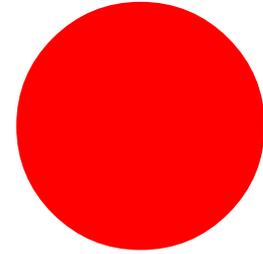


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Social Determinants of Women's Mental Health: *A Narrative from Gujarat*

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Introduction

Social determinants of health are the economic and social conditions under which people live which determine their health. Virtually all major diseases are primarily determined by specific exposures to these conditions. The field of social determinants is concerned with key aspects of people's living and working circumstances and with their lifestyles. Social determinants of health have been recognized by several health organizations to greatly influence collective and personal well-being.

Mental health concerns are usually considered as an individual problem and are not directly related to social issues. But there is a strong inverse relationship between social position and physical and mental health outcomes. Studies have shown that adverse health outcomes are two to two and a half times higher amongst people in the most disadvantaged social position when compared to those in better social positions. Women are at a disadvantaged social and economic position thereby making them more vulnerable to mental ill health (WHO, 2000).

There are many important factors that determine the health and mental health of individuals and population groups. The greatest share of health problems is attributable to broad social conditions.

This paper particularly analyses the social determinants of women's mental health.

Women and Mental Health

Socio-economic factors, cultural factors and women's social position in society affect their physical, mental and emotional well-being. According to the WHO, "women experience almost double the incidence of depression and anxiety than men." Theories on depression point very strongly to the overwhelming significance of life events especially those involving loss, humiliation, entrapment and a sense of lack of control and inferiority. Women's social status, poverty and subordinate gender roles place them at higher risk of sadness, loss of confidence and self-esteem, and less energy (WHO, 2000)."

Factors like socio-economic resources, family cohesion and perceived social support from family members and exposure to social stress are found to make significant independent contributions to the prediction of depressive symptoms (Barrett & Turner, 2005: 157).

Five separate studies were conducted in four low and middle-income countries (India, UK, Chile, Brazil and Zimbabwe) in different stages of economic development. It was found that women's mental health could not be considered in isolation from social, political and economic issues.

There are sufficient causes in current social arrangements to account for depression and anxiety experienced by women. There is a clear association between age, low income and education with common mental disorders. Low education is a potentially preventable risk factor. There is a high school-dropout rate, which arises due to the need to earn money early in life. Low-income groups are more vulnerable to suffer common mental disorders irrespective of the overall state of development of the society they live in. Older age is consistently associated with Common Mental Disorders (Patel et al, 1999).

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According to Ballantyne (1999), women's and men's experiences of health and illness are influenced by their access to economic resources and social integration. Economic status and social integration are widely recognized as social determinants of health because health, morbidity and mortality are stratified along these dimensions and it is these factors that contextualize health and illness. Morbidity and mortality rates are different for men and women and morbidities have different effects on men and women. Socioeconomic status and social integration are intricately linked for women and this interaction may help to explain gender differences in health status, morbidity and mortality. The relationship between health, socioeconomic status and social integration are complicated by the introduction of gender. But it is also true that if gender is examined as a mediating factor then a better understanding of the processes and effects of variation with respect to these determinants may be achieved.

Disaggregating the effects of gender on socio-economic status and health and social integration and health relationships is complicated because men and women appear to experience their lives in identical contexts, yet it is gender as an ideological and institutional structure that determines how men's and women's experiences in similar contexts are differentiated.

It is vital that women's mental health be examined within a social model, which encompasses the physical and mental health effects of stressors and events that are experienced by women. Due to the stereotypic gender roles assigned to women in the society, when a "socially incompetent" woman does not fit in, she is declared a "mentally ill" woman. There is evidence that depression in many women is a predictable response to events and difficulties in their lives that evoke a sense of humiliation, entrapment and lack of control over life. This can be due to socio-structural factors like inequality, patriarchal biases, experience of violence, burden of work, housework and reproduction including complete responsibility of the family, to name a few.

According to Vibhuti Patel (Patel, 2004), "psychosocial stressors originate from the external social environment such as women's inferior social position, lack of power, homelessness, economic hardships, man-made or natural disasters. They create learned helplessness (women's seeming passivity in the midst of crisis such as domestic violence, accidents, etc) and reduce motivation to lead an active life. Stressful events like illness in the family, death of one's spouse, divorce, accident that might reduce or destroy women's ability

to shoulder responsibility and lead to mental health. After marriage, women get displaced which brings about cultural loss and bereavement, loss of social networks and supports, and loss of traditional healing sites.

Violence against women affects women's rights as human beings. Unfortunately, scientific interest and research in the problem of violence against women and its links to poor mental health, has been of recent interest only, probably due to lack of understanding and awareness in this field.

Currently, the needs assessment of women's mental health, required for her effective health promotion, remains hampered by factors like – inadequate sources of data, an overly biological and individual focus in research, and theoretical models that neglect women's low social and economic status, within the family and society. These are important factors in determining women's mental health outcomes. The omission of these social factors from studies of women's 'vulnerability' to mental health problems, results in selection bias that prevents the possibility of examining how gender inequalities might determine women's emotional well-being. Hence it becomes important to document women's own voices and concerns about the health services they receive, its quality of care and the social determinants in mental health.

Methodology and Participants

In this paper we analyse the social determinants of women's mental health based on a study that examined women's perceptions and experiences of mental health services in the State of Gujarat with reference to the domains of quality of care, pathways of health-seeking behavior, social determinants and coping mechanisms. Within these broad domains the study addressed the client-provider relationship, infrastructure and facilities, technical competence of staff, medications, mechanisms for follow-up and continuity, cost of care, alternate therapies, sources of health services, role of family members and society, change in family life and status, coping strategies adopted by women and support systems available to women.

The sample comprised 30 women across different socio-economic backgrounds. Women were selected based on the following criteria:

- 1 Women who were either recovering or had already recovered from mental illness.
- 2 Women above the age of 18 years.
- 3 Women currently visiting a health centre for follow-up or ex-patients.

- 4 Women willing to be interviewed.
- 5 Women, who understood, responded and gave answers to the research questions.

The sites of the study included public hospitals and hospitals for mental health in Vadodara and Ahmedabad, private practitioners in Vadodara and the village of Devgadhi Baria in Panchmahals District of Gujarat. The tool was first developed based on relevant literature and some qualitative tools used in the European context specifically the quality of care framework (Bruce, 1990). An interview questionnaire was designed first, which was later transformed into a topic guideline.

Permission was sought from the hospitals. In-depth interviews consisting of one or two sessions with each woman were used to collect data. Permission of each woman was sought for the interview with assurance of confidentiality of name and other details. At any time during the interview she was free to leave, stop or choose not to answer a question. All the interviews were taped and fully transcribed in Gujarati and then translated into English to the closest meaning possible for the local phrases, connotations and slang. Wherever the exact closest meaning was not found, the original verbatim was retained. The interviews were then written up as stories and further results were organized thematically.

The analysis sought to understand what had worked, for whom and in what circumstances by mapping the mechanisms and looking for the common themes. Themes emerging from the data were categorized, classified and compared across categories. To enhance reliability, three members of the study team coded interviews independently. The study team then met to ensure agreement on the interpretation of the findings.

Findings

Profile of Women

Out of 30 women, 15 were inpatients and 15 were outpatients. The ages of the women ranged from 21 to 75 years. Five women were illiterate, whereas others were literate. With reference to marital status 15 women were married, five were unmarried, four were divorced, one was separated and one was a widow; 15 women who were inpatients worked in the occupational therapy unit in the hospital; of the outpatients, six were employed and nine were unemployed and managed their homes. Religion-wise, 26 women were Hindus and four were Muslims. In terms of family structures, 17 women were from joint families and 13 belonged to nuclear families [Table 1]

For this paper six case studies that best illustrate social determinants of women's mental health are selected to derive and discuss specific social determinants. Implications for mental health education, mental health services and policy is also discussed.

Contextual Analysis: Women in Gujarat

Gujarat is a State of disparities. It is recognized for its rapid industrialization, growing foreign investment and other economic development indicators. The National Family Health Survey (NFHS 3) points out that Gujarat is wealthier than the nation as a whole – almost one-third of Gujarat's households are in the highest wealth quintile compared to the one-fifth of households in India. Despite this, the coverage of health services for the vulnerable groups has actually gone down (institutional deliveries among SC/ST population from 62.3 percent in 2005 to 55.3 in 2006, women receiving post-natal care from 55.1 percent among SC/STs in 2005 to 23.6 percent in 2006).

Gujarat has a tribal population higher than the national average (14.8 percent against India's average of 8.2 percent). Socially marginalized groups constitute large proportion of the total population such as Scheduled Castes (7.2 percent, Scheduled Tribes (14.8 percent), Muslims (12 percent). Gujarat also has a large proportion of Below Poverty Line (24 percent) and urban poor (urban population is 37.36 percent compared to India's average of 27.8 percent). The coastline of the state is about 1600 kms, one-third of India's coastline, and almost 10 percent live in 36 coastal talukas. The desert and border areas are geographically hostile terrain having sparse and scattered population at the periphery.

With its rapid industrialization and port development program, Gujarat attracts large numbers of migrant labor both in the organized and unorganized sectors, working under hazardous conditions – an example is the stone crushing units in Godhra which cause high interstate mortality due to silicosis.

At the social level, patriarchal norms in Gujarat remain firmly in place. Women are considered valueless and expendable by men and often by women themselves. There is a sharp decline in the sex ratio in Gujarat and the growing number of illegal sex-determination and sex selective abortions have alarmed the policy makers. The son preference in most traditional families of Gujarat creates pressure on a woman who is unable to produce a male child; she is stigmatized and ridiculed in the society.

The Government of Gujarat has acknowledged the importance of improvement in the Mental Health sector

for the following reasons, (GOG, 2003):

- 1 The prevalence of mental disorders is high.
- 2 People suffering from mental problems are in a vulnerable position to demand for services.
- 3 There are serious capacity gaps for implementing services.
- 4 There are few advocacy groups for mental health if at all.
- 5 Stigma is high, also within the mental health services.
- 6 There is a strong relationship between mental health and poverty.

It is within this context that the stories of the women whom we interviewed have to be located.

Stories of Women

Maya

I am a widow. I am fifty-five. I got married when I was fourteen. I do not know what childhood is. My husband was elder to me by six years. The only thing I did after my marriage was to cry. Gradually I was not allowed to visit my parents. My husband was suspicious. He tortured me a lot. Even if I greeted a man in the neighborhood he beat me up thinking I am having an affair with him. He used to hit me hard in the presence of all the family members and nobody dared to tell him anything or ask him anything. I suffered silently because I had no other option. I never thought of leaving his home and running away. It was very painful. Then one day he died. I was relieved. After his death I was busy bringing up my children and doing housework. After many years my two sons and a daughter got married. My youngest son owns a *pan* shop. My eldest son runs a tea stall and one of my sons is an auto rickshaw driver. I started experiencing some problem and so I consulted a private practitioner. My illness got cured. But due to this illness my children started neglecting me. A few days before both my daughters-in-law started fighting with me. Because of that my sons also ignore me. They do not even ask me how I am feeling. I am financially dependent on my sons for my medicines. My youngest son and eldest son give me money for medicines whenever they feel like. The third one is not bothered and keeps quarreling with me. Initially all of them together decided to give me ten rupees each. But my eldest son stopped it saying he brings medicines so he will not give money. Because of this the other one also stopped. Now only my youngest one gives me money. I am still waiting for my sons to give me money. I have the prescription to buy medicines but no money. I am still waiting for my son. If he gives me money

I will buy medicines. If he does not give me money the paper (prescription) will remain as it is.

I am not educated and so I do not get work. I am feeling very lonely. I badly need some work so I can get some money for myself. I am tired of my life. I cannot stand the faces of people at home.

Rekha

I am twenty-five years old and unmarried. I live in a joint family. I am a graduate and I have an agency for cosmetics distribution. Two of my brothers are married and one is still studying. My mother heads a marriage bureau and my father has a grocery store in the village. When my brother got married I was in my second year of graduation. My sister-in-law used to misbehave with me. She wanted me to discontinue my studies and do all the housework. She used to restrict all my activities and my father supported her. I was very tense and my limbs started to tremble. I stopped talking to my friends and opted to stay at home most of the time. My brother and his wife kept fighting about petty things all the time. One day they had a big fight and his wife committed suicide. I was very depressed after her death. Even if she did not treat me well, I was lonely after her death. It was difficult for me to concentrate on my studies. I attempted to die twice.

My father was an alcoholic and he never took interest in family matters. My mother is suffering from mental illness because of my father's attitude. It is me who takes care of my mother. I am worried for my brother because he is all alone after his wife died. My family members keep telling me to get married but I am afraid to get married. My illness will create problems in my marriage. I always thought of committing suicide. I realized that something is wrong with me. So I went to see the doctor by myself. I had to leave my job because of my illness. I took treatment for a long time and then again started looking for a job. I could not find one so I distribute cosmetics to make a living. I had to change the doctor in the middle of my treatment as he got transferred to some other place. Another doctor gave me some medicines, which did not suit me. I told him but he never listened to me and continued with the medicines.

Now I have changed the doctor and I feel his treatment is helpful. I feel stronger and happier.

Veena

I am twenty-four years old and I do sweeping work in the occupational therapy unit. My life is bad but it was best before I got married. I worked in the diamond-cutting factory and earned six rupees per

diamond. I lived in a nuclear family with my parents and siblings and got married when I was eighteen. My husband always kept fighting with me. I was disturbed because of this. I always ran away from home and then came back when I liked. I felt like committing suicide. So my mother-in-law took me to a private doctor. I was hospitalized there and he gave me medicines and electric shock. But my condition did not improve. I started feeling giddy and clumsy. I did not take bath for ten days and sat in a corner alone. They took me home after ten days. After I came home my husband asked for a divorce. My in-laws left me to suffer at my parents' place. I was heartbroken. I was sure that my parents will be on my side but I was mistaken. This was not the end. My mother refused to keep me with her. My uncle took me to his home. I was so upset that my condition worsened in just three days. My uncle called my father. My father again took me to a private doctor. My condition got still worse. My parents were tired of me so they dumped me in the hospital. After I was admitted in the hospital I stopped menstruating. It seems I was operated for that. I cannot do any work. My illness has ruined my life. I know that my husband left me because I could not work for him. In all these years nobody has cared for me. My mother died and my father got married to some other woman. Nobody likes me and no one comes to visit me. I am all alone. Everyone is frustrated with me.

Sangeeta

I was born in Ahmedabad in a lower class family. I never went to school after the fifth grade. My parents got me married to an agricultural laborer who was illiterate. Getting married to him brought complete change to my life and way of living. It was a change; not for good. I gave birth to a dead child. I had to perform all the household chores by myself without any help from anyone. I worked for long hours in the field assisting my husband. Above all this I had to independently look after my three children; two sons and a daughter. All my children were nearly of the same age and had similar needs.

My husband was a very suspicious man. The only thing that he thought all day was that I was having an affair with other men in our locality. He always used to tell me that, I have another husband and that is why I do not listen to him.

I was tired of all this. I frequently got tense over petty issues and gradually lost interest in life. I told my father-in-law my problem but it was in vain. He gave a deaf ear to my problems. Then one day I tried to commit suicide. My daughter went and informed my

mother-in-law and she saved me. Slowly, my condition started to get from bad to worse. My in-laws took me to a traditional healer. We spent lot of money and I visited the traditional healer for many months but there were no signs of improvement. My husband never took interest in my illness as well as my treatment. He was so tired of me that he left me to suffer with my parents. My parents thought that I am mentally ill and they took me to the hospital for mental health in Ahmedabad. I was admitted in the hospital. My condition has improved but I miss my children. They still live with my husband and in-laws. I did so much for my in-laws but eventually they have left me here to suffer alone. When I was healthy and able to work, people liked me. Now, when I am sick nobody cares for me. Whom should I live for? I want to die.

Whenever I think of my husband and in-laws, I feel very angry and regret all what happened. But I miss my husband and children a lot. My children are not living with me. My husband questions my character. There is no reason to live.

Jaya

I got married when I was seventeen years old. We were very poor but my husband was a very nice person. My mother-in-law used to always nag my husband. My husband could not tolerate this and so he committed suicide. I had to go back to my parents. My in-laws refused to give me the custody of my son. My parents got me married again. For a few days everything seemed okay. My husband was good with me. Gradually everything changed and everyone started behaving rudely with me. I gave birth to two sons. But unfortunately my younger son died due to sickness. I was shattered due to this.

Once during Diwali I was visiting my parents because I wanted to be with them for the festival. Suddenly I felt giddy and I was unconscious. My parents took me to Ahmedabad civil hospital. I was hospitalized for a week. My parents were sure that I was affected by somebody's black magic spell. They took me to see the traditional healer. He tried to cure me but nothing happened. My condition did not improve for ten long years. When my husband knew about my mental illness, he told me not to come back till I was cured. I was not allowed to meet my son. My parents work as laborers. My father works in a paper factory and my mother sells clothes on the pavement. My family is very poor, yet they took me to a private medical practitioner. The treatment eventually got expensive and we had to then go to the Ahmedabad hospital for mental health. I was admitted in the female ward for one month.

They gave me electric shocks. I disliked it. Many times the nurse forgot to give medicines to the patients. If she remembered to give medicines, she forgot to give water. Nobody cared for us during mealtimes, whether we were given proper food or not. After I was discharged I continued treatment as an outpatient. Recently my health worsened and I was admitted in the family ward. My mother is staying with me. My mother is losing her wages and lot of money is being spent for my medicines. My father is growing old day by day. I miss my children a lot. My in-laws and my husband have never come to visit me. I know everything but I am helpless. I am illiterate but I am looking out for a job so that I can take care of myself. I have learnt tailoring from the occupational therapy unit. I miss my husband a lot. He was nice to me. I know and hope that one day he will come for me!

Fatima

I am forty years old and I live in a joint family, with my husband, children and grand children. I am extremely worried about my daughter's marriage. We are very poor. My husband and sons do not make enough living. Fifteen years ago, my husband turned into an alcoholic, he did not care about my children and me. At that time I kept thinking about our future. I wanted to commit suicide and get rid of all the tensions but I could not as where would my children go? This went on for five long years. Eventually my husband stopped drinking alcohol and started working. His income was not enough to support our big family. I had no choice but to work as a sweeper. Then I underwent an abortion. After abortion I would feel giddy all day. I experienced severe headaches and could not sleep. I consulted a doctor at the civil hospital. He said I have mental illness. I am not sure what kind of mental illness I have. We misplaced my case papers so my treatment was discontinued. My condition worsened six months ago and so I had to go about reopening my case papers at the hospital. I am fortunate that all my family members are very supportive. My son always insists on taking treatment from a private practitioner. He says doesn't matter if the treatment is expensive, at least I will recover soon. Yesterday I had a headache and they all really took good care of me.

My husband has stopped drinking. But I am still tense about the financial difficulties of our family and the marriage of my daughter.

Poverty, Financial Anxieties and Related Factors

The case studies reveal a number of social determinants of mental illness like:

- 1 Poverty, financial insecurities and anxieties, unemployment,

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- 2 Unstable family relations, violence, relatives experiencing burden etc.
- 3 Lack of family support, widowhood, loneliness, desertion and abandonment,
- 4 Gender and cultural beliefs and practices

For discussions related to mental and behavioral disorders, poverty can be understood as the state of having insufficient means, which may include the lack of social or educational resources. Poverty, lack of material resources, precarious livelihood options are the themes that are present in a number of women's stories.

Maya, an uneducated 55-year-old widow is dependent on her sons for her treatment. Sangeeta from a lower social class and extremely vulnerable economic class – her husband is an agricultural laborer has only five years of schooling. Jaya is also poor and illiterate and concerned that her mother is losing her daily wages to look after her daughter in the mental hospital. Jaya is also desperate that she finds a job so that she can pay for her medicines and treatment. Fatima is extremely anxious about her daughter's marriage and the implicated expenses.

Poverty and associated conditions such as unemployment, low education, deprivation and homelessness, affect women even in a relatively better off state like Gujarat.

Unstable Family Relations

'Fighting Husbands'

All the stories reflect that their families were unstable and many key relationships were problematic. The stories highlight that 'fighting husbands' was a key determinant of psychological and emotional disturbance for women. Maya, Veena and Sangeeta mentioned husbands fighting or being suspicious. Maya's husband was violent, torturing her, hitting her in public with no one around willing to stand up for her. Her husband was also suspicious, according to her. Veena says, "My husband always kept fighting with me. I was disturbed because of this." Sangeeta's husband was so suspicious that "The only thing that he thought all day was that I was having an affair with other men in our locality. He always used to tell me that, I have another husband and that is why I do not listen to him." Jaya is the only woman in all our stories who thought that both her husbands were good men and nice to her!

Other Key Relationships

Rekha was affected by the troublesome relationship between her brother and sister-in-law and her sister-

in-law's death due to suicide. Jaya was affected by her husband's suicide, which she attributes to his mother's nagging. Jaya was also affected by the fact that she did not get custody of her son after separation from her husband.

Marriage

Maya, Rekha, Veena and Sangeeta have mentioned marriage as a significant adverse event in their lives. Maya mentions that she got married when she was fourteen. *"I did not know what childhood is. My husband was elder to me by six years. The only thing I did after marriage was to cry."*

Veena says, *"My life is bad but it was best before I got married."* Before marriage, working as a diamond cutter and earning her Rs. 6 per diamond she seems to have been happier than after marriage being landed with a husband who fought with her.

Sangeeta says, *"Getting married to him brought complete change to my life and way of living. It was a change; not for good."*

Rekha's trauma came not from her own marriage but the marriage of her brother. *"When my brother got married I was in my second year of graduation. My sister-in-law used to misbehave with me. She wanted me to discontinue my studies and do all the housework. She used to restrict all my activities and my father supported her. I was very tense."*

The theme of Rekha's story, in fact, is an unstable family ecology. Her sister-in-law was oppressive towards her, her brother and sister-in-law had a troubled relationship, her sister-in-law committed suicide, her father was an alcoholic, and her mother had mental illness.

Lack of Family Support

Lack of family support is a major issue reflected through the stories of many women interviewed for the study. The experience of feeling alone and neglected is common and appears to be on a continuum. The long span of illness results in a decline in the family members' interest and caring. Husbands, parents, sons who used to visit regularly earlier, discontinue as the years pass, leaving the inmates waiting and watching. Many women felt that their status in the family decreased after their mental illness as they could not carry out the work they were supposed to do. The loss of utility value resulted in the loss of status within the family. As a result of this many women felt a lack of family support and care from family members and relatives. Those admitted in the hospital felt abandoned.

Maya felt neglected by her sons. *"Both my daughters-in-laws started fighting with me. Because of that now my sons also ignore me. They do not even ask me how I am feeling. ...I am feeling very lonely ...I am tired of my life."*

The theme of Veena's story is one of abandonment and loneliness. After her illness was diagnosed and her treatment began, her husband asked for a divorce, then her in-laws left her at her to suffer at her parents' place, Her mother refused to keep her and her uncle was persuaded to take her to his home. Then her uncle called her father and finally, *"My condition got worse. My parents were tired of me so they dumped me in the hospital."*

Jaya says, *"When my husband knew about my mental illness, he told me not to come back till I was cured. I was not allowed to meet my son."* Jaya's story also highlights how health care providers contribute to the patients' feelings of being neglected and abandoned. *"Many times the nurse forgot to give medicines to the patients. If she remembered to give medicines, she forgot to give water. Nobody cares for us during mealtime whether we are having proper food or not."*

Sangeeta felt that she had no one to listen to her when she first started feeling tense and upset because of overwork and listening to her husband's suspicion-ridden diatribes. *"I was tired of all this. I frequently got tensed over petty issues and gradually lost interest in life. I told my problem to my father-in-law but it was in vain. He gave a deaf ear to my problems. Then one day I tried to commit suicide."* Later, when her illness was confirmed, she says, *"My husband never took interest in my illness as well as my treatment. He was so tired of me that he left me to suffer with my parents."* She feels, *"When I was healthy and able to work, people liked me. Now, when I am sick nobody cares for me. Whom should I live for? I want to die."*

Rekha after her illness left her job, stopped meeting her friends and all this contributed to her sense of isolation. And now although she might want to get married, she is afraid. However, hers is the only story that has some positive dimensions. Rekha continues to work, take decisions about her treatment and her doctor and is feeling stronger and happier.

Gender and Cultural Beliefs and Practices

Several gender factors are seen in these stories. Maya's early marriage with virtually no childhood did not provide her an opportunity for emotional development to cope with a suspicious husband. Her mobility was severely curtailed. By not being allowed to visit her natal home, she could not avail of her support systems

and networks. The option of walking out of an unpleasant and abusive marriage never existed for her because she was uneducated. And now, at the age of 55 she is completely dependent on her sons even for her medical treatment.

Rekha was the care giver in her family, looking after the mentally ill mother and her brother after his wife's suicide – "*I am worried for my brother because he is all alone after his wife died*" – regardless of her own state of being single! The gender power relations between her sister in law and Rekha led to a tremendous mental tension for Rekha.

Veena's story again reflects a whole host of issues, early marriage, and an unpleasant relationship with the husband, being abandoned by the closest relatives once she was ill, her feeling that her worth was only because of her labor, "*My husband left me because I could not work for him.*"

Sangeeta's life story also revolves around gender roles and the sexual division of labor. She gave birth to a dead child soon after her marriage, thereby not living up to the societal prescription of all women as mothers.

With regard to construction of masculinities, we see that at least two of the significant men in the lives of our selected women subjects – Rekha's father and Fatima's husband – were victims of alcoholism at some stages in their lives. We also see that men are 'suspicious', jealous and accuse their wives of having affairs with other men. This tendency towards suspicion has been found by researchers studying violence against women and masculinities (Personal communication Audrey Fernandes, Nandita Kapadia Kundu).

Discussion

Rapidly changing economic and social contexts in fact contribute to conditions that exacerbate women's mental ill-health. Vindhya et al (2001) point out that increased migration which contributes to growth in the cities also leads to problems like unemployment, underemployment, pressure on civic facilities, congestion, pollution and so on which can affect people's well being. This study draws attention to the fact that even in economically and industrially developed states like Gujarat, prevalence of mental illness amongst women is high. This mental illness has its roots in factors like poverty, social institutions like marriage and family and gender and power relations.

As mentioned in the introductory section of this paper, several researchers have highlighted the interplay between socio-economic status of women and their

mental health (Vindhya et al 2001, Patel 2003). Our case stories show that poor financial condition, lack of control over resources and lack of decision making power appear to have aggravated the poor mental health conditions of women. There is also evidence, as in the case of Maya, that the *course* of mental and behavioral disorders and treatment seeking is determined by the socioeconomic status of the individual. This may be the result of an overall lack of mental health services together with the barriers faced by certain socioeconomic groups in accessing care.

Post-marriage Roles of Women

Women have primary responsibility for households and families, which creates a situation of economic inequality for women relative to men, inequality which is experienced at individual, family and societal level. They frequently face the pressure of dual roles, as they are increasingly required to be employed to keep their families out of poverty. Women's dual roles adversely affect their health through overload and stress.

In paid employment, women face obstacles that are distinct from those faced by men. They are confronted with differential opportunity structures and more often than not get lower wages compared to men. Powerlessness, dependence, lack of control over decision making or environmental constraints on decision making are usually associated with low status jobs in which women tend to be employed. Given that opportunities for women in labor market are constrained, their material conditions of life thus often depend upon their success in marriage.

These stories reinforce what has been written by other researchers on the role of marriage and women's mental ill-health. Marriage poses tremendous contradictions for women. Culturally marriage is the site of love, support, identify and interdependency whereas socially marriage is the site where gendered roles and their consequences are played out and experienced as was evident in the stories of Maya, Veena, Sangeeta, Jaya. Marital relationship is paradoxical for many women. Marriage may improve economic opportunities, while diminish control over paid and unpaid work – potentially increasing as well as compromising the health status of women. While women may receive health benefits based on social ties to others, when they are economically dependent on their spouse, their obligations and responsibilities to the marriage may effectively limit opportunities for interaction and the development of alternative social attachments as we saw in the stories of Maya, Veena, Sangeeta, Jaya and Fatima.

Marriage and family relations have differential benefits and costs for men and women. The cost of marriage to women are related to differentiated gender roles that put women in a disadvantaged social and economic position relative to their spouses and to women who do not marry. Much of the married women's life work is invisible and conducted in the relative isolation of the home. Sethi and Manchandaa (1980) point out that marriage in India happens at an early age when maturity and responsibility has not been incorporated in the overall personality. The woman has to perform the multiple roles of wife, a mother and also manager of the house. The burdens of responsibility produce work overload anxiety and frustration as well as mental ill health.

Family

In India, family is the single most important source of mental healthcare. Families are changing. The most important changes are (i) growing urbanization of India; (ii) breaking down of the traditional joint and extended families; (iii) increasing numbers of nuclear families; (iv) single parent families; (v) families with working parents; (vi) families in distress due to economic deprivation, social marginalization, alcohol dependence, chronic illnesses; (vii) growing numbers of elderly persons and families of mentally ill with elderly caregivers; (viii) increasing influence of mass media in shaping the aspirations of people.

Women in our culture do not occupy a position of authority in the family and are subjected to a perpetual conflict for establishing equality. They are expected to mould their thinking and other attitudes in conformity with the ideas and customs of the family. They are thus often emotionally tense, anxious and maladjusted in their personal, social and familial roles. As a consequence we find in them a greater occurrence of neurotic disorders (Murthy, 1979).

Violence against women including family violence constitutes a major social and public health problem, affecting women of all ages, cultural backgrounds, and income levels. It is emerging as a pervasive global issue and contributes significantly preventable morbidity and mortality for women across diverse cultures. Violence has serious psychological and emotional consequences including depression, anxiety, Post-Traumatic Stress Disorder (PTSD), dissociation disorders, somatization, sexual dysfunction and self harm behavior (Fischbach & Herbert, 1997).

Patriarchy, Power and Gender

The role of power, patriarchy and gender is central in the mental health of women. It clearly shows how these concepts interact to have an impact on the

perception of one's own mental health, mental health of others and the importance of seeking treatment.

The single status of women, which resulted from various factors like divorce, separation, widowhood and singlehood, also determines the poor mental health of women. The participants of the study attached high value to their status in the family and thus lack of support from family members during their time of need was upsetting for them. Women painfully realized that if they did not do what they were "supposed to" they were good for nothing for their family members. Women feel they are victims of poor mental health because they deserve it and one cannot do anything about it. Treatment seeking is not a priority among women as well as their family members. The culture of Gujarat promotes many traditional practices such as *jhaar phoonk* by *bhuas* and such practices are clearly visible in the case studies too.

In a patriarchal system as seen in Gujarat, the medical, nutritional, educational, emotional, and psychological needs of a girl or woman suffering from mental health problems tend to be placed last in list of priorities of a family, often leading to abandonment by their family members. Being a woman, in a poor family, with a mental disability, is a triple disadvantage, especially because it is very difficult for the family to understand the situation and honor issues are given greater priority rather than the woman's well being.

Implications and Recommendations

To improve the State's health outcomes it is therefore critical to recognize and cater for the needs of different socially and economically marginalized groups. Stronger and critical strategies are needed to cover the socially marginalized groups and address the social determinants of health, such as poverty, social discrimination, gender and other factors like literacy and traditional norms/practices.

Health is more than not being sick. Health is influenced by important factors such as the physical environment, health practices and coping skill, biology, health care service and the social and economic environment in which people live their daily lives. Some effective strategies for addressing social and economic determinants of health include the following:

1. Develop and promote education, literacy and employment policies that contribute to employment status.
2. Improve community environments that promote physical activity, mental well-being and quality of life.
3. Providing quality and affordable housing.

4. Addressing issues of unequal access to affordable and nutritious food. (Sheridan, 2008)

There is a need to formulate developmental plans that enable women to access greater and better educational, economic and health opportunities. It also calls for changing the deeply embedded cultural norms that put women at a disadvantage through a suitable program of social change: specific strategies are listed below.

- 1 Promotion of gender equity and equality within the family and society is required so that women are not bound by prescribed gender norms and gender roles. The findings of this study underscore the significance of empowerment programs for women aimed towards developing self-worth that is not solely defined by the cultural stereotypes of successful performance of gender roles and responsibilities.
- 2 Spaces need to be created for women where they can express their tensions, anxieties and feel validated and understood, to prevent escalation into severe mental illness.
- 3 Sensitization of the community towards mental illness, its causes and modes of treatment is of utmost importance.
- 4 Economic empowerment of women will greatly reduce their financial dependence on their families.
- 5 It is necessary to create models of psychiatric and mental health care giving, which address social determinants and which do not infantilize women. Care givers need to give information to women in ways that women can understand the diagnoses and treatment options, side effects as well as adverse effects of medication. Social models of mental health also need to emphasize

better client provider relationship, which will actively accelerate healing.

- 6 The important question is that amidst the multiple health priorities and economic inequality and poverty that exist in developing countries such as India, where does the mental health agenda fit in? This is an important question that the government has to address, especially in deciding the health budget and national health priorities. Women's reproductive health and rights have been of prime focus in recent times, but it is necessary to realize, that when referring to the overall health rights of women, the mental health aspect *cannot* be given lesser importance compared to other health issues.
- 7 Only by responding to the complexities from women's perspective can health promotion strategies hope to increase the opportunities women want and need to control the determinants of their health. Lack of documentation on the role of social determinants in mental health needs to be addressed as part of the larger picture of health care and support via society and the immediate family she lives with.

Acknowledgements

This study was supported by Department of Health and Family Welfare, Government of Gujarat, and Royal Netherlands Embassy. We thank Bapu Trust for undertaking this study in collaboration with WOHTRAC. We are extremely grateful to the women who gave so much of their time for the interview, and the hospital administrators and doctors for their support and cooperation. We thank our study team; Vaishali Zararia, Jaya Pujara, Mohsina Khan and Pratibha Chauhan.

Table 1 Profile of Women

Sr. No	Categories	Details	N=30
1	Place	1. Inpatients 2. Outpatients	15 15
2	Age	1. 21-30 2. 31-45 3. 46-55 4. 56-65 5. 66-75 6. No response	06 15 05 01 01 02
3	Education	1. Illiterate 2. Primary 3. Secondary 4. Higher secondary 5. Graduate	05 08 09 04 04

Sr. No	Categories	Details	N=30
4	Marital Status	1. Married 2. Unmarried 3. Divorced 4. Separated 5. Widow	15 05 04 01 04
5	Occupation	1. Employed 2. Unemployed/Housewife 3. Admitted in Hospital/working in Occupational Therapy	06 09 15
6	Caste	1. Hindu 2. Muslim	26 04
7	Type of Family	1. Joint 2. Nuclear	17 13

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Campaign against Net En - A Brief Update

- Sama Team*

Women's groups have long been grappling with the issue of ethics in medical research in the light of continuing ethical violations during clinical trials of hormonal contraceptives. On several instances, they had to contend with non-implementation of the existing ethical norms from injectable contraceptives being tested on women unaware that they were part of a trial, to inadequate follow-up and downplaying side-effects in trials on Net-en,¹ Norplant and anti-fertility vaccines, to illegal trials on quinacrine.

In April 1985, some members of the Stree Shakti Sanghatana (SSS), a women's group in Hyderabad, learnt of Net-en trials taking place in Patancheru. Women from the poorest classes were recruited for the trials. They were not informed of either its side-effects or contraindications. When SSS intervened and explained the side-effects and long-term implications of the drug to the women, only 5 out of 50 women remained for the trials. A public litigation was filed in Supreme Court by a few women's groups² asking for a stay order on the Net-En clinical trials in India, which was disposed of by the Supreme Court almost after 15 years.

Net-en has gained notoriety over the years not only because of its severe side-effects but also due to the government's persistence in trying to introduce it through the public health system. The government's obsession with 'population stabilization' begins and ends with contraception for women and injectables like Net en and Cyclofem³ are its current favourite.

There has been a proposed initiation of Phase IV trials for Net-en and Cyclofem through the public health system. This proposal was presented at a meeting called by the Ministry of Health and Family Welfare (MOHFW) on April 16, 2008 in Delhi. The participants at this meeting were informed that the Indian Council of Medical Research (ICMR) had already completed Phase III trials, on the basis of which 'experts' had approved the initiation of Phase IV trials to be conducted in 31 district hospitals/medical colleges through 9 NGO institutions. This proposal came unexpectedly and was not preceded by any form of public debate on the matter of such widespread implications. Moreover, the lack of representation from groups who have been involved in the campaign against injectables in the past was conspicuous in their absence.

When one such group⁴ based in the capital got information about the meeting and the ministry's proposal, they were quick to update other groups. Once again health and women's groups were mobilised around the issue, meetings were conducted to disseminate the information and plan the future course

of action. The aim was to mobilize collective action to reiterate the concerns and to challenge the proposed plan of reintroduction of injectables in the public health system

As a first step towards the revive of the campaign against injectables, the activists prepared a memorandum addressed to the Union Minister for Health, Dr. Anbumani Ramadoss on April 29, 2008. The memorandum was endorsed by over 50 groups, organizations and individuals, opposing the introduction of the injectables in the public health system and challenging the basis of the conduct of trials on women.

The memorandum demanded information regarding the new evidence of 'safety and acceptability' of Net-en that had emerged from the Phase III trials on the basis of which the Ministry was planning to launch the Phase IV trials of a contraceptive which has been proven to be unsafe and hazardous earlier. It also brought to light the fact that the Technical Committee of Drugs Technical Advisory Board had already opined that DMPA, the key constituent of Cyclofem, should not be allowed for mass use in family planning programme and demanded to know on what scientific reasons this recommendation was being overridden.

Some Demands from the Memorandum

- An immediate stoppage to any plans of introduction of hazardous hormonal injectable contraceptives through the public health system.
- All documents and information regarding the completed Phase III trials for Net En and Cyclofem - including study design, protocols, findings, content of informed consent forms, screening for contradictions, list of venues of the trials, as well as the legal and medical protection provided to the women who were research subjects, be made public.
- All documents regarding the study design, protocols and complete list of proposed district hospitals/medical colleges and NGO partners for Phase IV trials also be made public

Following the memorandum, the women's groups and health activists kept up the campaign by trying to contact different officials in the MOHFW. In this attempt a fax, requesting for an appointment, was sent to Dr. G.C. Chaturvedi, who had chaired the meeting called by the MOHFW on April 16, 2008 to present the proposal. The request was also forwarded to Dr. Jayalakshmi, the then Deputy Commissioner of the Family Planning Department. Consequently, the MOHFW called representatives of women's groups and organizations for a meeting. At this meeting, Dr. Jayalakshmi committed to making the findings of the Phase III trials public, as was demanded. The Ministry also committed to an

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interface regarding technical issues between the officials of MOHFW and groups/organizations through a meeting with the Technical Committee. It was also assured that the initiation of the trials would take a minimum of 2-3 months during which time, the Ministry would ensure that all these concerns would be taken into consideration.

As a first step towards this interface, as committed by the Ministry, albeit a couple of weeks late, summary reports of the Phase III trials of both Net-en and Cyclofem were displayed on the Ministry's website for feedback, clarifications, without having to file an application under the Right to Information Act. However, even a cursory look at these reports revealed the inadequate nature of these reports. They lacked major details which had been demanded in the memorandum and without which it was not possible to understand the process of the trials. The groups and health activists felt that the reports had merely glossed over important details such as inclusion and exclusion criteria for the participants in these trials, steps to be taken to rule out contraindications, and other technical details. This once again reinforced the need and the subsequent demand for a technical committee meeting by the groups.

Even after a month since the public display of the reports, there was no further response by the Ministry with regard to the other commitments it had made. It was at this point, that a letter addressed to Dr. Jayalakshmi was once again drafted, pointing out the existing inadequacies in the summary report, and reiterating the importance and urgency to bring together a technical committee. The letter also contained a set of pertinent questions concerning the Phase III trials of the two injectables.

Some of the questions were:

- Are we to understand that there is no difference between Cyclofem, Lunelle, mesigna, cycloprovera and the results can be extrapolated to others?
- What is the profile of women opting for these injectables in terms of parity, educational status, income levels etc., as compared to women opting for other spacing methods?
- What were the inclusion and exclusion criteria for Net en? What were the contraindications for use and how were these ruled out?
- What was the profile of women in whom return to fertility occurred within a few months and in those in whom it took 23 months, with Net en and Cyclofem?

A demand for an urgent meeting with Technical Committee was again put forward.

In response to this letter there was a prompt reply from the Ministry requesting more time, as these questions could only be answered by ICMR officials, who were currently in the process of putting their response

together. About 10 days after this request, there was another letter from the Ministry, with their response to the questions raised by the campaign groups. Although, this was a welcome step in the direction towards ensuring that women's health rights are not violated; once again these responses were an eye wash as compared to the real issue at hand.

The ICMR/MOHFW in their response, claimed that the drugs, Lunelle and Cyclofem along with mesigna, cycloprovera, etc., were infact very similar drugs, with a slight variation in their composition. The officials refused to comment on whether the results of clinical trials for any one of these could be extrapolated to the others. Similarly, in reference to the profile of the participants in the clinical trials, and their return to fertility, the report quotes the data from previous trials in the eighties and does not elaborate on details about the current trials. Although they do go on to give a concrete inclusion and exclusion criteria along with methods to avoid contraindications, they make no attempt to explain these in detail or clarify how the Ministry plans to ensure the implementation of these methods at every level. The letter carried no information on the public health policy measures that the Government was planning to initiate to create a safe-injectables environment for women

Further, as if to assure the campaign groups that the Phase IV trials will not be launched without taking these concerns into consideration, the letter proceeded to clarify that "The study has only recently been approved. After receipt of budget the formative phase (6 months) will be initiated which includes preparation of various guidelines (technical, operational etc) procurement of drugs, setting up of various committees for review monitoring etc."

However, at the same time, the letter gave no timeline according to which these processes would take place, and the time the whole process would take. The letter once again steered clear of any mention of a technical committee meeting and completely overlooked the memorandum's primary demand.

It has been over three months since the letter, but the groups have not heard from the Ministry at all. However, there is an attempt to keep the campaign alive through disseminating information and raising awareness on the issue to resist the introduction of injectable contraceptives in the Family Welfare programmes.

For further details contact; <sama.womenshealth@gmail.com>.

¹Net-en is a short form of Norethisterone Enanthate. The dosage is 200mg injection every two months.

²SSS, Saheli, Chingari filed a writ petition in the Supreme Court of India against the Union of India, ICMR, Drug controller of India (DCI) and others asking for a stay order on the Net-En clinical trials in India

³Cyclofem is a monthly combined injectable

⁴Sama Resource Group for Women and Health

How Should India Approach the Management of Severe Acute Malnutrition?

*A Position Paper**

The numbers of children who are currently suffering from malnutrition in India is an extremely serious matter of national shame and distress. Not only has this situation persisted for far too long, it remains intractable even during the recent phase of rapid economic growth. Of late, there has been intense debate and discussion on how best to intervene to make a change that is both substantial and rapid, and various groups of experts have presented strategies to policy makers as to the steps that need to be taken for both preventing malnutrition and treating its most severe forms.¹

This position paper responds to a particular strategy that has been introduced at state level without due process of discussion on its repercussions and implications; namely, the use of imported Ready to Use Therapeutic Foods (henceforth RUTF) for the management of Severe Acute Malnutrition (henceforth SAM).

The current situation is this –

1. A product called Plumpy Nut has been imported for distribution to children with SAM in several states, including Madhya Pradesh, Jharkhand, Orissa, Bihar and Maharashtra under the aegis of UNICEF and through the mechanism of Nutrition Rehabilitation Centres (NRCs). There is a proposal to make it the “prescribed treatment” for SAM.
2. This product is imported from a company called Nutriset in France. If produced in India, it would cost approximately US \$ 40 or approximately Rs. 2000/- per child per treatment²
3. Plumpy Nut efficacy has been demonstrated in other countries such as Malawi, Niger, Ethiopia, DR Congo and Mozambique in conditions of disaster and famine.
4. The studies demonstrating the efficacy of Plumpy Nut have been primarily conducted in disaster situations, where other community-

based treatments for SAM have not existed, eg. refugee camps, famines, etc. There are few studies comparing the impact of Plumpy Nut with other specific community-based treatments for SAM developed from local indigenous foods.

In juxtaposition of these facts –

1. The guidelines for community and home-based treatment of SAM formulated by a large group of experts and supported by the Indian Academy of Paediatrics recommends the use of home-based food (modified from the family pot). It specifically warns that commercially available international RUTF may not be suitable, acceptable, cost effective and sustainable³.
2. Many locally produced/produced foods that are culturally acceptable and relatively low cost have been used for SAM in India for many decades by reliable academic and medical institutions as well as by non governmental groups. The following table gives details of some of these mixes
 - 1 Working Group for Children Under 6, Strategies for children under six; special article, *Economic and Political Weekly*, December 29, 2007.
 - 2 1 sachet is 92g. Treatment for SAM requires 90 sachets per child of 10kg. (Nutriset site <http://www.nutriset.fr/index.php?option=com_content&task=view&id=30&Itemid=28>). Each kilo of RUTF, costs approximately US \$ 4. (Power point presentation by Steve Jarrett, UNICEF, 20th September 2008: Ready-to-Use Therapeutic Foods (RUTF): Addressing the situation of children with Severe Acute Malnutrition – Production in India.
 - 3 Gupta, P., Kapil U, et al, “National Workshop on “Development of Guidelines for Effective Home Based Care and Treatment of Children Suffering from Severe Acute Malnutrition”, Indian Pediatrics, Vol. 43, February 17, 2006.

* Statement drafted by Dr. Vandana Prasad, Radha Holla and Dr. Arun Gupta. Please send your endorsement by email to Vandana Prasad at <chaukhat@yahoo.com>, Radha Holla at <radhab@yahoo.com> or Arun Gupta at <arun@ibfanasia.org>.

Name of Mix	Composition and Calorific Value	Developed by	Locally prepared by	State
Davangere Mix	Laddus made of Equal quantities of groundnuts, roasted Bengal gram, jaggery and ragi. 100g. gives 400 calories and 15g protein	Medical College, Davangere	Women's groups	Karnataka
Shakti Nutrimix	Rice, Wheat, Whole gram (chana), Groundnut, Sugar, Salt, Cardamom, Black pepper, vitamins and minerals. Each 100 g. of mix provides 10.4g protein, 5.3g fat, and 402 calories	Shibpur People's Care Organisation, 23/1 Baze Shibpur Road, Shibpur, Howrah/Village and PO Tapan, Dt. Dakshin Dinajpur,	Women's groups	West Bengal
Nutrimix	Wheat (400g), rice (400g), grams (75g), Moong (75g), groundnut (50g);, sprouted, dried, roasted and powdered. 2 heaped spoons in glass of water or milk with sugar twice a day	Development Research Communication and Service Centre, 58A, Dharmotala Road, Bosepur, Kasba Kolkata - 700 042	Women's groups	West Bengal
Nutrimix	Wheat/rice and Bengal gram/ Moong in ratio 4:1. Used for treating SAM, for preparing F 75, F 100, as starter and catch up foods. Each 100 g cooked provides provides 120-150 Kilocalorie and protein 2-3grams, Can be made more energy dense by adding seasonal fruits, and micronutrient rich by adding Electolyte Mineral Solution	CINI (Child In Need Institute), Kolkata	Women's groups	West Bengal
LAPSI	Green millet, peanut, jaggery. Successfully used for quick recovery from SAM	Bharat Agro Industries Foundation and CAPART		Maharashtra
SAT Mix	Roasted and ground rice, wheat, black gram and sugar in ratio 1:1:1:2. Provides 380 calories per 100g.	Sree Avittom Thirunal Hospital		Kerala
MIX		National Institute of Nutrition, Hyderabad		Andhra Pradesh
HCCM (high calorie cereal milk)		Christian Medical College, Vellore		Tamil Nadu
Sattu Maavu ²	Wheat flour 42%, Maize flour 10%, Malted Ragi flour 5% Bengal gram flour 12%, Jaggery 30%, Vitamin Premix 1% 100g. provides Protein 9 to 10% and Calories 360	Nutrition Monitoring Programme (state programme)		Tamil Nadu

N.B: Shelf life is not a necessary condition for these locally produced ready to eat foods as they are prepared in quantities needed by local women's groups under the supervision of the respective hospital or NGO.

3. Several experiments are on using modified family foods to treat SAM. Jodhpur Medical College has been using a mix of energy dense khichri, milk, raar, dal, sugar, fruit, fruit juice and egg to treat SAM both in institutional and home settings. This is in the process of analysis and documentation. In Tamil Nadu, the Direct Nutrition Programme gives a mix of 80g rice, 10g. dal, 2g. oil, 50 g. of vegetables and condiments at a total cost of Rs. 1.07 to each child between 2 and 4 years of age. This provides 358.2 calories and 8.2g protein per child.¹ The Sattu Maavu listed in the table above is given as complementary food for children between 6 and 36 months of age and pregnant and lactating women, and costs approximately Rs. 15 per kilo. Other experiments by NGOs such as Mobile Creches have used common foods including eggs, soya products and milk for demonstrable impact at a cost of Rs 8 per child per day for full day-care nutritional facilities.²
4. These foods have been completely ignored in the haste to introduce Plumpy Nut, which, though an efficacious formula, seriously disturbs the concept of self-reliance in food security and creates an unnecessary dependence upon a product upon which families and communities have little control.
5. Alternate foods listed above have many additional advantages –
 - a. They promote local agricultural practices as they use millets and locally available foods
 - b. They promote local livelihoods amongst the very families what may be harbouring children with SAM in a milieu of general poverty and food insecurity thus conferring more than food supplementation – an opportunity to raise economic status. They may use the agency of existing women's groups and SHGs as well as small scale industry
 - c. By being much more decentralised a process, they allow greater community participation and control.

Evidently, though there are few formal studies documenting their efficacy there *are* some, along with plenty of anecdotal evidence of success. The very fact that these pre-existing attempts have not been properly studied, analysed and documented by research and expert bodies on nutrition is a matter of concern. It is hard to explain why it has been permitted for a somewhat alien product to be introduced at such large

scale without investigating the relative merits and demerits of the ready to use foods that we have been using in such prestigious institutes as mentioned above. It would not have been either difficult or time consuming to study these further for a few months before arriving at a suitable strategy for SAM that includes supplementary food.

Perhaps it leads us into our long standing recommendation and demand, that the country needs to develop a well discussed and debated policy of child nutrition rather than have to combat each contingency as it arises.

This policy necessarily needs to keep in mind that supplementary nutrition is *one*, though important, part of the multi pronged strategy to bring about overall food security for children and families, and the best SN would be one that promotes self reliance, decentralisation, community participation and is low cost and culturally acceptable. An imported or centrally prepared very expensive food that displaces other locally producible options can hardly hope to fulfil these criteria and should be abandoned in favour of the 'right' product. Adequate thought, planning and research should go into developing such policies rather than succumbing to various pressures in haste and allowing unsustainable processes that may prove difficult to reverse and will cause long term harm to the very communities and families whose children we aim to 'treat'. We also need to continuously remind ourselves of the comprehensive set of strategies that will bring about the ultimate goal of child health, nutrition and well being through services of general care, health and nutrition in an environment of overall food, economic and social security.

Endnotes

¹Working Group for Children Under 6, Strategies for children under six; special article, *Economic and Political Weekly*, December 29, 2007.

²1 sachet is 92g. Treatment for SAM requires 90 sachets per child of 10kg. (Nutriset site <http://www.nutriset.fr/index.php?option=com_content&task=view&id=30&Itemid=28>). Each kilo of RUTF, costs approximately US \$ 4. (Power point presentation by Steve Jarrett, UNICEF, 20th September 2008: Ready-to-Use Therapeutic Foods (RUTF): Addressing the situation of children with Severe Acute Malnutrition – Production in India.

³Gupta, P., Kapil U, et al, "National Workshop on "Development of Guidelines for Effective Home Based Care and Treatment of Children Suffering from Severe Acute Malnutrition", *Indian Pediatrics*, Vol. 43, February 17, 2006.

⁴Anuradha K. Rajivan, "History of Direct Nutrition Programmes in Tamil Nadu", <<http://www.righttofoodindia.org/data/anuradha.pdf>>

⁵Ibid

⁶Working paper Mobile Creches, Impact of Strategies for Children Under Six on Malnutrition; Evidence from Two Microstudies, 2008.

PIL on Closure of Vaccine Institutes

(Reproduced below is from the 'Synopsis' section of the PIL in the Supreme Court in which mfc is a co-petitioner. The complete text of the PIL, Dairy No. 3064 of 2009, is available at the files section of the mfc egroup at <<http://health.groups.yahoo.com/group/mfriendcircle/files/>>.

Petitioners

- | | |
|---|---|
| <ol style="list-style-type: none"> 1) Shri S. P. Shukla
Former Spl. Secretary, Family Welfare,
Govt. of India Former Member, Planning
Commission, Govt. of India
3260, Sector D, Pkt.-3, Vasant Kunj NewDelhi 2) Low Cost Standard Therapeutics (LOCOST)
A Registered Public Trust having its office
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Dandiya Bazar, Vadodara Gujarat – 390 001 3) All India Drug Action Network
Dr. Mira Shiva, Co-Convenor
A-60, Hauz Khas, New Delhi - 110016. 4) Society for Scientific Values
Registered Society having its office Through
its Former Secretary Dr. N. Raghuram
DST Centre for Visceral Mechanisms,
VP Chest Institute, University of Delhi,
Delhi - 110007. | <ol style="list-style-type: none"> 2) Dr. Anbumani Ramadoss
Union Minister of Health & Family Welfare
30/34, 4th Cross Street, Kasturibai Nagar,
Raja Anamalai Puram, Chennai-600 028,
Tamil Nadu 3) State of Tamil Nadu,
Through the Secretary,
Secretariat, Fort St. George,
Chennai - 600 009, Tamil Nadu 4) State of Himachal Pradesh
Through the Secretary
Department of Health & Family Welfare,
B - 6, SDA Complex, Shimla – 171009
Himachal Pradesh. 5) Pasteur Institute of India,
Through the Director,
Coonoor - 643 103, Nilgiris. Tamil Nadu. 6) BCG Vaccine Laboratory
Through the Director,
Guindy, Chennai – 600032, Tamil Nadu |
|---|---|

Respondents

- | | |
|--|---|
| <ol style="list-style-type: none"> 1) Union of India
Through the Secretary,
Ministry of Health and Family Welfare
Nirman Bhavan, Maulana Azad Road
New Delhi - 110011 | <ol style="list-style-type: none"> 7) Central Research Institute
Through the Director,
Kasauli, Distt, Solan - 173204,
Himachal Pradesh. 8) Drug Controller General of India
FDA Bhawan, Kotla Road,
New Delhi - 110002 |
|--|---|

PETITION UNDER ARTICLE 32 AND ARTICLE 256 OF THE CONSTITUTION OF INDIA

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| <ol style="list-style-type: none"> 1. At the outset petitioners state that it is possible that in respect of the subject matter of this petition under Article 32 of the Constitution of India, separate writ petitions under Article 226 of the Constitution of India could be filed in the High Courts. Petitioners are filing this petition under Article 32 as the petition is concerned with the closure of vaccine production facilities, malafide and against the public interest, in the state of Himachal Pradesh and in the State of Tamil Nadu. However, if this Honorable Court is not inclined to entertain this petition directly as the petitioners have not gone first to the High Courts, the petitioner is most willing to follow that course. 2. This petition raises very important issues vitally affecting public health. Vaccines are vital in the public health programme of all nations as they are necessary for the immunization programme which combats suffering, disability and death. | <p>The WHO campaign eradicated small pox. The Global Polio Eradication Initiative has caused infections to fall by 99%. Similarly, measles deaths have dropped dramatically. Production of essential vaccines in public sector units (PSUs) has had a major role in the success of the Universal immunization programme so far. The closure of production three of the most important vaccine PSUs under the Union Health Ministry in Jan 2008 using regulatory excuses has dealt a deathblow to a century old legacy of self-reliance in vaccine production and jeopardized the Indian immunization programme.</p> <ol style="list-style-type: none"> 3. India was an early bird in vaccines, unlike in most other areas of modern technology, where India lagged behind. India was a world leader in the invention and production of the plague vaccine. Modern medical research in India began with vaccines along with establishment of the Pasteur |
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Institute, Coonoor, the Haffkine Institute, Mumbai (which is also rumoured to be closed shortly) the Central Research Institute, Kasauli, the BCG Vaccine Laboratory, Chennai. Institutionalization of vaccine research and development and production began under the British. After independence the Indian Government took a lead in encouraging indigenous vaccine development. Soon after independence India became a member of the World Health Organization (WHO) and promoted indigenous vaccine production in the public sector. Government of India had strong policy support for self-reliance in vaccine technology and self-sufficiency in vaccine production until 2005 when R – 2 took over. He then began to reverse this policy causing much detriment to India's public health programmes, knowing fully well that the US, the UK and other developed countries, such as the Netherlands, regret allowing their vaccine production to drift into private hands and have significantly started reviving the public sector once again. Despite these international examples, R – 2 steered the Indian nation in the opposite direction to benefit the private sector vaccine companies.

4. India is among the largest vaccine makers and buyers globally. The current vaccine market in India is estimated at more than US \$ 150 millions in India and \$ 8 billion globally. Government purchases for universal immunization programme run into over thousand crores of rupees, making it an attractive business opportunity for private sector, but the predominance of the public sector manufacture of vaccines and their price competitiveness has been the biggest impediment for the private sector to capture the vaccine market, till Respondent No.2 and Respondent No.8 halted government production.
5. The public sector vaccine units of the Indian government manufacture vaccines for tetanus, diphtheria, pertussis, measles, polio and tuberculosis. The Pasteur Institute of India (PII), Coonoor, was the first institute in India to introduce antirabies serum-vaccine therapy for human beings in 1917 and to improve it through many rounds of indigenous innovations. Over the decades, it also produced oral polio vaccine, the DTP group of vaccines and more recently DTP-hepatitis-B combination vaccine, apart from developing cost-effective Japanese encephalitis vaccine and innovative improvements in the DTP vaccine. The Central Research Institute, Kasauli, is the only institute in South Asia that produced the yellow fever vaccine. It was also the first

laboratory in the world to produce anti-rabies vaccine. The Institute produces DTP vaccines, Yellow Fever, Typhoid, Japanese Encephalitis and Anti-Sera against Diphtheria, Tetanus, Rabies, Snake venoms and diagnostic reagents besides being a quality control testing and clearance center for vaccines manufactured by others. The BCG Vaccine Laboratory, Chennai, was the only institute under the Union ministry of Health and Family Welfare to obtain ISO 9002 certification. The pioneering work done by the three institutes now closed is set out from paragraphs 40 to paragraphs 48 in the petition. These instances show that the three government institutes had the inherent interest, will, ability and enthusiasm to remain productive, innovative and competitive. A cursory reading of the above mentioned paragraphs will show what disservice has been done to the nation by halting production in these pioneering research and production facilities.

6. The suspension of production in three most important vaccine units in the public sector undermines a century old effort of building vaccine self-sufficiency and self-reliance. Ironically, their closure happened at a time when the production in the 3 PSUs were peaking and the vaccine demand-supply gaps were narrowing down, and when there has been no complaint at all on the quality of the vaccines produced. As a consequence, India's health security and biosecurity, and especially that of its children, stand threatened.
7. The vaccines produced by public sector units costed only Rs. 30/- to vaccinate a child with all six essential vaccines for all the required number of doses. Now that they are no longer available, the private sector is already threatening to increase the prices of the vaccines they supply to the government. Moreover, as compared to this cheap supply of public sector vaccines, expensive combination vaccines that are considered unnecessary by experts in India are flooding the market in the private and biotech sectors and their agents are actively lobbying with officials in the health ministry for adoption under the Universal Immunization Programme at huge cost to the public exchequer. Given the fact that 25 million children are born annually in India, huge profits can accrue to private companies who manage to get contracts worth hundreds of crores to sell their vaccines to Government of India.
8. Petitioner has set out in Table 4 the comparative prices of vaccines manufactured in the public and private sectors to demonstrate that private sector vaccines are often 2 to 20 times more expensive.

Not only that, studies indicate that there are huge and growing shortages of essential vaccines in 23 states of India and these details are set out in the table in the petition. Thus, the government's action will not only exacerbate the situation of shortages, but will also result in huge extra expenses due to the government having to buy expensive vaccines from the private sector. The closure of production in public sector units occurred in January 2008, whereas the vaccine park is-will not be operation before 2011. Surely, the government understood the drastic consequences of closing production in the existing units at the time when shortages already existed.

9. In particular, and this is set out in substantial detail in the petition, respondent 2 and 8 are directly responsible for closing down vaccine production at the Pasteur Institute of India, Coonoor, the BCG Vaccine Laboratory, Chennai and the Central Research Institute, Kasauli, all of them from January 2008. All these closures were done under the flimsy pretext that these units did not meet the WHO standard of Current Good Manufacturing Practices (CGMP). The petitioner will demonstrate in the petition that these units were required to make certain reasonable investments – a paltry Rs. 50 crores in all - to upgrade their facilities in order to become compliant with these standards. The resources and expertise are available. Nevertheless, respondents 2 and 8 took a malafide decision to suspend production and effectively close down the units, using the non-compliance to CGMP as an excuse.
10. There is irony in this decision to close down manufacturing units that were not GMP-compliant, even though the government was not required to close down the units. The very same government that closed down its own production units citing CGMP non-compliance had imported Japanese encephalitis vaccine from a CGMP non-compliant Chinese manufacturer in 2006.
11. There are four further aspects to this malafide action. The respondents, particularly respondent 2, willfully did not make improvements in time so as to allow the facilities to remain without up-gradation. Interestingly, in all the three public institutions abovementioned, the directors were appointed by R – 2. Likewise, R – 8 was also appointed by R – 2. Thus R – 2 systematically put a team in place that would do his bidding and in one stroke demolished India's indigenous production of vaccines.
12. The second aspect of malafide is this. The Current Good Manufacturing Practices of the WHO are applicable only to countries who seek to export vaccines to the UNICEF. Therefore an option was available to R – 2 and R – 8 to stop only exports and continue with the manufacturing for domestic purposes, while simultaneously upgrading facilities to comply with cGMP, so that domestic immunization needs were met at reasonable prices and shortages prevented, as well as the credibility of the Who National Regulatory Authority was maintained.
13. The third aspect of malafide is indicated by the fact that in the last 12 months that have lapsed since production was suspended in the three suspended public sector units, the government displayed no intention or made no attempts to upgrade them or make them CGMP compliant to resume production. In fact, the terms of reference of the expert committee appointed by the Health ministry (in the wake of public criticism over the suspension of 3 vaccine PSUs) apparently did not include any item regarding making these units GMP-compliant and resuming production and instead focussed on “other” means of using the infrastructure and manpower for testing, training etc.
14. The fourth aspect of malafides is that R – 2, while closing down indigenous production abruptly, and refusing to invest the small required sum of Rs. 50 crores for up-gradation, is simultaneously setting up a ‘Vaccine Park’ in the constituency of the R – 2 in which R – 2 proposes to invest thousands of crores of rupees of the government to assist transnational corporations and other private companies that are manufacturing vaccines to operate from this vaccine park. Not only that, large plots of lands are being provided by the government to these private companies.
15. The new vaccine park led by Hindustan Latex Limited does not have the technology, experience or credibility to manufacture world class vaccines as compared to the closed institutes. In an interview given to R. Ramachandran in *Frontline*, R-2 admitted that Hindustan Latex is likely to go down the same path of merely bottling and repackaging imported stocks. The assertion by government officials that the vaccine park will be compliant with the Good Manufacturing Practices norms raises the issue as to why, if it is so easy to be compliant, the closed units which had longstanding experience with vaccines were not made compliant instead of closing them down and replacing them with a new more expensive facility.
16. Recent media reports have alleged that Dr. N. Elangeswaran (R-5 & 6), was said to have

facilitated the transfer of crucial resources such as seed virus, guinea pigs, well-trained human resource to new private companies, especially Green Signal Bio Pharma, which was registered in 2005. This company is owned by Mr. Sundarapariipooran, who apparently belongs to Ramadoss's party PMK and is a close associate of R-2, the Health Minister. (*The Pioneer*, 10th May 2008).

17. Another Chennai-based new vaccine company called Vatsan Bio Pharma that came up in 2006 is also apparently co-owned by Mr. Sundarapariipooran and his wife, with the wife of Dr. Elangeswaran as a major shareholder. (*The Pioneer*, 10th May 2008).
18. On July 21, 2007 Dr. Elangeswaran allegedly stopped guinea pig breeding in the institute, which led to disruptions and stoppage of vaccine production. (*The Pioneer*, 16th May 2008). WHO-NRA team visited PSUs in Aug 2007.
19. On September 21, 2007, an entire batch of 15 scientific staff of PII, recruited and trained under the direct supervision of the then director Dr. Elangeswaran, allegedly went missing from PII and defected overnight to Green Signal Bio Pharma. In effect, PII recruited and trained staff for the benefit of a private company! (*The Pioneer*, 19th May 2008).
20. In Oct 2007, 600 guinea pigs were apparently ordered to be transferred from PII to BCGVL by the then director, Dr. Elangeswaran. However the consignment never reached BCGVL and was instead routed to a private vaccine manufacturer's compound in Mettupalayam. (*The Pioneer*, 16th May 2008). WHO-NRA team visited PSUs in November 2007.
21. On 27th Dec 2007, Green Signal Bio Pharma apparently received a loan of Rs. 14 crore from Union Bank of India, Chennai, for starting the production of vaccines. The MOU signed between Green Signal Bio Pharma and BCGVL (by Dr. Elangeswaran) was hypothecated to obtain this loan. In other words, the then BCGVL director facilitated the bank loan as well as seed virus for Green Signal Bio Pharma.
22. The then PII director, Dr. Elangeswaran apparently gave the seed virus for polio vaccine production and DPT production free of cost to private companies, Bharat Biotech, Hyderabad and Serum Institute of India, Pune, respectively. (*The Pioneer*, 11th May 2008).
23. On May 11, 2008, it was reported in the media that Dr. Elangeswaran (R-5 and R-6) apparently stated that senior bureaucrats in the health

ministry pressurized him to close down the PSU he headed, to facilitate private company vaccine production. In the interview reported in the *Pioneer*, he named certain high ranking officials in the health ministry. Two days later, on May 13, 2008, the health secretary stated to the media that action would be initiated against Dr. Elangeswaran for his malicious allegations. No action was taken. R-2 then stated that he would form a committee to look into the fate of these closed units. Interestingly, the committee had two members from the private sector with competing interests!

24. On November 27, 2006, the then PII director, Dr. Elangeswaran, purchased measles seed from Green Signal Bio Pharma for Rs. 3.25 crores, which was otherwise available virtually for free from another PSU, Indian Immunologicals Ltd., Hyderabad. The Health Ministry sanctioned PII Rs 17.80 crores for branching out into measles vaccine production only after it entered into the deal with Green Signal Bio Pharma. The entire deal was allegedly executed to help the private company, as it stipulates that the PSU would produce measles vaccines from the seed and give away 70 per cent of the profit to Green Signal Bio Pharma. The agreement was signed on November 27, 2007, and soon thereafter, Sund arapariipooran withdrew Rs 2.5 crores. Interestingly, Green Signal Bio Pharma could purchase BCG seed from the PSU BCGVL (also headed at that time by Dr. Elangeswaran), for a mere Rs. 1.05 lakhs. This indicates that private firms get PSU resources for a song, whereas PSUs buy even free resources from favourite private firms by paying them the moon!

Hence the petition.

Prayer of the Petitioners

- a. For an order directing the setting up a Commission of Experts as prayed in the main petition.
- b. For an order directing the Respondents to forthwith restart production of vaccines at Pasteur Institute of India, Coonoor, Central Research Institute, Kasauli and BCG Vaccine Laboratory, Chennai and to take whatever steps that are required to ensure commencement of production.
- c. Pending final disposal of the Petition pass an order staying order dated 15.01.2008 of Respondent No.9 for suspension.
- d. Pass such other and further order/s as may be deemed just, fair and proper in the facts and circumstances of the case.

*Update***Gujarat Public Health Act 2009**

The draft of the Gujarat Public Health Act 2009 is available at the Gujarat Government's website, <<http://gujhealth.gov.in/public%20health%20act.pdf>>. Several members of the mfc and JSA were involved in helping formulate it. A National Public Health Act is in the offing following the Gujarat Act. A brief on the Gujarat Act follows.

What does the Public Health Act do?

- It makes the right to health care justiciable.
- Those who are denied health services, or not provided affordable, quality health services can seek justice through the legal route.
- Having such an act also makes the state more conscious of its obligation to provide, and fulfil its responsibility of ensuring affordable, acceptable, quality health services to its citizens.

Why should Gujarat have a Public Health Act?

- Constitution of India, NHRC, NRHM direct States to have such an act
- In a State like Gujarat with such high disparities – high economic growth rate and not so good social indicators, the PH Act is an additional instrument for ensuring that goals of social justice are achieved.
- It will be an instrument for the marginalised groups – the migrants who flock into the state for economic opportunities, the tribals, coastal area unorganised communities, other minority populations - to seek redressal in case of denial of services.
- In addition to Gujarat's progressive and innovative health programmes, it will be a legal complementary tool.
- It will complement the State's other efforts to provide the highest attainable standard of health care.

Salient Features of this Act

- It combines the determinants of health as well as the access to health care – the collective community/citizen rights to safe drinking water, environment, food etc with the individual right to health care.
- It brings the public health system and the private sector on the same platform for quality and accountability – both sectors have to be judged and evaluated on the same parameters.
- It addresses both the rights and responsibilities

of the users.

- It provides a redressal mechanism for denial of right to health care.
- It lays out a structure right from the community level to the state level to provide for the right to health care.
- It stresses on peoples' participation – the core principle of decentralisation and good governance.
- It recognises that capacity building of the service providers is integral to providing quality health services, in ways which respect the value of human life.
- It seeks to integrate preventive with promotive, public with private sector, rural and urban, Health with other sectors that have a bearing on health, Health with Family Welfare with other national vertical health programmes including HIV/AIDS.

What Civil Society expects from the Government of Gujarat, the Health Minister, et al?

- To study the contents of the Act and appreciate its progressive character
- To take the leadership role in creating an opinion among the political groups about how this Act will promote social justice in the state
- To assess the budgetary implications of this Act and to work towards the provision of adequate and progressively increasing budgets which are spent for the benefit of the larger public good.
- To ensure that the Act does not remain a paper exercise, that the necessary structures are established for its implementation, for dissemination of its contents.
- Also to ensure that the implementation is monitored – a progressive law has no meaning if not implemented in a way that will realise the 'letter and the spirit'

What is expected of Civil Society once the Act becomes Law?

- To use the provisions of the Act to make health care justiciable as and when required, hold the Government accountable in case of health access deficit, and in the long run, enable routine access to health services for the people of Gujarat to be a reality

A Surgery without a Surgery: A Case of Exploring All Options

-Prabodh Malhotra¹

When surgery seems inevitable and unaffordable, it may be worthwhile to explore and exhaust all other options first. For someone, who has lived in the West for 35 years, and who is involved in research in studying the pharmaceutical industry, it was a difficult decision to choose between therapies. This case study of my own experience illustrates that a surgery may not always be the only or the best option.

One morning last year, I felt acute pain in my right shoulder. I contacted my GP who, after seeing me, arranged for further examination. An ultrasound showed a tear of 14.7 mm in my supraspinatus tendon. I saw a specialist, who suggested a surgery on the shoulder, which would put me out of action for a few months. As I was finalising my thesis, I did not want any disruption. Over the next couple of weeks, the pain deteriorated and I couldn't move my arm up or down. A second ultrasound showed a full tear of the tendon. An MRI also confirmed the tear in the same tendon. A surgical specialist at a well-known Melbourne hospital requested an x-ray of the shoulder. This surgical specialist drew sketches of the surgical process and explained to me what he would have to do. He would have to make some room and grind back the bones on the shoulder, which have grown closer as a result of the tendon being torn, the surgeon told me. The process would involve a few days of hospitalisation that would be followed by an after-care schedule including a few months of physiotherapy. Altogether, it would cost me several thousand dollars and I could be out of action for up to six months.

I was not really keen on the idea of surgery, and the way the surgeon explained to me, it put me off even more. Furthermore, trying to survive on the research scholarship as a family of four, I was not in a position to have the surgery without running the family deeper into debt. So, I began exploring other options. One of the options was to have the operation done in India and save on costs. I contacted several surgeons in India. Some of the surgeons told me that the cost would vary, as it would depend upon the material of the plate that would be placed to hold together the torn tendon. A steel plate would be the cheapest, titanium at mid-level and the biodegradable would be the most

expensive of the options. I was more confused now than at the beginning of my enquiry.

During this period of turmoil, a Mumbai-based friend suggested that I go to an Ayurvedic hospital in South India, in which he had full faith. I discarded the idea altogether for a number of reasons. First, after having lived in the west for 35 years, I questioned the validity of these claims. Second, my own research has been around the pharmaceutical industry; hence, how could I opt for another therapeutic approach. Third, it did not make any sense to me that the Ayurvedic doctors would be able to repair the torn tendon without opening me. However, after pondering over for a few days, I decided to use the surgical approach as a last resort rather than the first option.

At this Ayurvedic hospital, the team of three doctors examined me, and checked the ultrasound, x-rays, and all the allopathic reports. They assured me that they would be able to fix it without surgery. The duration of my hospitalisation would be around a month, which would be followed by 3-4 months of oral medication and the application of medicated oil. While I remained sceptical of their claims, I wanted to go through just for the sake of it.

The treatment consisted of three phases. The pre-treatment phase lasted for 4-5 days. During this phase, a liquid made from extracts of different medicinal herbs was poured down my nostrils six times a day. Once a day, I was taken to the 'treatment room', where I was lying on this specially made table. After a short massage, medicated steam was applied to my entire body. Then I would bathe in warm water prepared with herbal leaves. The herbal mix for steam and nasal drops was changed daily to identify the category my body belonged to. On day 4, my body became terribly itchy straight after the treatment. While I was thinking, it was a reaction, like a side-effect, the doctors were satisfied with the result. They now 'knew my body'.

The second phase was the main treatment, which consisted of applying some paste to the affected parts of the body, more rigorous massage, and pouring down medicated hot oil on to the body. This part of the treatment always reminded of fish and chips being fried in hot oil. While the leaves and paste varied sometimes, the medicated oil continued for ten days. With the quality of daily massage, and 'bathing' in hot oil, I was getting curious to know the effect on the shoulder. The three times daily examinations by the team of doctors kept them up-to-date with my progress, about which they seemed relaxed. They told

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me that the recovery process on track.

The final phase or what I called was the post-treatment phase. Under this phase, a Plaster-of-Paris like paste made of herbs was applied to my shoulder every night that pulled it tight. The paste was removed in the morning. This material gave me a feeling of having my shoulder covered in fibreglass. The removal of this material was not a pleasant experience, but perhaps much better than 'going under the knife'. I was discharged after a month and given four months supply of medicines. After six weeks of leaving the hospital, I had an ultrasound as well as an MRI done. They both showed the supraspinatus tendon to be normal and had no sign of any tear.

I certainly saved on costs, and I felt like I had been transformed into a new body. I have trimmed down, and despite my 56 years of age, have become more energetic. Our director called me 'the living miracle'. Since my return to Australia, I have been taking it easy with my right arm as well as applying daily the medicated oil. However, I am glad to have followed this path. From this experience, I made a number of observations. First, a significant difference between

the allopathic and the Ayurvedic approach was that the allopathic approach sought to apply external interventions, cut open, and repair the defective part; whereas the Ayurvedic therapy adopted an internal approach by preparing and directing the body to repair itself. Second, the allopathic theory focused on the specific [damaged] body part; the Ayurvedic was more of a holistic approach that healed the whole body. Third, using Peter Sheehan's economic analogy, the allopathy approach was like the Russian transition to the market economy with a big bang, the results were faster but may be damaging in the long run. In contrast, the Ayurvedic approach was like the Chinese transition, gradual but safe.

From the patient point of view, the moral of the story is that a surgery may not always be the only or the best option in such or many other cases. All options should be carefully considered for best results. For surgeons, it may not always be in their best interest to describe to the patient in graphic details an operation that they are going to perform on the patient. For a researcher, the lesson learnt is that no idea should be discarded without fully exploring it.

In Memoriam

Masanobu Fukuoka (1913-2008)

*M.R. Rajagopalan**

Fukuoka the author of *One Straw Revolution*, which inspired many a person all over the world to convert to Natural Farming, is no more. He passed away at the age of 95 on August 16, 2008. I read this famous book, a third time, after a gap of 10-15 years, for writing this article. Often I got the feeling I am reading Mahatma Gandhi! The common point between Gandhiji and Fukuoka is that they practised first and preached later. One of the remarkable statements of Mahatma was "My life is my message". Though Fukuoka made no such statement, his life is his message in relation to Natural Farming. Nevertheless, it should be borne in mind that Gandhiji's life and message have universal application for truth, non-violence and village-based economy, whereas Fukuoka's message is restricted to Natural Farming.

Fukuoka was inspired by Buddha and Gandhi. In Fukuoka's words "I believe that Gandhi's way, a methodless method, acting with a non-winning, non-opposing state of mind, is akin to natural farming. When it is understood that one loses joy and happiness in the attempt to possess them, the essence of natural farming will be realized. The ultimate goal of farming

is not the growing of crops, but the cultivation and perfection of human beings."

Again Fukuoka says in some other place in his book: "Fast rather than slow, more rather than less – this flashy 'development' is linked directly to society's impending collapse. It has only served to separate man from nature. Humanity must stop indulging the desire for material possessions and personal gain and move instead toward spiritual awareness." Does this not sound like Gandhi?

As a young man, Mr. Fukuoka left his rural home and traveled to Yokohama to pursue a career as a microbiologist. He became a specialist in plant diseases and worked for some years in a laboratory as an agricultural customs inspector. It was at that time, while still a young man of twenty-five, that Mr. Fukuoka experienced the realization which was to form the basis of his life's work and which was to be the theme of the book, *The One-Straw Revolution*. He left his job and returned to his native village to test the soundness of his ideas by applying them on his own fields.

How the Revolution Started

The basic idea came to him one day as he happened to pass an old field which had been left unused and unplowed for many years. There he saw healthy rice

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seedlings sprouting through a tangle of grasses and weeds. From that time on, he stopped flooding his field in order to grow rice. He stopped sowing rice seed in the spring and, instead, put the seed out in the autumn, sowing it directly onto the surface of the field when it would naturally have fallen to the ground. Instead of plowing the soil to get rid of weeds, he learned to control them by a more or less permanent ground cover of white clover and a mulch of rice and barley straw. Once he has seen to it that conditions have been tilted in favor of his crops, Mr. Fukuoka interferes as little as possible with the plant and animal communities in his fields.

All three methods (natural, traditional and chemical) yield comparable harvests, but differ markedly in their effect on the soil. The soil in Mr. Fukuoka's fields improves with each season. Over the past twenty-five years, since he stopped plowing, his fields have improved in fertility, structure, and in their ability to retain water. By the traditional method, the condition of the soil over the years remains about the same. The farmer takes yields in direct proportion to the amount of compost and manure he puts in. The soil in the fields of the chemical farmer becomes lifeless and depleted of its native fertility in a short time.

In the area of Shikoku where Fukuoka carried on his experiments, rice is grown on the coastal plains and citrus (orange/lime varieties) on the surrounding hillsides. His farm consisted of one and a quarter acres of rice fields and twelve and a half acres of citrus plants.

Four Principles

He adopted four principles for farming this land.

The first is No cultivation – that is no plowing or turning of the soil. The second is No Chemical Fertilizer or Prepared Compost. People interfere with nature, and try, as they may, they cannot heal the resulting wounds. The third is NO Weeding By Tillage Or Herbicides. Weeds play a part in building soil fertility and in balancing the biological community. The fourth is No Dependence on Chemicals. From the time that weak plants developed as a result of such unnatural practices as plowing and fertilizing, disease and insect imbalance became a great problem in agriculture.

These four principles of natural farming comply with the natural order and lead to the replenishment of nature's richness. Ultimately, it is not the growing technique with is the most important factor, but rather the state of mind of the farmer.

A Self-supporting Farm

Apart from agriculture, Fukuoka also practiced animal husbandry, poultry, fisheries and bee keeping – These

factors ensured that life in the farm was self-supporting - the attainment of Gandhian ideal village where the entire requirements were locally produced.

Fukuoka had become a legend in his own lifetime. Naturally there were a stream of visitors and admirers not only from different parts of Japan, but from all parts of the world. Visitors were accommodated in mud huts like in Sewagram of Gandhi and had to participate in daily chores. To quote a visitor, "there are no modern conveniences in Fukuoka's farm. Drinking water is carried in buckets from the spring, meals are cooked at a wood-burning fireplace and candles and kerosene lamps provide light. The mountain is rich with wild herbs and vegetables. Fish and shellfish can be gathered in nearby streams and sea vegetables from the Inland sea a few miles away.

There are the daily chores of cutting firewood, cooking, preparing the hot bath, taking care of the goats, feeding the chickens and collecting their eggs, minding the beehives, repairing and occasionally constructing new huts, and preparing soybean paste and soybean curd."

Why the title "One Straw Revolution?"

The first sentence of the first chapter "Look at this Grain", begins like this: "I believe that a revolution can begin from this one strand of straw. Seen at a glance, this rice straw may appear light and insignificant. Hardly anyone would believe that it could start a revolution. But I have come to realize the weight and power of this straw. For me, this revolution is very real."

Elsewhere, he says "Spreading straw might be considered rather unimportant, but it is fundamental to my method of growing rice and winter grain. It is connected with everything, with fertility, with germination, with weeds, with keeping away sparrows with water management. In actual practice and in theory, the use of straw in farming is a crucial issue. This is something I cannot seem to get people to understand.

A Word of Caution

Before concluding this article, I would like to observe that what has become popular now as Organic Farming or Natural Farming is a little too different from Fukuoka's methods. The organic farmers prepare compost, vermicompost, Panchagavya, Bio-fertilizers, Bio-pesticides, etc. These methods are foreign to Fukuoka – who just left the soil to do its own work.

Yet, a word of caution would be in order. In some place in his book Fukuoka says "the geography and topography of the land, the condition of the soil, its structure, texture and drainage, exposure to sun light

insect relation, the variety of seed used, the method of cultivation etc. are essential factors. These vary from place to place.

Fukuoka's own farm was somewhat exceptional. It had a humid climate with rain dependently falling throughout the spring months. The texture of the soil was clayey. The surface layer was rich in organic matter and retained water well.

If we tried to follow Fukuoka's do nothing after scattering the seeds in the dry belts of central and southern Tamil Nadu, or for that matter in any part

of the world with scanty rainfall, or a sandy or loamy soil, the results would be disastrous.

Nevertheless, Fukuoka has created a new trend in farming. His method could be copied at least in some places. In other places with different soil and climatic conditions, one can avoid chemical fertilizers and pesticides and use organic fertilizers.

Lastly, what is inspiring, as one reads through Fukuoka's 'One Straw Revolution' is that he reminds us of Gandhi for his truthfulness, simplicity spirituality and living with nature as part of it with minimal interference.

From the mfc eforum

Dr Wishvas Rane (1930-2008)

From: Anant Phadke

Sent: December 13, 2008 9:59 PM

Subject: Re: Dr Rane Passes away

Dear all,

Dr. Rane was 'battling' (in his own way) for the last four years with carcinoma of the rectum. He has written a book in Marathi (accepted for publication by a renowned Marathi publisher) on his encounter with cancer. When first diagnosed four years back, he already had secondaries in the liver and in the aortic lymph nodes. His doctors thought that he would not survive for more than 2-4 months. But he survived for four years and for the last two years he had stopped all chemotherapy. Yet, he was continuing his home based routine till almost last week. His book shares all this very interesting story and tells us his philosophy behind stopping treatment. He survived for four years without much pain and other trouble partly because of his bold decision to face his own death in a somewhat detached manner. I met him about 15 days ago when I shared my suggestions about the draft of his book mentioned above. He asked me to write an introduction to it. I managed to send it to him two days back. Yesterday it was read out to him by a relative. Dr. Rane arranged to send it to the publisher, called up the publisher to tell him about it. That was perhaps his last serious dialogue with the outside world. From yesterday afternoon his condition worsened rapidly and he passed away at 11 pm.

All of us would miss him, remember him because of all the qualities that Mira, Amit, etc. have mentioned and because of his contribution to the All India Drug Action Network, the Pune-based Aarogya Dakshata Mandal, its Pune Journal of Continuing Education and now also because of his courage in facing cancer.

- Anant Phadke

From: Mira Shiva: December 13, 2008

Dr Rane, one of the founders of Arogya Dakshata Mandal and AIDAN and who contributed to the drug work selflessly, for over 3 decades passed away last night from cancer.

He and Dr Patwardhan of Arogya Dakshata Mandal for years brought out the *Pune Journal of Continuing Medical Education*.

He was the coauthor of all the 5 editions of *Banned and Bannable Drugs* and *Rational Drug Policy* published by Voluntary Health Association of India, contributing to Drug Policy Advocacy work.

Dr Rane contributed to the Rational Drug Movement, through his deep insight in the workings of the Drug Industry, during the E.P campaign, during the public hearings, monitoring Drug Prices after the policy changes of 1986 and 1994. Meeting with policymakers, parliamentarians, Chemicals Ministers, Secretaries and Members of Maharashtra Assembly during the Lentin Commission Report were among his many efforts as also contributing to the discussions on IFPMA and HAI Code way back in 1983. He wrote in *Sakaal* in his mother tongue Marathi on Drugs and Health issues.

Dr Rane was an extremely solid, wise, selfless person, who contributed to the Drug and Health Movement because of his commitment to the cause, with steadfastness, throughout the almost 28 years of working relation, using his writings, his words and his very presence for furthering the cause of the people.

His life reflected his value system Simple Living and High Thinking.

Dr Rane passed away last night. He was suffering from cancer. He has written his experience as a cancer patient in a book he was writing in Marathi.

Having been in the Drug and Health Movement for

over 28 years and having worked with Dr Rane closely, I recognize the tremendous loss of a person from whom there was so much to learn about the issues, about working selflessly, about the joy of meaningful work, about kindness in thought and action, about being non-compromising on key values, about mentoring, about being a good human being.

Dr Rane's passing away is a collective loss and a personal loss.

- Mira Shiva

From: Chinu Dec 13, 2008

Dr Rane was a gentleman to the core. I am a bit taken back although I knew he was suffering for some time. With sadness,

- Chinu

From: Gopal Dabade: December 13, 2008

I am moved to know about his demise. Dr Rane was a great supporter of AIDAN. His articles on Drug Pricing in *EPW* have been a great contribution. His thoughts and actions will continue to inspire all of us.

- Gopal

From: Narendra: December 13, 2008

I had met Dr. Rane roughly about 15 years back when AIDAN and MFC meetings used to happen together in Sewagram. I still recall him as a very learned and a person with great humor. It is very sad to know that he is no more.

- Narendra

From: Ravi Duggal: December 13, 2008

Dr. Rane's contribution to the rational drug movement and the literature on it is remarkable. It was enriching to read what he wrote. Condolences to his family and close associates. We will miss him.

- Ravi

From: Padma Prakash: December 14, 2008

I am so sorry to hear about Dr Rane's passing away. He ploughed a lonely furrow for so long on rational medicine. He used to write a monthly article for the *EPW* on drug prices, which although it appeared to be a bit of a disorganised, was, many readers used to tell me was most useful. I once had the cheek to tell him that it was difficult editing his pieces because he assumed that the readers would know a great deal about medicine, and I had to very carefully examine each statement he made. He pointed out gently that since I had wanted him to write and I should have known that he could only produce the content and not the text, and that it was my job in any case to edit it! The thing is he did so much painstaking work on them. And the *Pune Journal of continuing Medical Education* was a marvel.

mfc bulletin/October 2008-January 2009

In our 'movement' mode we tend to forget older stalwarts who had no movement to work with, and some inspired movements. And often they only feel the failures of not achieving their goals. I wish there was some way we could honour people like Rane so that they know how worthwhile was their work and inspiration, and how much it is part of the living memories of groups that have come later.

My deepest admiration for him and his work. I hope it was a peaceful going.

- Padma

From Jagannath Chatterjee: December 14, 2008

I have only heard about Dr Rane. I think translating his book from Marathi to English may be a good tribute to this fine soul.

- Jagannath

From Sathya: December 15, 2008

Dear Anant,

Thank you for sharing the last moments of Dr Rane with us. He was such a lovable person and he died as he lived, with courage, conviction and dignity. What a beautiful death (I have been reading about and contemplating death since Alpana's passing away). He was the most 'un-activist' looking of us all but the most consistent, stable, determined and single-minded in his pursuit of rational drug policy. In a world which is more and more 'ageist' (bias against age) he showed that with age comes a different level of knowledge and wisdom not found in the aggressive energy of youth. I request you to write an obit to celebrate a life so that others who did not have the privilege of knowing him will be inspired. Truly a great loss. A wonderful human being

Sathya

From Nimitta and Ashvin Patel: December 15, 2008

We had not met Dr. Rane for a long time. But kept hearing about him in the Drug movement, last in the Mumbai meet of AIDAN. But we do remember him in the early LOCOST days, when we were actively taking up Rational Therapy Cell activities. Our heartfelt tributes. We feel sad at this loss to all of us.

- Nimitta and Ashvin

**From: "Sundararaman T",
December 14, 2008 5:32 PM**

Dr Rane's passing away is saddening. Though I have not been in touch with him for a number of years now, I still remember him as one of the persons who brought the issue of rational drugs use into the agenda of people's movements. Soft spoken and gentle but firm of purpose- he will continue to inspire us.

- Sundararaman

*Indian Civil Society Statement***Attempts of WHO to Mainstream TRIPS-Plus IP Enforcement Measures and on the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)***16 January 2009*

The upcoming meeting of the Executive Board (EB) of the World Health Organization (WHO) is scheduled between the 19th and 27th of January 2009 at Geneva. Anti-counterfeiting measures including a definition of 'counterfeit medical products' will be discussed at this meeting. The International Medical Product Anti-Counterfeit Taskforce (IMPACT) is leading the negotiations regarding the definition and for the introduction of a resolution at the next World Health Assembly (WHA). In this regard, the WHO Secretariat has prepared a note titled 'Counterfeit Medical Products' which details the work of IMPACT and endorses it. It further suggests a draft resolution for a similar endorsement of IMPACT's work by the WHA and for the continuation of the group for another two years. This is a matter of great concern.

Background: Attempts to Confuse IP Enforcement with Public Health Issues

Over the past several years, multinational pharmaceutical companies and some developed countries have been pursuing what has come to be known as the 'Intellectual Property (IP) Enforcement Agenda'. This involves lobbying with governments to introduce strict IP enforcement norms in their laws and to rope in public authorities funded by tax-payers money to enforce their IP rights. Among these authorities are drug regulatory authorities (DRA). In the past attempts to include DRAs in the enforcement of IP have included trying to introduce policies such as patent linkages and data exclusivity. More recently, attempts have been focused on redefining the term counterfeit which generally refers to trademark disputes. This has been done effectively by blurring the lines between issues of real public health concern (i.e. spurious, substandard and adulterated drugs) with counterfeits. The term counterfeit is increasingly being used to refer to multiple problems leading to much confusion and the effective introduction of the IP enforcement agenda.

IMPACT: The "IP Enforcement" Agenda

IMPACT was launched in 2006 with the WHO as its secretariat to address the issue of counterfeiting. Its launch was not sanctioned by any WHA resolution i.e. by member countries of the WHO. IMPACT works closely with several organisations such as Interpol, Organisation for Economic Co-operation and Development (OECD), World Customs Organisation

(WCO), World Intellectual Property Organisation (WIPO), European Commission and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) which are institutions engaged in IP enforcement and in particular in promoting standards that go beyond the TRIPS Agreement. The majority of IMPACT's funding is from developed countries including the European Commission who has a recognized stand on counterfeiting and IPR enforcement.

IFPMA, the organisation of multinational pharmaceutical companies has been closely and openly involved in the work of IMPACT. IFPMA heads the Technology Working Group of IMPACT and is also a member of its Planning Group.

Of all the work of IMPACT, two activities require urgent attention. One is the definition being proposed by this group of the term 'counterfeit' which despite several meetings, clarifications and explanations continues to include vague terms and combines issues of trademark infringement, spurious and mislabeled drugs. The definition is being proposed as model text to be adopted by countries.

By confusing the issues of counterfeit medicines with concerns regarding spurious and mislabeled medicines, IMPACT is following the wrong approach. IMPACT's focus on policy and legislation on counterfeit drugs will be counter productive and will create barriers to trade in and access to legitimate medicines. Overemphasis on the need to take measures against counterfeiting is also drawing the attention of WHO and developing countries away from much needed efforts to tackle spurious and substandard medicines. This will in fact benefit the multinational pharmaceutical industry that is keen to enforce its private IP rights through anti-counterfeiting measures.

The second area of concern is a document proposed by IMPACT titled, '*Principles and Elements for National Legislation against Counterfeit Medical Products*'. This document proposes a harsh criminalization and enforcement regime and compares counterfeiting with drug trafficking. The problem with this is that allegations of counterfeiting may actually relate to drugs that are safe, legitimate and registered but on which there may be grievances of trademark

infringement.

IMPACT: Undermining TRIPS Flexibilities

The definition proposed by IMPACT and the *Principles and Elements for National Legislation against Counterfeit Medical Products* reflect in large part the interests of multinational pharmaceutical companies and certain developed countries in putting in place an IP enforcement regime. This is not surprising given the enormous influence they have enjoyed in the working of IMPACT. There are also concerns that the new definition undermines TRIPS flexibilities such as parallel importation by its use of vague legal language.

ACTA, SECURE and IMPACT: Same Actors, Different Arenas

The work of IMPACT must be seen in the light of other actions of multinational pharmaceutical companies and some developed countries. Key among these is the Anti Counterfeiting Trade Agreement or ACTA being negotiated between certain countries which many public interest groups fear is aimed at introducing a TRIPS-plus IP enforcement agenda. The World Customs Organisation (WCO) is also developing the *Provisional Standards Employed by Customs for Uniform Rights Enforcement* or SECURE which promote strict IP enforcement. IFPMA, the WCO, INTERPOL, the European Commission and other developed countries are heavily involved in all these initiatives.

It must be noted that the European Union and other developed countries have been working consistently to strengthen intellectual property enforcement. One such mode of enforcement is to amend regulations that govern practices by national authorities including drug regulators, customs, etc. This could lead to public authorities, seizing or delaying the movement of legitimate generic medicines, on suspicion of being "counterfeit". The creation of such barriers will lead to the delay in accessing affordable medicines for patients around the world.

Undemocratic and Non-transparent International Law and Policy Making

The manner in which IMPACT has functioned has completely bypassed the process of international negotiations of the World Health Assembly. The recent process of drafting and negotiating the *Global strategy and plan of action on public health, innovation and intellectual property* presents a model of international negotiation that involved all member States of the WHO, invited and included experts from across the

spectrum and used public health as the fulcrum for the entire process. This is in contrast to the manner in which the WHO has approached the counterfeit issue. While the IGWG process was member driven, open and transparent, inclusive of public interest groups and where international norms were set through negotiations between countries, the IMPACT process has been driven by a heavy involvement of the private sector, been lacking in transparency and has in effect substituted the process of international negotiations between countries in arriving at international law and policy.

WHO is failing to Focus on Public Health Concerns

The report of the WHO secretariat once again emphasizes counterfeit medicines. WHO's continued focus on counterfeit medicines have also led to concerns that instead of addressing the issue of substandard medicines and spurious drugs that represent a far larger risk to public health, the anti-counterfeiting measures it supports may actually create trade barriers that seriously affect access to legitimate generic medicines.

Its recommendation therefore that the Sixty-second WHA adopt a resolution on counterfeit medical products "to establish effective mechanisms of coordination and collaboration among health, enforcement and other relevant authorities in order to improve detection, investigation and prosecution of cases of counterfeit medical products", will be counter productive and will in fact be detrimental to public health as it allows the creation of barriers to the export and import of affordable generic medicines.

The report also endorses the Tunisia IMPACT definition resolution on counterfeit medical products. The adoption of the definition of counterfeit by India and other developing countries will legitimize IMPACT and the resolution on counterfeit medical products being proposed by the WHO secretariat.

While the substance of the suggestions made by IMPACT over the past two years is a great cause for concern, even more worrying is the manner in which this group without any sanction from the World Health Assembly has effectively substituted the democratic body of nations in making international policy. It is essential that India reject the working of this group and call on the WHO to immediately distance itself from IMPACT and institute a transparent and democratic process to confront real public health concerns.

In the above background, we call on the Indian government to:

- § **Reject the report of the WHO secretariat and the draft resolution on ‘counterfeit medical products’:** The draft resolution proposed by the WHO secretariat endorses the work of IMPACT and ensures its continuation for at least another three years. This is not acceptable.
- § **Call on the WHO to withdraw from IMPACT:** The funding and functioning of IMPACT has heavily involved agencies that have a clear conflict of interest and that have long been associated with hampering the supply of safe, effective and affordable generic drugs to patients around the world. India must call on the WHO to reject IMPACT and institute an open and transparent process in identifying and tackling public health priorities.
- § **Ensure that the safety, efficacy, affordability and accessibility of medicines remain the focal points of the work of the WHO:** Strengthen the systems of quality assurance in the procurement of essential drugs by developing countries. WHO pre-qualification system for anti-retrovirals has effectively proved that developing countries can not only effectively

treat AIDS but also produce the quality low cost generic drugs needed for the same.

- § **Call on the WHO to institute an open and transparent process in the identification and tackling of public health priorities:** Involve experts, civil society and governments from developing countries in identifying the issues, the negotiations and the development of draft texts of any resolution. All pharmaceutical associations and institutions with IP enforcement agendas should be prohibited from funding and participating in the negotiations and in policy making.
- § **Call on the WHO to reject the TRIPS-plus enforcement agenda:** The WHO must reject any and all attempts at bringing in a TRIPS-plus enforcement agenda whether through IMPACT, ACTA or national legislations.

National Working Group on Patent Laws, All India Drug Action Network (AIDAN), Jan Swasthya Abhiyan (JSA), All India People's Science Network, Initiative for Health Equity and Society, Healthwatch Forum, Drug Action Forum- Karnataka(DAF-K), Centre for Health and Social Justice (CHSJ), and Centre for Trade & Development (Centad)

Update on WHO Counterfeit Issue

WHO drops resolution on counterfeit drugs, major victory to generic drug makers¹

Due to the tremendous pressure exerted by the developing countries including India and Brazil, the World Health Organisation (WHO) has dropped the controversial resolution on counterfeit drugs. The WHO decision will prove to be a huge victory for the generic pharma industry in the developing world which has been opposing the WHO attempt on the plea that, once the resolution is passed, their products could be rejected as counterfeit products.

According to sources, the decision to shelve the resolution on implementing the IMPACT-proposed new definition on counterfeit drugs was taken at the WHO's executive board meeting held in Geneva. Top Indian health ministry officials had also attended the meeting. However, the WHO is yet to officially announce the decision in this regard.

Sources close to the development said, “Developing countries, in particular Brazil voted against the WHO Secretariat report and the attached draft counterfeit resolution (EB 124/14) presented at the WHO Executive Board meeting. Developing countries were concerned that IMPACT's focus on policy and legislation on counterfeit drugs will be counter productive and will create barriers to trade in and access

to legitimate medicines. The seizure of legitimate generic drugs in transit from India to Brazil as counterfeit by the EU on allegations of IP infringement, added to the fears of developing countries that the resolution could be misused to further the intellectual property enforcement agenda.”...

... In India, all the major industry associations like IDMA, IPA, SPIC, CIPI and FOPE have been opposing the WHO move as they feared it as yet another attempt by the big multinational companies to kill the Indian generic drug makers. The Indian drug manufacturers feared that if the changes go through as proposed by the IMPACT, foreign drug firms could stall exports of low-cost versions of patent expired medicines to key markets. Today, Indian firms have several brands that sound similar to those of multinational brands. For example, global drug major Pfizer has an erectile dysfunction medicine Viagra, while Indian companies make generic versions of Viagra with similar sounding names. Currently, this would at the most be treated as a trademark violation (under Indian Patent and Trade Mark Act). However, according to the definition proposed by IMPACT, the Indian product could be rejected as counterfeit.

¹Reproduced in Public Interest from *Pharmabiz.com* dated January 28, 2009.

The lone voice of support for the WHO move came from OPPI.

Fake Drugs in India: Points to Ponder

-Dr. Chandra M. Gulhati, Editor, MIMS

The two topics, viz. fake drugs and substandard medicines, are separate subjects. For example:

- Regulatory framework (CDSCO) exists in India to deal with Fake and Substandard drugs.
- Production and sale of fake drugs is essentially a criminal act.
- Production and sale of substandard drugs can be deliberate or due to negligence.
- Fault can also lie with distributors and retailers with regard to storage of temperature sensitive items that can render standard into substandard products e.g. Insulin.

Fake Drugs in India:

- Every now and then the mass media both in India and abroad carries stories on manufacture and sale of huge number of fake drugs in India.
- Figures quoted range from 20 to 25%
- Implication: Every 5th, if not 4th medicine being sold in over 600,000 retail chemist shops is fake.
- Based on this assumption, the total fake market business should be at least Rs. 6,500 crores every year!

Endless Repetition of Unreliable Data

- “One widely quoted WHO statistic places India as the leader, with as much as 35% of world’s production (of fake drugs)”: news item in the Lancet, 2 June 2001.
- As part of the “evidence” the case of narcotic analgesics being smuggled by Uzbek carriers but seized at New Delhi airport was quoted.
- The fact: the narcotic analgesics were illegally produced for smuggling but were NOT FAKE.
- Despite repeated denials by WHO, this misinformation continues to be repeated by the media even today.

Confusion due to Different Definitions:

- In India, the descriptions fake, spurious and counterfeit convey the same meaning.
- However as per WHO definition counterfeit drugs are those that have “been deliberately and fraudulently mislabelled with respect to identity and/or source.”
- Despite such a wide definition between 2002 and 2004, not a single case of counterfeit case was reported to WHO.

- In America counterfeit drugs include genuine, foreign medicines/brands not approved by the United States Food and Drug Administration (USFDA).
- No wonder according to USFDA, “Up to 25% of all drugs consumed in poor countries are thought to be counterfeit or substandard.” (Ref: *The Lancet*, Vol. 362, 22 November 2003)

WHO “Fact Sheet” Without Data, Without Proof:

- “There has been no full international survey but *estimates* from WHO and the pharmaceutical industry *suggest* that at least 5% of medicines in circulation (worldwide) may be counterfeit” (Ref: *The Lancet*, 5 October 2002)
- “Counterfeiting in Peru is as high as 80% according to Merck, Sharp, and Dohme.” How come everyone is alive!
- “In 2002, India’s pharmaceutical companies *suggested* that in India’s major cities, one in five medicines sold was a fake. They claimed a loss in revenue of between 4% and 5% annually. The industry also *estimated* that illegal drugs had grown from 10% to 20% of the total market.” (Ref: *WHO Fact Sheet revised*, 14 November 2006)

Figures Don’t Tally

- If fake drugs are so much in abundance in India, then why does the industry claim that their “loss of revenue” is between 4 and 5%?
- It should be more like 20% or even more.
- It can be less ONLY if fake drugs fall overwhelmingly in the cheaper range.
- But why cheap fake drugs should be manufactured and sold since the profits are not be worth the trouble and risk.

Let us look at an illustration: Paracetamol v/s Ceftriaxone

- Bulk paracetamol costs Rs. 180 per kg (1000g).
- Cost of active ingredient in one dose comes to just 9 paise.
- The production cost of a strip of 10 tablets (without active ingredient) comes to Rs. 1.50. Thus production cost is higher than cost of medicine.
- Sale price varies from Rs. 4 to 10 per strip.
- Bulk ceftriaxone costs over Rs. 11,000 per kg.

- Cost of active ingredient in one dose (1g) vial comes to Rs. 11.20.
- The production cost without active ingredient is Rs. 4.40.
- Sale price is over Rs. 70
- Will fake drug maker produce paracetamol or ceftriaxone?
- ***Profits lie in expensive products with large market.***

India: Fake v/s Spurious Drugs:

- In India, Fake is a commonly used word that means “Not Genuine.” This word is not specifically mentioned in our laws governing medicines.
- “Spurious”, as defined in the Drugs and Cosmetics Act (Section 17B) is not limited to fake products but also includes other cases such as products that use unauthorized names, manufacturers etc.
- Implication: A strip of 10 pure and genuine paracetamol tablets will be deemed to be “spurious” if it uses the name Crocin without permission from trade mark holder GSK.
- In many raids where the aggrieved informer is a manufacturer of the original product, primarily and at least initially the issue relates to unauthorized use of brand names.
- Thus manufacturers use the legal definition to their commercial benefit even when public health may or may not be at stake.
- How many of the “spurious” products were found to be fake as well?
- Is the definition exaggerating the figures of really fake drugs?
- Should the definition of Spurious drugs be

amended?

Strange Silence on Fake Brands

- Large drug industry associations (IDMA, OPPI) provide estimated percentage figures of fake drugs.
- Methodology and conclusions are neither listed nor supported with evidence.
- Concrete examples are often not given.
- Why should the drug companies shy away from giving specific details?
- Recently duplicate copies of a popular and very widely used cough remedy flooded certain markets in eastern India.
- The company found that its product’s sale was either stable or going up all over the country except certain markets in eastern India.
- The Company took action with local police help but did not involve drug controller.
- The reason? Media coverage of the existence of duplicate products would have led to boycott of the brand by patients and doctors all over India!

Conclusion: Urgent Need of Credible, Correct Data:

- Currently fake drugs are discovered through random sample collections by state drug inspectors.
- On receipt of complaints by aggrieved manufacturers.
- Rarely by patients.
- These are inadequate measures to determine the correct prevalence of the problem.
- ***National level scientifically structured large sample collection and testing is urgently required. CDSCO has probably already started the process.***

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