engagement, who are supposed to be the receivers of knowledge in the present form of pursuit of science. The discussion on the theoretical positions in risk framing calls for an extension of the analyses of risk frames as it is experienced in the practice of regulating technological risks. The translation of the theoretical positions on risk framing in to practice reflects in the mode of engaging public with science and technology issues especially with the regulatory aspects of technology. The following section discusses in detail the scope, model and implications of public engagement in governance of technological risks.

2.4 PUBLIC ENGAGEMENT IN REGULATORY GOVERNANCE OF TECHNOLOGICAL RISKS

Public engagement is inevitable for democratic decision making in three ways, they are, framing and assessment of issues, validation of knowledge and weighing of evidence[17]. Public engagement can have different goals including education, gaining public trust in emerging technologies, influencing the direction of scientific research or policy making[18]. The "Deficit model" of scientific knowledge dissemination which is based on the top to bottom education approach of public understanding of science is being replaced by more

17. Hagendijk, Rob and kallerud, E., "Changing Conceptions and Practices of Governance in Science and Technology in Europe: A Framework for Analysis", *STAGE Discussion Paper 2*, European STAGE Network, 2003, p. 3.
18. Ankeny, Rachel A. and Dodds, Susan, "Hearing Community Voices: Public Engagement in Australian Human Embryo Research Policy, 2005-2007"', *New Genetics and Society*, 27 (3), 2008, p. 217.

democratic approaches at least in the global north[19]. Attempts to debunk public participation in decision making related to technological issues on grounds that lay people cannot understand minute details of technologies had been countered by arguments like technology is not only about technological matters it also involves social values and technological details are not crucial in understanding social dimensions [20]. Lay people may not be able to grasp the complexities in the technology with perfection but they can understand issues in relation to application of these technologies and their social dimensions and hence make choices between different technologies and therefore can enrich the decision making process related to technological issues. For example public may be ill equipped to understand the complexities in the working of nuclear technology but their opinion can inform the decision making on where the plants can be situated or the necessity of investing in R & D in renewable energy sources as opposed to that in nuclear technology. The theory suggests different models of public participation based on variables like the complementarity, authority, freedom etc. The following section discusses public engagement with science and technology based on Callon's (1999) theoretical frame work.

2.5 MODELS OF PUBLIC ENGAGEMENT

Drawing from the taxonomy of Callon (1999) this sections explore the possible models of public engagement in the governance of science and technology. Callon categorizes the participation models on the basis of the interaction process between scientific expertise and lay expertise. They are, modalities that define the engagement between scientists and public i.e. the level of mutual acceptance of each other's position in the relationship, complementarity of lay knowledge and expert knowledge, the way the particular engagement attempts to solve the "crisis of Confidence experienced by technoscience", role of scientist and public in the production and dissemination of knowledge. Further, the following section examines the implication of each model for regulatory governance of science and technology risks.

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19 Hagendijk, Rob and kallerud, E., 2003, Opp cit.

20. Carson, Lyn and Martin, Brian, "Random selection of citizens for technological decision making", *Science and Public Policy*, 29 (2), 2002, PP.105-108.

'Public Education Model'

The 'Public Education Model', conceptualised by Callon accepts the rule of experts that scientific knowledge is considered as objective, universal and far superior to local knowledge. It not only argues for science literacy but claims that scientists have nothing to learn from public[21]. The ambiguities that creep in during the interpretation of science to the public allow the experts, in the public education model, to use science to their strategic purposes[22]. Scientists enjoy powerful and commanding positions in this model and the public is devoid of any agency. The education model helps scientists to maintain the 'epistemic hierarchy' which legitimises their position over other such actors like policy makers, historians and sociologists of science and the public[23]. Callon (1999) argues that, this model being the oldest and most widely practised one , the non acceptance of public in the decision making process, the delegitimization of local knowledge had constantly brewed the 'crisis of confidence experienced by technoscience' [24].

'Public Education Model' considers public as individuals and consumers, whose choices, expectations and demands are mediated by political and economic organizations [25]. Analyzing the difference in perception of GM foods among women and men, Roten *et al.*, (2008) argue that attitude towards science and technology (positive or negative) cannot be generalized over objective criterion such as individual or consumers, they depend on the social and gender roles and to the inherent values people imbibe in relating to these roles which cannot be grasped by the traditional models of 'trust and enlightenment' [26]. In the 'traditional' model of 'Public Understanding of Science' the use of scientific knowledge is aimed for practical purposes by passing information to the

21. Callon, Michel, "The Role of Lay People in the Production and Dissemination of Scientific Knowledge", *Science Technology & Society*, 4, 1999, p. 82.
22. Hilgartner, Stevan, "The Dominant View of Popularization: Conceptual Problems Political Uses", *Social Studies of Science*, 20 (3), 1990, p. 533.
23 Ibid, pp. 533-534.
24 Callon, Michel, 1999, op cit, p. 83.
25 Ibid.
26. Von Roten, C. F. and Elvita, Alvarez, "Women's Perceptions of Biotechnologies:The Case of Genetically Modified Foods in Switzerland", in F. Molfino & F. Zucco (eds.) *Women in Biotechnology: Creating Interfaces*, 2008, pp. 267-274.

public, consequently measuring the scientific illiteracy of the public[27]. The 'Public Education Model' takes a reductionist view of risk. The risks that are analysed and described by scientists based on scientific facts are considered as objective and those that are perceived by lay people are subjective since they are not supported by scientific facts[28]. Public Education Model thrives on the 'trust in the relationship between lay people and the scientist' and the legitimation of political decisions concerning scientific issues is made based on this trust[29]. This model is criticized for its assumption of science as an unproblematic body of sure and certain knowledge, for its characterization of public as lacking expert knowledge and its attribution of dislocations in the relationship of science and public to ignorance and misunderstanding of science[30]. Since trust on scientific community plays an important role in sanctioning of scientific practice the possibilities are high that only the scientific community is taken into account in making policy decisions and hence public can be excluded partially or completely from the regulatory governance. The public education model, the public debate model and the co-production of knowledge model, which are discussed below, exist at the same time in different societies depending on the social, cultural and political values prevailing in those societies. Similarly there are possibilities of overlapping among these models over a range of scientific and technological fields as science and technology is not a single entity as it existed a century ago.

TH-19052

'Public Debate Model':

The second model proposed by Callon is informed by two changes from the 'Public Education model'. Firstly the rigid totalitarianism of scientist in the 'Public Education model' is replaced by a complementary relationship between scientific experts and lay people in the 'Public Debate Model' and secondly 'public' assumed to be homogeneous individuals or consumers are replaced by heterogeneous groups 'depending on their conditions of life, their professional activities, their age, their sex etc., and hence an

27. Michael, Mike and Carter, Simon, "The facts about fictions and vice versa: Public Understanding of Human Genetics", Science *as Culture*, 10 (1), 2001, p. 7.
28. Callon, Michel, 1999, op. cit., p.83
29. Ibid, p. 83-84.
30. Durrant, Jhon, "Participatory Technology Assessment and the Democratic Model of Public Understanding of Science", *Science and Public Policy*, 26 (5), 1999, p. 315.

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increased complementarity of lay knowledge'[31]. The analytical emphasis of 'critical Public Understanding of Science' is cultural and context specific, recognizing that knowledge is embedded in local cultural contexts and intertwined with the social identity of those interacting with the knowledge[32]. Public participation is achieved through inquiries and public hearings, through which opinions, suggestions and comments are collected from different actors or groups of actors who wish to express themselves[33]. Allan Irwin (2001) views the changing context with a certain degree of doubt, and suggests that the 'public dialogue' seems to be the recycling of the familiar deficit model notions of uninformed public, unless equal status is guaranteed to public knowledge and scientific understandings[34]. In this model agreement on issues are not reached with the support of 'brilliant and self-confident science' but by compromise which is an outcome of complicated strategic games[35]. The complementarity of universal scientific knowledge and the local knowledge in this model is seen to be enriching the scientific knowledge, which is evident in the risk analysis of nuclear plants and testing of new drugs[36]. Callon (1999) argues that the possibility of expression facilitated by the 'Public Debate Model can avoid the 'crises' reflected in the 'Public Education Model'[37]. The third model proposed by Callon is 'The Co-Production of Knowledge Model'.

The Co-Production of Knowledge Model':

According Callon(1999) both the 'Public Education Model' and the 'Public Debate Model' is characterized by demarcation between scientist and the lay public to varying extent. The participation of public is complete in 'The Co-Production of Knowledge Model' because it actively involves lay public in the creation of knowledge concerning them[38]. Knowledge in this model is the single by-product of close collaboration between specialists and non specialists, which is marked by a greater level of mutual acceptance compared to other two models[39]. The potential of this model in legitimizing the role of

31. Callon, Michel,1999, op cit., p. 84-85.
32. Michael, Mike and Carter, Simon, 2001, op cit., p. 7.
33. Callon, Michel, 1999, op cit., p. 87.
34. Irwin, Alan, "Constructing the Scientific Citizen: Science and Democracy in the Biosciences", *Public Understanding of Science*, 10, 2001, p. 3.
35. Callon, Michel, 1999, op cit., p. 87.
36. Ibid, pp. 85-86.
37. Ibid, p.88.
38. Ibid, p.89.
39. Ibid, pp. 89-90.

lay people is demonstrated in the U. S. in late 1980s and early 1990s[40]. This is exemplified in the AIDS activists' intrusion in to the avenues of expert- bureaucratic bodies like the National Institute of Health (NIH) Committee on clinical trial. The AIDS activists' Challenged the hierarchical relations between the lay and expert people, through a blend of scientific-expert vocabulary and knowledge and non scientific- lay language and judgements.

The notion of public, a generalized and undifferentiated one in the 'Public Education Model', undergoes a subjective transformation to 'concerned' groups in the 'The Co-Production of Knowledge model', which affirms the existence of specific situations of human living and places the knowledge produced in local contexts[41]. Unlike in 'Public education Model', what concerns risk in 'The Co-production of Knowledge Model' is not the occurrence of unexpected events from the outside but the knowledge that threatens the very identity of the actors[42] . According to Callon, if the legitimization process in 'Public Education Model' and 'Public debate model' depended on trust in scientists and the representation of differentiated public respectively, the legitimacy of production of knowledge and identities in 'The Co-Production of Knowledge Model' depends on the 'concerned' groups 'ability to gain recognition for their actions' [43]. The implication for regulatory governance in this model can be the exclusion of those groups who are powerless to gain recognition for their activities in the production of knowledge, since they cannot legitimize the production of knowledge.

Analysing perception of public reaction and public engagement in these models in the governance of technologies, one can find that the 'Public education model' is based on the ignorance of public in scientific knowledge. In following this model policy makers and scientists assume that 'knowledgeable citizens' support new and beneficial technologies. Resistance arises out of public ignorance, superstition and irrationality[44]. The 'public debate model' appears to be a progressive and democratic way of engaging public with science. The underlying philosophy of this model seems to be mutual respect by promoting the participation of lay people in analysing and sanctioning science. The

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40. Epstein, Steven, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials", *Science, Technology, & Human Values*, 20 (4), 1995, pp. 408-428.
41. Callon, Michel, 1999, op cit., pp. 90-91.
42. Ibid, p.88.
43. Ibid, p.92.
44. Jasanoff, Sheila, 2002, op cit., pp. 366-367.

main constraints in practising this model are, the extent of debate or participation largely depends on political and social culture of the society. Secondly, the participation of public in terms of numbers or the representation from different sections of the society and their input in the debate in terms of knowledge and experience will largely depend on their access to resources. The Co-production of knowledge model suggests a radical approach in the engagement of public with science. Public participation moves ahead from mere tokenism to recognising public as equal contributors in knowledge production. The model can be a failure in practice unless the power and authority of expert is overcome through social and political instruments. Thirdly, groups with relatively less access to resources may be marginalised in the production of knowledge. The above debate can be summarized in the following table (Table 2.1).

Table 2.1: Public Engagement Model in Science

Dimensions of Relationship	**Public Education Model**	**Public Debate Model**	**Co-Production of Knowledge Model**
Science-Society Relationship	Hierarchical	Complementary	Participatory
Status of scientific Knowledge	Authoritarian	Based on Consensus	By-product of specialist non specialist interaction
Status of lay knowledge	Judgemental	Enriching Scientific	Equal contributor to scientific knowledge
Role of scientific community	Educators	Producers of Knowledge	Co-producers
Role of Public	Learners	Learners/analysers	Co-producers
Public is contributed by	Individuals/ consumers	Heterogeneous groups	Concerned groups
Legitimising Factor	Trust in scientists	Trust in science and consensus	Ability of concerned group to gain public recognition
Risk	Objective/ Calculated based on cost benefit	Context specific/ varies from person to person	Practices and knowledge that threaten the identity of concerned groups

Source: Callon, 1999, compiled

2.6 PUBLIC ENGAGEMENT AND POLICYMAKING IN RISK ASSESMENT

Analysing the historical and cultural imperatives, that led to the formal separation of risk assessment from risk management, which include the 'monolithic alliance of science and technology with state' and 'rise of mega corporations and the capture of politicians and decision makers by industry', Jasanoff (2002) argues that the validity of the following three propositions, which formed the basis of public policy making is being questioned. Stating the propositions Jasanoff calls to politicize science by opening up the production of policy- relevant knowledge for public scrutiny and input[45].

1. Technical analysis of policy problems should be separated from values and economic impacts.
2. Disagreement between expert and lay framing of risk reflects lack of scientific understanding and public resistance to technology is Luddite rejection of progress.
3. Cross national divergence in risk policy or in public perceptions of risk is a consequence of self interested protectionism or wilful disregard for science.

The challenges to these propositions are premised on the assumption that framing of issues in policy formulation emerges from a world view constructed by values, judgements and interests in a particular context. The first proposition for the separation of technical analysis is challenged on the ground that the values, judgements and interests influence the framing of policy issues in the beginning and hence provocative participation of the public is essential in the early stages of participation[46]. The argument here is that analytical judgements and decision making are strongly interrelated. The second proposition that opposition to science and technological progress stems from lack of understanding of science is challenged on the ground that risk frames divergent from experts reflect only the different perceptions of technology's social implications and feasibility of control[47]. The argument is that policy making should be a democratic process ensuring complementarity of lay and expert knowledge. The third proposition

45. Ibid, pp. 368-370.
46. Ibid, pp. 368-370.
47. Ibid.

that cross-national divergences in risk policy or public perceptions of risk are a consequence of self interested protectionism or wilful disregard for science is challenged on the ground that difference between countries and cultures should be recognised as reflecting important differences in values and commitments of democratic societies[48]. The argument is that policies are influenced by socio-cultural practices in respective societies are different , since no national perspectives can be considered as uniquely right or rational the need for harmonised policies cannot be considered as legitimate claim. The analysis suggests a transformation in policy making from a rigid expert driven policy making process aimed at harmonisation of policies to an accommodation of values, judgements and interests of different sections of the society.

Following the literature of sociology of public understanding of science and its idea of Science, Technology and citizenship, Mikko Rask (2003) proposes three main paradigms in citizen participation in policy making related to science and technology issues[49].

Mikko Rask (2003) suggests three paradigms in the public engagement with policy making related to science and technology. They are the Enlightenment Paradigm, Economic Paradigm and the Critical Paradigm. The policy mission in Enlightenment paradigm is the raising of all round science education or in other words increasing the science literacy. The policy mission in Economic paradigm is the development of favourable conditions for scientific and industrial development. The policy mission in Critical paradigm is a critical exploration in science and technology for socially sustainable decision making. The nature of communication in enlightenment paradigm is one-way and that in economic paradigm is one-way or multiple-way and that in critical paradigm is multiple way. The role of citizens in enlightenment paradigm is receivers of correct information, in economic paradigm the role is that of opinion formers and in critical paradigm the role is that of co-framers of S&T issues. The role of S&T community in enlightenment paradigm is provider of correct information, in economic paradigm the role is that of legitimiser of S&T and in critical paradigm the role is that of public scrutinizer of S&T.

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48. Ibid.
49. Rask, Mikko, "The Problem of Citizens' Participation in Finnish Biotechnology Policy", *Science and Public Policy*, 30 (6), 2003, p. 443.

Table 2.2: Paradigms in Public Engagement in Policy Making

	Enlightenment paradigm	**Economic paradigm**	**Critical paradigm**
Policy mission	Raising of all-round science education	Favourable conditions for scientific and industrial development	Critical public reflection on S&T, socially sustainable decision making
Nature of communication	One-way	One- or multiple- way	multiple-way
Role of citizens	Receivers of correct information	Opinion formers	Co- framers of S&T
Role of S&T community	Provider of correct information	Legitimiser of S&T	Public scrutinizer of S&T

Source; Mikko Rask, 2003, compiled

Analyzing the biotechnology policy in Finland, Rask (2003) argues that the biotechnology policy in Finland is dominated by enlightenment and economic paradigm[50]. Though these three paradigms appear to be rigid conceptually, in practice they can be overlapping or exist independently at the same time. The strategic nature of science in politics may lead to placing different streams of science in different paradigms or sometimes an overlapping of different paradigms. The paradigm followed in health biotechnology need not be the one applied for nuclear research or defence research. Similarly one can find overlapping of paradigms in food biotechnology and biotechnological applications used in warfare. In terms of the variable used to distinguish the different paradigms, what is being left out is the politics of expertise and the legitimating power of different actors. Another aspect overlooked is the role of market in shaping science and technological policies. An analysis of the role of market would question the feasibility of the paradigms itself. Arguably, the policy mission aims at industrial development only in economic paradigm. What is being implicitly suggested

50. Ibid, P. 451.

by Rask is that market intervention can only be seen in economic paradigm, which seems to be improbable approach in the present neo-liberal economic context. The disagreement here is that the role and logic of market intervention may vary from one paradigm to another. For example the logic in the enlightenment paradigm may be the betterment of the living conditions of the society; on the other hand logic in economic paradigm may be promoting market interventions, increasing the GDP or making the nation a global leader. The argument is that public engagement in policy making is not a one to one engagement between state and individual, it is a process circumventing an array of actors and institutions.

2.7 INSTITUTIONS, ACTORS AND REGULATORY GOVERNANCE

Drawing analogy between science and democracy Durrant (1999) argues that the paradox in science is similar to the paradox in democracy as articulated by Antony Giddens. The dissatisfaction in democracy and distrust in politicians in mature democracies as suggested by Giddens is very similar to the dissatisfaction in science and technology and the distrust in experts[51]. In their study of the consensus conferences in Norway, Denmark and France, Annika *et al.*, (2007) argue that public participation in the converging sphere of politics and science has different connotations depending on the values and meanings that the concept of democracy assumes, such as the actors who are legitimized participants, the relative power they have in society and the institutional ways of legitimizing political decisions [52]. Science and policy making across nations are linked by their respective political organization and culture which include structural factors such as relative autonomy among different branches of the government, institutions and process in the production and validation of policy relevant knowledge, forms of legal and political participation, cultural factors include 'preferred forms of evidence and proof', dominant modes of policy discourse[53]. Analyzing the role of political institutions in the building of regulatory regimes of biotechnology in Europe and United States Jasanoff (2005) argues that these institutions have failed to further the interests of deliberative

51. Durrant, Jhon , 1999, op cit, pp. 315-316.
52. Nielsen, A. P., Lassen, J. and Sandoe, P., "Democracy at its best? the consensus conference in a cross-national perspective", *Journal of Agricultural and Environmental Ethics*, 20, 2007, pp. 13–35.
53. Jasanoff, Sheila, 2002, op cit, pp. 370-371.

democracy in the area of safe product innovation[54]. Public problems are reflected in the policy agenda as framings that evolve from particular cultural commitments that predispose societies to fit their experiences into specific types of casual narratives which are grounded in the traditional institutional practices[55].

Analyzing the field of Genomics, Gottweis (2005) argues that since the mid 1970's strategies to regulate fields like Genomics has considerably changed and national governments have considerably lost their ground in both regulating and shaping the field of Genomics [56]. Analyzing the New Zealand government's delegation of decision making power on introduction of Genetically Modified Organisms (GMO's) to Environmental Risk Management Authority (ERMA) Cronin (2008) argues that the declining of state from the responsibility of decision making moved the locus of consideration from policy sphere, placing the focus on individual GMO technology rather than addressing the "normative or strategic dimensions" of the technology itself[57]. The questions that are central to regulation of biotechnology are legitimizing decisions, public trust, risk and uncertainty, environmental sustainability and how these issues can be incorporated in participatory citizenship[58].

The Asilomar conference of 1975, which is known as the first ever discussion forum for the regulatory policy making of recombinant rDNA was convened to facilitate a consensus among experts for self regulation in the wake of public concerns and thereby preventing political interference[59]. Contrasting the regulatory policy regime that succeeded the Asilomar rDNA conference and the European Union stringent policy style which he calls the ' Brussels style' , Abels (2005) argues that the aim of Asilomar style of policy making was to protect science from social intervention. If the legitimizing

54. Jasanoff, Sheila, "In the Democracies of DNA: Ontological Uncertainty and Political Order in three States", *New Genetics and Society*, 24 (2), 2005 p. 140.
55. Ibid, p.141.
56. Gottweis, Herbret, 2005,op cit., p. 176.
57. Cronin, Karen, "The Privatization of Public Talk: a New Zealand Case Study on the Use of Dialogue for Civic Egagement in Biotechnology Governance", *New Genetics and Society*, 27 (3), 2008, p. 294.
58. Hindmarsh, Richard and Gottweis, Herbert, "Recombinant Regulation: The Asilomar Legacy 30 years on", *Science as Culture*, 14 (4), 2005, p.302.
59. Abels, Gabriele, "The Long and Winding Road from Asilomar to Brussels: Science, Politics and the Public in Biotechnology Regulation", *Science as Culture*, 14 (4), 2005, pp. 342.

source in Asilomar style was scientific knowledge; it was democratic process in Brussels style[60]. According to him if the regulator was self regulation in the former it was political- legal regulation in the latter, the risk concept was technical, sanctioned by science in Asilomar style; risk is a social concept in Brussels style, while public where mere audience in the former, they are participants in the latter. In the Asilomar style the science society relation is based on knowledge; where as in the Brussels style the science society interaction is based on trust[61]. What Abels seems to have missed in his analysis is that it is not exactly the knowledge that characterizes the science society relation in the Asilomar style but it is the trust that evolves from the knowledge which characterizes the relationship. Examining what characterizes science society relationship in the Brussels style of policy making, one can see that it is the mutual acceptance of the corresponding knowledge of experts and the lay public which has evolved from the politicization of science.

An analysis of the permissive regimes of biotechnology in Israel shows that regulatory regimes are not only shaped by socio-political contingencies of the risk of these technologies as articulated by different actors, but the complementing values of science, religion and the state and the existential questions like the survival of the collective body of the Jewish state can provide the rational for embracing these technologies[62]. Institutional Transparency, Institutional reactivity to public concerns and the extent to which institutions involve public in the risk management decision making process determine the trust of public in regulatory institutions of science and technology[63] This argument calls for an inclusive policy making in risk management which can accommodate the concerns of different actors. There is a presupposition in this argument that policies can be the reflective plane of institutional transparency, reactivity and public involvement. The strengthening belief that different strands of thoughts about uncertainty and values play an important role in decision making related to science and technology risks has necessitated policy decisions to be complemented with different social, ethical,

60. Ibid, p. 347.
61. Ibid.
62. Prainsack, Barbara and Firestine, Ofer, "Genetically Modified Survival: Red and Green Biotechnology in Israel", *Science as Culture*, 14 (4), 2005, pp. 358-366.
63. Frewer, Lynn, 2004, op cit., p.393.

cultural and political considerations[64]. A paradox that is in play in the relationship between science, society and democracy is the de-institutionalization and fragmentation of the society in which the relationship between the science and politics is firmly institutionalized[65]. The point made here is that science- society interactions are not insulated from the changing nature of relationships between other institutions in the society, say the loss of trust in democratic institutions has implications for the trust of public in science.

The inflationary use of expertise in decision making, what Peter Weingart (1999) calls the 'Scientisation of Politics' which leads to the 'Politicization of Science' had questioned the political neutrality posed by the decisionist and technocratic models of scientific advice in policy making. Scientific knowledge and decision making are coupled in a complex relationship manifested by issues like how problems are framed, which knowledge is being elevated or legitimized, the degree of consensus between different actors over knowledge, the ways in which the knowledge is interpreted and the number of answers it provides to the problem and how that particular knowledge relates to the social values and political interests[66]. Public sphere which plays an intermediary role by democratic control and agenda setting between citizenry and politicians in different realms of the system can be found absent in the relationship between public, scientific expertise and policy makers[67].

In policy discourses antagonists bombard themselves with arguments and scientific facts with immunity over others in such a way that the disagreement with these facts seems to mask the conflicting belief systems or ideologies that these groups adhere to[68]. A clear conclusion evolving is that policy discourses are propelled by ideological predilections rather than science based on facts, as facts are produced by people on both sides across

64. De Marchi, Bruna and Ravetz, J. R. "Risk Management and Governance: A Post-normal Science Approach", *Futures*, 31, 1999, p.743.
65. Rutgers, M. R. and Mentzel, M. A., "Scientific Expertise and Public Policy: Resolving Paradoxes?", *Science and Public Policy*, 26 (3), 1999, p. 150.
66. Weingart, Peter, "Scientific Expertise and Political Accountability: Paradoxes of Science in Politics", *Science and Public Policy*, 26 (3), 1999, p. 156.
67. Edwards, Arthur, "Scientific expertise and policy-making: the intermediary role of the public sphere", *Science and Public Policy*, 26 (3), 1999, p.163.
68. Van Eeten, M. J. G., "Dialogues of the deaf' on science in policy controversies", *Science and Public Policy*, 26 (3), 1999, pp. 186–187.

the board, which cannot be refuted at least during the time of discourse which is metaphorically described in the policy analysis literature as the 'dialogue of the deaf' [69]. When the politics of experts, policy makers, politicians and ideologies are played out what is being threatened is the viability of democratic process and public participation in policy making. In a context where the primary motive of majority of people involved in science or politics is self-aggrandizement apart from a few 'statesmen', a minority who are self sacrificing people, institutional or governance structures facilitating public scrutiny and participation can not coordinate actors irrespective of the power structures in the society where they are placed[70]. If the above discussion featured the general characteristics of the dis-junction between institutions, actors and policy making in science and technology issues, the picture gets more complicated in issues related to policy making in the field of biotechnology. The main reasons for the complication seems to be the multiplicity of actors whose ideological allegiance vary over a wide range. At the heart of biotechnology is the experimentation with life which seems to bring the actors and ideologies in conflict. The following section offers a brief analysis of the complexities in the biotechnology policy sector.

2.8 ACTORS IN THE BIO-POLICY SECTOR

Analyzing the transnational governance in the field of genetic engineering in European Union Gottweis (2005b) argues that the governance is shaped by the "result of intricate and contextually bounded interaction between a multitude of actors, institutions- social and political and economic dynamics"[71]. Mapping the biopolicy Terrain Hindmarsh (2008) identify two contesting groups influencing the biotechnocratic developments, the "bioelites", a network of scientists, multinational life science industrialists, "biocrats"- bureaucrats supportive of technology, who strongly support the release of genetically modified organisms and opposing them are those who follow "biocivic policy approach" who include an informal coalition of concerned farmers, environmentalists, consumer

69. Sabatier, Paul, 1988, Cited in M J G van Eeten, "Dialogues of the deaf' on science in policy controversies", *Science and Public Policy*, 26 (3), p. 186.
70. De Jong, Martin, "Institutionalised Criticism: The Demonopolisation of Scientific Advising", *Science and Public Policy*, 26 (3), 1999, p. 195.
71. Gottweis, Herbert, "Transnationalizing Recombinant-DNA Regulation: Between Asilomar, EMBO, the OECD, and the European Community", *Science as Culture*, 14 (4), 2005, p. 326.

groups and other interest groups[72]. The actors include 'policy actors' from a number of General Directorates (DG's) from the European commission, representatives of the European Parliament, Environmental activists. Institutions include Organization for Economic Cooperation and Development (OECD), European Commission, European Parliament, Green Alternative European Link (GRAEL), the German Greens. An issue of any kind of risk includes a complexity of process involving the announcement of the risk through to public, identification, its official acceptance, quantification, legalization or regulation and monitoring, engaging a multiplicity of actors in different contexts whose perspectives on the issue is framed by their broader concerns[73].

Analyzing the policy options for the release of genetically modified organisms, Roger Strand (2001) shows how ideological affiliations of different stake holders in the regulatory regime can result in contradictory policy options. Strand categorises the stake holders in to three[74] a) 'Technological optimists' embrace modern biotechnology as a means to progress including increased food production, environment protection, decrease in chemical fertilizers and improvement in human health by medical biotechnology, they value potential benefits over the negative effects and the policy option evolving from this ideology is no regulation to the release of genetically modified organisms. b) the shallow ecologists who are concerned over the pollution of environment and depletion of resources by the introduction of high end biotechnology products in to the environment, they consider technology as a double edged sword and believe that technological benefits cannot reach the poor unless introduction of technology is complemented by socio-political reforms to ensure equitable distribution of resources. The policy option evolving from this ideology is a cautious approach to release of genetically modified organisms based on impact assessments including the social and economic impacts. c) Deep Ecologists out rightly reject the anthropocentric view of modern biotechnology and hence the impact assessment centred on human health and welfare, their opposition to modern biotechnology is grounded on a critique to modernity. The policy option evolving out of

72. Originally cited in Hindmarash, R., *Edging Towards Bioutopia: A New Politics of Reordering Life &the Democratic Challenge*, Crawley, Western Australia: University of Western Australia Press, 2008.
73. De Marchia, B. and Ravetz, J. R., 1999, op. cit., p. 744.
74 Strand, Roger, "The Role of Risk Assessments in The Governance of Genetically Modified Organisms in Agriculture", *Journal of Hazardous Materials*, 86, 2001, pp. 189-199.

this ideology is a unilateral prohibition pointing to the unethical character and practice of biotechnology infringing the rights of other organisms. The role played by personal and cultural values or world view in the evaluation of a particular technology is that the dimension or criteria for assessing is derived from the cultural context where the actors are placed, determined by the basic beliefs held by them[75].

Policy making is an arena for contesting groups who influence policy decisions by strategies like using media to bring the issues in to public debate.[76] The groups are also seen to bring in individuals in to debates, who have knowledge that is relevant to policy making.[77] The actors may be academics working at universities, international data providers, academics in government, social scientists in policy forums, political consultants, advisors, idea brokers or directors of influential research institutes.[78] In decision making process each actor has his own objective and hence effectiveness of policy options are judged in the light of his own view[79]. Reasons for the lack of alignment of key social issues among different social groups is analyzed as the polarization of views within these groups resulting from diversity in motivations, understanding and perceptions to members of other groups leading to failure in agreement on key issues or policy objectives[80]. The politics played out by policy makers, medical and scientific communities, researchers, physicians, pharmaceutical companies, public and private organizations and lobbying groups to steer regulations in such a way that research and innovation is not stifled in the U. S. is well documented[81].

The discussions in the previous sections on risk framing, public engagement in science and technology issues, institutions and actors in policy making regarding issues in science and technology shows that the issues, actors and institutions are interwoven when

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75. Siegrist, Michael, 1999, op cit., p. 2095.
76. Mentzel, Maarten, "Think Tanks, Policy-Making, and a Dutch Advisory Council", *Science and Public Policy*, 26 (3), 1999, p.175.
77 Ibid.
78 Ibid.
79. De Bruijn, J. A. and Ten Heuvelhof, E. F., "Scientific Expertise in Complex Decision-making Processes", *Science and Public Policy*, 26 (3), 1999, p. 180.
80. Frewer, Lynn and Salter, Brian, "Public Attitudes, Scientific Advice and the Politics of Regulatory Policy: The Case of BSE", *Science and Public Policy*, 29 (2), 2002, p.142.
81. Fisher, Jill, A., "Governing Human Subjects Research in the USA: Individualized Ethics and Structural Inequalities", *Science and Public Policy*, 34 (2), 2007, pp.122-123.

they are looked through the prism of regulatory governance. And hence it is imperative to contextualise regulatory governance in science and technology for a meaningful analysis of the interrogatory space of technology that has evolved by social, cultural and contextual interpretation of risk. Regulatory governance offers a scope for theoretically linking the topics discussed above and evolve an analytical framework in which risk framing can be used for the analysis of public engagement with science and technology issues. The following section contextualises the concept of regulatory governance.

2.9 REGULATORY GOVERNANCE

The literature on Governance spanning over the discipline of sociology, history, political science, business administration, law, public administration and geography gives the concept different meanings[82]. Surveying the literature across these discipline, Kersbergeni & Waarden suggest nine prominent modern usages of the concept of governance[83]. The first prominent usage of the concept is, in the field of economic development, by the multilateral organizations like United Nations and World Bank etc. calling for reformatory measures like increased spending in health, education and other social security measures by reducing the wasteful spending of public funds. The second prominent usage of the concept of governance can be found in the theory of international relations, which points to the possibility of international co-operation in policy issues, where there is no well defined hierarchy for the engagement of nation states. A third usage of the concept is found at the social-organizational level, where communities organize to manage common pool resources and prevent their depletion. A fourth usage of the concept is identified in the field of economic governance. The authors argue that neo-classical economists rather than classical economists, who emphasize that markets are not spontaneous social orders, but social institutions are needed to create and maintain them, have discussed governance widely. The fifth usage of the concept is located in the literature of corporate governance which calls for greater accountability and transparency in management of corporations. The sixth usage of the term can be found in the new

82. Kersbergeni, K. V. & Waarden, F. V., , " 'Governance' as a bridge between Disciplines' Cross disciplinary inspiration regarding shifts in governance and problems of governability, accountability and legitimacy ", *European Journal of Political Research* , 43 (2), 2004, p. 143.
83. Ibid, pp.144-49.

public management literature. The authors suggest that governance in new public management is understood in the context of the fusion of management concepts in the governance of public organizations, where market model is applied for policy implementation. A seventh usage of the term is found in the literature on governance through networks. According to the authors the main strands of networks covered by these are those between public, private and mix of both these types. An eighth usage, the authors suggest, is the notion of multilevel governance which can be seen in the international relations literature. The authors point to a ninth form of governance, a slightly nuanced form of multilevel governance existing in private sector between firms, which they claim to be a cooperation of small firms in networks.

In addition to the wide application of the concept "governance" across disciplines in differing meaning and context the concept takes more complicated forms like the one proposed by world bank namely "Good Governance", where the concept is not defined comprehensively[84]. World Bank's Concept of "Good Governance" 'appears to provide an emphasis on political pluralism, accountability and the rule of law' [85]. Kiely (1998) argues that the projection of East Asian Economies as successful model of good governance suggests that the concept calls for a market friendly approach and intervention by the state.[86] The European Commission white paper on Governance defines European Governance as the "rules, process and behavior that affect the way in which powers are exercised at European level, particularly as regards to openness, participation, accountability, effectiveness and coherence[87] Leftwich (1993) cautions that there are two parallel meanings for the concept of good governance based on their political nature. He argues that the World Bank interpretation of the concept is very limited and is primarily confined to the administrative and managerial terms; on the other hand the meaning associated with the usage of western governments is more political

84 Kiely, Ray, "Neoliberalism Revised? A Critical Account of World Bank Concepts of Good Governance and Market Friendly Interventions", *Capital & Class*, 64, 1998, p. 68.

85 Ibid.

86 Ibid, p. 69.

87 Commission of the European Communities, *European Governance: A White Paper*, European Commission, Brussels, 2001, p.8. Available at http://ec.europa.eu/governance/index_en.htm, accessed on 4.12.09.

since it emphasizes on administrative improvements and competitive democratic politics[88]. Governance structures are constituted by political and economic relationships and rules which govern the productive and distributive life of a society[89]. According to Terib *et al.*, (2007), in the most General sense Governance can be understood as the change in the nature of the relationship between state and the citizens. . Treib *et al,*. argue that the change in relationship is marked in two significant ways. Firstly in the sharing of the responsibility in making collective binding decisions, which was traditionally done by few elected representatives on behalf of the citizens and implemented by bureaucratic institutions. Secondly, there is a recognition that implication of government policies vary widely among a range of social sections, as a result governance takes into account societal actors in formulation and implementation of policies[90].

Treib et. al. (2007), suggest that there are three understandings of the concept based on the primary realms they belong to – politics, polity or policy[91]. Political dimension is ascribed to the concept when the process of governance is focused on the actors' constellation and power sharing between the actors. Polity dimension is ascribed to the concept when regulation becomes the focus of governance, which is expected to shape the action of social actors. The concept of governance takes the policy dimension when the steering instruments become the focus in defining how policy goals are to be achieved. Governance is marked by an emphasis on the process of governing as against the structures of government. The processes of governance concern cooperation, negotiation, concentration, accommodation and alliance formation as opposed to the traditional government process of coercion, control and command[92]. In an attempt to link the practice and process dimension of governance, Gottweis (2005) argues that governance should not be looked upon from a mere translation of preferences into policy choices, but to a critical moment of integration of 'technique of self into structures

88 Lefwich, Adrian, "Governance, Democracy and Development in the Third World", *Third World Quaterly*, 14 (3), 1993, p. 606.
89 Ibid. p. 611.
90. Treib, O., *et al.*, 2007, op cit., p.3.
91. Ibid, pp. 3-5.
92. Kersbergeni, K. V. & Waarden, F. V., 2004, op cit., p. 152.

of action and political decision making'[93]. The governance of risk transpires the conventional logic of risk assessment, risk management and risk communication in risk policy and aims to capture the social process and social interactions in an attempt to define the interface between state, society and economy[94]. In the context of environmental governance, governance is defined as "attempts by governing bodies or combinations thereof to alleviate recognized environment dilemmas"[95].

Deliberative Democracy in essence is the inclusion of all those who are governed in to the policy network[96]. According to Paul Hirst (1994) Deliberative Democracy is characterized by information exchange, consent and organized public participation[97]. The history of attempts to incorporate citizen-science engagement and inclusive participation in biomedical research can be traced back to the 15 bills filed in the U.S. Congress, which wrested upon local communities the right to impose regulations stricter than the federal measures, during the rDNA debates in 1977-98.[98] Analyzing the debate on regulating rDNA research Hindmarsh *et al.*, (2008) argue that the defeat of 15 federal bills lead to the high powered unannounced meetings attended by the selected scientists to develop strategies to defend rDNA research leading to the politicized "us and them" narratives, which eventually undermined the constructive and open debates to address the issues raised by genetic science and the emergence of "enclosed expert top-down style" of policy making[99].

93. Gottweis, Herbret, 2005, op cit., p.177.
94. Borra's, Susana, 2006, op cit., p. 64.
95. Davidson, Debra J. and Frickel, Scott, "Understanding Environmental Governance", *Organization & Environment*, 17 (4), 2004, p. 471.
96. Hirst, Paul, *Associative democracy: New forms of economic and social governance*, Cambrige: Polity Press,1994, Cited in Kees Van Kersbergeni & Frans Van Waarden, " 'Governance' as a bridge between Disciplines' Cross- disciplinary inspiration regarding shifts in governance and problems of governability, accountability and legitimacy", *European Journal of Political Research* , 43 (2), 2004, p. 19.
97. Ibid.
98 Hindmarsh, Richard and Du Plessis, Rosemary, 2008,op cit.,sss p. 183.
99. Ibid, pp. 181-184.

A policy can claim a certain level of deliberative, participatory and justificatory legitimacy if the following characters are explicit in the policy formulation[100].

1. Involvement of public and various stakeholders without presumptions and with the recognition of traditionally excluded and oppressed.
2. Adequate citizen participation in policy making process ensuring that the process is informed by values concerns and arguments of those who are affected.
3. Inputs to policy is well informed and reflects current knowledge of the technical and social aspects of the issues.

Inputs from participants and various stake holders emerge from their participation. Public actors are expected to bring ethical and social issues in to the discussion which are otherwise ignored by the over pouring of technical facts[101]. In the case of genetically modified organisms ethical concerns have become the dominant paradigm in which public responses are recognized, constructed and expressed[102]. Literature suggests that regulatory regimes still conceive public participation in terms of technical contribution. Ferretti (2007) argues that political and ethical choices are tacitly embedded in the regulatory frame work at implementation level what is expected from all actors including the lay public is a contribution of technical nature[103]. Shineha *et al.*,(2009), in their study of regulatory policy making on genetically modified organisms in Japan, argue that public concerns are inadequately reflected in the policy decisions[104]. Hindmarsh (2005) identifies four decisive moments in the Australian biotechnology policy development following the Asilomasr conference [105]. They are self regulation which has 'engendered an authoritative low risk perception of harm'. The second decisive moment was the Australian Academy of science Report, which enabled the construction of an authoritative

100. Jasanoff, Sheila, 2003, op cit., p. 220.
101.Ferretti, Maria Paola, 2007, op cit. p. 390.
102. Wynne, Brian, "Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs", *Science as Culture*, 10 (4), 2001, p. 446.
103. Paola Ferretti, Maria, 2007, op cit., p. 390.
104. Shineha, Ryuma and Kato, Kazuto, "Public Engagement in Japanese Policy-Making: A History of the Genetically Modified Organisms Debate", *New Genetics and Society*, 28 (2), 2009, p.146.
105. Hindmarsh, Richard, "Genetic Engineering Regulation in Australia: An 'Archeology" of Expertise and Power", *Science as Culture*, 14 (4), 2005, pp. 375- 387.

text to debunk the University of Melbourne Assembly Inquiry recommendation for a moratorium on rDNA research. The third moment was the House of Representatives Inquiry in which the inquiry committee was constituted by a Government majority who supported Science and Technology development and thereby marginalizing the concerns of environmentalists and those who argued for increased public participation biotechnology regulation. The fourth moment was the Gene Technology Act 2001 which institutionalized the control of biotechnology by big biotech corporations whom the author calls 'bioelites'. By ensuring an upper hand for bioelites in the Gene Technology act, in effect sidelined social and ethical issues which should have played an important role in the regulation of biotechnology. The regulatory frame works on biotechnology that emerged following the Asilomar conference can be seen to foster a science society interaction with an emphasis on expertise and 'scientization' [106].

According to Hayden (2005) 'Scientization', which is referred to as the way in which issue relating to possible outcomes of novel technologies can be framed in purely physical and scientific boundary line excluding the social, cultural and ethical implications, can be traced back to Asilomar conference. Analysis of the bodies constituted to inquire controversies, frame guidelines or draft bills show that experts played discursive roles and the way the bodies defined stake holders had an emphasis on expertise excluding public.[107]

It is observed with regard to the introduction of novel technologies in agriculture and health that there is an increasing tendency to reduce the frame work of decision making to risk assessment and risk management which eventually results in narrow interpretations of risk, privileging of expertise, sidelining the complex notions attributed to risk by different social groups[108]. The rising international trade and its impact on down playing of risks associated with outcomes of scientific research with a value for trade can be seen to forge a link of convenience between the existing regulatory apparatus through new policies. For instance, inadequate assessment criteria for environmental and health

106. Hayden, T. R., "Asilomar's legacy in Aotearoa New Zealand", *Science as Culture*, 14 (4), 2005, pp. 393-410.

107. See Hindmarsh 2005 and Hayden 2005.

108. Ross, Kerry, "Providing "thoughtful feedback": Public Participation in the Regulation of Australia's First Genetically Modified Food Crop", *Science and Public Policy*, 34 (3), 2007, p. 215.

risk such as familiarity and substantial equivalence implemented in the name of regulation were originally attempted to harmonize the Canadian markets with the exporting countries to serve the commercial interests of Canada using the notions of 'world leader in biotechnology' and national development there by effectively marginalizing the critical voices and foreclosing discussions on larger social and ethical voices[109]. Novel forms of citizenship like 'technological citizenship' , manifesting technological politics or claiming a social contract, defined by the impact of technology, 'questions the acceptance of statements by experts about the safety of novel technologies' [110]. Novel technologies are contested not only in terms of their risks to health and environment, technologies especially in biotechnology are challenged based on the pattern of change they have brought about in the pursuit of science, global and local production and consumption, subjectivity, surveillance systems and government policies[111].

Participatory public analysis of policy is preferred by relativist, critical and forensic policy analysts for instrumental and contextual reasons.[112] They believe that participation from public should be used in situations when knowledge of the local and regional conditions plays an important role in providing solution for policy problems.[113] Situations, where ethical and social issues, needs and wants of the public is strongly intertwined with problem at stake and when there is conflict of interest among the experts, also demand for public participation[114]. The approaches and mechanisms, like "public debate", "input from society", purported to incorporate public participation in decision making are sought to restore the legitimacy of science rather than to reconsider the institutional process, like the nature of innovation or the direction of research which

109. Barrett, K. and Abergel, E., "Breeding Familiarity: Environmental Risk Assessment for Genetically Engineered Crops in Canada", *Science and Public Policy*, 27 (1), 2000, pp. 3-12.
110. Frankenfeld, Philip J., "Technological Citizenship: A Normative Framework for Risk Studies", *Science Technology and Human values*, 17 (4), 1992, pp. 459-460.
111. Gottweis, Herbert, "Genetic Engineering, Democracy and the Politics of Identity", *Social Text*, 42, 1995, p. 145.
112. Hoppe, Robert, "Policy Analysis, Science and Politics: From 'Speaking Truth to Power' to 'Making Sense Together", *Science and Public Policy*, 26 (3), 1999, p. 208.
113 Ibid.
114 Ibid.

had led to the legitimacy crisis reinforcing notions of "rational judgments conflicting the irrational concerns" in science society relationship[115].

Emerging from analysis of literature are the following arguments that require further examination. Uncertainty on the technological outcomes and the social, cultural and contextual interpretation of risk have led to the emergence of a space for interrogation of science and technology and public engagement in decision making in issues related to regulation of science and technological risks. Secondly the lack of consensus among experts on controversial scientific issues places a legitimate claim for public engagement in issues related to science and technology. Thirdly public engagement informs regulatory policies with social implications of technologies, which are otherwise ignored or sidelined by the experts thereby enriching the regulation of technological risks. At the same time there is also an argument that, the emergence of risk as dominant paradigm for the interrogation of technologies need not necessarily transform in to stringent regulatory policies, rather policies are influenced by dominant interest groups. Regulatory policies serve as reflective plane for the analysis of the risks that are legitimised and that are de-legitimised. Fourthly articulation of risks brings together actors and institutions with ideological predilections making policy arena a negotiating space for different actors. Present study examines these arguments in the area of Assisted Reproductive Technology in the Indian context. The next chapter examines the divergent streams of interpretations of technological risks and technological uncertainty in the area of assisted reproductive technologies.

115. Levidow, Les and Marris, Claire, "Science and Governance in Europe: Lessons from the Case of Agricultural Biotechnology", Science *and Public Policy*, 28 (5), 2001, p. 348.

Chapter -III

DEBATES IN SOCIAL SCIENCE AND REPRODUCTIVE MEDICINE

This chapter provides an overview of the assisted reproductive technologies, to explore the debate on the risks of ART in the literature of social science and reproductive medicine. The chapter also explores and contrasts the divergence in the articulation of ART risks by practitioners and reproductive scientist and that by social scientists from the respective fields of sociology of medicine, ethics, gender studies etc. The chapter provides a summary of the history of Assisted Reproductive Technology starting from in vitro fertilization (IVF) which is commonly referred to as the third generation reproductive technologies. The second section provides an overview of the ART techniques. The third section covers the debates in the social science literature on the risks of ART, which include disciplines like Science and Technology Studies, Gender Studies, Bioethics and Sociology of Medicine. The fourth section explores the major debates on ART risks by scientists and practitioners in the area of reproductive medicine related to assisted conceptive techniques and attempts to discern the pattern of risks by reviewing the articles published in journals addressing issues in reproductive medicine. The fifth section analyzes the strategies employed by scientists and practitioners to legitimize assisted conceptive techniques. The sixth section of the chapter contrasts the ART risk articulated by social scientists and reproductive biologists and scientists, which furthers the scope of studying regulatory policies as the converging space of divergent view of technological risks.

3.1 ASSISTED REPRODUCTIVE TECHNOLOGY: A HISTORICAL VIEW

The year 1978, in ART literature, is refereed to as the mile stone in the research on assisted reproduction. It was in July, 1978 Lesley Brown, a patient with nine years of primary infertility, conceived *in-vitro,* delivered baby Louis Brown under the treatment of Patrick Steptoe and Robert Edwards at the Oldham General Hospital in England[1]. As it is evident from the case of Lesley Brown, the invention of ART was to

1. Wang, J. & Sauer, M. V., "In Vitro Fertilization (IVF): A Review of 3 Decades of Clinical Innovation and Technological Advancement", *Therapeutics and Clinical Risk Management* , 2 (4), 2006, pp. 355-356.

solve the mechanical problems of female infertility. Damaged fallopian tubes in females were a major cause of infertility prior to 1978 and surgical treatments for it hardly produced positive results[2]. Unlike the present ART which involves hormonal treatment for ovarian stimulation, which is also a major controversy discussed in ART literature, Lesley Brown was not medicated for Ovarian stimulation. The number of oocyte retrieved and number of embryos implanted was only one. This is referred to as natural in-vitro fertilization (NIVF) in the literature[3]. NIVF consisted of natural retrieval of one ovum. NIVF was abandoned in favor of IVF, which provided high success rate.

The challenge to increase the oocyte yield per retrieval and pregnancy rate brought about new innovative techniques including stimulation of ovaries using human menopausal gonadotrophin (hMG)[4]. The increased use of hMG for ovulation induction resulted in increased cases of premature ovulation due to multi follicular development[5]. Even though the problem was overcome through pituitary desensitization by administering gonadotrophin releasing hormone agonist (GnRHa) leading to increased pregnancy rates, it contributed to the rising incidence of ovarian hyperstimulation syndrome (OHSS)[6]. A major development in ART was pregnancy from oocyte donation in 1983, furthering the scope of ART for women with premature ovarian failure and those at the advanced reproductive age, which was followed by cryopreservation of embryos[7]. The mid 1980's witnessed the emergence of Gamete Intrafallopian Transfer (GIFT) to simplify and increase the success rate of ART. GIFT involved the immediate transfer of oocytes retrieved laproscopically in to the fallopian tubes along with the sperm, which limited ART procedure to one laproscopy and provided the natural environment for fertilization[8]. GIFT was followed by zygote interfallopian transfer (ZIFT), which involved the process of laproscopically retrieved oocytes fertilized in vitro and transferred in to fallopian tube at pronuclear stage through another

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2. Ibid, p.355.
3. Zayed, F. *et al.*, "Natural In-vitro Fertilization in Couple with Unexplained Infertility: Impact of Various Factors on Outcome", *Human Reproduction*, 12 (11), 1997, p. 2402.
4. Wang, J. & Sauer, M. V., 2006, op cit., p. 356.
5. Ibid.
6. Ibid.
7. Ibid.
8. Ibid, p.357.

laproscopic surgery[9]. Unlike in GIFT, ZIFT enabled the confirmation of fertilization in vitro. Technological developments in ultrasonography reduced oocyte retrieval from 1-2 hours procedure requiring operation in a hospital to one requiring only 10-15 minute procedure involving ultrasound transducers that can be performed in a office setting[10].

Efforts towards addressing male infertility led to the emergence of partial zonal dissection (PZD), sub zonal insemination (SUZI), intracytoplasmic sperm injection (ICSI) and testicular sperm extraction (TESE)[11]. PZD involved the facilitating of sperm entry in to oolemma through a small opening made in the zonal pellucida. In SUZI few motile sperms were micro injected through the perivittelline. ICSI involved a process in which a single spermatozoon was injected into the oocyte after passage through the zona pellucida and the membrane of the oozyte. ICSI is widely criticized for malformation in children born through the process.

Technological developments in ART in the 1990 focused on determining the genetical make up of the embryos before transplantation. The techniques like chronic villus sampling and amniocentesis provided the option of abortion if the fetus was found to be at risk of genetic diseases prior to 1990's. Techniques like Preimplantation Genetic Diagnosis Technique (PGD), which replaced chronic villus sampling and amniocentesis are widely accused of being eugenic and altering the process of natural selection. The number of genetically inherited disorders that can be diagnosed prior to implantation had expanded over 40 in last fifteen years[12]. Latest additions to the basket of ART are the cryopreservation of oocytes, ovarian tissues for those undergoing radiological treatment for diseases like cancer.[13] The mushrooming of the ART clinic in the last two decades can be attributed mainly to the vaginally guided ultrasound oocyte retrieval[14]. Introduction of the technique drastically reduced the complexity of oocyte retrieval in terms of the required expertise, effort, equipments and time. The process got transferred

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9. Ibid.
10. Ibid, p.358.
11. Ibid,p.359.
12. Ibid,p.360.
13. Ibid,p.362.
14. Silverio, M. M. & Hemminki, E., "Practice of in vitro Fertilization: A Case Study From Finland", *Social Science and Medicine*, 42 (7), 1996, p. 978.

from operation theaters to small and medium clinics. The time required for the process reduced from 1-2 days to several minutes. The spread of IVF technology from medical colleges & multi-specialty hospitals in cities to clinics in small and medium towns was mainly the result of vaginally guided ultrasound oocyte retrieval. Though there are numerous techniques which are added in to the basket of ART on a day today basis, a cursory glance of the websites of the ART service providers in India suggests that the most common techniques claimed to be offered are IVF, ICSI and IUI.

3.2 ASSISTED REPRODUCTIVE TECHNIQUES

The assisted reproductive techniques can be broadly divided in to two groups: In Vitro techniques and In vivo techniques. In Vivo techniques are the simplest techniques where conception is facilitated inside the body. In Vitro techniques are complex techniques where the gametes are taken out of the body and fertilization takes place outside the body. In Vitro Fertilization techniques like IVF and ICSI and In Vivo technique like IUI is discussed below.

In-vitro Fertilization (IVF)

IVF involves natural in-vitro fertilization (NIVF) and stimulated in-vitro fertilization. In NIVF the IVF cycles are completely natural. Clomiphene citrate, a compound used for ovarian stimulation, is not used in NIVF. Eggs are collected by the detection of spontaneous leutinising hormone (LH) surge[15]. In NIVF ovum release is not induced by an external agent but by closely following its natural cycle and retrieving it laproscopically. In SIVF clomiphene citrate is used in conjunction with human menopausal gonadotrophin (HMG) to stimulate and sustain spontaneously recruited follicles for ovum harvesting[16].

Intracytoplasmic Sperm Injection (ICSI)

The observation that failure in IVF resulted from sperm-zona pelucida binding or zona pelucida penetration (fertilization of ovum occurs when the nucleus of the sperm fuses

15 Zayed, F. *et al.*, 1997, op. cit., p. 2403.

16. Zayed, F., *et al.*, "Comparison Between Stimulated In-Vitro Fertilization and Stimulated Intrauterine Insemination for the Treatment of Unexplained and Mild Male Factor Infertility", *Human Reproduction*, 12 (11), 1997, p. 2408.

with the nucleus of the ovum which occurs when sperm penetrates in to the cytoplasm of the ovum) led to the development of micromanipulation techniques[17]. ICSI is a micromanipulation technique. ICSI enable sperms to penetrate the egg vestment to access the cytoplasm. Intracytoplasmic sperm injection (ICSI) evolved as treatment for male infertility caused by azoospermia[18]. Azoospermia is a medical condition of male infertility resulting from the absence of sperms in semen. The introduction of ICSI was expected to cope with the failure of IVF' in extending the interval of fertilization[19]. Though ICSI has resulted in improved fertilization results, it has compounded the risks and rocketed the cost of treatment[20].

Intra Uterine Insemination (IUI)

Intra Uterine Insemination (IUI) is a commonly used In Vivo fertilization technique. In IUI sperm is extracted from the seminal fluid, washed and directly injected in to the uterus of the women. With subjects of treatment requiring low level of follicle stimulating hormone (FSH) and with the absence of highly specialized techniques like egg collection and culture, Stimulated Intra Uterine Insemination (SIUI) is proved to be cost less per maternity, i.e. amount spent to achieve live birth, compared to stimulated in-vitro fertilization (SIVF)[21].

Being discussed the history of In Vitro Fertilization and the Assisted Reproductive technology in brief the chapter proceeds to highlight the scientific and social debates around Assisted Reproductive Technology, the articulation of risks in different social and cultural context. Exploring the debates on ART in reproductive biology and social science enables to understand the divergence in the different streams of thought. It also discerns the contesting actors and contested issues more clearly. Divergences among actors and issues serve as analytical tools in examining the regulatory policies in the light of their converging and assimilating capacities.

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17. Tesarik, J. & Mendoza, C., "Using the Male Gamete for Assisted Reproduction: Past, Present and Future", *Journal of Andrology*, 24 (3), 2003, pp. 319-320.
18. De Croo, I., *et al.*, "Fertilization, pregnancy and embryo implantation rates after ICSI with fresh or frozen–thawed testicular spermatozoa",*Human Reproduction*, 13 (7), 1998, p.1893.
19. Ibid.
20. Felberbaum, R.E., *et al.*, "Are we on the verge of a new era in ART?", *Human Reproduction*, 13 (7), 1998, p.1778.
21. Zayed, F., *et al.*, 1997, op cit., pp. 2410-2411.

3.3 SOCIAL, LEGAL AND ETHICAL ISSUES IN ASSISTED REPRODUCTIVE TECHNOLOGIES

This section provides an overview of the major streams of debates on the social, legal and ethical issues raised by ART technologies. It analyzes the articulation of ART risks in the social science literature. It also analyzes the divergence in the stands of feminist theorists on ART. The liberation argument versus the victimization argument is analyzed in detail. Further, the section analyzes the 'pro-life' argument entangled with the politics of right wing in Europe and US and the Catholic Church. The section also discusses the eugenic argument and the ethical and legal issues debated in the social science literature.

FEMINIST AND RELIGIOUS CRITIQUE OF ART

Informing different strands of debates on reproductive technologies, Michelle Stanworth argues that the reproductive technologies in itself offer possibilities for looking at the relationship between the reproductive technologies and society in a new light[22]. The debates, according to her, span over three categories. Firstly, the ethical and practical problems arising from the manipulatory potential of these technologies on human beings i.e. the manipulation of eggs, sperms and embryos outside the human body. Questions on the sanctity of human life, scientific and commercial exploitation of embryos, exclusion of people with imperfections, the possibility of 'super humanness' and its implications are debated in this stream of thought. Second stream of debate is mainly concentrated on the relation between biological reproduction and social reproduction. These include the complication of the structure of parenthood entailed by the reproductive technologies, the 'ownership' claim of children produced from donated eggs and sperms and legal status of children born from surrogacy and donated egg. The rupture in the mother-child bond, as there can be a biological mother, a surrogate mother and a commissioning mother who is neither the owner of ovum nor she carries the pregnancy, due to in vitro fertilization and surrogacy. The result of these divisions in the reproductive role, according to Stanworth, is the weakening of the institution of

22. Stanworth, Michelle , (ed.), *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, pp.1-9.

motherhood. The third stream of debate, according to the author, is contributed by the feminist writers. The debates in this stream revolve around the impact of changes in reproduction on the women's' bodies and lives. The impact of these technologies on the health, safety and choices of women, as women are going to be the target in the role of patients, donors of egg and surrogates of these technologies. Feminists question the medicalisation of women's body, pregnancy and reproduction, the subjectification of women's body by paternalistic science.

According to Michelle Stanworth, there are three vantage points which mark the departure from the above stands of critic. They are the multiplicity of reproductive technologies which can offer indispensable resources for women depending on their circumstances and priorities. Conceptive technologies are often treated synonymous with 'high-tech' medicine, while the reality is that they include techniques that can be practiced with least know how and on the other hand they include technologies like in vitro fertilization which requires sophisticated clinical, surgical and laboratory practices[23]. The impact of fertility and the fulfillment of reproductive roles vary among women which needs to be understood from a ethnic, social class and cultural context and hence a credible critic of reproductive technologies should be rooted in this context. An overemphasis of the risks of reproductive technologies distract attention from the political process that shape and reinforce inequalities.

Stanworth (1987) offers the possibility of understanding the politics driving the reproductive technologies by analyzing the groups and institutions who have an interest in the development of reproductive technologies[24]. According to her the primary group is formed by women who are themselves consumers of reproductive health care and have a 'demand' for techniques which would help them to control their fertility. Another form of demand is from the sate which selectively funds for the development of reproductive technologies which may not reflect the interest of the women. The development of knowledge is essential for maintaining hegemonic relationship of the expert. According to the author, gynaecologists and obstetricians needed the

23. Stanworth, Michelle, "Reproductive Technologies and the Deconstruction of Motherhood", in Michelle Stanworth , *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, p. 11.
24. Ibid, pp. 12-13.

development of new and sophisticated technologies to demonstrate their command over the branch of human reproductive biology. The pharmaceutical companies and the market for infertility treatment and resulting opportunities for investment had exponentially contributed to the development of reproductive technologies.

The theoretical approach used by Stanworth views in these new technologies a means for men to wrest not only control of reproduction but reproduction itself[25]. The implications of which will include the 1)deconstruction of motherhood- in the place of the single biological mother there will be ovarian mothers who supply eggs, uterine mothers who give birth to children and social mothers who raise them . 2) delegitimating genetic parenthood 3) parenthood will be separated from 'the sexual act' and marriage. According to Stanworth 'for some women, motherhood remains their only chance of creativity, while economic and social circumstances compel others to relinquish motherhood altogether '[26]. Stanworth looks at reproductive role of women from their social and economic context, which informs her critic of reproductive technologies. This approach does not see reproductive technologies as an invasion of human body, what the approach calls for is the creation of 'political and cultural condition in which the technologies can be employed by women to shape the experience of reproduction according to their own definitions '[27]. The argument that reproductive technologies are imposed on women is countered on the ground that the victimization of women argument obscures the particular reality of infertile women and lesbians who utilize ART for achieving pregnancy[28]. Historical evidences show that the women were not passive receptors of 'male' reproductive technologies, the 'market' for pill, sterilization, IVF, amniocentesis and high-tech pregnancy monitoring facilities show that the developments resulted from the shared situation of reproductive demands by men and women rather than a mere victimization of women[29].

The feminist debates on ART starts with Shulamith Firestone's liberation through birth-

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25. Ibid, p. 16.
26. Ibid.
27. Ibid, p. 35.
28. Petchesky, R. P., "Foetal Images: The Power of Visual Culture in the Politics of Reproduction", in Michelle Stansworth , *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, p. 77.
29. Ibid, p. 72.

technology argument[30]. Firestone argued that the 'development of birth-technology is potentially liberating for women, because it could free them from the burden of biological motherhood'[31]. This position is opposed by feminist scholars like Maria Mies and Gena Corea, who view the development of ART like in vitro fertilization as the patriarchal exploitation of women's bodies[32]. The above positions reflect two divergent streams of thought in feminism – radical feminism and cultural feminism[33]. Radical feminism locates women's oppression in the contemporary sexual division of labour. Hence stripping off the biological responsibility of reproduction is seen as choice of liberation for women. Cultural feminism, on the other hand conceives women's oppression in the appropriation of women's lives and bodies by men and male principles. And hence assisted reproductive technologies are seen as tool for exploitation and appropriation of women reproductive materials and their reproductive capacities. Furthering the victimization and exploitation argument, Gimmenez argues that the separation of the mode of reproduction from the mode of procreation facilitated by the conceptive technologies creates not only new objects like ova, sperms, wombs or embryos for sale but also new historical subjects like women willing to sell or donate their egg or womb, couples contracting their biological reproduction to another women, couples willing to donate extra embryos for another couple etc[34]. Radical feminism locates the problem in the intrinsic biological capacity of reproduction and its social relationship. For cultural feminism the problem of oppression is extrinsic to women's body and inherent in the patriarchal structures of the society. From this stand point cultural feminism not only views ART as technologies for appropriation of women's reproductive capacities but also as technologies for reinforcing patriarchal structures on women. The ideas of 'choice and liberation' has undergone much transformation and articulated in more nuanced forms. For example, Naomi Chan suggests that reproductive

30. Zipper, J. and Sevenhuijsen, S., "Surrogacy: Feminist Notions of Motherhood Reconsidered", in Michelle Stansworth , *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, p. 120.
31. Fire stone, S. *The Dialectic of Sex*, 1970, cited in Ibid, p. 120.
32. Zipper, J. and Sevenhuijsen, S. , 1987, op cit., p. 120.
33. Ibid, p.124.
34. Gimenez, M. E., "The Mode of Reproduction in Transition: A Marxist Analysis of the Effects of Reproductive Technologies", *Gender and Society*, 5 (3), 1991, pp. 347-348.

technologies can rescue women from two social dilemma enforced on them due to the possession of the reproductive capacities[35]. They are the Coerced 'baby vessel' to a voluntary motherhood and from compromising the career out of social compulsion to become mother at young fertile age. These articulations though have changed in the form, implicitly echo the argument of choice.

The issues debated by these streams of thought include the 'wish for a child', 'right to a child', arguments for and against adoption. The 'wish for a child' is proposed as a part of understanding the different contexts in which women's lives are embedded while asserting that the concept of 'right to child' should not be considered as submission to ideology dictating motherhood for every women[36] . Invoking adoption as an alternative to surrogacy or assisted reproductive technologies is countered on the grounds that, the suggestion ignores the legalities, financial and ethical barriers involved in adoption[37]. It is also accused that those feminists opposing surrogacy and reproductive technologies form dangerous alliances with 'pro-life movements and conservative politics where choices of women's liberation like contraception, abortion, divorce and surrogacy are prohibited[38].

RELIGIOUS AND ETHICAL ISSUES

The pro-life argument is one of the major debates involving technologies of conception and technologies of contraception. The propounders' of the argument include religious bodies mainly the Catholic Church and right wing political parties in Europe and US. The opposition from religious bodies, especially the Catholic Church, over the use of artificial methods in human reproduction can be traced back to the late 1930's, when artificial insemination with donor semen was introduced for the first time in England[39]. The Catholic Church restated its opposition to artificial insemination using donor semen for two reasons. One it involves masturbation, a practice condemned by the Church and

35. Chan, Naomi, "Accidental Incest: Drawing the Line- or The Curtain?- For Reproductive Technology", *Harvard Journal of Law and Gender*, 32, 2009, p. 68.
36. Zipper, J. and Sevenhuijsen, S., 1987, op cit., p. 132.
37. Ibid, p. 134.
38. Ibid, p. 136.
39. Pfeffer, Naomi, "Artificial Insemination, In vitro Fertilization and the Stigma of Infertility", in Michelle Stansworth , *Reproductive Technologies : Gender, Motherhood and Medicine*, Cambridge: Polity Press, 1987, p.92.

secondly the intervention of the technique in to the holy sacrament of marriage. The dire opposition of Vatican to ART involves issues such as experimentation with human embryos, human genome and cloning, patenting of human life, the areas where the conflict is between the interests of person already born and the life of a unborn human being[40]. Similarly IVF was also denounced as unnatural. The Roman Catholic Bishops of Victoria, Australia rejected IVF for intervening into the 'naturalness' of 'baby making' by separating sexual intercourse and procreation[41]. According to the Church IVF also included moral flaws like masturbation and possibilities of research leading to the creation of animal-human hybrid.

The ethical issues raised by the excess retrieval of ova include the ownership of extra embryos that are frozen or cryopreserved, issues related to the sale of ovum and embryos, the role of courts and legislators in regulating these transactions, power and process of decision making on the future of the cryopreserved embryos in situations where the couple die, divorce or disagree, the issues in subjecting embryos for research, allowing scientists to produce embryos for research, issues related to the status of the embryo as it develops and the issues related to the pregnant women's rights[42] . Anonymity of the sperm and ovum donors is an important ethical issue raised from different quarters after the increasing use of donated ovum and sperms in assisted reproductive treatment. Equally debated is the issue of the right of child born using ART to know their biological parents.

Eugenics is another ethical issue related to the ART. The eugenic argument against the reproductive technologies coincides with the use of artificial insemination. The pronatalists and eugenicists supported artificial insemination for numbers and quality of human beings, declining fertility rate and male fertility[43]. Parallels were drawn between the livestock promotion program using high quality bull semen and artificial insemination using donor semen.

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40. Mons, H. E. & Tauran, J. L., *The Defence of Life in the Context of International Policies and Norms*, Vatican, 2000. Available at :http://www.vatican.va/roman_curia/secretariat_state/documents/rc_seg-st_doc_20000211_tauran-acdlife_en.html, accessed on 25.04.10.
41. Gallagher, Janet, "Eggs, Embryos and Foetuses : Anxiety and the Law", in Michelle Stanworth , *Reproductive Technologies : Gender, Motherhood and Medicine*, Cambridge: Polity Press, 1987, p. 140.
42. Ibid, p.141.
43. Pfeffer, Naomi, 1987, op cit., p. 93.

LEGAL ISSUES

Legal issues involving assisted reproductive technologies largely emerge from its threat to the institution of family and the role of family in the devolution of private property. Legal construction of families is based on the biological or blood ties. The process like conception through donor semen and ovum or surrogacy trivialize very construction of legal family in biological and blood ties. During the introduction of artificial insemination the apprehensions were, children conceived through donor semen were seen as attempts to bring illegitimate children to the institution of marriage or the use of the techniques for illegitimate claims to titles and estates[44]. Using of artificial insemination by donor semen without the consent of the husband was proposed as new, separate ground for divorce by The Royal commission on Marriage and Divorce[45]. According to the commission, artificial insemination was a serious threat not only for the legitimacy of the child but also for the legitimacy of the marriage. Who constitute to be eligible for assisted reproductive treatments is legally designed to promote certain forms of families over others[46]. Heterosexual nuclear families are promoted for the use of ART while widow, lesbian and homosexual couples are prevented from using ART. Surrogacy raises legal issues like men's claim on the product of their sperm, abortion rights, visitation rights and custody rights of the surrogate mother[47].

The social, ethical and legal issues of ART seem to be a slippery slope where the interests of different groups are in coercion to the extent of threatening each other's life. Take for example the case of 'Foetal rights' in conflict with the rights of pregnant women[48]. The conservatives and the pro-life supporters, who oppose research on human embryos, raising the issues of 'foetal rights' insist that all the fertilized eggs should be implanted into the women. One can find that ART presents situations in which the

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44. Ibid, p. 94.
45. Morton, Lord, *Report on the Royal Commission on Marriage and Divorce*, 1956, cited in Carol Smart " 'There is of Course the Distinction Dictated by Nature': Law and the Problem of Paternity", in Michelle Stansworth , *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, p. 107.
46. Smart, Carol, " 'There is of Course the Distinction Dictated by Nature': Law and the Problem of Paternity", in Michelle Stansworth , *Reproductive Technologies : Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, pp. 98-117.
47. Zipper, J. and Sevenhuijsen, S., 1987, op cit., p. 130.
48. Gallagher, J., 1987, op cit., p. 147.

interest of a living person is in conflict with the life of an unborn person. A similar dilemma posed by ART is related social construction of family. On the one hand the ART technologies reinforce the notions of family as a constitution of the blood relationship of parents and children by enabling couples to reproduce; on the other hand technologies like artificial insemination with donor semen or fertilization threatens the basis of social construction of family by limiting the 'biological' continuities of parents and children.

Hillary Rose (1987) suggests that 'if we are to begin to find ways of controlling the new reproductive science and technology in the interests of women, it is important that we distinguish between those technologies of ideological significance which serve to control through moral panic and those grounded in scientific and technological possibility'[49].

The above statement becomes clearer while analyzing the study conducted among the public and private ART clinic, which reports significant variance in the maximum number of cycles given to women and the maximum age limit for treatment[50]. The average maximum cycles given to women in public clinics was 3 and the average maximum cycles given to women in private clinic was 5. The average upper limit of women for availing treatment in public clinics was 39 where as the average upper limit of women for availing treatment in private clinic was 42. The significance of both these variables is that it has been widely documented in the scientific literature on ART that the health risks to mother and child increases with increases in the number of cycles and age without any significant increase in pregnancy rate. What is more significant is the control of the technology itself. Control of technology can be neither scientific nor social but a convergence of both.

3.3 DEBATES ON ART IN REPRODUCTIVE SCIENCE

An assumption that can be made from the analysis of the debates in the reproductive science on issues on ART is that the debates are based on the uncertainty of the

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49. Rose, Hilary, "Victorian Values in the Test-Tube: the Politics of Reproductive Science and Technology", in Michelle Stansworth, Reproductive *Technologies: Gender, Motherhood and Medicine,* Cambridge: Polity Press, 1987, p. 159.
50. Silverio, M. M., & Hemminki, E., 1996, op cit., p. 978.

therapies, techniques and drugs. The unknown risk and uncertainty can be traced in these debates. Understanding the nature of risk helps to contextualize the debates in the field of reproductive science on ART. A key inference on the characteristic of risk that can be made from the analysis of practitioners' discourse on risk is its omnipresence in human activity. Take for instance this statement, 'In a world where each step we take entails some risk, the actual risk of Creutzfeldt-Jakob disease (CJD) being transmitted is extremely minute or even zero'[51]. Scientific articles do acknowledge risk, but the way in which they are acknowledged, in itself down plays the risk. Like the statement given above risk is ascribed a generality, one that is inherent in human enterprise and hence science is also not devoid of it. The following section tries to understand what are the risks articulated, and their pattern, by practitioners and scientists in the field of ART and reproductive medicine. It categorises risk articulation in the assisted reproductive science literature in to four. They are health risk, risk related to success rates, therapeutic efficacy and economic risk. The risks do not exist separately or articulated independently, they overlap and reflect connections in understanding ART. Analysis of these risks also reveals the major debates in the field.

Health Risk:

Health risks from the therapies and drugs used in ART became a serious concern following the occurrence of Creutzfeldt-Jakob Disease (CJD) , caused by the contamination of a product used in the preparation of in-vitro fertilization (IVF) culture media[52]. Analyzing the contamination episode and its implication for those who had been treated with the product, Kemmann, suggests that 'this experience teaches our programme (i. e. Assisted Reproductive Treatment) the need to modify our consent form to indicate that human blood products are utilized in the process of the IVF laboratory, that IVF may entail risks that cannot be foreseen at this time and will prompt us to attempt to quantify the risk of ART as part of the Informed consent process'[53]. Health risks are contemplated by practitioners and taken care of in practice. The question arises

51. Kemmann, E., "Creutzfeldt–Jakob disease (CJD) and assisted reproductive technology (ART): Quantification of risks as part of informed consent", *Human Reproduction*, 13 (7), 1998, p. 1777.
52. Ibid.
53. Ibid.

that then why should it require a modification in the consent form. One can see that the ascribing of a general status to risk and forcing it as a general principle of action make risk to be perceived as a unavoidable outcome of therapy and practitioners will try to mitigate it. Suggestion to modify the consent form and the quantification of risk shows that , in practice the responsibility of risk is forced on those taking the treatment effectively relieving the practitioner of any liabilities of risk. The health risks to mother arising from multiple pregnancies are higher incidence of anemia, pregnancy induced hypertension (PIH), pre-eclampsia, polyhydramnios, gestational diabetes, higher maternal morbidity due to increased incidence of dystocia and caesarian sections and postnatal problems like isolation and depressive illness[54].

One of the major health concerns discussed by health experts of continuous infertility treatment is the risk of ovarian cancer, which is the most frequent cause of death from gynecological malignancies in western societies[55]. The common factor of the protective effects of pregnancy, breastfeeding and oral contraceptive pill against ovarian cancer is explained by their role in ovulation suppression[56]. Both the assessment evidently suggest a correlation between ovulation and ovarian cancer and hence a probability of increased risk of ovarian cancer among those undergoing ovulation induction. Another important risk in ART suggested by safety studies is the still birth of pregnancy. A study in Denmark involving 27072 women compared the risk of still birth in singleton pregnancies among women who conceived after ART-IVF and those who conceived in less than one year of marriage[57]. The study suggests that compared with spontaneously conceived pregnancies, IVF/ICSI pregnancies had four fold risk of stillbirth. A study comparing the health outcomes of twin children born through assisted conception and spontaneous conception suggests that the complications during delivery are more for the assisted group compared to the spontaneous group[58]. Preterm delivery, cesarean

54. Ombelet, W., "Access to Assisted reproduction Services and Infertility Treatment in Belgium in the Context of the European Countries", *Pharmaceuticals Policy and Law*, 9, 2007, p. 192.
55. Nugent, D., *et al.*, "Ovarian Neoplasia and Subfertility Treatments", *British Journal of Obstetrics and Gynaecology*, 105, 1998, p. 584.
56. Ibid, pp. 584-585.
57. Wisborg, K., *et al.*, "IVF and Stillbirth: A Prospective Follow-up Study", *Human Reproduction* , Advance access published on February 3, 2010, pp. 1-5.
58. Baxi, A., *et al.*, "Outcomes of Twin Pregnancies Conceived after Assisted Reproductive Techniques", *Journal of Human Reproductive Sciences*, 1 (1), 2008, pp. 25-28.

delivery and increased neo-natal intensive care unit (NICU) stay are common among twins of assisted group than spontaneous group. The health risks include respiratory distress syndrome and sepsis. The risk of neonatal morbidity and mortality in the second twin if delivered vaginally prompts obstetricians to resort to cesarean delivery.

Theoretically there is a possibility of reduced fertility among oocyte donors due to a decrease in the quantity or quality of oocytes resulting from repetitive ovarian stimulation or from pelvic injections or adhesions[59]. The risk of bleeding, ectopic pregnancy, heterotopic pregnancy, miscarriage and OHSS increases with the increase in the number of treatment cycles[60]. In a study conducted among 155 women, where the mean year since the first oocyte donation was 9.4 years reported the immediate post retrieval complications like some degree of OHSS (30.3%), OHSS related hospitalization (11.6%), Infertility and changes in menstrual cycle (26.4%) and new fertility problems (9.6%)[61]. The study also found that in the US only 2.6per cent of the donors were contacted by the clinic after the ovum donation, which points to a severe gap in the follow up of donors and possibility of risks at a later stage. The risk of ovum donation to the donor increases with the increase in age, the donors are vulnerable to the risk of Down's syndrome and risk of lowering fertility, which has led countries like Spain to restrict the age of ovum donation to 35 years[62].

A key inference from analysis of the above literature suggests that the uncertainties of therapies and drugs are very evident in the health risk articulation of practitioners and the mitigation of the risk proposed is by forcing the responsibility on to the couple. It is commonly understood that couples undergo treatment, but almost 100per cent of the risks fall on the woman and the child. Men who are part of the problem do not share any health risk of the treatment.

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59. Karmer, W., *et al.*, "US Oocyte Donors: A Retrospective Study of Medical and Psychosocial issues", *Human Reproduction*, 24 (12), 2009, p. 3145.
60. Klemetti, R., *et al.*, "Complications of IVF and Ovulation Induction", *Human Reproduction*, Vol. 20, No. 12, 2005, pp. 3293-3300.
61. Karmer, W., *et al.*, 2009, op cit., pp. 3146-3247.
62. Marina, Simon, *et al.*, "Oocyte Donor Selection From 554 Candidates", *Human Reproduction*, 14 (11), 1999, p. 2773.

SUCEES RATES

Success rate is a key term in the treatment of infertility. Couples are wooed to infertility centers by projection of success rates. Success rate can be a useful analytical tool in risk articulation and understanding major debates because success rates act as link between health risks and economic exploitation. The ambiguities in defining success rates are used by infertility clinics to project themselves as good and exploit the couples.

The multiple pregnancy rates across the world is estimated to be 20per cent in 1993[63]. The multiple pregnancy rates is an indication of importance of success rate in ART. Achieving pregnancy is the single most important indicator of success rate. To increase the possibility of pregnancy large number of oocytes, to the extent of 30 per stimulation is retrieved[64]. More oocytes are fertilized in-vitro and transferred in to the uterus. Health risks in ART have a linear relationship with success rates. Hyper stimulation for ovum retrieval is a major debate in the field of ART. Practitioners accept that the knowledge about the safety of hyper stimulation is primitive, since its aftereffects will be manifested only after a long time[65]. The immediate health risk of excess ovum retrieval is Ovarian Hyper Stimulation Syndrome (OHSS). Estimates show that OHSS has increased from less than 1per cent in 1988 to 7 per cent in 1996[66]. There seems to be a direct correlation between the rate of multiple pregnancies and increasing rate of OHSS. With complicated methods being employed in ovarian stimulation, the number of follicles produced per stimulation has increased from 2 to even 50 in some cases[67]. J. Roest (1999), citing Abramov *et al.*, argues that the rise in incidence of OHSS has reached a state of epidemic which needs to be considered as iatrogenic, which can be considered as the single reason for restricting ART to only those couples where all other

63. *ART World Collaborative Report*, XVth World Congress on Fertility and Sterility, Montpellier, September 17–22, 1993.
64. Felberbaum, R.E., *et al.*, 1998, op cit, p. 1778.
65. Edwards, R.G., *et al.*, "Time to Revolutionize Ovarian Stimulations", *Human Reproduction*, 11 (5), 1996, p. 917.
66. Felberbaum, R.E., *et al.*, 1998, op cit.
67. Edwards, R.G., *et al.*, 1996, op cit.

treatment options has failed[68]. Studies show a sharp correlation between high order ovarian stimulation and ovarian cancer, which is insidious and damages will be manifest only after several years[69].

Multiple pregnancies are a major cause of maternal and fetal morbidity and the premature deliveries resulting from multiple pregnancies have deleterious effect on the health of mother and child[70]. A major share of health care cost in ART is related to multiple pregnancies, obestric care costs are 2.1, 4.5 and 7 times greater for twins, triplets and quadruplets compared to singletons[71]. In order to maximize the success rates more than one embryo is transferred in to the uterus. The resulting multiple pregnancies rocket the cost of ART by the spending on maternal and neonatal intensive care and the spending on childhood disabilities. Multiple pregnancy in effect is iatrogenic to both mother and children. Practitioners defend transplanting multiple embryos by arguing that maximum number of embryos should be transplanted to optimize the chances of conception in consideration of specialists' situation in treating older women due to social trend of postponing pregnancy[72]. On the other hand there are studies that show that the health of children conceived through IVF can be improved through the promotion of single embryo transfers[73].

The debate on the success rate informs us two possibilities in ART. They are the possibilities of controlling the technology and exploitation of the technology. Lack of credible criterion for judging success rate can be deleterious to women's health and could lead to economic exploitation of couples. The ambiguity and uncertainty is more exposed in the debates on the therapeutic efficacy.

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68. Roset, J., "Severe OHSS: An Epidemic Caused by Doctors", *Human Reproduction* , 14 (9), 1999, p. 2183.
69. Edwards, R.G., *et al.*, 1996, op cit., p. 917.
70. Ibid.
71. Ombelet, W., 2007, op cit., pp. 189-201.
72. Adonakis, G., *et al.*, "The Role of the Number of Replaced Embryos on Itracytoplasmic Sperm Injection Outcome in Women over the Age of Forty", *Human* Reproduction, 12 (1), 1997, p. 2544.
73. .Klemetti, Reija, *et al.*, "Health of Children Born as a Result of In Vitro Fertilization", *Pediatrics*, 118, 2006, pp. 1819-1827.

THERAPEUTIC EFFICACY

The debate on using recombinant FSH over urine derived FSH for ovulation induction therapy provides insights in to larger issues related to therapeutic efficacy and economic efficacy of assisted reproductive treatment. FSH is basically gonadotrophin hormones which stimulate the release of ovum from the ovaries. Postmortem pituitary extracts and the urine of post menopausal women were the original source of gonadotrophins for therapeutic use[74]. Gradual up gradation and innovation took place in the therapeutic application of post menopausal urine extracts. In the 1940's purification of post menopausal urine was pioneered in Italy resulting in the production of Human Menopausal Gonadotrophin (HMG)[75]. It required 20-30 liters of post Menopausal urine for the treatment of one patient with one cycle of HMG. Further, innovations sophisticated the process of extraction. The invention of monoclonal antibodies in the 1980's enabled the extraction of Follicle stimulating hormone (FSH) from the bulk of HMG[76]. Pharmaceutical companies began to explore the possibilities of genetic technologies when the problems of supply, collection, transport, storage and processing of urine compounded with the increase in the demand for FSH[77].

An analysis of the debate on the therapies using urine derived FSH and recombinant FSH reveal that the protagonists and the antagonists of either drugs perceive advantages and disadvantages of each therapy. Scientists like Harumi Kubo, Balen H. Adams, Chatherine J. Hayden and Anthony Rutherford who favor recombinant version of FSH argue that the advantages are homogeneity, unlimited supply, low risk of infection, purity and specificity[78].

The arguments in favor of rFSH over urinary gonadotrophins are[79].

1. Pure product was in principle preferable to an impure product.
2. Human products carry a risk of infection by slow-viruses.

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74. Balen , H., *et al.*, "Clinical Efficacy of Recombinant Gonadotropins", *Human Reproduction*, 14 (6), 1999, p. 1411.
75. Ibid.
76. Ibid, p.1412.
77. Ibid.
78. Ibid.
79. Gleicher, Norbert *et al.*, "Bye-bye urinary gonadotrophins? Recombinant FSH: A real progress in ovulation induction and IVF?", *Human Reproduction*, 18 (3), 2003, p. 477.

3. Human products, since impure, carry a risk of immunogenecity.

4. Human products had repeatedly demonstrated to be uneven in biological potency.

Unlike the urine derived FSH, which is derived from large quantity of heterogeneous urine, rFSH is derived from homogeneous compounds using improved logistics of pharmaceutical process providing homogeneous products with reduced inter-batch variability. rFSH is manufactured through recombinant DNA technology by using Chinese hamster ovary (CHO) cell lines transfected with genes encoding human FSH[80]. The non-human based mass production of rFSH will ensure continuous supply and therefore unhindered clinical practice. Non-human based production of rFSH ensures that there is no infection from drugs consumed by people who are the source of urine. The purity of gonadotrophins is estimated to be less than 5 per cent[81]. rFSH is considered to be highly pure because it does not have a human origin. rFSH is considered to be highly specific because small amount doses yield predictable results. rFSH is supported for its higher level of clinical response, i.e. the ability of rFSH to aspirate maximum number of follicles and retrieve large number of oocytes which is also attributed to reduction in the number of repeated cycles and there fore cost effectiveness[82]. The biggest disadvantage considered by the supporters of rFSH is the increased price of the product compared to the uFSH. The average cost of drug per treatment cycle using rFSH was more than double compared to using uFSH [83]. Those supporting urinary gonadotrophins contest rFSH on the issue of affordability and those supporting rFSH contest urinary gonadotrophins on the issue of safety. They argue that it is not the cost of rFSH that should decide the affordability of ART. Treatment decisions should be determined by the overall risk/benefit and cost/benefit of using

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80. Kubo, H., "A Systematic Review of Controlled Ovarian Stimulation (COS) with Recombinant Follicle stimulating Hormone (rFSH) Versus Urinary Gonadotropin in GnRH Protocols for Pituitary Desensitization in Assisted Reproduction Cycles", *Journal of Mammalian Ova Research*, 22 (4), 2005, p. 216.
81. Out, H. J., *et al.*, "Recombinant Follicle Stimulating Hormone (rFSH; Puregon) in Assisted Reproduction: More Oocytes, More Pregnancies. Results from Five Comparative Studies", *Human Reproduction*, 2 (2), 1996, p. 162.
82. Daya, S., *et al.*, "Cost-effectiveness Modelling of Recombinant FSH Versus Urinary FSH in Assisted Reproduction Techniques in the UK", *Human Reproduction*, 16 (12), 2001, pp. 2567-68.
83. Jacob, S., *et al.*, "Outcome From Consecutive In-Vitro Fertilization/Intracytoplasmic Sperm Injection Attempts in the Final Group Treated with Urinary Gonadotrophins and the First Group Treated with Recombinant Follicle Stimulating Hormone", *Human Reproduction*, 13 (7), 1998, pp. 1785-1786.

rFSH against urinary gonadotrophins. One reason for the variation in the cost between both the products is that urinary gonadotrophins have come off the patent production and can be sold like generic medicine on the other hand recombinant formulations are recent innovations and are highly protected by patent regimes[84].

Scientists like S. Jacob, L. Drudy, R. Conroy and R. F. Harrison, who are suspicious of the claims of the studies that reckon a greater efficiency and cost benefit of rFSH over uFSH argue that the pioneering study by Out *et al.*, in 1996, 'Comparing Follitrophin Beta (rFSH) with urinary FSH seems to have tempted the manufacturers to extrapolate from their original study intentions to suggest that their brand of rFSH as used in that study was more effective than urinary FSH, and that lower doses and shorter treatment periods were therefore needed to achieve pre-ovulatory conditions' [85]. Scientists like Norbert Gleicher, Mary Vietzke and Andrea Vidali who support urinary gonadotrophins put forward the following arguments in contesting rFSH[86].

1. Even a single case of contamination of urinary gonadotrophins in clinical use has not been reported over the past thirty years, a credible period for action of slow viruses if they were present.
2. Recombinant products have the potential biological risk of introducing animal viruses into humans.
3. Comparative studies on the therapeutic efficacy of uFSH and rFSH are limited in number and not substantial enough to arrive at any conclusion.
4. With lower Lieutinising Hormone (LH) levels urinary gonadotrophins appear to be therapeutically effective from a theoretical point of view.
5. The data published on cost effectiveness is limited and can be suspected since they are not based on actual experience.
6. Market prices indicate that urinary products offer a very significant cost advantage.

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84. Gleicher, Norbert, *et al.*, 2003, op cit., p. 476.
85. Jaçob, S., *et al.*, 1998, op cit., p.1786.
86. Gleicher, Norbert, *et al.*,2003, op cit., pp. 476-482.

According to Juan Balasch and Pedro N. Barri 'the number of oocytes obtained would be the best efficacy parameter to evaluate, since it is the primary objective and the most direct result of ovarian stimulation with gonadotrophins and most easily observed and assessed' [87]. Their argument is that considering the unitary cost, uFSH would appear more attractive than rFSH , analyzing the cost-effectiveness ratio combining the efficacy and efficiency would reveal that in terms of pregnancy rates per cycle recombinant FSH is more cost effective than uFSH[88]. The argument may be up to the point if ART were to be treated in terms of mass production of goods or commodity. An interrogation of such arguments should begin from the questioning of the objective of ART treatment itself. Is the objective of ART treatment is to have one pregnancy or many? What is being missed out here is the health risks that are unknown and may emerge in future. The hidden cost that the women might have to pay for each extra ovum retrieved from her. Another study which analyzes the studies that project recombinant gonadotrophins as 'super drugs', which are largely industry-sponsored or associated research, analyze that the surge in the study reports on recombinant gonadotrophins had not been of any use to practitioners and these reports have 'blurred the line between scientific information giving and marketing' [89].

The debates on the therapeutic efficacy of drugs used in ART acknowledge the sense of uncertainty over therapies and drugs among practitioners and the risks arising out of the drugs and therapies. The papers produced in favoring some drugs without clear evidences as referred in the above section points to the unholy alliances of some practitioners with the pharmaceutical industry. This is a clear indication of economic exploitation of those undergoing treatment. Literature also points to the different economic risk articulated by scientists and practitioners which is discussed in the following section.

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87. Balasch, J. and Barri, P. N., "Reflections on the Cost-effectiveness of Recombinant FSH in Assisted Reproduction: The Clinician's Perspective", *Journal of Assisted Reproduction and Genetics*, 18 (2), 2001, p. 46.
88. Ibid, pp. 45-55.
89. Meniru, G. I. "What are the Clinical Benefits of Gonadotrophins? Is Puregon a 'Good' or 'Super' Drug", *Human Reproduction*, 14 (6), 1999, p. 1410.

Economic Risks:

Any analysis of the economic issues associated with ART should begin from estimating the cost of undergoing ART treatment. The problems with estimation of the cost of treatment are:

1. Infertility is not recognized as disease.
2. Insurance services are not provided for ART treatment except the cost of drugs in some countries
3. Private sector is the major player in providing ART services.

These three issues contribute to the economic uncertainty in infertility treatment. The first two issues marginalize infertility to a private sphere of life. The lack of recognition of infertility and lack of insurance coverage has resulted in irresponsible economic practices in this field as the clinics are not accountable to state or any other institution. Estimates show that 70- 90 per cent of the IVF cycles in Italy are performed in the private clinics[90]. Tariffs vary from clinic to clinic depending on the location and facilities provided. Another area of economic risks analyzed by experts is the comparative costs and benefits of different strategies used in treatment. A study contrasting r- FSH and u-FSH strategy in IVF in Italy shows that greater therapeutic efficacy of r-FSH strategy enables to attain higher economic effectiveness in infertility treatment and helps in reducing the societal cost of infertility treatment[91]. rFSH is recombinant technology and u-FSH is a urine derived technology which are used in the stimulation of follicle and harvesting ovum for fertilization. The therapeutic effectiveness r-FSH is substantiated by another study which concludes that glactosemia resultant infertility, a condition characterized by the deficiency of enzymes in the metabolism of galactose, can be better treated with rFSH to achieve pregnancy and birth[92]. The economic risk associated with using u-FSH is seen in scientific journals on

90. Mantovani, L.G., *et al.*, "Pharmaco-economic Aspects of In-Vitro Fertilization in Italy", *Human Reproduction*, 14 (4), 1999, p. 954.
91. Ibid, pp. 953–958.
92. Menezo, Y. J., *et al.*, "Pregnancy and Delivery After Stimulation with rFSH of a Galatosemia Patient Suffering Hypergonadotropic Hypogonadism: Case Report", *Journal of Assisted Reproduction and Genetics*, 21 (3), 2004, pp. 89-90.

two grounds. Firstly, the lower therapeutic efficacy leading to increased treatment cycles and secondly the scarcity of raw materials for uFSH compared to rFSH, which escalates the cost of uFSH. According to Mantovani *et al.,* (1999) lower therapeutic efficacy of u-FSH poses economic risk by increasing the number of treatment cycles, which leads to loss of employment days of the couples, expense in traveling etc. which increase the overall societal cost for the treatment. There is a tendency here to separate the different risks of a particular treatment and view the economic risk in isolation. Lower therapeutic efficacy in ART becomes different from other treatment because it leads to repetition of the treatment cycle. Repetition of the treatment cycle means that the same drugs are used again and again, obviously leading to increased health risks.

The risk articulation and debates in the literature of reproductive medicine shows that the practitioners and scientists perceive risk based on the uncertainty of the therapies, techniques and drugs used in assisted reproductive treatment. The risk perception is purely technical. The debates also indicate that a point of contention among scientists' is the manipulation of research for commercial interest. That also shows that how commercial interests play out in ART in promoting techniques, therapies and drugs which are not really necessary or the efficacy of which are ambiguous. The perception of risk is not always technical; social issues are invoked to project certain risks to counter moves from any corner to regulate ART. Risks are also articulated in social context by practitioners and scientists to promote ART. The following section discusses the risks, which are articulated in social context to promote ART.

3.5 STRATEGIES OF LEGITIMISATION

The strategies employed by scientist and practitioners range from using research studies, patronizing pressure groups and interpreting laws to suit particular context. For example interpreting human rights declaration to project a condition of childlessness as denial of human rights. The strategies are employed to legitimize, to promote ART procedures, to justify the inclusion of certain groups in provisioning of the ART under public health service. The strategies include the political strategies like pressure groups and patient support groups, the politics of expert patronage, interpretation of social and demographic changes in favor of adopting technological solutions, strategies to promote

ovum donation by differentiating it from organ donation and interpreting it basically as an altruistic act, and down play donation related issues like consent of the partner, status of the donor. Take for instance Balen *et al.,* (1999) have reviewed the recent advancements in the ART technology and suggest that the ART technique has become 'user friendly' and 'promote' the welfare of the women, the significance of such conclusions is that scientific facts are used to justify ART techniques at time when they have come under severe attack of feminists for the medicalisation and exploitation of women's bodies. The study quotes:

> " ..... developments in the IVF laboratories and with the gonadotrophin preparations, there have been significant changes in the practice of assisted conception itself. Stimulation protocols are being modified to enhance 'friendliness' to the patient. (Olivennes and Frydman, 1998). Strategies include simple ideas such as using an oral contraceptive agent for 2–3 weeks prior to starting a GnRH agonist; and thereby ensuring pituitary desensitization without the need for additional scans and without the risk of cyst formation (Biljan et al., 1998). Ultrasonography has become the mainstay of monitoring both the ovarian and the endometrial response to stimulation, without the need for frequent blood tests of endocrine parameters (Tan, 1994; Wikland et al., 1994). The introduction of GnRH antagonists should further improve the welfare of women receiving treatment by first obviating the often distressing side effects of oestrogen deficiency caused by the agonists and second shortening the length of the cycle by being able to commence gonadotrophin therapy in the early follicular phase and preventing an LH surge with appropriately- timed administration of either a single or multiple doses of an antagonist (Olivennes et al., 1998; Ganirelix Dose-finding Study Group, 1998). The total dose of gonadotrophins used also appears to be reduced when compared with a conventional 'long agonist protocol' (Olivennes et al., 1995). Furthermore antagonists can also be used in spontaneous cycles to minimize the cancellation rate of 'natural cycle IVF] and thus allow 'low burden, user friendly' conception treatment in appropriately selected cases"[93].

The above quotation highlights how the IVF treatment has improved from the risky and time consuming procedures to an easy one with the improvements in the gonadotrophins, drugs, with the improvement in the monitoring and diagnosis equipment. The simplicity achieved in the overall treatment is conveyed through words such as 'enhance patient friendliness', 'welfare of the women', 'low burden user friendly'. It also points to convenience achieved by avoiding procedures like additional scans, avoiding frequent blood tests, shortening the length of the cycle reduction in the dose of gonadotrophins. The strategies in explaining the overall simplification of ART

93. Balen, H., *et al.,* 1999, op cit., p. 1415.

treatment is achieved partly by projecting a qualitative psychological experience of 'feeling good' for the patient with the overall treatment and partly by employing a quantitative physical experience of lowered effort one needs to take in the treatment, like lowered attempts of blood tests etc. These strategies may be attempts to overcome the criticism that ART treatment procedures endure psychological stress for women and require physically painstaking process. Scientific facts strategically presented to argue that the development of new techniques had lowered the medicalisation of women's infertility and the new techniques in effect had simplified the process which is oriented towards 'welfare' of the women.

Similarly strategies contextualize problems in human rights framework to counter attempts restrict ART treatment. Take for example this quotation, "Adherence to rigid BMI cut off values in denying access to fertility treatment may represent adoption of utilitarian values at the cost of individual welfare"[94]. The authors accuse the policy decision for restricting obese women from availing infertility treatment as being utilitarian. Individual welfare is being compromised in an attempt to save public money. Moral judgments along with scientific facts are employed in making arguments and defending certain positions. Ethical grounds are invoked to infuse genuineness to issues that are contested. What is unethical to these scientists is the restriction of a needy person from availing treatment – an infringement of individual right to lead a healthy life and procreate. Reference to the infringement of individual right goes to the extent of citing Article 9 of the charter of fundamental rights of the European Union, i. e. the right to marry and right to found a family[95]. The word 'Utilitarian values' is blended in to a context that mystifies the prominent usage of the term. The alliance of medical knowledge and market is often accused of being driven by utilitarian values and medicalizing pregnancy and birth. Utilitarian values in the context of BMI cut off values is articulated by the scientists as the values adhered by the state that aims to save public money by preventing the needy obese women from accessing infertility treatment.

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94. Pandey, S., *et al.*, "Should Access to Fertility Treatment be Determined by Female Body Mass Index?", *Human Reproduction*, 25 (4), 2010, p. 817.
95. Ibid.

Strategies also include invoking ethical issues like patient autonomy to counter policies of exclusion in ART. Take for example the following quotation, "As long as women understand the risk of proposed treatment, and the overall clinical benefit is deemed to be greater than any attendant risks, we should be cautious in allowing our inherent paternalism to override patient autonomy"[96]. The argument places patient autonomy above all. What is being actually done in the name of promoting patient interest is transferring the onus of risk on the patient and exploiting the distressed condition of the patient to make decisions by comparing the costs and benefits of undergoing the treatment. What is being missed out here is the hierarchical nature of Doctor-Patient relationship in which very limited information is shared. The question is how can the patients be expected to understand the risks of treatment and take decisions under such a hierarchical relationship. The strategy employed in the articulation of the practitioners is the comparison of costs and benefits in qualitative terms aimed at criticizing the projection of risks in quantitative terms and thereby the attempts of state to protect the subjects from the risks.

A strategy employed in the suggestion to cover the cost of ART services and include infertility services in the public health programme by the state, what according to Rod S Taylor is 'baby friendly policies', is to link the issue of declining fertility rate with declining gross domestic product (GDP)[97]. Political strategies of legitimization include formation of country specific support groups or self help groups by infertility couples, which are coordinated by umbrella organizations at regional and global levels. At global level International Consumer Support for Infertility (ICSI) provides the platform for patient support leaders from 39 countries all over the world[98]. Professional associations of ART practitioners patronize the patient representative leaders' organizations. One such example is ESHRE patient leaders forum (EPLF) which has been established with in European Society of Human Reproduction and Embryology (ESHRE)[99]. EPLF initiatives include advocacy and lobbying for policy changes in the countries in

96. Ibid.
97. Taylor, R. S., "'How Much Does a Baby Cost?' - Economics of Demographic Policies", *Pharmaceuticals Policy and Law*, 9, 2007, pp. 121-128.
98. Dill, S. K., "International Treatment Differences: Policy, Politics, Partnerships and ART", *Pharmaceuticals Policy and law*, 9, 2007, p. 148.
99. Ibid.

European Union (EU), which include meeting of European parliamentarians, formation of Assisted Conception Task force (ACT) to provide expert advice to people facing infertility problems. In countries like Germany, severely declining fertility rate is used as strategic tool to make a case for ART through policy interventions - to liberalize ART treatment, strike down stringent laws, and covering complete cost of ART[100].

The literature survey throws light on another set of strategies aimed at equating the normal conception and birth to the assisted conception and birth. Economic models and scientific facts are used to prove that there is not much difference between a child through normal birth and an ART child. The strategies include calculating the 'cost of the IVF-baby' and prove their profitability- a form of legitimating ART economically and suggesting that the process is worth doing for the society. The average cost of a baby in Sweden is estimated to be 22,000 Euros, 'which is 10 per cent of the Swedish estimate of what a human life is worth to the Swedish society' [101]. Similarly in UK the 'lifetime net present value' of a naturally conceived child was calculated and compared with that of a ART child. A model was developed to analyze the financial interaction between the state and the individual and the return of 'lifetime positive net present value' to the government was calculated[102]. The difference between the monetary contribution of an individual to the state in the form of tax returns and the monetary support provided by the state to the individual in terms of education, health, pension benefits etc. The model shows that only extra burden due to an IVF child on the British state is 14,829 Euro. It was shown that the lifetime net present value of naturally conceived child was 2, 13, 000 Euros and that of ART child was 2,33,000 Euros suggesting that ART children are slightly more expensive[103].

A study analyzing the comparison of the health status of children born through ovum donation and IVF suggests that there were some interesting differences in the groups

100. Thaele, M. and Uszkoreit, M., "Legislature's Impact on the Outcome of Infertility Treatments – The German Political Contradiction", *Pharmaceuticals Policy and Law* , 9, 2007, pp. 221-227.
101. Sunde, A., "Europe's Declining Population and the Contribution of ART", *Pharmaceuticals Policy and Law*, 9, 2007, p. 86.
102. Ledger, W., *et al.*, "Present Discounted Value of Children Born Using IVF Compared with Naturally Conceived Children: A Simplified UK Calculation", *Human Reproduction*, 21, 2006, pp. i74-i75.
103. Sunde, A., 2007, op cit., p. 87.

regarding the daily care of the child[104]. Analyzing the behavioral patterns(reported by mothers) like less fear to strangers, advancement in language development, which are better in children born through ovum donation than through IVF, the study suggests that the findings in the Ovum donation group can be 'cautiously' interpreted as positive signs reflecting good parent infant relationship and well being of the children. The reason pointed out by the study for the favorable findings in the ovum donation group is the young age and lower level of anxiety among the ovum donors compared to those mothers who have been undergoing infertility treatment for long time. It seems that the study takes pains to argue that child birth through ovum donation is a relatively better process compared to IVF. An attempt to promote ovum donation from those young women who are not undergoing ART.

A study countering the Human Fertilization and Embryology Authority's (HFEA) suggestion for abolition of paid donation of ovum as against altruistic donation of ovum argues that even in case of paid donors it was the opportunity of helping others that motivated the donors than the financial incentives[105]. The study counters the proposals of HFEA, that paid ovum donation can lead to the exploitation of financially vulnerable women. The study argues that 49per cent of the egg share donors were middle class women with tertiary education aged 30-35 and hence it is difficult to conclude that these women are socially vulnerable and easy to persuade. The study also argues that 86per cent of the egg share donors and 79per cent of egg share enquirers were motivated by the idea of helping others. Secondly the life of the child born will be affected if the issue of paid donation is revealed to him/her at a later time. The study argues that, considering the large amount of money spent for ART treatment and adoption services this argument seems to be insensible. A study which argues for maintaining a registry of ovum donors suggests that financial remuneration is essential for establishing ovum donation as a standard programme, altruism only comes at later stage[106].

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104. Anttila, V. S., *et al.*, "Health and Development of Children Born After Oocyte Donation Compared With That of Those Born After In-Vitro Fertilization and Parents' Attitude Regarding Secrecy", *Human Reproduction*, 13 (7), 2009, p. 2013.
105. Ahuja, K. K., *et al.*, "Egg Sharing and Egg Donation: Attitudes of British Egg Donors and Recipients" *Human Reproduction*, 12 (12), 1997, pp. 2850-2851.
106. Lindheim, S. R., *et al.*, "Recruitment and Screening Policies and Procedures Used to Establish Paid

ACCESSABILITY:

A major debate related to accessibility of ART is the one on restricting obese women from accessing infertility treatment in countries like United kingdom (U. K.), where the ART is provided through public heath services. A study analyzing 1280 cases in New Zealand shows that 52 per cent of women with Body Mass Index (BMI) higher than 32kg/m^2 were less successful in giving birth compared to women with BMI less than 32kg/m^2 [107]. At the same time authors criticize the use of same threshold for women of European origin and women from Maori and Pacific island[108]. Another study conducted among 3586 women who received assisted reproduction treatment in Adelaide, Australia, shows that high or low body mass index was associated with reduced probability of achieving pregnancy among women undergoing assisted reproductive treatment[109]. The findings of this study are severely criticized and defended from being translated in to policy outcomes. The evidences presented in support of the argument are, there is evidence only against negative association between obesity and success rates following ovulation induction or reports of increased drug doses or episodes of ovulation, there is no evidence against definitive end points like pregnancy and live births, there is no evidence against cycle cancellation or fewer embryos, 56 per cent and 61 per cent of all women in UK and USA respectively are obese, BMI cut off values vary from country to country and hence are arbitrary and "probably based on select experts' opinion", interventions aimed at weight loss are not always successful [110].

3.6 DONATION RELATED ISSUES

Argument against demanding consent of the partner in donation is that, the practice runs counter to the commonly accepted and widespread principle of a person's complete right over one's body and its parts, the consideration of body and body parts as an individual

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Donor Oocyte Registry", *Human Reproduction*, 13 (7), 1998, pp. 2020-2024.

107. Gillett, W., *et al.*, "Prioritizing for Fertility Treatments—The Effect of Excluding Women with a High Body Mass Index", *BJOG*, 113, 2006, pp. 1218–1221.
108. Ibid, p. 1221.
109. Wang, J. X., *et al.*, "Body Mass and Probability of Pregnancy During Assisted Reproduction Treatment: Retrospective Study", *British Medical Journal*, 321, 2000, pp. 1320-1321.
110. Pandey, S. *et al.*, 2010, op cit., pp. 815-820.

property and therefore the way one wishes to use it[111]. Donation does not infringe any legal rights of the partner. Demand of consent can be seen only as a moral obligation in which the hospital, doctor or the state has no assignment to make donors of their moral obligations with the partner and therefore no reason to introduce legal requirement to demand partners consent[112]. The different marital aspects cited in favor of asking consent are[113]

1. Sexual exclusivity and adultery.
2. Family Composition.
3. Procreational exclusivity.
4. Interests of the partner is hurt by the donation

Traditionally donation of sperms is objected on the grounds that donation can amount to adultery as the donation requires masturbation, which is associated with juvenile, homosexual or adulterous behavior. The opposite view is that the requirement of the infertile couple changes the very image of donation itself. The argument regarding to family composition is that the participation of a member of a family as donor has long term consequences and hence the family members should be consulted. The counter argument is that, what is referred to as consequences is not clear. The social and legal link between the donor and offspring is kept anonymous which practically nullifies the consequences if there are any. The argument for procreational exclusivity is that the donation of reproductive material constitutes a breach of mutual agreement in marriage as reproductive materials are directly linked to family-making and sexuality. The counter argument is that donation assumes meaning only in a social context. It is always presented as a helping act. The donation of ovum can damage the interest of the partner when the gametes that can be used for the couples reproductive goals become limited as result of the donation or if the donation itself becomes detrimental for the donors chances of conception. The partner's legitimate interest of procreation is hampered here.

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111. Pennings, Guido, "Partner consent for sperm donation", *Human Reproduction,* 11 (5), 1996, p. 1132.

112. Ibid, p. 1136.
113. Ibid., pp. 1132-1135.

When the donor is from the social network, donation has the possibility of resulting in psychological and emotional complications in the life of the donor and the partner. Studies to defend the exploitative nature of oocyte donation try to portray it as conceived as an altruistic action by the donor. A study conducted among 554 women in the age group of 18-25 in Italy argues that educated women who donate ovum considered it as a altruistic action and the donor receives economic compensation to meet the expense arising from the donation process[114]. The study implicitly suggests that the donors are 'educated' women who are thoroughly aware of the consequences of donating their ovum. It suggests that the donors are only 'economically compensated' for those expenses inquired to them during the process and hence this cannot be equated to the selling of one's body parts. The study tries to define ovum donation as consensual action; economic transaction is limited to compensatory role devoid of any profits and above all an action motivated by altruism.

Another prominent debate on the issue on ovum donation is on the status of the donor. Should the donor be a third party or the one who undergoes infertility treatment?. Studies that support a third party donor target the egg sharing programme. A study analyzing 621 donor cycles from 1991-1997 suggests that pregnancy success rate is directly proportional to the age of the donor[115]. The younger the age of oocyte donor the higher probability of pregnancy. This study also argues that the age of the receiver is not very significant to success rate in donor programme. The findings in the study can have implications on the ovum sharing programme. Ovum sharing programmes are arranged between women seeking infertility treatment where the donors are likely of higher age and are given reduction in the cost of treatment there by making it accessible to groups of lower income. The most severe implication of the finding can be the probability of bringing third party women in to the health risks of ovarian stimulation in the demand for ovum from young women. The questions raised by the translation of these findings in to policy are two. One is of accessibility, arising from the lower preference to ovum sharing programme and other is of health risks to more women, with the increased demand of ovum of younger women to increase success rates.

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114. Marina, S., *et al.*, 1999, op cit., p. 2775.
115. Cohen, M. A., *et al.*, "Donor Age is Paramount to Success in Oocyte Donation", *Human Reproduction*, 14 (11), 1999, pp. 2755-2758.

A study countering the HFEA proposal for 'unpaid' donation of eggs, which equates egg sharing programme to payment of money in return for ovum, employs the language of altruism to resonate the empathetic attitude of infertile ovum donors towards the infertile receivers, the waste of ovum through cryopreservation and the long term health risks to non-patient donors to argue that egg sharing programme are the viable option amidst the scarcity of ovum[116]. Another paper written by the Ahuja *et al.,* (1998a) criticize HFEA for prohibiting all forms of paid ovum donation[117]. The authors present the case of women who contracted colon cancer and died after five years of her donating ovum to her sister. The authors only point to a strong possibility of ovarian stimulation drugs to be causative agents of colon cancer in women. They also refer to studies which suggest strong correlation between infertility treatment and different cancers. They further suggest that most of the ovum donations take place with the uncharted knowledge of physical and psychological effects on recipients and donors. The authors raise a question of economic justice against the HFEA Act to prohibit all kind of paid donations. The authors ask why should a person who is not directly benefited by the ART donate ovum and face its deleterious effects. The axe of the authors is directed on the proposal for ovum sharing among family members. By arguing strongly against ovum donations involving those not undergoing ART, the authors make a case for legitimizing the egg sharing programme amongst those undergoing ART.

It appears that this debate is driven by practitioners' position for and against increasing success rate. A criticism against ovum sharing programme is distress among donors after a failed treatment arising from the feeling that donation had reduced their chances of being pregnant, i.e. more number of ovum could have increased the chance of pregnancy[118]. Practitioners therefore against egg sharing programme argue that the number of embryos for implantation in ovum sharing programme is low affecting the success rates, whereas non patient donation programme can offer more embryos for implantation and hence increase success rate. Another debate that is going on in the

116. Ahuja, K. K., *et al.,* "An Assessment of Motives and Morals of Egg Share Donors: Policy of 'Payments' to Egg Donors Requires a Fair Review" *Human Reproduction*, 13 (10), 1998, pp. 2671-2678.

117. Ahuja, K. K., *et al.,* "Cancer of Colon in an Egg Donor: Policy Repercussions For Donor Recruitment ", *Human Reproduction*, 13 (1), 1998, pp. 227-231.

118. Ahuja, K. K., *et al.,* 1998, op cit., p. 2673.

issue of consent is what should be the criteria for a person to give consent[119]. Is it the genetical relation of the person with the donor makes him eligible for consent or the closeness of the person with the donor. A patient satisfaction survey on the management of infertility in Scotland reveals that 21per cent of the patients who participated in the survey felt that little or no information was provided to them on the possible causes of their infertility and 23per cent of the women reported that they have not received any information on the possible side effects of medication[120]. Around 86 per cent of the patients reveled that they have not received any type of counseling[121].

3.7 CONCLUSION

An analysis of the risk frames in the reproductive science and social science literature reveals the divergence of issues debated, the multiplicity of positions taken- within the discipline and amongst different disciplines and the diversity of actors involved in the scientific and social terrain of assisted reproductive technologies. It is evident throughout the chapter that the points of convergence for the issues, actors and positions are very few. And the real challenge in ART lies in identifying the instruments of convergence.

A cursory reading of the literature on reproductive science throws light on the issues and debates in the fields. The discussion in the chapter enables to categorize the actors. Those supporting recombinant therapies and those favoring urine derived therapies, those supporting egg sharing programme and those supporting third party egg donation, those supporting BMI cut off and those opposing BMI cut off, those favoring multiple implantation of embryos and those supporting single embryo implantation. The inference that can be made from the discussion is that practitioners and scientists are divided over the uncertainty of technological outcomes. The issues get complicated when the technological interwove with the social.

On the other hand the debates in social sciences include issues like the rupturing of the social construction of motherhood and biological parenthood- deconstruction of

119. Pennings, G., 1996, op cit., p. 1135.
120. Souter, V. L., *et al.*, "Patient satisfaction with the management of infertility", *Human Reproduction*, 13 (7), 1998, p.1833.
121. Ibid.

motherhood, the delegitimization of genetic parenthood, Separation of sexual act from marriage. These are: 1) Implications for women's lives, status and bodies- the liberation versus victimization debate. 2) The possibility of existing social and political conditions to prevent women from accessing the technologies to suit their context. 3) The reinforcement of patriarchal notions of womanhood, motherhood, family by forcing technology on each and every childless women irrespective of their wish and choice. 4) The emerging commercialization of reproduction and the creation of exchangeable objects like ovum, sperm and womb, subjects like biological mother, genitical father, surrogate, social mother and social father. 5) Interventions in to the sanctity of family, marriage and procreation and life – debates on the acts of masturbation and artificial insemination with donor semen, research on embryos, cloning . 6) Conflicting identity politics – the rights of feotus versus right of pregnant women, contested alliance between right wing political parties and cultural feminists. 7) The debates over adoption and monetary compensation for surrogacy. 8) The debates over ownership of biological material once they are sold or donated and eugenic possibilities of ART.

Though the debates seem to be divergent they are neither disconnected from each other nor in vacuum. They represent two sides of the same coin. The analysis of literature in the field of reproduction and social science confirms that the uncertainty on technological outcomes and the social, cultural, economic and contextual interpretation of risk is a dominant paradigm for interrogation of Assisted Reproductive Technology. Secondly, the discussion suggests that the technological and social issues are not divergent; they are interwoven. Take for example the issues like success rates, BMI cut off, limiting the age of women seeking ART and issues related to donation, there are technical risks which are accentuated by social conditions in such a way that it is difficult to differentiate them. The inference substantiates the second theoretical argument that technology is not only about technological issues, technological issues are interwoven with social issues and public engagement can inform debates with the social side of the technology. And above all these issues are debated without consensus among the scientific community. Both these points bring our discussion to the third argument that lack of consensus among experts facilitates public engagement in science and technological issues. Being proved the first two argument theoretically, the study sets

out to examine following three arguments with reference to regulatory policies.

1. Does the technological uncertainty and the social, cultural and contextual articulation of risk has created a space for critical view of ART in Indian context?
2. Is the entangled nature of technological and social issues recognized in ART in Indian context?
3. Does the lack of consensus among experts facilitate public engagement in ART in India?

The convergence of divergent streams of debates is expected theoretically to be accomplished by policy instruments. The avenues of policy making is expected to be the space for convergence of divergent streams ideas, which can be called as an expert and lay interface. The next chapter will attempt to analyze the convergence of divergent streams of actors, ideas and public engagement in the Assisted Reproductive Technologies (regulation) bill 2008 by analyzing the representation of risk frames by practitioners, patients and civil society organizations in the ART (regulation) Bill 2008.

Chapter- IV

REPRESENTATION OF RISK FRAMES IN ART (regulation) BILL 2008

The chapter analyzes the risk frames of different actors like practitioners, patients or couples/individuals and civil society organizations and their reflection in the ART bill and draws on public engagement model in the area of assisted reproductive technology. The chapter is divided in to five sections. The first section explores the historical evolution of the ART bill 2008. The second section offers a critical analysis of concepts and definitions in the ART bill. The third section analyzes and categorizes the risk frames of different actors using sources like studies conducted by civil society organizations like SAMA and Rural Women's Social Education Centre which provide the risk perceptions of women, couples/individuals, practitioners, women's rights group and laymen. The other sources include websites of infertility clinics which articulate the risk perceptions of practitioners. The third source which is employed in the chapter to substantiate the arguments is the data generated from interviews conducted by the researcher among the key respondents. The fourth section analyses the reflection of different actor on risk frames in the ART Bill 2008.

4.1 HISTORICAL EVOLUTION OF THE BILL

Concerns about the ethical and social implications of ART first raised at international level was during the 52nd world health assembly. World Health Organization (WHO) was asked to review the recent developments in the field of ART and to assess their social and ethical implications[1]. The WHO Department of Reproductive Health and Research convened a meeting on the medical, ethical and social aspects of assisted reproduction on 17-21, September 2001. Participants from 22 countries attended the meeting, including clinicians, embryologist, social scientists, ethicists and consumer representatives. The report christened Current *Practices and Controversies in Assisted Reproduction: Report of a Meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction"* provided an interdisciplinary approach to assisted reproduction.

1. Vayena, E., *et* al., (eds.), *Current Practices and Controversies in Assisted Reproduction*, Geneva : World Health Organisation, 2002, p. xvi.

The Ethical Guidelines for Biomedical Research, Published by Indian Council for Medical Research (ICMR) in 2000, was the first official document to refer to ART in India.[2] The official version of the evolution of ART Bill 2008 is as follows[3]. The discussions on regulating ART in India came up when the Ministry of Health and Family Welfare, in 2000, requested Indian Council of Medical Research (ICMR) to develop standards for ART treatment. In response to the call from Health Ministry, the Director General (D. G) of ICMR constituted a committee to draft national guidelines for accreditation, supervision and regulation of ART clinics in India. The guidelines were drafted in September 2002 and released for public debate in the same month, which was followed by public debates organized by ICMR in Mumbai, Delhi, Kolkatta, Chennai, Hyderabad, Bangalore and Jhodpur. The national guidelines was approved by the government and published in 2005. Realizing that the feedback on the guidelines was not satisfactory the Government asked ICMR to translate the guidelines in to law in 2006. ICMR constituted a committee and redrafted the bill. The bill was drafted and posted for comments in 2008. Comments were received from various miniseries and some issues like nationality of the child and issuing birth certificate have come up, which is to be discussed in a meeting scheduled on 12th April 2010(the interview was conducted on 31st March).

4.2 CONCEPTS AND DEFINITIONS: A CRITICAL ANALYSIS

An analysis of the concepts and definitions in the bill throws light on the priorities of the policy makers. It also provides insights in to position of the policy makers in approaching and regulating the technology. It points to the omissions, inclusions and exclusion which are important in analyzing the bill. The following section analyses the two important definitions, Assisted Reproductive Technology and Infertility, which are key to the regulation of assisted reproductive technologies.

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2. SAMA TEAM, "Assisted Reproductive Technologies: For Whose Benefit", *Economic and Political Weakly*, 44 (18), 2009, p. 25.
3. Interview with a key policy maker in ICMR.

Assisted Reproductive Technology (ART)

The ART draft bill 2008 narrowly defines Assisted Reproductive Technology which has limitations in capturing the complexity of social issues raised by the technology. The bill defines assisted reproductive technology as:

> "'assisted reproductive technology", with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or embryo into the uterus;"[4]

There are two major flaws in the definition, which can be detrimental to the scope of regulating the technology and dealing with the complex social, economical and ethical issues raised by the technology. The definition primarily excludes in-vivo assisted reproductive techniques, this owes significance on the grounds that the availability of the data on various techniques is not available.

Secondly, in -vivo reproductive techniques also follow the therapies more or less similar to in- vitro, say for example ovulation induction and hence the physically and psychologically exhausting process the infertile couples need to undergo, especially women, is not very much different from in- vitro fertilization. The possibility is that the present regulation, by excluding in- vivo techniques from its ambit may lead to the exploitation of infertile couples, reliving practitioners from the responsibility and liability of the treatment. Take for instance the case of a respondent who had been undergoing ART treatment with in vivo techniques for the last thirteen years[5]. The respondent's wife has undergone a surgery, both take drugs and hormonal injection, the couple face the problem like lack of information, frequent trips to the clinic, the respondent's wife have side effects like hair fall and obesity. To the question how much has he spent on the treatment, the respondent answered "lakhs". The experience shared by the respondent and the experience of those who had undergone IVF, as narrated in studies conducted by civil society organization like SAMA has commonalities in terms of physical and psychological suffering, the economic exploitation, attitude and approach of practitioners and the vulnerabilities and risks the couple face. The discrimination or the exclusion of in vivo techniques can be questioned on these grounds.

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4. The Assisted Reproductive Technology (regulation) bill 2008,p.3.
5. Interview with a male respondent who is undergoing ART treatment.

Thirdly, gestational surrogacy is also excluded from the definition of ART. Surrogacy arrangements have in recent times increased manifold with the boom in the medical tourism sector and there had been many issues and controversies, mainly legal, with the commissioning of surrogate mothers. The depth of the market, the terms and conditions in the arrangement and ambiguous issues like whether it really benefit the women or they are exploited. Surrogacy arrangements had in recent times raised many legal, ethical and social issues like exploitation of poor women. In this context the exclusion of surrogacy may aggravate the condition.

Lack of clarity in defining the subject matter of the bill of, i.e. assisted reproductive technology, and inclusions and exclusions determining what should contribute to as the technology offers insights in to how regulatory policies are expected to influence the use and development of the technologies. The bill seems to focus on high end technology while leaving grey areas in engaging with the low end technologies like in-vivo techniques, which may be used to treat majority of the infertile couple. The exclusion of gestational surrogacy points to an inclination towards the promotion of commercial interests especially with the boom in medical tourism.

The International Committee for Monitoring Assisted Reproductive Technology (ICMART) emphasizes the need for properly defining treatments and therapies[6]. According to ICMART, proper definitions at national and international level are necessary for standardization, to harmonize international data collection and to monitor availability, efficacy and safety of ART interventions. The definition of Assisted Reproductive Technology given below was the one adopted in the first ICMART glossary in 2006. The same definition was maintained in the revised ICMART and WHO glossary of ART terminology in 2009.

> "All procedures or treatments that include the *in vitro* handling of the human oocytes and sperm or the embryos for the purpose of establishing a pregnancy. This include but is not limited to, IVF and transcervical embryo transfer, gamete intra-fallopian transfer, zygote intra-fallopian transfer, tubal and embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation and gestational surrogacy. ART does not include assisted insemination (artificial insemination) using sperm from either woman's partner or sperm donor."[7]

6. Hochschild, F. Z., *et al.*, " The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) Revised Glossary on ART Terminology 2009", *Human Reproduction*, 24 (11), 2009, p. 2684.
7. Hochschild, F. Z., *et al.*, " The ICMART Glossary on ART Terminology", *Human Reproduction*, 21 (8), 2006, p.1969.

Though the emphasis of the definition is on *in vitro* techniques it does not exclude *in vivo* techniques as it is specified that all procedures used for the purpose of establishing a pregnancy is defined as Assisted Reproductive Technology. The definition is also clear about embryo donation and gestational surrogacy and includes a range of techniques used in assisted reproduction. In the case of the ART bill 2008 the definition sounds murkier with the inclusion of the terms 'handling or manipulating the sperm or oocyte outside the human body'. It is interesting that when the technology is well defined by WHO as early as 2006 why didn't the bill which was finally drafted in 2008 adopt an ambiguous definition.

Infertility

The bill defines infertility as

> '"Infertility" means the inability to conceive after at least one year of unprotected coitus'[8]

The ICMART glossary 2006 defines infertility as

> 'Failure to conceive after at least one year of unprotected coitus'[9]

On the other hand the 2009 ICMART & WHO revised glossary on ART terminology defines Infertility as

> 'Infertility (Clinical definition): a disease of the reproductive system defined by the failure to achieve clinical pregnancy after twelve months of regular unprotected sexual intercourse.'[10]

There are two points which need to be emphasized regarding the definition of Infertility. Primarily, the definition attributes a status to the problem which is deemed to be tackled using specific knowledge or technology. Infertility is the problem that is at stake which requires intervention of a specialized knowledge or technologies like IVF, ICSI etc. The legitimacy of interventions like- the extent to which the technologies need to be regulated, the role of state and the type of intervention required or the extent to which various sections of the society can be involved in regulating the specialized knowledge and techniques, the accountability of the specialist, the responsibility of the individual/

8. The Assisted Reproductive Technology (regulation) bill, 2008, op cit., p.4.
9. Hochschild, F. Z., *et al.*, 2006, op cit., p. 1969.
10. Hochschild, F. Z., *et al.*, 2009, op cit., p.2686.

couple subjected to any form of treatment, the responsibility of state and society-definition of the problem plays a decisive role in the interpretation of the above mentioned factors both in theory and practice. Scope of public engagement in scrutinizing and legitimizing the specialist knowledge is closed down for ever. The ICMART & WHO glossary 2009, by defining infertility as a disease has placed it in a broader context, which requires not only the examination of the technological fix to that problem (i.e ART treatment) but also a range of causes and problems of infertility. Secondly, the practical problem with the definition of infertility is with the time frame of one year. Unless the definition of infertility is specified in relation to the age of the couple/individual, there is a risk of forcing ART on people who can otherwise conceive naturally. The following response shows how definitions can be problematic in particular social context.

> ' Nine women had their first contact with the providers was within the period of one year, which highlights the fact that ambiguous definitions of infertility are internalized by the women, and are used as yardsticks to decide on when to seek treatment. Thus, the medical definition of infertility does not remain restricted to the medical domain of providers and researchers, but is also imbibed by the women, and influences their understanding of it as well.'[11]

The above response shows that how medical definitions are internalized by people. It can be found that the social context plays an important role in the internalization. The social stigma attached with infertility and inquiries from friends parents and relatives on conception immediately after marriage force couple to look for alternatives if they are not conceiving normally. The result is forcing of technology on couples, especially on women as pointed by the following response.

> ' ...technically say, some body marries at thirty five years and trying some couple of years, she is not getting pregnant and investigating it is not such a crime in my eye because you know your fertile period is limited but some body marries at thirty five years and trying some couple of years, she is not getting pregnant and investigating it is not such a crime in my eye because you know your fertile period is limited but if somebody is marrying at the age of twenty or twenty two even for those women now, this period of one year two year is getting applied. So woman are called name and told they are infertile and they need to do something. I think this is forcing technology on women'[12]

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11. SAMA, *ARTs and Women: Assistance in Reproduction or Subjugation*, New Delhi: SAMA, 2006, p.39.
12. Interview with a female scientist cum activist at NII.

The response shows how women's rights activists look at the ambiguous definition of infertility. It also points to the divergence in feminist positions as actors in the debate on regulating ART (the respondent is also an office bearer of a women's right organization). The respondent favours the contextual use of the technology rather than out rightly rejecting it. This statement is in resonance with the theoretical argument of Michelle Stanworth (1987) discussed in the third chapter that the multiplicity of reproductive technologies can offer indispensable resources for women depending on their circumstances and priorities.

According to WHO, 'in many developing countries, infertility is the result of genital tract infections which include sexually transmitted infections (STIs), postpartum or postabortal infections and pelvic tuberculosis or schistosomiasis. Tubal blockage is responsible for up to two third of infertile nulliparous among women in sub Saharan Africa and between one-quarter and one-third of infertile women in developed and developing countries, respectively. It is often argued that solution to the problem of infertility can only be found in prevention of infertility through prevention of STIs and unsafe abortions. Therefore the use of ART to manage infertility is a contested issue in the context of the cause of the problem,'[13]. An important lacuna in the bill is that it has not tried to explore Infertility in its different dimensions. As discussed above infertility in the bill is restricted to the simple definition. Infertility is being defined as a personal inability and hence placing the onus on individual couples.

4.3 RISK FRAMES

Risk frames in the study refer to the perception and articulation of risk in public by actors related to ART. Risk frames are used as indicators to understand the how risk frames are categorized by actors and how are they represented in the ART (regulation) bill 2008. The following section explores the risk frames of different actors including the Practitioners, Couples/ Patients and Civil Society Organizations.

13. Vayena, E., *et al.*, (eds.), 2002, op cit., p. XV.

4.4 RISK FRAMES OF PRACTITIONERS

The source of data for the analysis of practitioner's risk frames are the websites maintained by infertility clinic. Most of the clinics in the cities have well maintained websites. The boom in the medical tourism seems to be a reason for this. The websites present the views regarding the risks of different techniques in the form of Frequently Asked Questions (FAQ) either authored in the name of chief physician or without giving the name of the author. Details of different techniques are also provided in the website in a combination of simple and technical language and the specialty of the particular clinic in that technique.

The following statement was given as an answer for the question 'What are the disadvantages of Freezing Embryos' on the website of Advanced Fertility Centre. The risk frame articulated in the statement is of uncertainty, economic risk and risk to the embryo. The statement implicitly points to the uncertainty of the process in terms of the survival of the embryo depending on the type of the procedure, which it claims to be 60-70per cent and vitrification method to be 90 per cent. The frame also points to the economic risk to the couple and risk to the embryos as the process runs the risk of damaging / killing the embryo.

> 'As this is not a physiological procedure there is always a risk of damaging/killing the embryos during this procedure. The embryos may damaged partially or entirely. As long as 50% of the embryo still survives the procedure it has the capability to give rise to a good pregnancy. The ability of the embryo to survive this procedure depends upon the grade, quality and stage of embryo and also method used for freezing them. Thus it is not possible to predict before hand the ability of the embryos to survive this procedure. The embryo survival by slow method is 60-70% while with vitrification method it is around 90%.'[14]

The statement shows that risk in ART techniques are calculated on a cost benefit analysis, which admits the inherent nature of risk. The statement argues if fifty percent embryos survive there is a chance of 'good' pregnancy. What is important here is the possible outcomes of risky techniques are analyzed in qualitative terms and advocated to couples/individuals to take decision. Secondly, the answer does not cover the risks to child which results from the process.

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14. Advanced Fertility Centre, Bangalore. Available at: http:// www.afcivf.com/Servicesfaq. html# SERstepsivf, accessed on 15.05.2010.

Similarly, the following statement was give in the form of an FAQ analyzing the risk of oocyte freezing technique. The statement offers insight into the practitioner's basis of analyzing risks in ART.

> 'what are the risk involve with oocyte freezing?
>
> Ans : There have been studies on mouse as well as human oocytes, & it suggest that there is no damage of intricate structures with in the egg, or structures responsible for organizing the the chromosomes [the genetic building blocks with in the egg]. There have been healthy babies born from this technique, but the safety of oocyte freezing is still to be proven.'[15]

The statement suggests that the uncertainty of different ART techniques forms the basis to practitioner's risk frames. The uncertainty of the particular technique, though it has been tried successful among mouse, is best reflected in the statement.

The following statement was given under the heading 'Risks associated with AH'. AH is Assisted Hatching, an advanced technique in IVF. The risk frame converges both risk to the embryo and the mother.

> 'If not done with expertise the procedure can damage/kill the embryo itself. Some centers have reported a slight increase in the incidence of identical twins (monozygptic). This is so because while making a hole in the zona, the embryo may sometimes split into two giving rise to monozygotic twins. However there has been no reported increased incidence of birth defects in children born as result of this procedure. Rare side effects to the mother from the accompanying steroid and antibiotic may be there.[16]

The above statement along with suggesting risk to mother also attempts to down play risk. The term 'rare side effects' symbolizes how certain risks are negated by practitioners. This brings us to a point discussed in the third chapter on the biological reductionism discussed in the context of CJD. There are similarities in downplaying risks both in literature of reproductive science and in practice.

Contrary to the analysis of the literature, that the scientists' risk frames are based on technical uncertainty and social issues are invoked in favor of promoting ART, the statements from the websites of ART clinics articulate two social risk frames. They are the social risks like sex-selection and the psychological and social issues to children and parents when the undergo ART at very late age.

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15. Dr. Rama's Institute for Infertility,Hyderabad. Available at: http://www.fertilityindia.com/faq-on-freezing .html, accessed on 15.05.2010.
16. Advanced Fertility Centre, Bangalore, op cit.

> 'While PGD represents the cutting edge of reproductive technology, and give us an idea of what may be possible for the future it also raises a number of worries and concerns, especially in India, where people are worried that it may be used for sex-selection.'[17]

The above statement articulates the potential risk of ART techniques in sex selection. The risk frame articulated is that of social, which follows from the experience of the pre-natal diagnostic techniques which widely used in sex-selection of foetus throughout country resulting in skewed sex ratios.

> 'Though a women of fifty years might be able to give birth to a baby without complications, there are other important aspects, which have to be kept in mind. For example, if the couple is around 50 years of age, by the time the child is even 10 years, the parents would be around 60 years age and it might be physically strenuous for them to bring up the child. In talking into consideration such issues, the aspect of compassion also becomes important. The huge age difference between the parents and the child (generation gap) might also be problematic for both of them in future.'[18]

The risk frame articulated in the statement is regarding the role of age in selection of the patient. The practitioners perceive a potential social and psychological risk with increase in the age of couples/ individuals undergoing ART treatment. Another risk prominently perceived by practitioners in western societies is body mass index of women due to possibilities of failure. So there is also an economic angle to it in those societies where ART is also provided through public health system. Since ART is largely available in private sector in India, this concern is not voiced by the actors. The risk regarding the age of the women undergoing ART is reflected in the bill, by restricting the age to 45.

> 'There are a lot of problems involved in case of donor sperms. If a man donates sperms for his brother, later on he may he may come and claim that it is his child. It complicates relationships. There was one case where a woman wanted to use her sister's egg and her own husband's sperm to be implanted in her own uterus. But the sister wanted the sperm to be of her husband. So basically, it would be the sister's and the spouse's child which she would carry.'[19]

The above statement echoes the concern shared by most of the practitioners about donation by family members, relatives or friends. They perceive that the process has the potential risk of complicating relationships in the future. And this risk frame is reflected

17. Malpani Infertility Clinic,Mumbai. Available at: http://www.drmalpani.com/book/chapter26.html on 15.05.2010.
18. SAMA, 2006, op cit., p. 28.
19. Ibid, p.58.

in the bill. The bill bans egg or sperm donation among family members, relatives and friends. The statement shares the same concern theory that if the donor is from the same social network there is possibility of psychological and emotional complications.

The risk frames articulated by the practitioners are summarized in the following table (Table. 4.1).

Table 4.1: Risk Frames of ART Practitioners

	Object of risk	**Risk**	**Nature of Risk**
1	Cryopreservation	Kill/damage embryo	Economical and health risk
2	Assisted Hatching	Kill/damage embryo multiple gestation	Health , economical
3	Egg or sperm donation by family members, relatives or friends	Complications in relationship in the future	Psychological
4	Age of patient	Generation gap, physical problems to take care of the child	Social, psychological and health
5	PGD	Sex-Selection	Social

Source: compiled from various sources

The practitioners' risk frames shows that the basis of their risk frames are the uncertainty in ART techniques, the unpredictable outcome of therapies when applied to human beings. They seem to articulate risk frames based on social issues, where the practice like sex-selection is regulated by existing rules.

4.5RISK FRAMES OF CIVIL SOCIETY ORGANIZATIONS

Civil society organizations, especially women's rights groups articulate risks related to ART technology. The women's groups like SAMA conduct research studies on issues related to ART. They organize conferences which serve as platform for people and

organizations from civil society to voice their concerns on issues related to ART. The following section analyses and categorizes the risk frames of civil society organization. The data for the analysis of risk frames of civil society organizations, couples/ individuals undergoing ART treatment has been derived by the textual analysis of a study conducted by SAMA.

Economic exploitation of the social compulsion for having a child by private ART clinics and practitioners is strongly articulated by the women's rights groups. Take for instance the following statement.

> 'This arbitrariness in cost of treatment however, cannot be said to be the feature of ART industry alone, but is applicable to the unregulated private health sector in India. However, the field of assisted reproduction is unique in the sense that it capitalizes on individual vulnerability and the social pressure to have a child.'[20]

The above statement articulates the economic exploitation of vulnerability and social compulsion for having a child. The lack of standardization in the services and the cost of ART is common feature in private unregulated ART sector. The risk frame is that of economic exploitation. The statement also challenges the patriarchal notions of family that leaves couple in a vulnerable condition.

The practices in ART are problemetized by feminists when moral judgments intervene in the decision making regarding scientific issues. The following statements conveys the risk in such emerging practices

> 'The articulation of the service providers were more guided by their notions of morality in who should donate eggs rather than medical reasons.'[21]
>
> ' Thus, there is no attempt on the part of the providers, to question this social pressure. Rather it is reinforced by their perception of infertility, "as a major issue in our society", and by finding technological solutions to a social problem. By promoting these technologies, they believe that they are actually providing a "solution to those couples who are desperate to have their own children."'[22]

The above statements point to the risk perceived by women's movements that ART technology can reinforce the social and cultural notions of morality. Science, rather than questioning the social conditions which compel women to have child and infertile couple

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20. SAMA, 2006, op cit., p.55.
21. Ibid, p.58.
22. Ibid.

to seek ART reinforces the subjugation of women, which is problematic to the women's groups. The risk frame is the social reinforcement of inequalities and patriarchal values.

Similarly women's groups also apprehensive of the possibility of ART being established as the only solution to infertility leaving people without any other options. The following statement points to the potential risk of ART in discouraging people to seek other socially relevant options like adoption.

> 'Among the 15, eight providers were of the view that adoption is the last resort, considered only when all other treatment options fail. However three other providers felt that, people who were open to adoption would not come in for treatment at all and adoption cannot be imposed on couples as a viable action.'[23]

The statement suggests the possibility of practitioners suggesting adoption as an option or couples giving a serious thought on adoption, even though it is suggested in the ART bill, is becoming a remote possibility with increase in ART.

The following statements point to risks of ART due to the lack standard definitions for success rate. This ambiguity surrounding the success rate becomes a tool of exploitation by the ART clinics through their advertisements.

> 'The fundamental cause of "doctor shopping" is that in advertising about the ARTs, their success rate is over emphasized.'[24]

> 'The quoting of implantation rate as success rate indicates an attempt to mask the actual success rate i.e. live birth per IUI/ IVF cycle. The way in these various terminologies like implantation rate, chemical pregnancy rate gets synonymous with live birth rate brings out new meanings of "what it means to be pregnant'.'[25]

Success rates hold an important role in the ART. Couples who have tried one practitioner for a point of time with no results get disappointed and look for other options and easily fall prey to the misrepresentation of data and eventually leading to economic exploitation. It can be found from the discussion in the third chapter that the issue of indicators for success rate is still a debate among scientists and practitioners and what is being experienced in field is a mere reflection of that. These controversies surrounding success rate offer an opportunity to understand Callons (1999) argument.[26]

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23. Ibid, p.31.
24. Ibid, p.31.
25. Ibid, p.52.
26. The possibility of experts manipulating scientific facts to their strategic interests in their enlightenment mission in public education model is discussed in chapter two.

The following response points to a major concern of feminist groups regarding the risk of ART. The risk perceived is that the social conditions of women would lead to the medical exploitation of women's bodies.

> 'The responses of the providers can be taken as a pointer to show us how there is a high probability of women from lower class becoming the suppliers of reproductive material.'[27]

The above response shares the concerns articulated by feminist theorists that the pertaining socio-economic condition will be aggravated through ART and the possibility of economically vulnerable women falling prey to the organized business of ART.

A similar concern was shared by a women's right activist in the interview.

> 'Because of the pressure on women, the pressure to take on technology is somehow on her and her family, you know. ...why is that options like adoption are not being promoted. I think somewhere the whole idea of market and the role it plays is real'[28]

The response from her suggests that it is not only the economically vulnerable but well off women will also be exploited. The easy availability of ART will have pressure on the women and her family to take up the technology. Not only surrogacy and ovum donation will lead to exploitation on women but unregulated expansion of ART will lead to the forcing of technology on women to have a child. The statement echoes the same concern articulated by cultural feminists that the possibility of exploitation of women's bodies and their reproductive capacities, as discussed in second chapter.

Women's rights groups' criticism of ART also include the Eugenic possibilities of the technology. Take for instance the following response, which points to the eugenic risk of ART.

> 'It is worth noting that eight out of nine providers said that the recipient couples look for sperms/eggs from fair skinned donors. Some of the other characteristics that were specified by them were, 'intelligence, good looks, healthy, educated, same religion and same caste.' '[29]

The provider's response shows that there is preference for those traits which are considered by the society as superior. Such preferences are often racial and eugenicist. Same concern is shared by another respondent:

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27 Ibid, p.58.
28 Interview with a women's right activist.
29. . SAMA, 2006, op cit., p. 59.

'you have come across a kind of marketing, you know the kind of promotion...showing those sort of designer babies, you know, all those information through the website...all those promotional blue-eyed babies, blond hair...it is kind of drawing people to those ideas or notions of accepting beauty'[30].

The response shows that the practitioners also promote notions of beauty like offering babies of desired traits, which the respondent calls "designer babies". The eugenic risks perceived by the women's rights activist, market and state promoting the preferable traits, seem to draw parallel with the attempts to promote citizens with quality by eugenicists during the introduction of artificial insemination as suggested Naomi Pfeffer (1987).

An important issue raised by women's rights group is related to the health of those women who undergo ART treatment. The health risks of retrieving large number of eggs, multiple pregnancies and the ethical risks posed by the left over embryos and stem cell research is articulated in the following response.

' There are many issues raised by large numbers of egg retrieval and implantation. Retrieving large number of eggs, requires hyper stimulating the ovaries through intake of hormonal drugs, which often entails serious medical complication for women. Moreover, the procedure in itself is highly invasive, and may result in serious damage/harm to the women undergoing it. Often more than two embryos are implanted to improve chances of pregnancies. In this case, the women had to undergo foetal reduction which again poses many health risks. Another pertinent question raised is what happens to the spare embryos? Are they sold or donated for research or simply discarded? This process of large number of eggs also poses many ethical questions in the context where the spare embryos were supplied by IVF clinics for stem cell research.'[31]

The above response articulates the medicalisation of women's bodies and conception and its health risks to women in retrieval of ovum by administering hormonal drugs, implantation of multiple embryos and foetal reduction. It suggests how women are subjected to such life threatening practices. By raising the issue of left over eggs and embryos the response points to ethical risk of appropriating women's reproductive materials. The articulation combines both the health and ethical risks. The health risks and the ethical issues in handling ovum perceived in the field are in line with the observation of Janet Gallagher (1987) which is discussed in the third chapter.

The prevalence of reducing risk only to simple side effects can be found among the

30. Interview with a women's rights activist, op cit.
31. SAMA, 2006, op cit., pp. 47-48.

doctors and scientists which is imposed on the patients. The following responses point to such practice of biological reductionism of risk.

> ' Nineteen of the 23 providers spoke about the side effects and complications of the drugs and procedures. In general, they said that there were no health risks. Some did name some risks, when they were probed, but tried to minimize them by presenting it in the form of a risk benefit analysis.'[32]

Table 4.2: Risk frames of civil society organizations

	Object of Risk	**Nature of Risk**	**Risk**
1	Private unregulated ART sector	Economic exploitation	Social compulsion for having a child
2	ART	Social risk	Reinforcing patriarchal values
3	ART	Social risk	Discouraging adoption
4	Extrapolated success rate	Economic risk	Lack of monitoring of success rate
5	Increased demand for ovum and surrogates	Exploitation of women's bodies	Social and economic condition of women
6	Retrieval of large number of ovum and multiple pregnancies	Health risk and ethical risk	Social compulsion for having a child

Source: compiled from various sources

4.6 RISK FRAMES OF PATIENTS

The patients include couples/individuals who had undergone assisted reproductive treatment. The data for analysis is mainly derived from the study conducted by SAMA. A major risk perceived by the patients is the cost of treatment. A limitation with the analysis of cost is that there is no credible data on the cost of treatment in India and it varies from clinic to clinic.

32. Ibid, p.48.

The most important risk articulated by patients is the economic liability incurred during the treatment. Take for example the following response

> 'There is a lot of costs involved if you include the cost of laproscopy, the diagnostic tests, the medicines, the travel cost you incur, the loss you suffer if you are running a business. '[33]

The above response points to the huge amount of money required for infertility treatment. The information given on the websites of infertility treatment clinics include only the cost of particular treatments like IVF or ICSI. The actual cost of treatment can be understood only by including the money spent on different diagnostic tests and medicines and other expense on travelling, lodging etc. The literature takes in to account only the cost of drugs, procedures and practitioner's fee but there are also hidden cost, which include travelling and lodging cost as patients go to reputed clinics in cities and the cost in terms of lost working days. Take for instance the following response of a patient

> ' A lot of money is required for the treatment. I have spent lakhs over the past sixteen even without going for techniques like IVF or ICSI.'[34]

The following response points to stress and strain when women go through the tiring process repeatedly one after another cycle desperately to have a child. The psychological risks involved with medical technologies are often not accounted for.

> 'What has been difficult in this entire process is that it has been mentally exhausting. I am generally a person with a fighting spirit but I have gone through moments of utter desperation and depression and I feel that the world has come to a halt. Once the IVF cycle fails, you feel utterly dejected and don't really know how to explain the whole thing to yourself and others. You feel frustrated. It is not easy going through this process.'[35]

The response suggests that the continuous process of ART treatment has severe psychological impact on couple, especially women. The problems that women face after every failed cycle in explaining themselves and other are reported to be highly frustrating.

The information asymmetry is very much evident in the following words. Patients are not given proper information about the treatments, the risks involved in the treatment or the

33. SAMA, 2006, op cit., p. 56.
34. Interview with a male respondent who had undergone ART treatment, op cit.
35. SAMA, 2006, op cit., p. 62.

options they have other than ART. Mostly the uneducated and the rural women do not have any idea of the treatment process that they undergo. Either the process are only explained to their male counter parts or technical jargons are used in such a way that finally the patient does not bother to ask in detail about the treatments.

> ' They leave half the things unsaid or they say it in a way that seems very simple. Only the one who is going through it understands the pain of it. When they were doing the laproscopy, that it would entail a minor cut. But when they actually did it, it was so painful. I could not get from the bed for the next two to three days.'[36]

Some of the responses like the one given below show that practitioners maintain a hierarchal relationship by providing very little information even if that poses trouble to the patients.

> ' The last time I was here, they said I had to go for an oral glucose tolerance test(OGTT), i.e., some kind of a insulin/sugar test. If the report is positive I have to take Metformin. When I called up to check the result of the test, the doctor got angry and asked me to come and her and not to inquire over phone. She also said to start the medicine. If they can start the medicine without the report, then what was the need to ask me to go in for the test? It's just a waste of 2000.'[37]

The responses from two other women go like this[38]

> ' No information was given. She (doctor) is so busy that there is hardly any time for her to talk to us or explain or listen to our problem.'
>
> No information was provided. The doctor said she would tell us what to do as and when required.'

The limited information provided to people and the hierarchal relationship between the practitioner and patient point to the dynamics of the practitioner-patient relationship. The practitioners seem to capitalize on the social compulsion of women to have child. This also indicates lack of transparency in the functioning of the clinic. The risk frames of the patients are summarized in the following table (Table 4.3).

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36. Ibid, p. 63.
37. Ibid, p.62.
38. Ibid, p.46.

Table 4.3: Risk Frames of Patients

	Risk	Nature of Risk	Object of Risk
1	Hidden costs (travelling, diagnostic costs, lost working days)	Economic risk	Unregulated ART sector
2	Repeated cycles	Psychological risk, economic risk	Unregulated procedures
3	Information asymmetry	Heath risk, economic risk	Lack of monitoring systems

Source: Compiled from various sources

4.7 RISK FRAMES IN THE ART (regulation) BILL 2008

The perceived risk of ART by the state that is being reflected in the policy is the potential of assisted reproductive technologies to fragment the social and legal construction of family. The concept of confidentiality is emphasized throughout the bill as to mitigate this risk. At the same time cautious attempt is made to overcome the negative outcomes of confidentiality or the break in information flow. The tool employed to overcome the negative outcomes of confidentiality is selective dissemination of information from practitioners to patients. At one end the state attempts to resist the fragmentation of social and legal construction of family and at the other the attempt is to promote a desired citizenry of matching with the dominant social constructions including education, health, ethnicity, skin colour etc. Take for instance the following clause

> ' It shall be the responsibility of an assisted reproductive technology clinic to obtain, from semen bank(s), all relevant information other than the name, personal identity and address, of possible gamete donor, and assist the couple or individual desirous of the donation, to choose the donor.'[39]

This clause mandates semen banks and the clinic to keep the identity of the donor confidential. It only requires keeping the personal details like name and address confidential. The bill has given much importance to semen and ovum banks while at

39. Assisted Reproductive Technologies (regulation) Bill, 2008, op cit, p.15.

present the banks are not separate from the clinics. It seems the undue importance given to the banks is very important for confidentiality. The role of semen and ovum banks becomes clearer in the following clause.

> ' When a semen bank receives a request from an assisted reproductive clinic for a donor oocyte, a responsible member of the staff of the semen bank will accompany the particular donor to the Assisted Reproductive Technology clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made aware of the fact that any step leading to disclosure of the identity (i.e. name and address) to the recipient couple or individual or to anyone else, shall amount to an offense punishable under this act.'[40]

The above clause shows that how attempt is made to incorporate confidentiality in to the functioning of the semen and ovum bank. The clause places the onus of adhering to confidentiality on both the bank and the clinic. The penalties laid down in the clause also suggest the importance given to confidentiality. Why is such confidentiality demanded? The state seems to perceive the risk of fragmentation of the legal and social construction of family from the increased use of assisted reproductive technology. The risk frame is a legal and social risk of ART whereas the following clause is employed to overcome the constrains of confidentiality by permitting selective disclosure of information through which the couple can select the desired qualities.

> ' Either of the parties seeking assisted reproductive technology treatment or procedures shall be entitled to specific information in respect to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not known.'[41]

The above clause eliminates the negative impact of the clause mandating confidentiality. This clause also serves the purpose promoting a desired citizenry- an educated, healthy citizenry with desired traits. The desired citizenry is more clear in the following clause

> ' Assisted reproductive technology clinics shall obtain donor gametes from semen banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any of them, surrogate or child.'[42]

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40. Ibid.
41. Ibid.
42. Ibid.

The above clause in the bill points to risk frames that are mainly concerned with the health of the actors who participate in assisted reproduction. One clause mandates clinics to ensure that the reproductive materials do not pose any health threat to the actors. The clause also signals long term and short term health risks to actors, especially those receiving the reproductive materials and the child, being framed by the state. The long term risk frame of health may be the result of considering the possible burden on the health system in the future.

The bill clearly emphasizes the need for information dissemination by ART clinics. Take for instance the following clause.

> 'Assisted reproductive technology clinics shall provide professional counseling to patients or individuals about all the implications and chances of assisted reproductive technology procedures in the clinic and in India and internationally, and shall also inform patients and individuals of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple or individual arrive at a decision that would be mostly likely to be the best for the couple or individual.'[43]

> 'Assisted reproductive technology clinics shall explain to couples or individuals, as the case may be, the choice or choices of treatment available to them and the reason or reasons of the clinic for recommending a particular treatment, and shall clearly explain the advantages, disadvantages, limitations and the cost of any recommended or explained treatment or procedure.'[44]

The above clause though points to the risk in information asymmetry and emphasizes the need to overcome it; it implicitly places the onus of taking decisions and the responsibility of the implications resulting from that on the patients. This also shares the practitioner's attitude towards risk and its responsibility. Take for instance the following response.

> 'But after one month (of delivery) whatever goes wrong is not the responsibility of the clinic. We are only helping women of Haryana and the world.'[45]

The above response by the practitioner who has 'helped' Bhateri Devi, claimed to be the oldest woman conceived through IVF, shares the practitioners' approach to sharing responsibility, which is well resonated in the above clause of the bill. The experience

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43.Ibid, pp. 15-16.
44. Ibid, p.16.
45. "Bhateri's child dies, other 2 still at child care centre", *The Indian Express*, July 2, 2010, p. 9.

from the field substantiates a key inference, that the practitioners place the responsibility of outcomes on the patients made from the analysis of literature in the third chapter. Similarly the following clause in the bill on the donation of sperm or oocyte share the practitioners' views

> 'No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the patients seeking assisted reproductive technology treatment or procedure.'[46]

The following clause points to ethical risk frames in cryopreservation of reproductive materials and possibilities of manipulating reproductive materials for embryonic research.

> 'No assisted reproductive technology clinic shall use any human reproductive material to create an embryo or use an in vitro embryo for any purpose without the specific consent in writing of all the parties to whom the assisted reproductive technology relates.'[47]

> ' The sale of any gametes and embryos for or their transfer to any country outside India, is absolutely prohibited and shall continue a criminal offence under this act.'[48]

The following clauses point a potential risk of ART technologies that can be used for sex-selection.

> ' Pre-implantation Genetic diagnosis shall be used only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority.'[49]

> ' No assisted reproductive clinic shall offer to provide a couple with a child of a pre-determined sex.'[50]

4.8 DISCUSSION

The clauses on the number of oocytes that can be retrieved (i.e. 14 oocytes), the number of times a woman can donate oocytes and the interval between each donation are the provisions which have serious implication for health of women and potential for exploitation of women. The possibility of many cycles that can be performed during the retrieval and the knowledge of the number of oocytes retrieved beyond the capacity of the donor make women more vulnerable to exploitation. Similarly, the number of

46. The Assisted Reproductive Technologies (regulation) Bill, 2008, op cit., p. 16.
47. Ibid, p.17.
48. Ibid, p.23.
49. Ibid, p.19.
50. Ibid.

attempts/surrogacies is restricted to three in the bill, without taking in to consideration the number of children the surrogate has or without specifying the spacing between each pregnancy. Restriction of ART services to non heterosexual couples in the bill is very clear reinforcing the hetero-normative notions of gender and family. Similarly the age of individual/ couple is considered as criterion for selection of the patient whereas BMI has been left out. Due to the possibility of failure, ART among women with high BMI poses health and economic risk. The prevalence of health and economic risks demands criteria for selecting patients. With criteria for selection in place, clinics will be responsible to provide services to eligible couple, which would also prevent exploitation of couples/ individuals who are not likely to conceive.

ARTICULATION OF RISK IN THE BILL

The concept of risk in the bill resonate the practitioners' perception of risk. There is not only an attempt to play down the social and ethical risks of the bill but also to place the onus of health risk on the couples/individuals who opt for ART. The following clause clearly reflects the position of the bill in negating the risks as 'small risk' nevertheless conferring the responsibility of the risk on the patients too. It not only confers the responsibility of risks on the patients but also frees practitioners from the responsibility of the treatments they provide.

> 'ART procedures carry a small risk both to the mother and the offspring. These risks must be explained to the couple and appropriate counselling done. ART procedures are to be initiated only after patients understand these risks and still want to undergo ART.'[51]

The conception of risk in the bill can be traced the common risk perception among scientific experts and practitioners, i.e. risk is inherent in every human activity which can

51. Ibid, p.67.

be contained. This perception of risk had over years translated in to a public perception of risk, which is evident in the statement of the representative of a civil society organization. The following risk perception by practitioner shows the risk perception among practitioners and scientists are understood in a framework of risk-benefit analysis.

> 'what are the risks and complications of IVF?
>
> Risks and complications of IVF and GIFT
>
> Many couples are worried that babies born after IVF are abnormal or weak. You need to remember that in one sense there is nothing "artificial" about these babies – they aren't synthetic babies which are being manufactured in the laboratory! Remember that IVF is a form of assisted reproductive technology, where technology is being used to assist Nature to accomplish what it has failed to do for the infertile couple! Over a hundred thousand babies have now been born after IVF treatment, and the risk for birth defects is not increased after IVF treatment.'[52]

Even in case of highly complicated risks like multiple pregnancy, there is an attempt to place the onus of the risk on the patient while her consent is not at all taken in the implantation stage. For instance the ART bill states

> 'Where a multiple pregnancy occurs as a result of assisted reproductive technology, the concerned assisted reproductive clinic shall inform the patient immediately of the multiple pregnancy and its implications and shall, if so instructed by the patient carry out foetal reduction.'[53]

The concepts like informed consent is used to place the responsibility on the patient for any undesired outcome while the patient is not informed about the number of ovum retrieved or the number of embryos implanted. The ground reality is reflected in the following response

> ' The providers attempt to place the burden of risks and complications of the procedures on the women, who "willingly" undergo the procedure to have a child. In a attempt to "justify" or "defend" potentially risky techniques, these side effects are portrayed as minor, negligible in comparison to the necessity and "desirability" of having a child.'[54]

The response shows that practitioner's concept of risk is based on a cost-benefit analysis. Risks are reduced as minor and negligible in comparison to their hypothetical benefit. It

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52. Malpani Infertility Clinic,Mumbai. Available at: http://www.drmalpani.com/book/chapter25h.html, accessed on 15.05.2010.
53. Assisted Reproductive Technologies (regulation) Bill, 2008,op cit., p. 18.
54. SAMA, 2006, op cit., p. 49.

is interesting to see how this techno-expert conception of risk has been translated as the popular understanding of risk. The following response shares a similar concept of risk.

> 'Any new technology which comes into the world always carries some sort of risk. But since it is not new. It is not a new technology. It is world wide, well tested....in India, we have fantastic, very beautiful, very good ART clinics in this country. They are providing IVF services of international standards, international quality. No doubt about it. They are following international standards, ICMR standards, whatever we have drafted. So there are so far risk is concerned, risk in terms of failure is there and that is because of we are not maintaing the quality of services. Then the chances of failure are there which leads to the monetary losses of the infertile couple basically and also the emotional loss because infertile couple coming to the IVF clinic is wasting the...investing the money with the hope that he will get a child. But if the quality of service is not good, if it is not going to get a child, then after all, what is he going to do. But so far if the couple is in good hands and they are providing, they are using the standard methodology, the standard techniques, I think there should not be any problems.'[55]

The response from the key policymaker who supervised the drafting of the bill suggests that official perception risk relates to those which are normally present in technology which can be mitigated. The reductionist view of risk is very much evident when they view risk only in terms of the failure of the technology and necessarily because of not maintaining the standards, which is followed by economic and emotional risks.

> 'of course, you have to...when you donate your ova that woman's body has to be induced to release a large number of ova at the same time. It is normal treatment. But that is a risk. It is normally in my view it is not a huge risk.'[56]

> 'All risks, all notions of risks at this level are related. This is not a risk of such high frequency that in my view is that we need to be banning it automatically.'[57]

The above response shows how scientists down play risks. They tend to suggest that the procedures are normal and normal procedures have risk. Especially the term 'huge risk' suggests that risks are considered in a cost-benefit frame, which categorizes risk in to 'huge' and 'small' and legitimizes certain risks in practice.

> 'whenever you are using the technology there are always risks associated.'[58]

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55. Interview with a key person who supervised the drafting of the bill.
56. Interview with a male scientist at the Indian Institute of Immunology.
57. Ibid.
58. Interview with a male representative of a civil society organization.

The response shows that how practitioners' and scientists' risk frames are converged in to the public discourse. Risks of technologies are often accepted in such a way without realizing the different dimensions of it.

The conception of risk in the bill is a reflection of the scientist-practitioner risk frame. The frame work that the bill offers to understand risk is a linear, quantitative and uni-dimensional one, where risk is inherent in every step of life and hence needs to be quantified, placed in blocks like 'huge' and 'small' and actions should be guided by the analysis of risk in the cost-benefit frame work. What is also equally important is the social and cultural conditions that force couples/individual to take the risk which is neither identified nor addressed in the bill.

Similarly undefined terms in the bill provide a key to understand how certain risk frames are left out, which provide space to practitioners for manipulation. Success rate is one such area the bill fails to address the risk frame of patients. Success rates are often extrapolated to woo patient to the clinic. The lack of proper definition for clinical abortion, clinical pregnancy, clinical pregnancy rate and clinical pregnancy with fatal heart beat permits practitioners to manipulate data and project their clinics as highly successful. Similarly birth defect is not defined in the bill which comes under the health risk. Cancelled cycle is not defined in the bill and is not a criterion for limiting repeated attempts, which entails economic risk and health risk to women. Congenital anomalies, cumulative delivery rate, delivery rate after ART treatment per patient, procedures like GIFT, MESA, MESE, TESA, TESE etc., omplantation rate, live birth delivery rate, multiple gestation/birth, OHSS, and severe OHSS are not defined in the bill which have significant role in understanding the health risks of ART.

The bill and the thrust for standardization need to be looked at in the context of booming service sector in India, especially the health care industry. While standardization from a consumer point of view is a means of promoting the sector, the bill needs to be understood from this context. The provisions in the bill seem to be at the best interest of promoting ART sector. The promotion of third party donation is one way through which the commercialization of ART is promoted through the bill.

> ' A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.[59]'

The above statement clearly shows how third party donation and surrogacy are promoted through the bill. The clause is widely criticised by women's rights groups as an attempt promoting commercialisation.

PUBLIC ENGAGEMENT MODEL:

Drawing from the Callon's (1999) public engagement model discussed in the second chapter this section makes infrence on the public engagement model underlining the bill. Indicators like purpose of engagement between expert and lay public, the role of public, nature of relationship between expert and public, role of expert, view of risk, and exclusion of public in decision making derived from Callon's Model is used for making the inferences. Regulatory policies set the norm of engagement between the expert knowledge and public. Take for instance the following clause

> 'ART procedures carry a small risk both to the mother and the offspring. These risks must be explained to the couple and appropriate counselling done. ART procedures are to be initiated only after patients understand these risks and still want to undergo ART.'[60]

The clause admits that the ART procedure carries risk and it mandates the expert to explain the risks to the couple. The norm promotes an enlightenment mission. It mandates the expert to provide scientific literacy to the public about the benefits and cost of the technology. The emphasis on counselling throughout the bill also points towards a similar approach in engaging the lay public. This also clarifies the role of expert. The expert is considered to be knowledge provider for the lay public. Similarly the role of public is envisioned as an individual or a consumer. For example the following statement clearly states the role of the public

> 'everything is mentioned in this bill because we have designed it such a way that the exploitation of common man should be stopped. Another very important issue the quality of services has to be very good and the exploitation of the common man should be stopped and it should be ethically practised. Unethical practices should be stopped'[61]

The above statement from a policy maker in ICMR points to two aspects on the purpose of the bill. The purpose of the bill defines the role of public, who is referred to as

59. Assisted Reproductive Technologies (regulation) Bill, 2008, op cit., p. 20.
60. Ibid, p. 67.
61. Interview with a key policy maker in ICMR, op cit.,

'common man' in the statement. The purpose of the bill is to protect public from exploitation and improve the quality of service. Both these aims can be attributed to the purpose of regulating market. The role of common man in market is nothing other than that of a consumer. The statement suggests that the role of the public is that of a consumer, who needs to be protected from exploitation from the ART market. Similarly analysis of data on the risk frames of the patients and civil society organizations in this chapter suggests that the nature of relationship between the expert and the couple/individual is hierarchical and the bill has a reductionist view of risk. The inference that can be made from the above analysis is that a public engagement model in issues related to Assisted Reproductive Technology is characterized by an enlightenment model.

PUBLIC ENGAGEMENT IN POLICY MAKING IN SCIENCE AND TECHNOLOGY ISSUES

Drawing on Mikko Rask's (2003) models of public engagement in policy making related to science and technology issues this section analyzes the public engagement model in policy making in ART. Indicators include objective of the bill, role of public, nature of communication and role of practitioners.

> ' this bill was drafted based on the thing that we will try and impose the quality of provided by the ART clinics in the country. Therefore, we believe that once this bill is implemented, the quality of service given to the infertile couple will improve and the success rate will also be increased. Today, we don't know the success rate. So we presume that if the quality of the service provided by the ART clinics in the country improve, success rate will automatically increase.'[62]

The above statement suggests the objective of the bill. The objective of the bill is to improve the quality of ART services provided in the country. It also aims to improve the success rates. These objectives have an implicit nature of market regulation. Considering the fact that majority of the clinics providing ART in the country are in the private sector the aim is towards standardizing services and promoting the market. This satisfies the first criteria of economic paradigm in policy making. Similarly analysis in the last section of the chapter suggests that the role of public is envisaged in the bill as receivers of correct information and standardised services. And the role of practitioner is that of provider of correct information. Similarly the nature of communication that should take

62. Ibid.

place between the expert and the lay public on the issues of ART as envisaged by the bill is one, the expert providing information on the developments and possibilities in ART in India and abroad and about the risks of the technology. All the three indicators suggest an overlapping of economic and enlightenment paradigm in public engagement in policy making in issues related to science and technology.

INSIGHTS ON ACTORS, INSTITUTIONS AND PUBLIC ENGAGEMENTS

Drawing on the analysis of Hindmarsh (2008), on the actors in biotechnology regulations in Australia, this section offers some insights on the actors and institutions. Actors slightly different from those identified by Hindmarsh [63], those support biotechnology and those oppose biotechnology, can be identified in the assisted Reproductive technology regulatory zone. Unlike Hindmarsh's category no actor is in complete opposition to the technology. In the Indian context the visible actors fall largely in to two categories, the first category includes practitioners and policy makers who have an optimistic approach and second category include women's rights activists who have a cautious approach in promoting ART. The policy suggestions evolving from the ideological predilections of the actors share resemblance with those suggested by Strand [64]. The practitioners and policy makers, who are optimistic of ART, emphasize on the potential benefits of ART over the negative effects and call for minimizing regulations. The women's rights groups, who have a cautious view of ART, argue that minimal regulations will lead to the exploitation of women's bodies and reproductive capacities. Another inference that can be made for the analysis is the absence of a space for all sections of the society to present their views and concerns, what Arthur (1999) calls the 'Public sphere'. According to him the 'Public sphere', which plays an intermediary role by democratic control and agenda setting between citizenry and politicians in different realms of the system can be found absent in the relationship between public, scientific expertise and policy makers[65].

The bill clearly incorporates the practitioners' risk frames like the risks of cryopreservation, age of the patients, use of PGD in sex-selection and risks in donation

63. Originally cited in Hindmarash, R, *Edging towards bioutopia: a new politics of reordering life &the democratic challenge*, Crawley, Western Australia: University of Western Australia Press, 2008.
64. Strand, Roger, 2001, op cit., pp. 189-199
65. Edwards, Arthur, 1999, op cit., p.163.

by family members, relatives or friends. Provisions are laid out in the bill from the practitioners' risk frame work clearly transferring the onus of risk in cryopreservation, implantation of embryos and the health of the child over patients, restricting the age of patients to 45, legalizing only third party donation. While risk frames of civil society organizations and women's rights groups risk framework which include risk of lack of standardization, reinforcement of patriarchal values, exploitation of women bodies and discouraging options like adoption and patients risk frame work like standardization of procedure, economic exploitation have been neglected or aggravated in the bill.

Annika *et al.*, (2007) argue that public participation in the converging sphere of politics and science has different connotations depending on the values and meanings that the concept of democracy assumes, such as the actors who are legitimized participants, the relative power they have in society and the institutional ways of legitimizing political decisions [66].This seems to be a valid argument in the overall analysis of the bill. The enlightenment model of public engagement reflected in the bill, an overlapping of enlightenment and economic paradigm visible in the public engagement in policy making. Due representation of practitioners' risk frames, exclusion of risk frames perceived by patients and civil society organisations point to the adherence of culture of representative democracy where science and state building go hand in hand and the hierarchical roles experts especially medical professionals are held in the society.

66. Nielsen, A. P., Lassen, J. and Sandoe, P., 2007, op cit., pp. 13–35.

Chapter V

CONCLUDING OBSERVATIONS

The present study has attempted to analyze the public engagement in the regulation of biomedical technologies by analysing the representation of risk frames in the regulatory policies in the area of assisted reproductive technologies in India. The research problem in the study was whether the uncertainty of technologies and the social, cultural and contextual articulation of risk and the lack of consensus among experts over controversial scientific issues has facilitated public engagement in regulating assisted reproductive technologies in the Indian context. This was studied by analysing the representation of risk frames of different actors in Assisted Reproductive Technologies (regulations) Bill 2008. The study was set out from three theoretical propositions.

1. Uncertainty on the technological outcomes and the social, cultural and contextual interpretation of risk has lead to the emergence of a space for interrogation of science and technology and public engagement in decision making in issues related to regulation of science and technological risks.
2. The lack of consensus among experts on controversial scientific issues places a legitimate claim for public engagement in issues related to science and technology.
3. Public engagement informs regulatory policies with social implications of technologies, which are otherwise ignored or sidelined by the experts thereby enriching the regulation of technological risks.

The study has examined these arguments in the area of assisted reproductive technologies in detail by analysing the debates on ART in the field of reproductive science and social science. The third chapter analysed the social and scientific issues raised by ART. The fourth chapter studied the risk articulation by actors like practitioners, patients and civil society organisations and their reflection in the bill was analysed to draw inferences on public engagement based on Callons (1999) models of public engagement in science and technology issues and public engagement paradigms in policy making based on Mikko Rasks (2003) theoretical models of

public engagement paradigms in policy making related to science and technology issues. The findings are as follows.

The analysis of the literature on ART in reproductive medicine and social science suggests that the articulation of risk by the actors in the scientific and social realm is based on the uncertainty in the therapies, techniques and drugs. While social actors relate the uncertainty of ART to both technological risk and social risk , the scientific actors relate the uncertainty of techniques, therapies and drugs only to the health risks and economic risks. The articulation of risk by social actors has resemblance both in theory and in the field. Scientists' and practitioners' risk articulations are limited to the literature available in the scientific journals. This risk perception based on the uncertainty among the practitioners is not reflected in their public articulation and its translation in to the policy.

Practitioners invoke social issues in articulation of risks in particular context to counter efforts to regulate ART. Policies excluding certain groups from assisted reproductive treatment are problematized in human rights framework. The strategies in countering criticisms and attempts to regulate ART range from using scientific facts to project new technological innovation as 'user friendly' and 'promoting the welfare of women'. Stringent regulatory measures are defended by invoking patients' rights and human rights against exclusion of women from ART treatment in public health programme. The strategies to promote assisted reproductive technologies include projecting ART as technical quick fix to the declining fertility problem to promoting advocacy groups patronized by professional organisations for lobbying politicians. Strategies include presenting scientific facts and economic modelling aimed at blurring the difference between the ART child and normally conceived child. Legislations like restricting ART for obese women, which have come up based on scientific studies, are opposed by presenting contradictory studies by practitioners suggesting the mutability of expert knowledge in scientific discourse.

Practitioners counter feminist argument that ovum donation is exploitative by using scientific studies suggesting that most of the donors are educated and are primarily motivated by altruistic considerations. It suggests that donations of these kinds do not have a scope for exploitation. On the other hand, practitioners try to differentiate ovum donation and sperm donation from organ donation.

The debates over using recombinant drugs and urine derived drugs, shared ovum programmes versus third party donation and number of embryos to be implanted provide insights in to the major theme of debate among the ART practitioners and scientists. It can be inferred that the scientists are divided over the issue of success rate in ART treatment. While a group of practitioners promote strategies and techniques to increase success rate the opponent group emphasize the need for minimizing success rate and improving the quality of treatment. The debate owes significance considering the social, health and economic implications for couples/individuals undergoing the treatment.

The definition of assisted reproductive technology and infertility offers insights in to conception of technology and the problem it aims to address. It points to the interests in formulating the policy. The bill seems to focus on high end technology, like in IVF, while leaving grey areas in engaging with the low end technologies like in-vivo techniques, which may be used to treat majority of the infertile couple. The exclusion of in vivo technologies from the ambit of regulation may further the economic exploitation of individuals/ couples as there is no data available on the ART treatment in India.

Infertility is defined as the inability to conceive after one year of unprotected coitus. The definition calls for a simple technological solution. While the cause of infertility is physical, social and occupational any intervention needs to take in to different aspects like age, occupation etc. The definition has reduced it to physical problem without addressing the interrelated causes. The narrowed definition of infertility, which requires the intervention of specialised knowledge and techniques like IVF,ICSI etc., without considering the multiple dimensions of the problem, the definition has limited the scope of public engagements. A multi dimensional approach to the problem would have promoted debates like the extent to which the technologies need to be regulated, the role of state and the type of intervention required or the extent to which various sections of the society can be involved in regulating the specialized knowledge and techniques. And the focus of regulatory policy would have shifted to issues like enhancing the accountability of the specialist, promoting the interests of the individual/ couple subjected to any form of treatment, recognizing the implications of the technology for various sections of the society and the scope of their participation for regulatory governance. Definition of the problem

plays a decisive role in the interpretation of the above mentioned factors both in theory and practice.

The practitioners risk frames are characterised by quantifiable risks, for e.g. 'embryo survival is 60-70 per cent while with vitrification method it is around 90per cent'. The techniques are analysed in a cost-benefit framework and advocated to patients to take the decision by themselves. The possible outcomes of such risky techniques are presented in qualitative terms, for e. g. 'As long as 50per cent of the embryo still survives the procedure it has the capability to give rise to good pregnancy'.

The patients' risk frame suggests that the patients do not perceive the technologies as inherently risky. Rather they perceive risk in their day to day negotiations with the expert, their economic condition, their roles in their personal and public life in want of a child and above all the technical failure which threatens their very purpose of undergoing all the hardships.

To women's rights group, risk is the potential of assisted reproductive technologies to reinforce patriarchal norms, notions of motherhood, social compulsion to have child, sustaining the notions of family and furthering the exploitation of women's bodies and their reproductive capacities.

The risk framework perceived in the bill is that of a legal and ethical one, which is apprehensive of the fragmentation of the legal and social construction of family. The bill tries to ensure the mitigation of this risk by providing prominent role to sperm and ovum banks in mediating the transactions with the clinic and maintaining the confidentiality of the donor.

The conception of risk in the bill is a reflection of the scientist-practitioner risk frame. The framework that the bill offers to understand risk is a linear, quantitative and uni-dimensional one. Where risk is inherent in every step of life and hence needs to be quantified, placed in blocks like 'huge' and 'small' and actions should be guided by the analysis of risk in the cost-benefit frame work.

Thus it is clear from the study that the uncertainty of technology and the social, cultural and contextual articulation of assisted reproductive technology among the actors in the field have not facilitated public engagement in regulation of the technologies. The model of public engagement in issues related assisted reproductive

technology is the public education model suggested by Callon (1999). The study also suggests that the public engagement paradigm in policy making related to assisted reproductive technology is an overlapping of enlightenment paradigm and economic paradigm as suggested by Mikko Rask (2003).

The findings of the study have limitations for a generalization as they have not captured the risk frames of various sections of the society. And hence there is a scope of a wide empirical study to draw more insights from different sections of the society in to the problem of risk framing and public engagement. Similarly the study also points to the need for analysing the process in the formulation of ART bill 2008 to understand the role of actors in regulatory governance of ART.

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Appendix-I:

Interview guide for scientists

I. Respondent Profile:

1. Name:
2. Sex:
3. Educational Qualification:
4. Religion:
5. Name of the organization:
6. what are the major developments in ART treatment in India?
7. What are the progressing areas of research in reproductive biology?
8. What is the nature of ART related research? (role of public and private sector)

III. Risk Perception:

1. Is there any laws regulating ART in India.
2. What are the risks to those undergoing ART ?
3. What are the Risks to those who donate eggs and sperms?
4. What are the risks to embryo and the newly born?
5. What are the risks of Biomedical research(stem cell research)?
6. What are the risk associated with Surrogacy?
7. How far is taking consent of patients viable in Indian?
8. What are the risks associated with donation of surplus zygote for research or preservation?

9. Do you think that these risks can be regulated? How?

III. Regulation:

1. what are the debates about ART technologies going on in India?
2. What do you think about the implications of ART(regulations) bill 2008 0n ART treatment?
3. How far, do you think the bill will be able to regulate the risks on those undergoing ART treatment?
4. How far do you think the bill will be able to regulate the risks on donors and Surrogates?
5. How far do you think the bill will be able to regulate the risks on zygote and the newly born?
6. What do you think are the implications of ART(regulations) 2008 on biomedical research, Zygote donation or Preservation?
7. What are the aspects of ART ,that you think, needs to be regulated?

IV. Participation:

1. Is there a need for public to engage in the regulation of technologies like ART?
2. Is there any avenue for public participation in making regulatory policies related to technologies?
3. Who were the major players in mooting ART regulations bill 2008?
4. Did you or anybody representing your group participate in the framing of the bill?
5. Was the process of the framing of the bill adequately representative?
6. What should be the extend of participation required in framing the bill?

Appendix- II

Interview Guide for Civil Society Organizations

1. What are the debates on Assisted Reproductive Technology (ART) in India?
2. What are risks of ART?
3. Do you think that these risks can be regulated?
4. Is there any laws regulating ART?
5. What will be the impact of ART (regulation) bill 2008 on ART treatment?
6. How far does the bill deals with the risks of ART?
7. Is there a need for public engagement in regulating health technologies?
8. What are the avenues for public engagement?
9. Did you or anybody representing you participated in drafting the bill?

Appendix-III

Interview guide for policy makers

1. What were the main concerns that led to the drafting of ART bill 2008?
2. Who are the people engaged in the drafting of the bill?
3. What will be the implications of the bill in ART treatment?
4. What do you think are the risks of ART?
5. How did public engage in the drafting of the bill?
6. How will the different people (those undergoing treatment, donors, surrogates) be protected by the bill?
7. What is the scope of public engagement in regulating medical technologies?

Appendix-IV

Interview Guide for Patients

1. Name:
2. Sex:
3. Education:
4. Religion:
5. How long has it been since you got married?
6. Is yours a joint family or a nuclear family?
7. For how long have you been undergoing treatment?
8. How many doctors have you consulted since then?
9. From where did you came to know about ART?
10. Have you met anyone who had undergone treatment before you tried ART?
11. What are the therapies have you undergone till date?
12. What are the information given by the doctors when you go for treatment?
13. Will they tell you in detail about the therapies?
14. What is your opinion on ART technology?
15. What do you think are the risks of this treatment?
16. Have you heard about ovum donation?
17. What do you think about the claims on success rate?
18. Is there any health related problems immediately after injecting for ovum stimulation?
19. Have they taken consent or got any consent form signed from you?
20. How much money have you spent for ART treatment?
21. Do you think these problems faced by you can be regulated by laws?