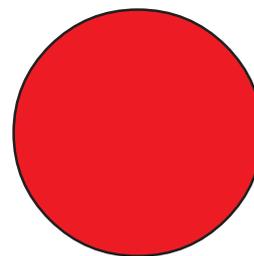


# 309 medico friend circle bulletin



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February - March 2005

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## Constitution Violated:

### Patents (Amendment) Ordinance, 2004 and Patents (Amendment) Rules, 2005<sup>1</sup>

-Advocate Narendra B. Zaveri<sup>2</sup>

#### Re: Validity of Ordinance

1. *Promulgation of Ordinance Unconstitutional?*  
The Constitution of India by Art. 123 empowers the President to promulgate an Ordinance:

- (i) when Parliament is not in session;
- (ii) the President (i.e. as per Art. 74, the Council of Ministers) is satisfied;
- (iii) that situation has arisen requiring immediate action.

#### 1.1 *Whether the Cabinet had approved the Ordinance?*

On Friday, the 24<sup>th</sup> December 2004, after coming out of the Cabinet meeting, the Commerce Minister in a televised briefing informed the waiting media people: "Cabinet discussed the Patents Amendment Bill. Various options have been discussed to meet our obligations under the TRIPS agreement but no decision was taken." and further, "We will now finalise the route and what should be done to meet our obligations."

PTI on Sunday 26<sup>th</sup> December reported from Delhi: "The Cabinet, which had discussed the amendments at its last meeting on Friday without taking a decision, is likely to take up the issue again next Wednesday and consider the need for an Ordinance."

#### 1.2 *Was the President misinformed?*

In absence of Cabinet advice, is the Ordinance validly

<sup>1</sup> The Patents Act 1970, the subsequent amendments including the Ordinance 2004 and Rules 2005 are accessible at <<http://www.patentoffice.nic.in/ipr/patent/patents.htm>>

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promulgated?

The President could not have (Art. 74 of the Constitution) and would not have signed or promulgated the Ordinance on 26<sup>th</sup> December 2004, if he knew or was informed that the Cabinet, had not taken final decision at its meeting on 24<sup>th</sup> December 2004, either on the Patents Amendments or the Ordinance. He must have been misinformed about Cabinet indecision.

#### 1.3 *Did the circumstances justify immediate action by issuing Ordinance?*

The only circumstance relied upon by the Government to justify recourse to Ordinance powers is the obligation under TRIPS to introduce product patents for drugs, medicines, foods and agro-chemicals effective from January 1, 2005. In this context, the following facts and issues require consideration:

- The TRIPS requirements were known long since.
- The Bill for proposed amendments adopted for the Ordinance was already prepared and introduced in the Parliament in December 2003 was readily available.
- Apparently the UPA Government has decided to adopt the same Bill text, and had also prepared and kept ready the draft of the Rules with 70 Clauses, 121 pages and 27 revised forms ready. The notification for amending Rules was also issued on 28<sup>th</sup> December 2004.
- Why was the Bill not introduced in Parliament earlier?
- Why did the Government avoid introducing the Bill in Parliament and discuss the various proposals,

objections etc openly in the House, or by referring to a committee instead of private discussion?

- Why did the Government wait till the Parliament sessions were over?
- Why did the Government wait till last week of December 2004, i.e., with only few days left for TRIPS compliance? Was this done to justify Ordinance route?
- Was the Government deliberately trying to avoid discussions and possible adverse vote in Parliament?
- Whether in the facts of the case, was the Parliament deprived of its jurisdiction, functions and duties to make laws? And is now being faced with a situation where their allies parties have to vote for the Bill to save the Government?

#### 1.4 *Only one amendment (out of 77) required for TRIPS compliance -*

Removing bar of sec. 5 for product patents for drugs, etc., effective from 1.1.2005 was the only amendment required for TRIPS compliance. This could have been achieved by amending (as in sec. 4 of Ordinance), sec. 5 of the Patents Act 1970 (“Inventions where only methods or processes of manufacture patentable”). This could have been passed during winter session without problem.

Why did the Government insist on the remaining 76 sections not required for TRIPS compliance being included in the text?

Was TRIPS compliance only a pretext to bypass the Parliament and to avoid discussion and possible rejection of such amendments in view of left parties opposition to some of the changes?

#### 1.5 *Ordinance - a Trojan horse?*

Was inclusion in the Ordinance of the other 76 sections involving drastic changes not required for TRIPS compliance, and for which there was no urgency, bonafide exercise of Art. 123 powers?

Does Art. 123 power permit the Government to undo what the Parliament done only recently after detailed study, deliberations and unanimous Report of JPC?

#### 2. *Can the Government exercise Art. 123 powers to issue Ordinance?*

- in violation of Constitutional provisions:
- depriving Parliament of its legislative jurisdiction, powers and functions?
- guaranteeing fundamental rights?
- in respect of subject matter covered by the State List of Schedule VII of the Constitution?
- in a manner which obstructs/disables the States in discharging their Constitutional powers, functions

and duties as per Directive Principles of State Policy?

- in breach of obligations under Human rights Conventions?
- to totally change and reverse the basic character and policy of the law from a model welfare legislation serving public interests and convert it into a law designed to promote and protect private interests (80% foreigners) giving it primacy over public interest?
- to undo what Parliament has done only recently in 2003 after detailed study and deliberations on unanimous recommendations of JPC? ( few specific instances of such amendments are provided in Annex. 1.)
- to appropriate to itself the powers to amend specific and substantive provisions of the Act by transferring such provisions to the Rules/Rule making powers?
- by amending the existing sec. 159 provisions (“Power of Central Government to make Rules” in the original Patents Act 1970), to expand the scope of its own Rule making powers already provided in the Act by the Parliament for the purpose, particularly to include also the power to decide, frame and enforce such amended Rules with immediate effect?

The Government has also amended section 159 (3) of the Patents Act 1970 (“The power to make rules under this section shall be subject to condition of the rules being made after previous publication”) to assume powers to issue final notification for amending Patent Rules without prior publication. This will empower the Government to make final Rules and enforce them without prior publication as draft Rules.

In fact in exercise of these assumed powers the Government has already issued the final notification on December 28, 2004. This will deprive the interested parties to make any suggestion or changes in framing of the Rules.

In past the DIPP (Dept of Industrial Policy and Promotion, Ministry of Commerce and Industry) has abused the Rule making power to make Rules contrary to the specific provisions of the Act and in favor of applicants/grantees of patent/EMR, and against public interest by making vast changes not justified by the Act provisions. (Few specific instances of abuse of Rule making powers are set out in Annex. 2.)

3.1 This provision will give to the DIPP very wide and uncontrolled powers. This will directly deprive Parliament of its powers to legislate and the people of

the benefits of assurance and protection of direct and immediate parliamentary control over legislation, affecting their lives and rights. It is necessary therefore to consider the questions :

- who in the Government will exercise these powers?
- whether there will be any external influences as international treaties and conventions and foreign parties are involved ?
- what will be the guiding considerations?
- whether post-facto checks under the amended (per the Ordinance) section 159 (of the Patents Act 1970) would be effective?

3.2 Actual experience shows that Ministers and senior Secretaries, who are assigned this work, have limited knowledge of the subject, are subject to frequent changes, their terms and time available to them are too short for them to understand the requirements, problems and implications of the complicated Patent law and constitutional issues and take independent decisions. In actual practice, most often Joint Secretaries in the Department decide and act on basis of the study made and notes prepared at Director's level. They have little knowledge, experience or training, in the subject to take effective decisions.

3.3 Such vital matters affecting the lives and fundamental rights of people; economic, technological and industrial development of the nation; and long term international commitments have to be decided after detailed studies, open public discussions, and deliberations in and out of the Parliament by collective decisions of representatives of the people. Such matters cannot be left to be decided in total secrecy by a few individuals - however respected and careful they may be. The Constitution scheme also mandates this approach.

3.4 The Patent Law amendments have been drafted and pushed through by resorting to emergency powers under Art. 123 and sec. 159 , and on each occasion, there has been systematic erosion of national and public interests, and bias in favor of applicants/patentees (80% being foreigners). The present Ordinance deliberately, systematically and effectively dilutes all obligations on part of applicants/patentees; removes all safeguards available for other citizens and public interest ; and takes away and limits the rights of the citizens and States even in case of emergencies and urgencies. **The character of the Patents Act 1970 has totally changed the law of the people, by the people, and for the people in favour of a law for the MNCs and by the MNCs. Even the Constitution has not been spared.** There is thus clear and undisputable evidence of foreign influences regulating or guiding exercise such powers to the detriment of the people and the nation.

4. *Article 13(2) of the Constitution states:*

“The State shall not make any law which takes away or abridges the rights conferred by this Part and any law made in contravention of this clause shall, to the extent of the contravention, be void.”

Art. 12 defines ‘States’ to include the Parliament. As such Parliament cannot make any law which takes away or abridges any of the fundamental rights guaranteed in Chapter 3 of the Constitution.

The Patents (Amendment) Ordinance 2004 takes away or abridges the fundamental rights set out in Part III (of the Constitution) as under:

(i) *Violation of Art. 19(1)(a)*

By sec. 10, 20 & 33 (of the Patents Ordinance), the right of citizens to know and seek information being part of fundamental right to freedom of speech and expression, guaranteed by Art 19(1)(a) is taken away, abridged or rendered ineffective. Publication in Gazette and right of inspection before grant, have been provided in existing act and in patent laws of most countries to enable interested parties to know and obtain information about patent claims, and provide sufficient time and opportunity before grant of patent, to inform the Patent Office about their objections and also to oppose grant.

(ii) *Violation of Art. 19(1)(g) & 21*

Grant of a patent entitles the patentee to exclude or prevent all other citizens from making, using, selling, offering to sell or importing the product protected by the patent. It thus takes away, or abridges fundamental rights of other citizens to practice their profession, or to carry on their trade or business and also the right to life guaranteed by Articles 19 (1)(g) and 21.

#### ***Reasonable Restriction Exception***

The public interest safeguards protecting rights of other citizens through sec. 5 (of the original Patents Act 1970 dealing with scheme of process patent, i.e., permitting production by other processes); pre-grant scrutiny (sec. 6 to 23 of the 1970 Act); pre-grant opposition (sec. 25 of the 1970 Act); compulsory license/Government use provisions of Chapter 16 –17 of Patents Act, 1970) operated to bring the existing Patents Act provisions within scope of ‘reasonable restrictions’ exception to fundamental rights.

**However, by deleting or diluting these public interest safeguards, as briefly referred in Annex. 1, the Ordinance provisions deprive such patent grant, of the safety of protection as reasonable restrictions, and bring it in direct violation of fundamental rights.**

#### ***Ordinance against Spirit of Doha Declaration***

Doha Declaration on TRIPS is an official and binding

interpretation of TRIPS Agreement. It clearly asserts primacy of public health over commercial interests, and recognizes rights of member nations to take all measures necessary to provide healthcare to their people treating TRIPS as flexible. It also places a moratorium on raising of WTO disputes under TRIPS till next Ministerial Conference, to facilitate members adopting such measures without anxiety. Doha Declaration thus removes scope of confusion, doubts or disputes.

The Ordinance even goes far beyond the requirements of TRIPS - seriously compromising public interest and third party rights conferred by TRIPS itself. The most glaring example of such approach is of the provisions for compulsory licences. The JPC has taken considerable care in formulating the policies and principles (set out in proposed sec. 83) to be followed for considering application for grant of compulsory licences. Unfortunately however, the good intentions get defeated by the elaborate conditions and time consuming procedures prescribed for such grant in proposed sec. 84, 87, 92 & 117A.

The Ordinance makes no exception from procedural requirements of sec. 87, even for cases of 'national emergency' or 'extreme urgency'. Even after issue of gazette notification and declaration by the government of such situations, proposed sec. 92 & 87 require the same procedure to be followed before Controller of Patents, with right of appeal to Appellate Board as per sec. 117A, involving delay of not less than 2 years when every day's delay adds to the death toll in thousands.

Neither TRIPS Agreement, nor Paris Convention, contemplates a right to oppose holding of elaborate inquiries or appeals for grant of compulsory licences or government use in public interest. However, the now amended sec. 87 prescribes such procedures permitting even strangers to oppose the grant of compulsory licences, which virtually nullify this vital public interest safeguard.

Unless clear, effective, efficient and enforceable safeguards are provided in law, it may turn out to be 'now-or-never' situation for the millions of poor victims of AIDS/HIV and other pandemics - many of them innocent children and women, and also for the generic industry, which could be greatly marginalized.

There is no room for any complacency and ambiguity or hesitancy. The time is to act, and act decisively and with determination. No reliance can be placed on promises of FDI or R&D by foreign pharma companies in India, particularly in view of the systematic closure and disposal, even of their existing production facilities,

fixed assets, sale of brands, and withdrawal of capital and investments from India during last 7 years.

Having regard to the pressing need to control the health crisis; the constitutional obligations to protect fundamental right to life for all citizens, and right to trade for generic industry, and also in furtherance of Directive Principles of State Policy, it is imperative that Parliament and Government review, not only the Ordinance, but even the Patents Act 1970, to provide more effective safeguards for national and public interest in respect of patents for healthcare inventions.

#### **Crucial Issues**

- Only a microscopic minority in India can afford to pay the resulting draconian drug prices.
- Can a welfare State make or enforce a law, which benefits less than 1% of its population, ignoring the sufferings, and compromising interests, of the remaining 99%?
- What good is research for modern drugs, if its benefits are denied to the vast millions of the poorest, leaving them to suffer their pains in silence - if at all they survive - for 20 long years?
- Indeed the Ordinance will kill in the long-run, more people than the unfortunate tsunami that hit our country on December 26, 2004.

#### **Annexure 1**

##### **Some Objectionable Features of the Ordinance**

By sec.4, the Ordinance removes the bar against grant of product patents for '*substances intended for use or capable of being used as food or medicines*', but though permissible under TRIPS and as reaffirmed in Doha Declaration, the Ordinance fails to provide the following counterbalancing measures absolutely necessary to protect and promote public interest in view of the total monopoly to be allowed under product patents:

- The words 'product', 'novelty' and 'inventive step' have not been defined leaving it open for the claimants to claim, and for Patent Office to grant patents even for common place items like dosai, pulav, varieties of ice-creams, chocolates, etc., or for wrongful claims for product patents of matter already in public domain, or traditional knowledge; or for "me-too" drugs with little innovation. Such claims without contributing any technological advance or benefit only deprive people of their lawful rights to matter already in public domain and add to the disputes, litigations and miseries for them.
- By sec. 6 to 22 of the Ordinance, the provisions in the 1970 Act relating to pre-grant search, examination,

scrutiny and publication are being diluted or rendered ineffective. This will encourage claims for subject matter already in public domain, or is part of traditional knowledge, and promote wrongful, frivolous, fraudulent, excessive, repetitive claims; and there by deprive other citizens of their lawful rights to make use etc such knowledge and products.

- By sec. 23 of the Ordinance, the existing provisions of section 25 of Patents Act 1970 providing for right of other interested citizens to oppose granting of patents on the grounds specified therein, is taken away.
- The bias in favor of the applicants and against public interest is most glaring in case of procedures prescribed for oppositions to grant of patent (sec. 25 of the Patents Act 1970 and Rules 55 to 58 of the Principal Rules as amended by the Ordinance), and the procedure prescribed in sec. 87 to 92 A (as amended in the Ordinance) for opposing grant of Compulsory License (CL). Whereas, in case of opposition to patents (sec. 25 of Patents Act 1970), public interest requires proper procedure and thorough enquiry to eliminate wrongful claims, in case of CL public interest requires expeditious grant of CL. But the procedures prescribed in the Ordinance 2004 and Rules 2005 in both cases favor even wrongful claims made by applicants and abuses practised by patentees and are designed to facilitate and expedite grant of patents even for obviously frivolous and fraudulent claims, and to delay and defeat applications for CL even in gross cases of exploitative prices, non-use, public emergency situations and exports for benefit of suffering people. There is a clear bias in favor of applicants/claimants and against public interest.
- More effective and practicable compulsory license provisions necessary to ensure sufficient availability of drugs and medicines required for treatment of millions of poor at affordable prices should have been made. However, the elaborate and time consuming procedures prescribed for grant of CL – even in case national emergency, urgency u/s. 92(1), 92(3), & 92A (as amended under the Ordinance) makes these provisions totally ineffective. (sec. 92 (3) specifically required such procedure to be avoided for drugs required for pandemics, and now Rule 96, 97 etc., apply the same procedure as for other CL).
- By failing to make provisions for honest/prior use exception to grant of patent/EMR - though permissible under TRIPS Agreement (Art. 30 & 31) - the Ordinance fails to protect fundamental rights of citizen. It thus takes away, or abridges fundamental rights of other citizens to practice their profession, or to carry on their trade or business and also the right to life guaranteed by Articles 19 (1)(g) and 21. Such specific provision

was necessary particularly in view of the scope of patents being extended to cover product patent for foods, drugs and medicines and also to all fields of technology, and providing a longer term of 20 years with stronger protection.

## *Annexure 2*

### **Specific Instances of Abuse of Rule Making Powers**

The Ordinance amends many of the existing specific substantive/procedural provisions of the Act by substituting the words: ‘as may be prescribed’ in several sections to transfer the powers from the Act to the Rules which would be subject to changes from time to time. No guidelines have been provided to control exercise of such powers by the Government. In past the DIPP has exercised such powers beyond the scope of the Act provisions, and almost in all cases to benefit the applicants/patentees and against public interest. Two such specific examples of such misuse are :

- (i) Drastically amending the Patent Rules of 1972 by about 66 clauses and totally substituting the fees schedules and 28 prescribed forms in place of about 62 forms, Patent Amendment Rules 1999, consequent upon the Patent Act 1999 containing only 9 sections, when for identical amendments of 1994 Ordinance, the draft Rules framed and notified by the Government on 31.12.94 contained only 4 amending clauses and 6 new forms. All the new forms were designed to enable applicants to suppress adverse information and avoid giving declarations.
- (ii) Rule 33 O of 1999 Rules limiting the scope of ‘public interest’ provided in sec. 24 D for Government use of EMR and reproducing the same as Rule 53 of the 2003 Rules, ignoring Bombay High Court guidelines.
- (iii) The Patent Controller, ignoring the specific provisions of sec. 11 A (3) requiring publication in the Gazette, of all applications after 18 months, avoiding such publication by issuing a note on 31.05.2003 that all applications filed before 31.10.2001 shall be deemed to have been published. This will make even the pre-grant representation by opposition provisions meaningless.
- (iv) The Rules have been drastically amended in less than 20 months. Once again the 2005 amending Rules totally change the fee schedules and the forms and introduce 70 clauses to amend the Patent Rules 2003.

## Ordinance and After: Issues in Focus

*-B.K.Keayla*

Government of India is honoring its binding commitment to change the Patents Act 1970 to conform to the TRIPS provisions. In this process the Act has been amended twice in 1999 and 2002 and now the Patents (Amendment) Ordinance 2004 has been promulgated in December 2004. In-depth examination of these legislations reveals that safeguard measures to protect the public health are being compromised and the flexibilities and freedom available are being ignored. The amended patent regime will help the powerful multinational corporations to monopolies our market. The result be that the country will face high cost economy, inflation, de-growth in certain sectors of industry and unemployment. Serious phenomena. A number of studies have also pointed out the implications of TRIPS Agreements and made certain useful suggestions.

Safeguard measures available within the TRIPS framework and the Doha Declaration on TRIPS Agreement and Public Health should have been stipulated in the amending process. Some of important patent components ignored in this regard which should now be incorporated in the Third Patents (Amendment) Bill are as follows:

- i) Appropriate definition of patent terminologies to contain volume of patent claims restricting them to the genuine patentable subject matter need to be stipulated now. The definition of invention should be restricted to basic novel invention. Pharmaceuticals patentability should be restricted only to new chemical and medical molecules/entities. This will help exclusion of frivolous claims. Otherwise the volume of claims may rise to the same level as in USA and China, which are faced with flood or patent applications over 3 lakhs annually due to weak and unrestricted definitions. For India such proposition would be totally unmanageable and there would be chaos, as the market would have massive volume of protected products.
- ii) Life forms including microorganisms should be specifically excluded form patentability as WTO has yet to complete its mandated review. This has implication of widening the scope of patentability. Considering the criticality of spread of HIV/ AIDS phenomena in the world including India, it is important to consider exclusion of all relevant present and future drugs for this disease from scope of patentability or declare health emergency to facilitate authorization of domestic enterprises to produce these drugs for domestic and export demands. The expansion of patenting of technical application to software industry or a combination with hardware also should not have been provided through the Ordinance.
- iii) Pre-grant opposition of patents as available presently in the Patents Act 1970 should not be amended. There is no TRIPS requirement to provide for any change in this provision. The proposed amendment of stipulating pre-grant representation and post-grant opposition has serious implications. The post-grant opposition will be directed against the Controller and he would vehemently oppose opposition, as he would himself dispose of recommendations of Opposition Board.
- iv) Role of domestic enterprises to ensure competitive environment to protect public interest about the availability and affordability of medicines is important. In this direction Article 31(b) of TRIPS permits grant of compulsory licence if the effort of obtaining licence from patent holder on reasonable commercial terms and conditions do not fructify within a reasonable period of time. This is an important TRIPS provision and should find prominent provision in our amended patent regime.
- v) There are over 9000 applications in the Mail Box received during the transitional period of 10 years from 01/01/1995. Article 70 para (3) of TRIPS Agreement specifically provides that no protection shall be provided to Mail Box products if they have fallen in public domain. Non-inclusion of these provisions in the amendments has serious implications. There are a number of Mail Box products which are being produced by the domestic enterprises and their turnover is over Rs.3000 crores. Alternatively specific provision should be provided for grant of automatic compulsory licences to these manufacturers to enable them to continue their production on payment of royalty otherwise there would be serious shortages and the availability of the relevant products from the patent holders at prices which will be 10-15 times higher than the prices of Indian manufacturers. This will also give rise to a large number of court cases.

vii) Many small countries and LDCs are dependent upon imports of pharmaceutical products from India. The Para of Doha Declaration procedure prescribed for imports by these countries is totally unworkable. The main reason being that there has to be pharmaceutical companies producing the patented drugs under compulsory licences for meeting the domestic demands in India and supply to needy small and LDCs. Only in this way the exports from India would be viable. Almost 45 percent turnover of Indian companies is presently being exported and it is important that the law must strengthen the role of Indian companies in their export efforts to small and poor countries. The entire world is seriously concerned about the weaknesses in the changes already made and those under consideration for supplies to poor and dependent countries. Formal representations have been made by the mass organization from all over the world to the highest authorities in India to safeguard the interest of the people in these countries.

To sum up there is a need for a serious and precision approach in framing the final amending Bill replacing the Ordinance. There should be no haste in pushing the enactment of the Bill. Reference to Joint or Standing Parliamentary Committee is very important and in public interest.

(Reproduced with thanks from: Keayla, B.K. *Patents (Amendment) Ordinance 2004: A Critique*. National Working Group on Patent Laws, February 2005. Email: <wgkeayla@del6.vsnl.net.in>).

## **Patents Ordinance: Ensuring Corporate Control, Neglecting Public Health Concerns**

*-Mira Shiva<sup>1</sup>*

The Patent Ordinance was announced on December 26, 2004 ironically the day Tsunami hit several countries in South and South East Asia – a double disaster in every sense.

On Feb 1, 2005, National Working Group on Patent Laws and the Research Foundation on Science, Technology and Ecology (RFSTE) with Transform India organized a colloquium on Social and Economic Implications of Patent Ordinance.

The emergency meeting was to highlight the serious implications for public health, agriculture, food security, food sovereignty as well as for software and IT.

Richard Stallman, founder of Freedom Software movement emphasized that there is a significant difference between copyright, trademark and patents. The calculated projection of their being similar was to confuse the public. Copyrights and trade marks are fairly acceptable to majority. Using intellectual property in the same breath was basically to ensure its unquestioned acceptance as a concept specially with the clever use of the word ‘property’ and rights.

The fact that intellectual property rights was a substitute term for patents and patent laws – terms which should be used was known to few.

Corporate control on knowledge on basic ideas would not be acceptable to many as there had been built on what existed, and it was bound to block growth and development in software by non-patent holders of these ideas and increase inequities.

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Since several ideas are used in a single programme, with patenting of these ideas, their use by others would be treated as ‘violations’ and infringements of patent rights. Richard refuses to use the word ‘intellectual property rights’ and actively discourages using it.

Mr. BK Keayla, Convenor of the National Working Group on Patent Laws since its beginning in 1988, highlighted that four People’s Commission Reports on patents had been prepared and submitted before each patent amendment 1999, 2002, 2003 and 2004.

The nation was misled by statements by the Commerce Minister that R&D, exports, etc., will increase and that access and prices of medicines will not be affected.

The letter of concern by WHO to the Health Minister about India’s failure to use the existing TRIPS flexibilities was noted. This would effect not just the poor in the country but also in other poorer countries already in deep debt which depend on India for cheaper generic equivalents.

Mr. William Haddad of Generic Manufacturers Association, USA, former adviser to John F. Kennedy, and former Senator, said that generic manufacturers in US depend on bulk drugs and raw material from India for making cheaper generic equivalents available to the poor in US. He emphasized that TRIPS was not in the interest of public health and the Patent Ordinance 2004 was extremely unfortunate.

Dr. Vandana Shiva, Director, RFSTE, focused on the implications of Patent Ordinance on agriculture with patenting of “traits” in seeds. The changes being

brought in the Seed Act would be disastrous for agriculture and food sovereignty.

Representatives from mass movements, trade unions and some Left parties shared their views as well and assured participants that they would express their concerns as it was a question of national sovereignty.

### **Key Concerns**

The main concerns about the Patents Ordinance 2004 are as follows:

- Procedural violation of Constitution bypassing the Parliament.
- Exclusion of many flexibilities which TRIPS allows.
- Inclusion of several sections which were beyond TRIPS requirements and are therefore TRIPS Plus.
- Patentability *criteria* needed to be stricter allowing patenting only for inventions based on novelty and restricted only to new chemical entities and *not* new use of old drugs, dosage forms, drug delivery system, etc.
- Earlier existing clauses have been removed which could have taken care of frivolous claims.
- There continues to be the most problematic concern about representation, implications on domestic including public health once the 7000 patent applications in the mailbox are granted patents. The Post-Grant Opposition would only imply questioning the patent granter.
- Rules Making: Many sections indicate “as per rules” which will be made by Commerce Ministry bureaucracy.

The failure to incorporate public concerns in presentations made to Joint Parliamentary Committee was pointed by those who had made presentations.

When concerns were raised during the 1<sup>st</sup> and 2<sup>nd</sup> Amendments, during the NDA regime, one of the key persons involved with public health aspects of patents was told by a senior government servant that “the Amendments had been seen and approved by the Americans, so why were needless objections being made !”

This form of policy making is unacceptable to the citizens of a sovereign country – which belongs not just to those involved in trade and those belonging to large corporations, but to those involved in public health work and the people who give their blood, sweat and tears to survive and to keep humanity alive.

The bottomline is that even today large majority cannot afford to buy medicines and medical care.

With grant of patent for 20 years and EVERGREENING of patents, extended monopolies will be ensured

affecting ACCESS TO medicines as well as PRICES.

Only 300 new drugs were patented in last 5 years world over. Now with no pre-grant opposition per the December 2004 Ordinance, it can be well imagined what the granting of the 7000 patent applications in the mailbox mean to domestic industry which is already manufacturing those drugs.

**Protection of those drugs which are “already in public domain”** (that is manufactured domestically by Indian industry as of 1.1.2005) is permitted under TRIPS Art 70.3 but shockingly *has not been ensured* in the Ordinance. This means that existing domestic production becomes a *violation and infringement* of the patents held by the patent holder. Stoppage of Rs 3000 crores worth of medicines could take place, spiraling drug prices, increasing indebtedness, decreasing drug availability, emergence of drug resistance, etc., worsening the already high morbidity and mortality suffering pain and death amongst the most vulnerable.

No one involved in or concerned about public health can accept this without raising strong objections.

The Joint Action Committee against Patent Ordinance has decided to launch nationwide protests on the February 26, 2005 joined in by mass movements health and public health community health organisations, farmers’ movements, social action groups, academicians, intellectuals and activists.

On February 13, 2005, Basant Panchami, RFSTE and farmers’ movements will be involved in activities highlighting impact of Patent Ordinance, Seed Act, etc., on Agriculture and Food Security.

Basant Panchami is celebrated in the North at a time when yellow mustard fields are in full bloom and customarily yellow clothes are worn.

Our seeds in our Hands  
Our health in our Hands  
Our knowledge in our Hands

for PUBLIC GOOD and not Corporate profits in the name of Patents through UNJUST INEQUITY, PERPETUATING trade regimes at global and national levels.

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**-Editor**

## Tsunami: Some Health Considerations

-C.Sathyamala<sup>1</sup>

### *Disposal of the Dead and the Tsunami*

The most visible area of intervention of the state was in the disposal of the dead.

Post tsunami, there was some delay before the bodies were cleared and thus we see photographs of a main road littered with the bodies of the dead and people walking around it with little concern (see for instance *India Today*, *Outlook*, etc.). The dead were brought to government hospitals and health centres. Those who were identified by relatives were handed over to them but the rest, the unidentified or unclaimed ones, were buried in mass graves or mass cremated. Photographs bear mute testimony to the way we handled our dead. Bodies were “tossed into huge pits”, thrown in pell-mell, men, women and children, piled up in hideous heaps, many with their clothing awry or with no coverings at all. The question arises, what was the tearing hurry to dispose the dead in such a crass manner? We need to ask this question on three counts:

1. the extent of public health risk that bodies in natural disaster pose,
2. the rights of the survivors to have had a reasonable chance to identify their dead, and
3. the concept of ritual pollution in the caste-based Hindu tradition.

The Pan American Health organization's (PAHO) guidelines<sup>2</sup> on management of the dead following natural disaster, states that the basic principle is, “Bodies of victims of natural disasters who died as a result of trauma do not pose a risk of epidemics.” [See also: Claude de Ville de Goyet, “Epidemics caused by dead bodies: a disaster myth that does not want to die” at <[http://publications.paho.org/english/editorial\\_dead\\_bodies.pdf](http://publications.paho.org/english/editorial_dead_bodies.pdf)>

Oliver Morgan<sup>3</sup> in his scholarly work of a review of the existing literature on the subject (which forms the basis of the PAHO guidelines) concludes that in natural disasters, victims who usually die of trauma are unlikely to have more acute or “epidemic-causing” infections than the general population. Hence in such situations, the risk that dead bodies pose to the general public is

<sup>1</sup> Email: <[sathyamala@yahoo.com](mailto:sathyamala@yahoo.com)>. The complete article is posted at <[www.mfcindia.org](http://www.mfcindia.org)>

<sup>2</sup> Morgan O. “Infectious disease risks from dead bodies following natural disasters”. *Rev Panam Salud Publica*. 2004; 15(5): 307–12. Available at <[http://publications.paho.org/english/dead\\_bodies.pdf](http://publications.paho.org/english/dead_bodies.pdf)>

<sup>3</sup> Morgan O., *op.cit.*

<sup>4</sup> Reports have it that they were brought from other places like Madurai, etc (personal communication, Mr Subbu of TMKTS).

extremely small. Though the human body is host to many organisms only few are pathogenic. With death, these too die within a short period due to lack of suitable environment. Organisms involved in putrefaction are not pathogenic.

However, persons (rescue workers, volunteers, and military personnel) who deal with the disposal may be at some risk as they handle dead bodies in large numbers. They may be exposed to chronic infectious hazards, particularly blood-borne infections (which is more likely if trauma due to disaster produced severe bleeding injuries) and tuberculosis, if adequate precautions are not taken. Preventive measures would include following simple rules of basic hygiene such as hand washing, use of protective gloves, masks and observing universal precautions for blood and body fluids.

The greatest risk that exists is in transmission of gastrointestinal illnesses caused when bodies, dead animals or bones contaminate drinking water sources although, as Morgan (2004) notes, communities will rarely use water supply in such instances. According to him, the risk of epidemic in the aftermath of natural disasters is from the survivors themselves due to unsanitary conditions and overcrowding prevailing in the temporary camps.

In Tamil Nadu, with notable exceptions, members of a particular community (Dalits, belonging to the ex-untouchable castes) were brought in specifically to remove the bodies<sup>4</sup>. They were given a pair of gloves, a mask and plenty of alcohol to deaden senses. If anyone was at risk of contaminating any infections from the dead, it was these men who were probably not given clear enough instructions on self-protection and if they were, were in no position to follow them, being in an inebriated state.

The other populist measure that was tried out was the use of chemicals and disinfectants. The Secretary for Rural Development, Ms Shanta Sheela Nair was reported to have contacted the Gujarat State Disaster Management Authority (GSDMA) to help dispose of bodies still lying uncleared a week after the tsunami disaster (Sreenivas, 2005). The GSDMA Joint CEO, V. Thirupugazh, was reported to have sent to Tamil Nadu, more than 10 tonnes of chemicals to hasten decomposition and disinfectants to be sprayed on mass graves. A team had also flown in with spraying machines to spray chemicals and disinfectants all over the district to counter the threat of epidemics. These “heroic” efforts are considered to be of little use even

if the risk of infections was to be real and their value is merely “cosmetic” (Ville de Goyet, 2004).

In the tsunami disaster, in most cases, death was due to drowning with sand filled seawater and the bodies that were initially removed appeared fresh with no signs of putrefaction. Hence the question of quick disposal because of unpleasant sight or smell due to the setting in of putrefaction did not arise in the early stages and therefore there was really no need for a hasty disposal.

The total lack of respect, insensitivity and utter disregard to the sentiments of the survivors in the manner of the disposal of the dead was yet another injury heaped on the survivors. But the issue is not merely that pertaining to decency we accord our dead.

The PAHO guidelines do not recommend mass cremations<sup>5</sup> or mass burials of unidentified bodies in collective graves are also not recommended, again because of the near impossibility of ever identifying the victim. There is a compelling health reason for this guideline (Ville de Goyet, 2004). It has been shown that identification of the body and the following normal process of grieving have a direct bearing on the mental health of the survivors. By not performing death rites, important socio-cultural-religious needs of the survivors have been dismissed as unimportant.

Denying the right to identify the deceased or suppressing the means to track the body for proper grieving adds to the mental health risks facing the affected population (Ville de Goyet, 2004). The inability to grieve fully in the absence of a certainty allows no closure to the loss and will add to the mental suffering and mental illness of the surviving members for a long time to come.

The survivors should have been given every opportunity to identify their dead. Provisions should have been made to preserve the unidentified and unclaimed bodies for a few days to allow survivors adequate time to identify their family members. By mass cremations and mass burials, we have denied the survivors the right to claim their dead. Could it have had anything to do with their position in the socio-economic hierarchy? One cannot help comparing this with the manner in which the Thai government handled the bodies of foreign tourists who died in the tsunami disaster. The Thai government vowed that not a single body would be disposed off till all efforts were made to identify it. There are also reports that in Nagai, the volunteers from the Muslim community handled the dead in a more humane way. In Vellankanni, the bodies

<sup>5</sup> Even if indeed there is a possibility of infection, mass cremations are unpractical way of disposal because large quantities of fuel is required to achieve a high enough temperatures of 650° C for up to 3 hours to make all remains non-infectious.

were videotaped for future identification.

### *Media and the Tragedy*

The media played an important role in publicizing the unfolding of the tragedy. However, often the reporting was high pitched verging on the hysterical. The same images were played again and again. Only in the early phase of the disaster that one TV channel (Sun TV's 24-hour news channel) advised the parents not to let children view the images as they might disturb young minds. But soon channels were vying with each other to show gorier images and heart-rending stories. The news was also selective with the camera refusing to move downwards from Nagai. It was only much later that information from Kanyakumari district, which is also seriously affected, was brought in.

Media also indulged in passing on incorrect information. For instance, one of the national dailies had a headline on page 3 “Health Bomb ticks on” (Agencies & Sharma S., 2004). Three days later, the same newspaper announced in a front-page headline, “Viral storm Brewing in Nicobar” (Sen, 2005). The first paragraph reads, “Dead bodies float all around the waters in the Nicobar islands waiting to be cleared. But death, in the form of the V Cholera virus (*sic*) floats just beneath in the estuarine environment of the Nancowrie islands.” The reporter goes on to describe the “viral” characteristics of the bacteria *Vibrio cholerae*, “... The scariest thing about the virus is the fact that it lives freely in estuarine areas ... the conclusion is chilling: the virus could be in any stream or pond in the Noncowries – are all of them... The virus has remained dormant for the last two years, but if it were to choose a time to strike no time is better than now... With ships - and people – moving between islands, the virus will have no shortage of carriers”. The reporter had apparently based his news on a published report of the ICMR unit in Andaman & Nicobar Islands on a cholera outbreak in 2002 in which “dozens” of people had died. The next day, the Health authorities issued a denial, which was carried in another national daily, “Centre denies reports of ‘viral storm’ in Nicobar” (Correspondent, 2005) without really taking the newspaper that had reported the news item to task.

### *Physical and Mental Health Effects*

Physical injuries do not appear to have been of major consequence of the disaster in Tamil Nadu. This is unlike what we hear about the situation in Indonesia. But the consequence to mental health is of enormous proportions. Psychic injury has been caused by the traumatic event itself, loss of family members, special problems due to loss of children,<sup>6</sup> injury to people's self-esteem and self-respect (doling out of relief in a

de-humanising manner) and the anxiety about loss of livelihood.

The families that have been impacted adversely can be classified into the following categories:

- households with no surviving members
- those who have lost some members
- those who have been displaced by the evacuation efforts; and
- those whose livelihood have been affected

These categories are not mutually exclusive and the worst affected are those who have lost members, have been displaced and have lost livelihoods. But the largest proportions of the families that have been affected belong to the last two categories. It is estimated as of January 10, 2005, more than 1,50,000 families have been adversely impacted by the tsunami.

The mental health consequences of the disaster, both pattern and the morbidity rate, may be different in each of these groups both because of the varying levels of stress they would have experienced as well as the varying abilities of coping. Coping capabilities would be linked to former individual and community capacities and support structures. The ability to regroup and reform, which will be determined by the previous cohesion of families and communities, will be an important variable in the ability to cope. For instance, the stress due to anxiety caused in searching for family members will obviously have a different consequence in those families who found all the members alive from those who have definite knowledge that their family members are dead to those whose family members are missing. There would be age, class, caste and gender related differentials. Families that have lost children will be different from families that lost adult earning members. The existence of extended family and community ties such as that present in the close knit fishing communities may have a different impact as compared to the individualistic existence present in the urban, peri-urban slum communities.

Three weeks have passed as of the day of writing this report. Stage 1 of the mourning process, which typically lasts up to 2 weeks following the loss, would have passed (personal communication, Parappully). This stage is characterized by shock, numbness, disbelief and denial.

As the affected people begin to register the reality of their loss, there will be irrational guilt (survivors guilt), self-blame, and self-recrimination. We expect the pattern

<sup>6</sup> *Tamil Nadu has a high tubectomy rate with people, even those from the working class, adopting the two child family norm; this would affect women and men differentially with men opting for second marriages leading to increase in desertion, and abandonment of women.*

of psychiatric morbidity to range from insomnia, panic attacks, anxiety neuroses, depression, and suicidal ideation. In the context of Tamil Nadu where the rate of suicide is very high, this is an area of grave concern. A disaster such as this will also aggravate mental health problems in people with pre-existing disease.

The issue of Post-Traumatic Stress Disorder (PTSD) is a complex one and again likely to affect different sub-groups varyingly. It is possible that PTSD will become more prevalent in "land-dwellers" as compared to the fishermen whose life is the sea. Fishing is considered to be the riskiest occupation in the world (John, 2004). In the state of Kerala, the accident death toll of fishermen over the last decade was one fisherman every four days. Fishermen, particularly those who use the catamarans have learnt, as part of their daily living, to deal with the sea in all its fury. Therefore, the likelihood that this group will manifest PTSD is low. However, the state and the media are portraying the fishermen as being terrified of entering the sea again. This is one of the strategy by which we believe the state is trying to maintain a state of instability and "fear psychosis" going to prevent normalization of these communities.

The long-term consequences of untreated or incompletely treated trauma could be other manifestations such as hypertension, Coronary Artery Disease, ulcerative diseases of the GI tract, and illnesses such as asthma. There is a likelihood of increase in substance abuse specifically alcohol (prevalence of chronic alcoholism is high in Tamil Nadu among the working class population), addiction to tranquilizers (in the second week of the disaster there were reports that affected people were being prescribed anti-depressants and "stress management"<sup>7</sup> tablets). There may be an increase in reckless behaviour (this could be a particular problem with the fishermen), and escalation of violent impulses (increase in domestic violence?).

It appears then that an epidemic of mental health problems is likely in the affected population unless adequate steps are taken now to ensure that the effects of trauma are minimized. The second part of this paper will deal with this and other important issues pertaining to long-term rehabilitation.

#### **Acknowledgements**

The information presented in this paper is based on the first-hand account of Mr Subbu of the Tamil Nadu Manila Kattida Tholilazhar Sangam (Tamilnadu State Construction Workers' Union) who visited some of the severely affected areas in Tamil Nadu (districts of

<sup>7</sup> *The newspaper that published this information did not specify what they were.*

Cuddalore and Nagai) in the week immediately following the tsunami disaster and from the presentations made at the Citizens' Forum meeting on January 1, 2005 in Chennai, by representatives of mass movements, NGOs and others who had made a field-level assessment of the devastation in the coastal area of Tamil Nadu. I was in Tamil Nadu at that time although not in any of the coastal towns. I attended the Jan 1 meeting in Chennai. I would also like to acknowledge Dr Jose Parappully, clinical psychologist, for generously sharing his knowledge and material regarding psychological consequences of disasters.

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**Table 1 : Numbers of Dead and Missing in Tsunami-Affected Countries**

Country	Number
Indonesia	1,13,306
Sri Lanka	30,513
India	9,571
Thailand	5,246
Maldives	82
Malaysia	68
Myanmar	53
Bangladesh	2
East Africa	187

Source: Data as of Jan 10, 2005, reported at <[www.rediff.com/news/tsunami.htm](http://www.rediff.com/news/tsunami.htm)>, Jan 11, 2005

**Table 2 : Deaths in Tamil Nadu**

Place	Deaths
Nagapattinam town	2400
Others parts of Nagapattinam dist.	1000
Velankani	1500
Kanyakumari	800
Cuddalore	>500
Pondicherry	500
Chennai	200
Kalpakkam	100
No. Injured	500

Source: Data as of Jan 10, 2005, reported at <[www.rediff.com/news/tsunami.htm](http://www.rediff.com/news/tsunami.htm)>, Jan 11, 2005

## Why the IMS Act Needs to Stay

-Radha Holla Bhar<sup>1</sup>

### *Issue*

January 15, 2005. The Ministry of Food Processing Industries, Government of India, proposes to REPEAL the IMS Act and some other Acts. The reason: a new proposed Bill "Food Safety and Standards Bill 2005". Under Section 108, Schedule 1 of the Bill, it is proposed to repeal certain Acts including the IMS Act. Government of India has asked for comments and suggestions. Do we need to repeal this highly relevant legislation concerning lives of millions of young children?

In 1992, India became the 8<sup>th</sup> country to take a definite stand for children's rights. The Indian Parliament unanimously enacted the *Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992* (IMS Act). The IMS Act controls marketing practices of baby food manufacturers.

The statement of objectives presented in Parliament during the enactment of the IMS Act clearly stated: Inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in our children. Promotion of infant milk substitutes and related products like feeding bottles and teats do constitute a health hazard. Promotion of infant milk substitutes and related products has been more extensive and pervasive than the dissemination of information concerning the advantages of mother's milk and breastfeeding and contributes to decline in breastfeeding. In the absence of strong interventions designed to protect, promote and support breastfeeding, this decline can assume dangerous proportions subjecting millions of infants to greater risks of infections, malnutrition and death...

Thus the Act had a clear intent: the saving of millions of children's lives and improving their nutritional status by preventing the baby food industry from enticing mothers and the health system to give babies artificial foods.

In 2003, following increasing information on the benefits of exclusive breastfeeding for the first six months, the Act was amended to include weaning foods.

The IMS Act is one of the laws being repealed under the new THE FOOD SAFETY AND STANDARDS BILL, 2005.

### *Differences*

There are considerable differences between the potential impact of the IMS Act and the new Food Safety Bill. Firstly, the former was the brainchild of the Department of Women and Child Development: infant health and social concerns were at the heart of the IMS Act. The Ministry of Food Processing Industry, in contrast, is developing the Food Safety Bill: industrial health underlies the objectives.

Secondly, the objective of IMS Act is to protect, promote and support breastfeeding; it prohibits any kind of promotion of infant milk substitutes, infant foods and feeding bottles; it ensures proper education of pregnant and lactating mothers about breastfeeding by providing accurate information; it ensures proper use of substitutes, and defines the role of health workers and their associations and health care institutions in promoting breastfeeding as well as prohibiting promotion of baby foods. The IMS Act also prohibits donations and gifts, prohibits direct promotion of baby foods and feeding bottles to pregnant women. Thus the IMS Act encompasses social and health concerns of the community at large.

The object of this new bill is to harmonize laws related to food and lay down 'science based standards for articles of food and regulate their manufacture, import, export, storage, distribution and sale, to ensure availability of safe and wholesome food for human consumption (including other matters relating thereto)...'. In an advertisement placed in the leading newspapers of Delhi, the ministry of food processing industries states that the law also seeks to "meet the dynamic requirements of international trade and Indian Food Trade & Industry." The Food Safety and Standards Bill, therefore, has as its basis enhancement of trade in foods that meet safety standards.

### *Are Infant Foods Necessary at All?*

However, the issue with infant foods is not safety standards, rather it is the question of whether such foods are necessary at all or not. Medical evidence

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from across the world states categorically that infant milks are not adequate substitutes for breastmilk, which is the best food for infants. There is also overwhelming evidence that infants who are not breastfed suffer from malnutrition, and that this early malnutrition can cause irreversible setbacks to optimal physical, emotional, mental and intellectual growth of infants. Further evidence exists that in countries like India, where clean drinking water and fuel are at a premium and where incomes are low, artificial infant milks and foods are a leading cause of malnutrition, disease and death of infants. Thus, medically and scientifically speaking, infant milks and foods, even if they are of the highest standards, are actually harmful to infant health because they tend to deprive the baby of the best food – breastmilk. This was the basis of the IMS Act, and this aspect is wholly missing in the new Food Safety Bill.

On the whole, there are very few situations when an infant needs artificial milks and foods to survive. Such foods are therefore, in a way, equivalent to special drugs needed in rare cases when patients suffer from rare illnesses. To that extent, like other occasionally essential drugs, they are not just necessary *in very limited quantities*, but also need to meet safety standards. However, given their food-like nature, they have far greater potential for misuse and abuse than pharmaceuticals, and thus justify the need for special laws, such as the IMS Act, which not merely prohibits the unregulated production and marketing (including advertising) of these foods, but also demands that there be cautions on the containers regarding their use.

The battle to mainstream the regulation of the infant milks and foods industry is today more than half a century old. It saw the first coming together of the medical profession, consumer activists, health activists, social activists, legal activists, NGOs, governments, UNICEF, WHO and other international bodies in a bid to save the lives of millions of children from the unregulated actions of industry. The process saw international codes being developed, international standards being set, both for food safety as well as for action by governments and industry. India was the eighth country to adopt the code into law, and became a beacon for all countries that sought to improve the health of their children. Repealing the IMS Act, and

bringing the regulation of the infant food industry under the trade-oriented Food Safety Bill is tantamount to laying the lives of the India's millions of infants at the feet of corporate profits.

*Please write your letter supporting the above stand (sample letter in box).*

#### Draft Letter

Mr. A.N.P Sinha  
Joint Secretary  
Ministry of Food Processing Industries  
Government of India  
Panchsheel Bhavan, August Kranti Marg  
New Delhi  
Fax 91-11-26497641  
Email <sumsingh@email.com>

*Sub: Repeal of Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (IMS Act) proposed by the new draft "Food Safety and Standards Bill 2005"*

Dear Sir,

We are extremely concerned to note that the Section 108 Schedule 1 of the "Food Safety and Standards Bill 2005" proposes to repeal the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (IMS Act).

We appreciate the role of MOFPI for proposing a new integrated "Food Safety and Standards Bill 2005". However, having carefully gone through the Bill and its objectives, and the one proposed to be repealed among others, we feel that the two Bills are totally different with different objectives. The Food Bill ensures quality and deals with adulteration issues and the IMS ACT aims at reducing child malnutrition and reduce infant and young child mortality. No logic is seen in repealing this highly socially relevant Bill.

Therefore, we urge you NOT to REPEAL the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (IMS Act) while adopting the new "Food Safety and Standards Bill 2005".

Yours, etc.

## A Gender and Rights Approach to Breastfeeding Promotion<sup>1</sup>

-Lakshmi Menon and Radha Holla<sup>2</sup>

### Introduction

The decade of the 1990s up to the 21<sup>st</sup> century saw more of the breastfeeding promotion carried out from a rights perspective, particularly after 1995-96, when the human rights discourse became popular within many social movements. Several international declarations and UN instruments supporting the rights of children to food and health were adopted, providing a rationale for the breastfeeding movement. The international declarations included the *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding of 1990*, and declarations from the World Summit for Children in 1990 and the International Conference on Nutrition in 1992. The UN instruments included the *International Code of Marketing of Breastmilk Substitutes* and subsequent World Health Assembly (WHA) Resolutions, the *Convention on the Rights of the Child (CRC), 1989*, and the *Global Strategy on Infant and Young Child Feeding* adopted by WHA in 2002. A CRC provision is of particular significance: "that State Parties recognise the right of the child to the enjoyment of the highest attainable standard of health". This was interpreted as implying that children have a right to mother's milk as the only fully adequate form of child nutrition in the first six months. Much of the focus of breastfeeding promotion was thus on the child - on children's right to be breastfed.

### Real Situation of the World's Women

However, we must keep in mind that it is women who are actually at the center of breastfeeding. It is a truism to say that the situation of the woman determines her ability to breastfeed successfully. Women have, through millennia, breastfed successfully. Even today, in most parts of the world, women continue to breastfeed their babies. And yet, breastfeeding continues to be a challenge. In most cases, it is neither adequate nor exclusive in the first six months of life. To address these challenges, we need to look at the reality of women's lives, to identify what makes breastfeeding a difficult choice, and to create a world where women can successfully breastfeed their babies adequately for as long as is needed.

<sup>1</sup> This is an edited version of the discussion paper prepared for WABA's Gender Strategy Meeting held on 2-3 December 2004 in Penang, Malaysia.

The original paper is available from: <waba@streamyx.com>

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Because women constitute the core of biological reproduction, over centuries and millennia, claims have been made on their lives by society, by the community and by the family. As a result of this process of disempowerment, women have multiple burdens, including financial contributions through their work, resource management, household responsibilities, as well as the care of children and the elderly. In many societies, few women are able to exercise their social and economic rights including rights over basic necessities such as food and health care.

### Breastfeeding and Women's Issues

#### 1. Breastfeeding and Maternal Nutrition

WHO/UNICEF recommend that a baby be exclusively breastfed for the first six months of its life. After this, appropriate and adequate complementary foods need to be given in addition to breastmilk, which should continue to be given till the child is at least two years old (WHO/UNICEF, 2002).

A breastfeeding woman produces 700 ml of milk per day during the first six months and progressively less till the baby is fully weaned off the breast. While breastfeeding, she needs an additional 500 kcal per day for the first six months; after that, this requirement is reduced to 400kcal per day (Manual of Clinical Nutrition Management, Picciano 2003).

Studies have shown even the most undernourished woman can breastfeed her baby adequately. How do women who get barely enough calories to maintain their bodily system get the extra calories required to produce breastmilk? They use up essential body fat and tissue, to the further detriment of their already compromised health, to make milk for their babies.

Data from 32 studies examining protein energy malnutrition (PEM) among women in developing countries shows that women generally consumed only about two-thirds of the WHO recommended daily allowance for energy, and that their average weight-for-height was well below the average for small-frame women in the US (Anthology on Women). Women in many cultures around the world, particularly in South Asia, eat last and least in a family. They suffer from malnutrition and anaemia in the best of times. When they become pregnant or breastfeed, the demand on their already weakened bodies is even more, especially as they rarely get extra nutrition during this period.

**Women's Health Status****Maternal deaths per 100,000 live births**

Sub-Saharan Africa - 1,098  
 Arab States - 509  
 South Asia - 427  
 Latin America and the Caribbean - 188  
 East Asia and the Pacific - 144  
 Central and Eastern Europe and CIS - 55

**Countries with high maternal deaths per 100,000 live births**

Ethiopia - 1,800  
 Sudan - 1,500  
 Nepal - 830  
 Lao PDR - 650  
 Bangladesh - 600.

Source: UNDP Human Development Report 2003

**Pregnant women with anemia in 1975-91**

88% in India

64% in Indonesia and Ghana, and over 50% in Bangladesh, Nepal, Lao, Thailand, Malawi, Nigeria, Tanzania, and Trinidad and Tobago

Source: UNDP Human Development Report 2000

**Births attended by health personnel during 1995-2001**

East Asia and Pacific - 80%  
 Latin America and the Caribbean - 82%  
 Central and Eastern Europe & CIS - 96%  
 South Asia - 36  
 Sub-Saharan Africa - 38  
 Yemen - 22%  
 Bangladesh - 12%  
 Nepal - 11%  
 Ethiopia - 6%.

Source: UNDP Human Development Report 2003

**No of Women with HIV/AIDS Between 15 to 49 years in 2001**

Sub-Saharan Africa - 15 million  
 South Asia - 1.5 million  
 Latin America & the Caribbean - 640,000  
 East Asia and Pacific - 600,000  
 Central and Eastern Europe & CIS - 270,000  
 Arab states - 260,000

Source: UNDP Human Development Report 2003

**2. Breastfeeding and Work**

The problem that women face at their work place with regard to breastfeeding is often extremely complex and not given to easy solutions. Across the world, the situations of women at work vary. In some countries, there are laws that provide maternity benefits; and women have adequate transportation to carry the baby to work or to a nearby crèche. Though given the facilities to breastfeed successfully, many of these

women have often chosen artificial feeding because they are both ignorant about the benefits of breastfeeding and have the capacity to provide safe, affordable artificial feeding. In many cases, these women have been the main targets of breastfeeding promotions and campaigns.

For the majority of the world's women, particularly women who work in low-paid, itinerant jobs like domestic work or vending on the streets, no affordable or convenient crèche facilities are available, and they have no option but to continue working in distressing circumstances because their income is crucial to their families.

According to a UN report, "In 1990, labour force participation rates were high for women in their 20s, rose through their 30s and 40s, and declined only after age 50. Increasingly women remain in the labour force during their child bearing and child rearing years." (World's Women, 2000). The report pointed out that while women's participation in work increased highly, their working conditions did not improve much. It is crucial to remember that the majority of the world's women work in the unorganised sector, as agricultural labour, as contract or seasonal workers, as domestic workers, as itinerant vendors on streets. For example, the report pointed out that women's participation in non-agricultural labour force in the informal sector during 1991-97 was 97% in Benin and Chad, 96% in Mali, 91% in India, 88% in Indonesia, 83% in Guinea, 82% in Kenya, 74% in Bolivia, 69% in El Salvador, and 67% in Brazil.

Besides, women have also to spend much more time in household chores than men. A particular mention must be made of women's burden of work. A UNDP study (2004) reported that in urban areas women work as much as 10 hours a day and in rural areas about 12 hours a day. The time they spent on non-market activities ranged from 60% to 69% while for men it ranged between only 21% and 31%. Women spent much of this time on household chores, which is mostly unappreciated and undervalued.

For women who work in the organised sector, often the problem is getting paid maternity leave. While over 120 countries have laws providing for some maternity leave (hardly any country gives paid leave for six months), going on long leave means that the job may be taken over by someone else. And now, under the dictates of globalisation, workers' protections are generally being dismantled to allow investors to hire cheap contract labour; in such situations, even the existence of strong maternity protection laws does not help the woman to successfully breastfeed, if the survival of her entire family is at stake. In the unorganised or informal sector, the situation is even worse. No government has yet found ways to translate existing maternity benefits in such ways as to make them accessible and meaningful to women working in this sector.

The problem of combining breastfeeding with working is further deepened by the fact that in an increasing

number of cases, the woman is the single earner in the family. In the organised sector particularly, women are the first to lose their jobs in case of retrenchment. Thus women are often forced into a situation where they have to choose between breastfeeding the baby and earning to keep the family alive.

### 3. Violence against Women

Women, across all ages, caste, race, and economic status, are victims of violence.

Besides the obvious violence, such as harassment, beatings and rape, women are also victims of hidden violence perpetuated by society – which has resulted in their low social and economic status, especially in terms of education, health and nutrition and income

In spite of the fact that women are often important income earners, they are not only given no help in house work, they are often also reprimanded for not doing it properly.

In many cultures, society places women at the bottom. Thus girl children are viewed as a burden and social conditioning as well as social pressure cause women to neglect themselves and their girl children. For example, in many parts of North India, girl babies are breastfed for shorter periods than boys, so that women can get pregnant again quickly in the hope that the next child would be a boy. Women have no say in any major decisions, including how many children to have and when, as well as what to feed them. Maternal and child health workers, often including those promoting breastfeeding, ignore this, and target women with their messages. Such targeting worsens the situation by causing the women to feel guilty and more helpless.

Yet another kind of violence against women occurs when companies producing breastmilk substitutes, aided by the health professionals and workers, try to convince mothers that their own milk is valueless or inferior to artificial milk.

Violence against women in any form, both overt and hidden, causes stress. Stress affects breastmilk production and secretion as the brain affects the hormones controlling these functions. The letdown reflex that prompts breastmilk flow is a very sensitive reflex and can be easily inhibited by psychological factors, and turned off by anxiety, tension and stress (Esterik and Menon, 1996).

### Women's Rights to Health

While children's right to "highest attainable standard of health" is the focus of advocacy by the breastfeeding movement, it must be remembered that women too have the right to good nutrition and health care on which depends the child's nutrition and health.

Women's rights to health are specifically enshrined in various international instruments, starting with the Universal Declaration on Human Rights of 1948. More recent UN instruments adopted specifically on women's rights to good health were at the 1979 Convention on the Elimination of all Forms of

Discrimination Against Women (CEDAW), the Fourth World Conference on Women, Beijing, 1995, and the International Conference on Population and Development (ICPD), Cairo, Egypt, 1994

The Convention on the Rights of the Child, 1989 also pointed out the need, "to ensure appropriate pre-natal healthcare for mothers". In addition, the International Labour Organization revised the Maternity Protection Convention (C103) of 1952 and adopted the Maternity Protection Convention 183 in 2000.

### Rationale for Gender Perspective

In view of these stark realities of women's lives, it is important that the breastfeeding movement develops a broader gender perspective instead of focusing narrowly and exclusively on breastfeeding and childcare. A gender perspective provides the basis for understanding the dynamics of why women do what they do. Though it may seem that they "choose" to do what they do, in reality, they are in a situation where they can exercise very little choice. Society-engendered gender roles and demands are the driving force behind women's apparent "free" choice.

Without this broader gender-based understanding that sees women and their lives in totality and in their real situations, healthcare and childcare approaches will be fragmented and have a very narrow focus, seeing women as mere child-bearers and nurturers, and will not bring about social transformation and social equity. If breastfeeding is to be a woman's reproductive health right<sup>3</sup>, then meeting her other rights that ensure her survival with dignity and health should be the first step. As a corollary, it is equally important to recognise that others in the family, particularly men, have duties and responsibilities to create the circumstances where a woman can adequately breastfeed.

Recognising men's duties and responsibilities becomes especially important in the context of the unequal relationships between men and women. Men should share equal responsibility not only in housework and childcare, but also in fertility control, in safe sex (particularly with rising rate of HIV/AIDS) and to treat women with the respect due to an equal partner. This means violence against women in all its forms must be recognised and addressed. It must be acknowledged that patriarchy is at the root of violence and discrimination against women – within the home, at the workplace, and by society (including corporate pushing of breastmilk substitutes). The solution to improving breastfeeding practices is thus to address the problems caused by patriarchy, by weaving gender justice into all aspects of breastfeeding promotion programmes.

<sup>3</sup> The gender workshop at the WABA Global Forum II, Arusha (September 2002) came up with a suggestion that breastfeeding be recognised as a women's reproductive health right in order to find common ground with women's groups. This suggestion needs to be taken further.

The broad framework for analysing the political, economic, social, cultural and gendered contexts at national and international levels must be based on:

- Level of women's nutritional status
- Level of women's health status
- Level of women's status in law
- Women's access to economic independence
- Women's access to independent political participation
- Women's power to take decisions
- Involvement of men in shared responsibilities and roles
- Focus on the right health and development messages
- Level of women's social status (irrespective of relationship to men).

### **Gender Strategies for Promoting Breastfeeding**

Recognising that such a gender perspective on social issues would help refine action strategies to bring about desired results for social change and equity, the World Alliance for Breastfeeding Action (WABA) which is a global network of individuals, organisations and networks in 120 countries, is tuning its programmes towards this end. In line with this view, WABA established a Gender Working Group in 2004 to promote gender awareness among breastfeeding advocates calling for gender sensitivity in all breastfeeding promotion activities.

Further, in December 2004, WABA organised a gender-training workshop for 32 participants from 15 countries. Following this, it conducted a Gender Strategy Planning Meeting for members of the Task Forces and Working Groups on Mother Support, Men's Involvement/Father Support, and Women and Work, HIV/AIDS, Health Care Practices/ Birthing Practices.

The meeting recognised the importance of protecting, promoting and supporting breastfeeding keeping in view both children's and women's health needs and a gender- and rights-based approach to breastfeeding promotion. The meeting also reaffirmed the Arusha statement (see box) as guiding principles for a gender-sensitive breastfeeding promotion.

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### **TOWARDS A COMMON ADVOCACY AGENDA**

Statement made at the Second WABA Global Forum in Arusha, Tanzania, 23-27 September 2002, by the workshop on *Outreach to Women's Groups*

Breastfeeding is a basic human right and it is agreed that the protection of women's right to breastfeed is a shared position of the women's movement and breastfeeding movement. Women can fully exercise this right only where there exists an appropriate social and political environment whereby women's contribution to productive and reproductive work, including nurturing, is recognised.

#### **Breastfeeding is a human right.**

Breastfeeding support means changes in all social environments and policies.

- Gender equity is basic to breast feeding movement
- Right to life and survival
- Right to choose free of commercial, medical and political pressure
- Right to food, irrespective of race, class, caste, religion, region, age.

#### **DEMANDS**

#### **Need for social transformation at all levels to bring about gender equality.**

Women's groups and breastfeeding groups have decided to put on their advocacy agenda the following demands:

- To recognise the common concern of the adverse effect of globalisation and privatisation on healthcare services and the increasing feminisation of poverty.
- Women's right to accessible, affordable, comprehensible, high quality and gender-sensitive women's health services.
- Women's right to breastfeeding based on informed choices, free of commercial, medical and political pressure.
- Social recognition and value of women's work at home as care givers and nurturers.
- Implementation of maternity protection for women at paid work in the formal and informal sectors.
- Women's right to food, adequate nutrition, rest, safe water and shelter.

*Book Review***“On the Take”: déjà vu in America***Anant Bhan<sup>1</sup>*

*On the Take: How America's Complicity with Big Business Can Endanger Your Health*, Jerome P. Kassirer, Oxford University Press, October 2004, ISBN 0-19-517684-7 0195176847, hardback, 272 pages, Price: \$28.00

Jerome P. Kassirer is respected worldwide as clinician, teacher, academic and researcher. He was the editor-in-chief of the *New England Journal of Medicine* (NEJM), one of the leading international medical journals. The publishers, the Massachusetts Medical Society, ousted him from the journal in 1999. The disagreements arose from the increasing use of the NEJM for promotion of commercial products and Kassirer's concerns that the fierce independence of the journal was being compromised by its increasing commercialization. Being no stranger to controversy, he deals with the extent and range of physicians' collaborations with the pharmaceutical industry in America, and its consequences. The book is based on the author's vast experience and interactions with physicians in the course of his varied roles.

***Thin Line***

In the introduction, the author speaks about the lure of money as a powerful motivator, and how, many physicians have become prey to the buzz of a marketplace that values profitable bottomlines, and promises enormous personal wealth. The author raises the importance of asking the question whether the commercialization of medicine and financial relations with drug companies has led to over-ordering of tests, and promotion of particular products and/or medications. The pharma industry-medical profession nexus does not stop merely at doctors acquiring trinkets bearing drug company logos and displaying drug company names in their chambers. It runs much deeper. The highly profitable pharma/medical device/biotechnology industrial complex offers largesse and allurements to doctors in the form of sponsoring their research, trips, meals, expenses of continuing education, etc. Realizing that profit margins hinge on marketing and physician prescriptions, drug

companies have infused money into physicians' pockets. Young physicians, often in debt when they begin their practices because of large student loans (a parallel in India would be large capitation fees in private medical colleges), are easy prey for pharma giants. Acceptance of lunches, dinners, and gifts from industry explains how once idealistic medical students and interns gradually become acculturated into accepting, and later even demanding, donations from industry. The author mentions that he is not opposed to the pharma industry, or to capitalism per se, that has been fuelling America's phenomenal economic growth as a superpower. Yet the same industry has also given rise to a dilemma: where does the line exist between advancing the cause of science and the betterment of patient care on the one hand, and the pecuniary interests of the physicians collaborating with industry to produce scientific advances on the other? Kassirer mentions that this debate has been sidetracked and only occasional articles appear mentioning it. Even serious issues like deaths of research subjects have short shelf lives. Pseudo-scientific studies continue to be performed and articles published. Many physicians have become marketing agents of companies. This could lead to burdening of the patients by requiring excessive and unnecessary visits to the doctor, being exposed to inappropriate and dangerous diagnostic tests, given wrong medications, forced to incur unnecessary expenditure on prescription drugs, and being refused valuable tests or treatments, even as they are exposed to potentially harmful effects in clinical research experiments. Patients need to know about conflicts of interest. Medicine is a social institution and depends on the public's trust for its viability. Patients must be able to trust that their doctors recommend treatments that benefit them, and that their doctors involve them in research projects for the right reasons.

***Ignoring Conflicts of Interest***

The first chapter deals with free gifts/meals/education, and special deals. Most physicians are hard working and dedicated, and sincerely believe that a few free meals would not cloud their professional judgments. However some of them go to the extreme of not only

<sup>1</sup> Centre for Study in Ethics and Rights, Mumbai, and University of Toronto Joint Centre for Bioethics, Canada; email: <anantbhan@gmail.com>

taking sponsored meals, gifts, and trips, but also join drug company advisory boards and speaker's bureaus, and give industry-sponsored clinical talks and write industry sponsored brochures. The author speaks about the dazzling stalls at medical conventions where "beautiful" people entice doctors with freebies. Doctors often cluster around stalls making it easy for their colleagues to spot where the freebies lie and often there is jostling for trinkets like pens, notebooks and T-shirts. The doctor ends up becoming a walking advertisement. Often gifts cannot be collected without parting information about the doctor's practice and answering a questionnaire about a drug or two, and not without hearing a sales pitch trying to ingrain a drug's superiority over its competitors. Doctors often receive in the mail (or through drug representatives) incentives to attend pharma-sponsored events. These might include concert tickets, paid-for dinners in fancy restaurants, gift certificates, etc. Kassirer quotes from his personal experience as well as that of others. Many professional organizations are deeply involved with the industry and receive payments to cover scientific meetings, professional education, and on-going operating expenses. There is often active solicitation of funding from industry for this purpose with the promise of being the conference main sponsor, banquet sponsor, etc. Many physicians are on the board of drug and biotech companies or serve on scientific committees that deal with various aspects of drug development. Some physicians even become engaged in the business aspects (including marketing) of companies. In recent years in America, some of the extraordinary subsidies that physicians take have been revealed and the complex conflicts of interest that these generate have been exposed. In 2001, the pharma industry spent two billion dollars in the US for meetings and events for physicians, a figure that represents a doubling over the previous five years. The American Medical Association (AMA) released guidelines that allow physicians to take gifts if they entail a benefit to patients and only if they are not of "substantial value" and meals if they are "modest" ones. So pens, notebooks and office items would be acceptable but not tickets to concerts, sport events or dinners with spouses. In mid-2002, even the Pharmaceutical Manufacturers Association (PhRMA) issued its own guidelines that are similar to those of the AMA. Implied in the PhRMA guidelines, is the intention to cut back on money spent on physicians, but given the importance of the idea of marketing to industry, this

looks a difficult act to follow.

Pharma drug representatives make friends with interns and residents when they are young, underappreciated, overworked and often debt-ridden. In this mindset, they are often susceptible to a narrow set of desires: more sleep, more encouragement, a few hours of relaxation, a little kindness, and free, accessible food. Instances of pseudo-consultations for drug companies by physicians are mentioned – the only consultations offered at the meetings organized in fancy resorts is which wine to order, and activities such as golf, skiing and white-water rafting.

Many clinician researchers are working with companies to develop new drugs and devices, and in this process often become part owners of patents and small companies. Some receive stock, or stock options, worth a lot of money. With the AMA mandating Continuing Medical Education Programs for physicians to get re-registered to make sure that they keep to date with medical trends, industry has stepped in. Meetings are held in exotic locales and physicians sign and get credit for attending, but do not actually attend any academic presentations/discussions and rather spend time playing golf, sightseeing, etc. When there is an academic input, it is by physicians on the company's pay roll who promote the company's products. Many medical journals now require authors of papers to disclose all their financial associations, and the journals often publish these associations. Kassirer gives examples where the conflicts of interest section is so long that it cannot be published in the print version of the journal and has to be made available on the journal website.

### *Modus Operandi*

Having established that financial conflicts of interest are rife in medicine, the author examines the industry's modus operandi of recruiting physicians to be members of company-sponsored speakers' panels. These lists are circulated to hospitals and physician groups across countries, which select speakers for their various educational programs. The sponsoring companies pay for the speakers' expenses and provide a substantial honorarium. Companies recruit physicians to discuss off label uses of medicine, thus bypassing official channels and thereby using a potent marketing force involving physicians. Pfizer was fined US \$ 430 million in May 2004 for this tactic for its drug Neurontin, doctors having been paid to speak about many uses not approved by the Food and Drugs Administration

(FDA). Other instances of doctors being used for marketing to colleagues have been described. The abominable practice of ghostwriting, essentially “advertising that calls itself education” has been described. Doctors have also sold free samples and risky dietary medications, as well as helped drug companies avoid lawsuits.

Devoting a whole chapter to Conflict of Interest and the bias it can lead to, Kassirer quotes examples from articles, practice and also institutional conduct. Often detecting the bias is difficult. The reactions from many physicians have been one of protest when attention is brought to their surreptitious and the-not-so-surreptitious wooing by big pharma. They believe that the occasional gifts and lunches cannot influence them.

However it is well known that we feel inclined to reciprocate even if a small gift is received. Psychologists believe that reciprocation is one of the most powerful instruments of influence in our society. The subtle influence of culture with acceptance of gifts, dinners, consulting arrangements, appointments to speaker’s panels, and other perks of industry among peers is also a driving force. The issue of complicity of journal editors given the dependence on pharma for advertisements in journals is raised. The free continuing medical education sessions are often partial, and so are books written on clinical practice guidelines and public pamphlets that promote off label use of drugs.

The involvement of professional organizations of cardiologists, pulmonologists, psychiatrists, pediatricians, etc., as well as the AMA, with pharma companies is documented extensively.

Engaging his readers who are members of the public, Kassirer asks them whether they can trust their doctor. Talking about the fee for service model and the self-referrals that are commonplace in America, he speaks about the implications for healthcare. Physicians often profit from the machines, gadgets, and implants used in the treatment of their patients. The author makes a plea for incentives to be based on quality of care and also for a disclosure of financial incentives in direct patient care. He then raises questions about the medical research system and the conflicts in it. Quoting many famous examples, he demonstrates how researchers have intimate ties with for profit companies that are often bankrolling the research, including often stakes and share holdings. With the shift of research from Ivy League medical schools to the community, clinical trials now involve general practitioners too who might be

paid several thousand dollars per patient enrolled. The oversight of clinical research needs to be revised to reflect some of the concerns. Using the penultimate chapter to trace the origins of the problem, Kassirer speaks about the influence of commerce on the practice of medicine, the rise of the academic physician, the runaway cost of care, changing financial incentives, inflated income expectations, and changes in patent law.

### *Transparency and Disclosure*

The final chapter is the author’s blueprint for change. He speaks about the need for adherence to the highest professional creeds and principles. He delves through the positive and negative implications of transparency through disclosure. Finally he opines that disclosure, even with the flaws, is better than no disclosure at all. He makes a case for professional organizations to have better policies, and for comparative conflict of interest guidelines that exist for lawyers, federal government employees, etc. Regulatory agencies need to overhaul their policies to be more effective. Kassirer argues for lesser ties with industry and for a higher standard for norms and values on which medicine is based. He appeals to the public to get involved in heralding the change. He ends by giving some positive examples and rounds up with a proposed roadmap. Kassirer ends his book stressing that the medical professions is under siege by big business and not enough was being done to rescue it.

*On the Take* is a landmark book. The issues raised in the book have been well known to physicians and people involved with research and the healthcare industry. However using his extensive experience to vividly illustrate the extent of pharma’s influence on the practice of medicine in the US, Kassirer does manage to reflect the urgency of paying attention to the issue. The context might be American, but the book will appeal to an international audience as the same issue plague healthcare in other countries too. It might be an opportune time for an Indian researcher or author to take up cudgels to unmask the situation in our country too. I have a feeling a similar, if not worse, unholy nexus of business and healthcare will be uncovered.

Conflict of Interest: The author of the review serves on the editorial committee of *mfc bulletin* and shares the distaste of Kassirer about the falling standards of the medical profession.

## About Bayer's Nazi-Past

IG Farben was the only German company in the Third Reich that ran its own concentration camp. At least 30,000 slave workers died in this camp; a lot more were deported to the gas chambers. It was no coincidence that IG Farben built their giant new plant in Auschwitz, since the workforce they used (altogether about 300,000 people) was practically for free. The Zyklon B gas, which killed millions of Jews, Gypsies and other people was produced by IG Farben's subsidiary company Degesch.

In Germany a growing number of people do not understand that IG Farben's successors Bayer, BASF and Hoechst still refuse to apologize for their misdeeds. It is hard to accept that after the war the companies were allowed to keep IG Farben's entire property, whereas the surviving slave workers received nothing. Until today Bayer, BASF and Hoechst did not pay any wages to their former workers.

In 1995 the coalition "Never again!" was created by the German Auschwitz Committee, critical shareholders and several organizations of former slave workers. In a joint appeal the coalition demands that there has to be an appropriate compensation by the companies for slave-workers and their descendants. Also the maintenance of the memorial at Auschwitz, which reminds the public of IG Farben's victims, should be paid by the corporations. "Never again!" states that without verification of the past we always have to be present so that these crimes might never happen again. More than 1,500 individuals and about 100 German groups have signed this platform. The activities were organized by the Coalition against Bayer-Dangers, a group that has monitored Bayer for 25 years.

### *Life as a Human Guinea Pig*

For years an Auschwitz survivor has tried to win compensation from the pharmaceutical giant that carried out medical experiments on her. Now living in Dundee, she tells her story in a BBC documentary.

Zoe Polanska Palmer never imagined she would survive Dr Mengele's experiments in Auschwitz. Nor did her German doctors. Like thousands of other children, she was destined to be gassed once her usefulness to Nazi science had ceased.

During her two years at the camp, 13-year-old Zoe was forced to take tablets and pills as part of a series of pharmacological experiments, believed to be part of early birth control tests. But Zoe refused to die. Saved by a Russian doctor who evacuated her to Dachau, she recovered and eventually settled in Scotland.

Now in her early 70s, she has been fighting for compensation and an apology from the German drug manufacturer, Bayer.

"I still find it difficult to take aspirin," she says. "I remember one of the SS doctors holding my jaw open and forcing pills down my throat. I'm still very wary of men wearing white coats."

Eyewitness testimonies held in the Auschwitz camp archive claim the doctor who force-fed her pills worked for the pharmaceutical company Bayer when it was part of the IG Farben conglomerate.

His name was Dr Victor Capesius. It's a name that Zoe can never forget.

He helped Dr Mengele to conduct genetic experiments, usually on children, and also selected thousands of prisoners at the huge death camp, choosing those who might be useful and sending the rest to an immediate death with a flick of his finger.

Dr Capesius was tried in Frankfurt for war crimes in 1963 and served time in prison.

Another longtime Bayer employee, Helmut Vetter, also worked as a SS doctor at Auschwitz. He was involved in the testing of experimental vaccines and medicines on inmates and after the war he was executed for administering fatal injections.

### *Denial of Culpability*

"The concentration camps were used as a huge laboratory for human experimentation," says Wolfgang Eckhart, the Professor of Historical Medicine at Heidelberg University. "We have to look upon the camps as outposts of pharmacological research. The Nazis wanted to sterilise the population of the east, especially Russian people, but enable them to continue to be useful as workers."

### *Pain has yet to Heal*

Bayer says the company which exists today has nothing to do with its wartime counterpart.

A spokesperson told the BBC: "Between 1925 and 1952, no company named Bayer existed, neither as a subsidiary of IG Farben nor as any other legal entity.

"Bayer has worked in good faith with the German government to establish a fund to help those who have suffered. The company's contribution to this fund amounted to more than £40m."

***Damaged beyond Repair***

Although it is nearly 60 years since the end of World War II, for survivors like Zoe the consequences of the war are as alive today as they were in January 1945 when the Russian Army liberated Auschwitz.

After the war, Zoe married and settled in Scotland. There she underwent several painful operations to repair the damage done to her body. But she has never been able to have children.

Now suffering from cancer, she is a remarkably cheerful woman whose home in a quiet suburb is punctuated with laughter from her jokes and tears from her memories.

When I first travelled to meet her in July 2002, she was angry that she had been ignored for so long by the authorities managing the compensation fund set up by German industry and the German government.

She had campaigned for 28 years but received nothing.

"They want us all to die so they won't have to pay out so much money," Zoe says.

Within weeks of the authorities being contacted by the BBC, Zoe received a cheque for a little over £2,000 from the German compensation fund.

"I want to make sure people remember what happened to people like me when I was a child at Auschwitz," she says. "I was just one of thousands of children treated in this way. But I was one of the very few lucky ones who managed to survive." (By Mark Handscomb, BBC Radio 4 reporter for It's My Story )

***Bayer "Aryanized" Jewish Cemetery***

Documents show that in 1942, IG Farben's branch office in Uerdingen, Germany, got hold of the town's Jewish cemetery. The forced sale price was way below the actual market value: 100,000 square meter property for 3,000 Reichsmark. After the war the property was passed on to IG Farben's successor Bayer AG.

The Nazis dissolved the Jewish Community of Uerdingen in 1942. Today all traces of the Jewish cemetery in Uerdingen have been completely obliterated. The city archive indicates that the cemetery was located approximately where the main gate to the Bayer factory currently stands.

The Coalition Against Bayer-Dangers demands that the company publicly apologize for the defilement of the Uerdingen cemetery and affix a memorial plaque to the main gate of the company's Uerdingen works. Hans Frankenthal, former slave worker in IG Farben's plant in Auschwitz and board member of the Jewish Community: "I was terrified when I learned from this

offence against Jewish belief. According to our faith, taking possession of the cemetery without exhuming the bodies is tantamount to defiling the graves."

Bayer today is living off the fruits of Nazi legalism. On paper everything was legally correct: Julius Israel Kohn from the "Association of Jews in the German Reich" and Bernhard Hoffmann, the representative of IG Farben, signed the sales agreement in a notary's office, and the copy of this seemingly standard real estate transaction has a stamp from the Krefeld tax office.

At the same time the former culprits are publicly honored in Uerdingen. Fritz ter Meer served on the IG Farben board of directors from 1926 to 1945 and was the head officer directing the operations of the IG Farben factory at Auschwitz. The Nuremberg War Crimes Tribunal sentenced him to seven years in prison. He was released after serving only four years. Not long after, in 1956, Ter Meer was elevated to the chairman of the supervisory board at Bayer, a position he held for seven years. His grave in Krefeld has a meter-high wreath on it - donated by Bayer in recognition of his services.

Coalition Against Bayer-Dangers (Germany)

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Views and opinions expressed in the bulletin are those of the authors and not necessarily of the MFC. Manuscripts may be sent by email or by post to the Editor at the Editorial Office address.

#### Subscription Rates

	Rs. Indv.	Inst.	U.S\$ Asia	Rest of world
Annual	100	200	10	15
Life	1000	2000	100	200

*The Medico Friend Circle bulletin is the official publication of the MFC. Both the organisation and the Bulletin are funded solely through membership/ subscription fees and individual donations. Cheques/ money orders/DDs payable at Pune, to be sent in favour of Medico Friend Circle, addressed to Manisha Gupte, 11 Archana Apartments, 163 Solapur Road, Hadapsar, Pune - 411028. (Please add Rs. 15/- for outstation cheques). email: masum@vsnl.com*

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#### MEDICO FRIEND CIRCLE BULLETIN PRINTED MATTER - PERIODICAL

**Registration Number: R.N. 27565/76**

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1st Floor, Premananda Sahitya Bhavan  
Dandia Bazar, Vadodara 390 001

