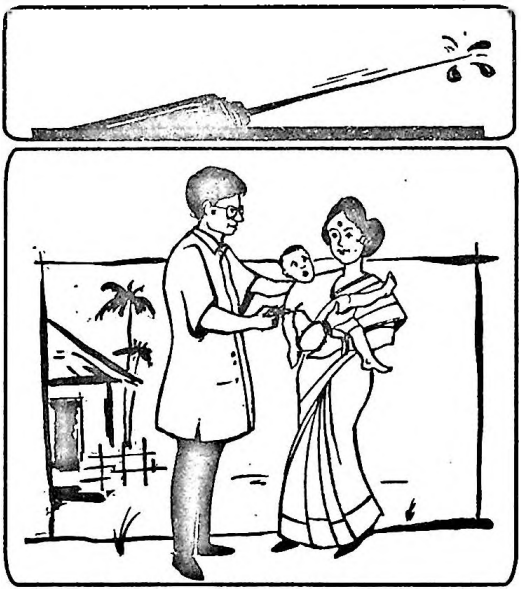
Hepatitis B Vaccination

Misleading Policy & Promotion



Drug Action Forum – Karnataka
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Chennai

HEPATITIS B VACCINATION – MISLEADING POLICY AND PROMOTION IN INDIA. By Dr Gopal Dabade of Drug Action Forum – Karnataka. A critical appraisal of the policy of the Government of India on hepatitis B vaccination.

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Drug Action Forum - Karnataka campaigns for the rights of the people for Rational Drug Therapy & Policy.

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PREFACE

Last week in my sleepy home town there was a news item about a quack who was going around and pressurizing public to get vaccinated for hepatitis B vaccine, which in reality was not even a vaccine. The local bodies including the doctors' association caught him and handed him to police for further probing and action. That was indeed a good job by the local vigilant community and the doctors.

But what happens when the policies of the government are formulated by 'quacks' or by policy makers who hijack the issues in favour of the business world and are NOT in favour of people's health. Health policies of any country effect each and every individual. Little do we realise that people in far off rich and big cities plan if a child in a remote village should get a particular vaccine or not. If the policies are pro people it definitely helps people if not they can be catastrophic. Often the common man is at a loss to understand the policies. Drug Action Forum – Karnataka has taken up this particular issue on hepatitis B vaccination policy so as to make it available to common man the policies of the Government of India in a simple presentation. It is one such effort of DAF-K to demystify medicine for common man.

We also want to reach the policy makers and groups that would be interested in such issues. Please help us in reaching them. So we look forward for your involvement and suggestions on this.

In this booklet we also present our correspondence with the Karnataka State Drug Controller, Bangalore and the drug companies. DAF-K had taken note of a misleading advertisement by a leading drug company.

Let it NOT be presumed that DAF-K is against vaccines. Far from it. We need vaccines and vaccine policies that help in

preventing diseases with keeping people as priority. In fact we need much more than vaccines and Drug action Forum – Karnataka believes that:-

1. Health is not only a right but also everyone's responsibility. This is more true in a situation where we live in a world where medical information is NOT demystified.
2. Knowing about the drugs and vaccine that the person is using is one's right.
3. A well informed non medical person is in a much better situation to prevent and treat common health problems.
4. Medical information needs to be demystified so that non medical persons are in charge of their health problems.

"Health for All, now" can only be achieved when people have access to information. And this is one such attempt by Drug Action Forum – Karnataka.

The last page in this booklet is a tear page. Kindly send the letter to the Health Minister and mark us a copy of the same.

Dr Gopal Dabade
Drug Action Forum – Karnataka

People's Health Movement

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- International People's Health Council (IPHC)
- Third World Network (TWN)
- Women's Global Network for Reproductive Rights (WGNRR)

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FOREWORD

The 'Health For All' challenges in countries like India need responses that are relevant to the 'socio – economic – cultural - political context. These responses cannot be just passive transfers of global guidelines or recommendations often derived from practitioners of Public Health in very different types of health care systems and social realities.

Technology transfers in response to public health challenges also need to be subservient to people's needs and national capacities and not only determined by 'pulls' and 'pressures' from the promoters of the technology. Public and professional debate and dialogue, based on technical and social evidence, is therefore, crucial in this search for relevance and context.

Immunisations have been a significant part of the public health armamentarium, especially for improving child health. However, the

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non-government organisation,[3] in India, CEHAT (Centre for Enquiry into Health and Allied Themes) (http://www.cehat.org/), which is a active critic, in the field of public health. The major concerns of it has been on the issue of lack of resources for introducing the vaccine and the absence of epidemiological basis of hepatitis-B and also in addition has come out with better alternatives for the same.

Today vaccination policies seem to have shifted towards Public-Private Initiatives (PPIs) and away from equity. The Director General of the WHO has come out strongly in favour of such Public-Private Initiatives (such as GAVI) to treat infectious diseases. Health has become an economic asset and is no longer primarily seen as a basic human right. In vaccination programmes the focus now appears to be creating markets for new vaccines. Achieving equity in access to a limited number of essential vaccines, the objective of the EPI does not seem to be the primary objective any more. The notion of market failure and the lack of new vaccines are attractive ideas for the pharmaceutical industry as it can play a leading role in 'supporting' the development of new vaccines.[4]

It is interesting to note that the first disbursement by GAVI made for the year 2000/2001, totalled US dollar 150 million from the initial commitments totalling US dollar 1.03 billion. Of this initial disbursement 90% was allotted for the introduction of new vaccines and single use injection materials, while only 10% went to strengthen immunisation services. Anita Hardon commented: *"The emphasis on the introduction of new and under-used vaccines in GAVI reflects a more general shift away equity towards technological innovation and disease eradication in global health programmes. This appears to indicate fundamental move in vaccine policy from the values of the Post-Alma Ata (PHC) era."* For more details look under "Vaccination Policy and the Public Private Mix", page number 13.

Lack of resources

The Indian Academy of Paediatrics (IAP), an organisation

representing the paediatricians of the country has recommended that all the new born infants should be vaccinated with hepatitis B vaccine and to implement which would cost Rupees 1250 million (around 26 million US$) annually for the hepatitis-B vaccine alone, at the rate of Rupees 50 (around 1.04 US$) per new born for the 25 million annual births in India. Compare this with the budget in the year 2000-2001 of Rupees 1250 million (around 26 million US$) allotted by the Government of India for its National Tuberculosis Programme. And Rupees 1050 million (around 22 million US$) for Malaria control. Tuberculosis & Malaria obviously being major killers in India.

According to World Health Organization (WHO); "India has more TB cases than any other country in the world. Every year, 2 million people in India develop TB and nearly 500,000 die from it – more than 1,000 every day. The disease has become a major barrier to social and economic development. More than 300,000 children are forced to leave school each year because of their parents' tuberculosis, and more than 100,000 women with tuberculosis are rejected by their families due to social stigma."[5]

It is necessary to address these questions in a developing country like India, where financial resources is always a constraint. Secondly, in any case, modern health care management should consider cost efficacy and effectiveness of any healthcare intervention that is paid through public money.

Also given the fact that for the maximum efficacy of hepatitis-B vaccine, to prevent the 'mother to child' (which is the most dangerous mode of transmission in India), this vaccine would have to be given during the first twelve to twenty-four hours of birth as per the recommendation of WHO, the American Academy of Paediatrics and other major agencies. This would be impossible, because 77% of deliveries, in India take place at home.

Absence of epidemiological basis

Recommendations by WHO are that, Universal and Selective Vaccination for countries with a carrier rate of and below 2%, respectively, should be carried out. In India, there has been controversy over the prevalence of the disease. The quoted study, by medical bodies has been that of S.P.Thyagarajan et. al., which puts the carrier state in India at 4.7%. This is not acceptable, as it suffers from three errors as per Phadke Anant & Kale Ashok;

1. HBsAg (hepatitis-B surface antigen) positive rate has been confused with carrier rate- the studies used are all one time, cross-sectional studies of prevalence of HBsAg positive in mostly blood donors. This positive rate is quite different indicator than the carrier rate. Carrier stage in hepatitis-B virus infection is persistence of infection for six months or more.
2. Thyagarajan, et al have included three studies on professional blood donors and one from the dental personnel. The basic limitation of blood bank data is that, some of the blood donors are professional blood donors (blood donation is often income generation, for the donor), all though they are recorded as voluntary blood donors. The prevalence of hepatitis-B is quite high in professional blood donors. Also many of the blood donors do so repeatedly. So it is wrong to include such high-risk groups in estimating prevalence in general population.
3. An elementary error had been committed in calculating the average from various studies. The average of 4.7% has been calculated by simple taking average of the averages of individual studies, irrespective of number of the cases in the studies.

Phadke Anant & Kale Ashok have used the same data used by Thyagarajan et al, and have rightly excluded the studies on professional blood donors and dental personnel, and

calculated the average of the HBsAg positive rate in different centres. In this process, excluded studies, which did not mention the number of persons tested. The average of the positive rate in the remaining studies was found to be 2.64%, which broadly agrees with the data available from other studies. For example, in the same book in which Thyagarajan et al's paper has been published, a study of HBsAg positive rate in pregnant women coming to the antenatal clinics was found to be 2.8%.

Phadke Anant & Kale Ashok further clarify that the rate of 2.64% based on the data used by Thyagarajan et al is not the point-prevalence. To find out the proportion of the HBsAg positive, being actually infected with the hepatitis-B virus, apply the corrective factor of Positive Predictive Value (PPV). Assuming the sensitivity and specificity of the HBsAg test to be 100 and 99 percent respectively, the PPV of this screening test is 67.1% at the prevalence rate of 2%, as mentioned in the chart given next page. Assuming for a moment that the prevalence of HBsAg positive in India is around 2% then the true prevalence of HBsAg positive would thus be :

$$\frac{\text{(HBsAg positive rate) (Positive Predictive value)}}{100} = \frac{2.64 \times 67.1}{100} = 1.77\%,$$

Which comes to 17.7 million in a population of 1000 million.

Studies, which have followed up initial HBsAg positive patients for six months, have found that about 75 to 80% of these continue to be positive and hence are carriers. Extrapolating from these findings to the above estimation of HBsAg point-prevalence of 1.47% in India, HBsAg carrier rate works out to be :

$$1.77\% \times 0.80 = 1.42\%.^{6}$$

Based on low carrier rate alone, it is clear that the Universal Strategy is invalid in India.

Chart A

Positive Predictive Values (PPV) of a screening test with a sensitivity of 100% & specificity of 99% with a varying degree of prevalence subsets of population of 10,000 each.

Prevalence	Infected Persons	Sensitivity 100%		Non-infected persons	Specificity 99%		PPV (c/c+g) x100
		True (+) -tives	False (–) -tives		True (+) -tives	False (–) -tives	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
1%	100	100	0	9900	9801	99	50%
2%	200	200	0	9800	9702	98	67.1%
3%	300	300	0	9700	9603	97	75%
4%	400	400	0	9600	9504	96	80%
5%	500	500	0	9500	9405	95	84%
6%	600	600	0	9400	9306	94	86.5%
7%	700	700	0	9300	9207	93	88.2%
8%	800	800	0	9200	9108	92	89.7%
9%	900	900	0	9100	9009	91	91%
10%	1000	1000	0	9000	8910	90	91.7%
25%	2500	2500	0	7500	7425	75	97%

Alternatives

The critics are of the opinion that Selective Vaccination Strategy is an alternative, where in screening of all pregnant women for HBsAg and then give the first dose of the vaccine within 24 hours of birth, to the newborns of only hepatitis-B positive mothers. This strategy can be further be made Highly Selective Vaccination (HSV) strategy which would involve the following:-

1. In first year, screening all pregnant women for HBsAg positive and then from second year onwards, to conduct

this screening every year for the primigravida only.

2. Administer the first dose of vaccine immediately after birth, to all the new born of the HBsAg positive mothers in the first year and also to subsequent newborns of these HBsAg positive mothers.
3. From second year onwards vaccinate also the newborn of every additional group of HBsAg positive primiparous women.

It has been observed that the cost efficacy of this Selective Vaccination Strategy, (around Rupees 5227, which is around 109 US$), is much greater, than Universal Vaccination Strategy, (around Rupees 9260, which is around 193 US$) per infant protected from HBeAg (hepatitis B e antigen). Secondly, to cover all the pregnant women and their newborn in a year, the total annual cost of the programme for Universal and Selective vaccination for a cohort of 10,000 would be Rupees 5,00,000 (around 10425 US$) and Rupees 1,15,000 (around 2398 US$) respectively.

This cost can be further reduced considerably, if we screen only the primagravida pregnant women from the second year onwards, and continue to vaccinate infants subsequently borne to the cohort of the HBsAg positive mothers detected earlier.

Apart from the cost-efficacy advantage described of this Highly Selective Vaccination Strategy, it would automatically provide data for monitoring the prevalence of HBsAg positive rate amongst childbearing women. Secondly this strategy is logistically much more practical than the Universal Vaccination Strategy, as it gives 6-7 months to screen the pregnant women for HBsAg during antenatal check-ups. Secondly only about 3% of the newborns will have to be vaccinated within 24 hours of birth. The mothers of these babies would have been detected well in advance and it would be much easier to track down and vaccinate within twenty-five hours, five (around 3%) of the 150 births that would occur in one year in a 5000 population. [7]

Comparative Cost Efficacy of Universal and Selective Hepatitis-B Vaccination in a Cohort of 10,000 Pregnant Women and Their Newborns

		Selective Strategy	Universal strategy
1	Cost of HBsAg screening for 10,000 antenatal cases (at Rs. 10) [A]	Rs. 1,00,000	
2	HBsAg Positivity Rate	3% [B]	
3	Number of HBsAg Positive mothers	300	
4	Vaccine cost of the vaccination of the newborns of positive mothers at 50 per child for 3 doses[C]	Rs. 15,000	Rs.5,00,000
5	Cost of screening and vaccination (row 1 + row 4)	115,000	5,00,000
6	Number of HBeAg carrier children prevented [D]	22	54
7	Cost of preventing one HBeAg carrier (row 5 /row 6)	Rs. 5227	Rs. 9260
8	No. of primi gravida to be screened from year II onwards, annually [E]	3000	
9	Annual cost of screening additional batch of primigravida and vaccinating babies of HBsAg positive primiparous women (30% for row 5)	Rs. 34,500	
10	Cost of vaccinating 600 babies that would be borne to the cohort of 300 HBsAg positive mothers in say next 5 years	Rs. 30,000	
11	Annual cost of this vaccination if spread over 5 years	Rs. 6,000	

Contd....

12	Total annual cost of the programme (row 9 + row 11)	Rs. 40,500	
13	Total annual cost of this programme if all the 25 million pregnant women in India are to be included in this programme (40,500 x 25 millions/ 10,000)	Rs.101 million	Rs. 1250 million (25 million x Rs 50)
14	Total cost of this programme in year I, if all the 25 million pregnant women in India are to be included in this programme (115,000 x 25 millions/10,000)	Rs.287.5 million	Rs. 1250 million(25 million x Rs 50)

NOTES –

A) The kit cost per test during September 2001 was around Rs.20 per test, (with some price variation with different manufacturers). We assume that in the mass screening, this cost would come down to Rs.10/- per test,

B) Kant Lalit, Arora Narendra; Transmission of Hepatitis B Virus in Children : Indian Scenario; in Hepatitis-B in India. Sarin S.K., Singal A.K., (editors) CBS Publishers and Distributors, 1996, Table-2. (We have rounded off this figure in table II)

C) The cost of the vaccine during September 2001 was Rs.100/- per child for 3 doses. We have assumed that this would come down to Rs.50/- per child in a mass-vaccination programme.

D) Row 6 from table II

E) With around a 3-child norm in India, we assume that 30% of all the pregnant women would be primigravida.

F) Assuming the 3 child-norm, each of these 300 HBsAg positive mothers would on an average, give birth to two more children in the subsequent, say five years.

The other additional alternative is Intradermal Vaccination of hepatitis-B, as this would reduce the vaccine cost to one-fifth, since the dose of vaccine in intradermal route is one fifth, that of intramuscularly route. Though there are no studies that have followed up the vaccine for 3 to 5 years, but there is evidence that this could give adequate protection, though further studies are required to confirm these results. Majority of the published studies show that intradermal route, when given in adequate dose, is as effective as intramuscularly route and that acceptability is not a problem, if it is much cheaper then it is more likely to be widely used. [8]

Summary and conclusion

Of the adults who are infected with the virus, almost 95% will recover most with no symptoms at all and all with life long immunity to the virus. Fewer than 5% will live essentially "symptom – free", with declining but continues infectiousness. About one fourth of this 5% will face life threatening liver complications decades later.[9]

So it may be concluded that hepatitis-B virus infection is not a priority issue in India, as Indians have a lifetime risk of less than 0.1% of dying due to consequences of hepatitis-B infection. Today in the Indian situation there is no need to eradicate hepatitis-B infection, but rather should aim at reducing HBeAg pool. This is because the HBeAg positive, persons are the ones which have much higher risk of developing serious liver disease and are the most infectious to others. Persistent presence of HBeAg in the hepatitis-B virus carrier is often associated with Chronic Active Hepatitis.[5]

Even if the Universal Vaccination of infants is done it will not eradicate the hepatitis-B virus infection in the near future, because it will take forty years to stop the vertical transmission. So after forty years of Universal Immunisation all the 'below forty' (i.e. childbearing population) would have been protected and hence vertical and also horizontal transmission would be

stopped, in this age group. To stop the horizontal transmission amongst the above forty year-age group, it would take another twenty-five years of Universal Immunisation (as life expectancy in India is at present sixty-five years, though this figure is likely to increase, with further increase in the demand of the vaccine.)

As mentioned earlier vaccine cost for Universal Vaccination of only the newborn would be Rupees 1250 million (around 26 million US$), at Rupees 50 (around 1.04 US$) per child, for three doses. If all the children up to the age of two years (as covered by under EPI), the vaccine cost would be Rupees 3750 million (around 78 million US$) in the first year of the programme. Compare this with the cost involved in Highly Selective Vaccination, which would be around Rupees 287.5 million (around 6 million US$) in the first year and Rupees 101 million (around 2 million US$) per year there after.[6]

Though 152 countries have already introduced the hepatitis-B vaccine and 39 more countries will introduce it, the work of Phadke & Kale indicates that there is a need to have critical fresh look at this programme.

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TO WHOM IS THE VACCINE HEAPTITIS B INDICATED

1. To newborn if mother is hepatitis B positive.
2. To individuals who come in contact with blood and blood products like:-
   - Pathologists and hematologists,
   - Surgeons and dentists,
   - Persons working in blood bank,
   - Individuals needing repeated blood transfusions,
   - Medical students,
   - Others with such similar exposure to blood.

VACCINATION POLICY AND THE PUBLIC-PRIVATE MIX

Public-Private 'Partnerships'

Addressing Public Health Needs or Corporate Agendas?

Report on the HAI Europe/BUKO Pharma – Kampagne Seminar 3 November 2000

HAI Europe (http://haiweb.org/campaign/PPI/seminar200011.doc)

by Anita Hardon, Medical Anthropology Unit, University of Amsterdam

Global vaccine efforts led by UN agencies have slowly given way to more donor-appealing initiatives led by private foundations. This shift in public health policy is already affecting how money is being spent on vaccines. Greater involvement by the research-based industry and private charities has promoted new, more hi-tech medicines against more diseases. At the same time, up to 25% of children in many developing countries still receive no vaccinations. In her presentation, Anita Hardon, traces how donor-driven projects have started to weaken the role played by long-standing public bodies, national governments and local industry. She also raises concerns about how today's vaccine campaigns leave little room for voices from the South and consumers.

Vaccination programmes are critically important for public health. They are also extremely appealing to donors. When one considers the reason why, the various aspects of vaccines make the answer clear: By supporting such initiatives one can change the world, eradicate a disease, make war against viruses and sign your name on the cure.

In the past, donors supported vaccine programmes for a number of reasons, including:

- prevention is better than cure
- vaccines are a cost-effective intervention
- contributing to the eradication of disease
- delivering a "magic bullet" cure

- the ease of delivery, and
- no compliance problems.

Progress on immunisation over time :

In 1974, WHO expanded its public health programme called the Expanded Immunization Program (EPI). In 1978 the importance of vaccines was included in the declaration released on the Alma Ata Conference. A few years later, in 1984, the Child Survival Taskforce was created, this was an early public-private partnership. The taskforce made an effort to increase vaccinations through the Universal Coverage of Immunization (UCI) campaign. UNICEF declared the reaching of UCI, i.e. 80% coverage of the world's children, in 1990. Following this achievement, the 1990's ushered in an era of donor fatigue and decreasing vaccination coverage rates in many developing countries.

In the 1990's, three new vaccine campaigns were introduced. Firstly, there was a move to eradicate polio backed by huge private funding (US$400 million was donated). This private money skewed regular public services as EPI's regularly scheduled national immunisation days were interrupted by new polio vaccine drives. The second campaign involved the introduction of user fees in the Vaccine Independent Initiative sponsored by UNICEF. With this change in policy, UNICEF announced its belief that some countries should start paying for their own vaccines. The third campaign was the 'magic bullet' approach which promoted new and improved vaccines financed by private foundations in the so-called "Childhood Vaccination Initiative (CVI). The CVI was created in 1997 to solve the sustainability problem faced by many vaccine initiatives. Global industry and public monies worked together within its programme. The emphasis was placed on development and products instead of health systems. A year later, the CVI was damaged by donor tensions and concerns about the weakening of the UN system. Commercial interests started to

dominate CVI. The programme itself received criticism for focusing on technical solutions.

Industry's interest in vaccines: magic bullets

Today vaccination policies seem to have shifted towards public-private 'partnerships' and away from equity. The Director General of the WHO has come out strongly in favour of public-private ventures to treat infectious diseases. **Health has become an economic asset and is no longer primarily seen as a basic human right**. In vaccination programmes the focus now appears to be creating markets for new vaccines Achieving equity in access to a limited number of essential vaccines, the objective of the EPI does not seem to be the primary objective any more. The notion of market failure and the lack of new vaccines are attractive ideas for the pharmaceutical industry as it can play a leading role in 'supporting' the development of new vaccines.

Industry is keen to develop new vaccines, although only an estimated 74% of the world's children are covered by current vaccine programmes[1]. The population already reached by vaccination programmes is a huge potential market for new vaccines and there is more profit in it than in trying to reach the remaining 30%-40% that currently receives no vaccines. (The 74% figure hides the fact that some countries still have only 40% coverage.) Pharmaceutical companies want to expand the number of vaccines included in the EPI. Currently, six generic antigens are used in it. Sixty percent of the vaccines are produced locally so an inexpensive generic alternative is available and used. Now companies and donors are looking for new magic bullets - new vaccines - that will prevent more diseases. Such an approach is much more attractive to donors than working to reach the children still not receiving the basic mix of vaccines.

New vaccine campaigns

Since the beginning of 2000, there have been three new approaches to address vaccines:

The Global Alliance for Vaccines and Immunisations (GAVI, largely supported by the Bill & Melinda Gates Foundation)

The Children's Vaccine Programme (CVP, also funded by the Gates Foundation)

UNICEF's Global Fund for Kids Vaccines (GFKV)

Today vaccination policies seem to have shifted towards public-private 'partnerships' and away from equity.

These initiatives have overlapping goals. The Gates Foundation has donated hundreds of millions of dollars towards the first two funds for a five-year period. (Interestingly, this support will be facilitated by the NGO PATH, which coincidentally happens to be based in Seattle, near the headquarters of Gates' company, Microsoft.) Unlike earlier vaccine campaigns, these initiatives spend little time discussing sustainability. Instead there is a great deal of talk about the need to create new systems and new vaccines. Critics have raised concerns that these private initiatives reduce local capacity to produce vaccines. The fact that GAVI and the other programmes will work with newly developed vaccines generated by multinational firms could cause people to believe that locally produced vaccines have lower quality. It is also important to note that in initial disbursements of GAVI only 10% goes towards health systems support. Ninety percent goes towards new vaccines such as hepatitis B. This may change in the future, but it is indicative of the emphasis of support to vaccination programmes.

GAVI is an interesting case study to analyse. One can see where its financial support comes from, but who runs its Board? At present, its Board comprises some of the most influential international actors involved in public health today. The current members include four renewable members[2].

- The Bill and Melinda Gates Foundation
- UNICEF
- The World Bank Group
- WHO

In addition, it has eleven rotating members which include various stakeholders:

- Three Northern (OECD) governments (Canada, The Netherlands, Norway)
- Two developing country governments (Bhutan, Mali)
- One OECD industry (Aventis Pasteur)
- One developing country industry (Center for Genetic Engineering and Biotechnology (CIGB))
- One foundation (The Rockefeller Foundation)
- One NGO (PATH /Bill & Melinda Gates Children's Vaccine Programme)
- One research institute (US National Institutes of Health (NIH))
- One technical health institute (US Centers for Disease Control)

Such a large initiative involves benefits and risks. GAVI's advantages include the increased resources brought to the vaccine issue and its cost-effectiveness. Some of the initiative's negative consequences include the reinforcement of donor dependence, a skewing of health programmes, a large emphasis on creating markets, the weakening of UNICEF's independence, a lack of sustainability for traditional vaccines suppliers and technical transfer, greatly reduced transparency, and limited involvement by developing countries and consumers. One has to wonder what will happen to this initiative after its five years of funding has been used.

There is a great need for more consumer voices to be heard on this issue. Vaccination policy has changed rapidly during the past few years and consumer input has been lacking. We must start asking critical questions about such public-private interactions to ascertain the long-term consequences for public health. In such a high-profile area as vaccines, participants including donors, governments, and industry have a clear

vested interest. Consumer voices need to make sure that the public health interest is represented as well.

[1] GAVI: Global Immunization Challenges: One in four children is excluded, taken from GAVI website 23/3/01, http://www.vaccinealliance.org/reference/globalimmchallenges.html.

[2] GAVI Board members as of 23/3/01.

UNSAFE INJECTION & HEPATITIS B

It is estimated that children and adults who are ill or hospitalised, including those infected with HIV, are often exposed 10-100 times to injections. An average of 95% of all injections are curative, but the majority of which were judged to be unnecessary. At least 50% of injections were unsafe in 14 of 19 countries (representing five developing world regions) for which data were available. Five studies attributed 20-80% of all new hepatitis B infections to unsafe injections, while three implicated unsafe injections as a major mode of transmission of hepatitis C. **In conclusion, unsafe injections occur routinely in most developing world regions, implying a significant potential for the transmission of any blood borne diseases. Unsafe injections currently account for a significant proportion of all new hepatitis B and C infections.** This situation needs to be addressed immediately, as a political and policy issue, with responsibilities clearly defined at the global, country and community levels.[1]

12 billion intramuscular injections are administered worldwide each year, and that about 90% of these are given for curative indications. The risk of transmission from needle injury is about 30% for hepatitis B virus (HBV) and about 3% for hepatitis C virus (HCV), he said. **"The incidence of viral hepatitis in a given population is a good indicator of the effectiveness of hospital infection control and injection**

safety practices in that setting," Margolis said. **"A significant proportion of cases of viral hepatitis is iatrogenic."** (iatrogenic means a disease introduced by the doctor).

Epidemiological studies have shown that the risk of hepatitis B in adults is significantly associated with a history of injections received in hospitals, dental offices, and clinics and other outpatient settings. **In some parts of the world, it is said, 50% of cases of hepatitis B infection in adults are directly related to a history of receiving intramuscular injections while only about 15% of cases are attributed to sexual transmission. In children in developing countries, a history of injection is a predominant risk factor for both hepatitis B and hepatitis C infection.** [2]

"Roughly 12 billion injections are given each year globally," said Dr. Keith M. Sabin, an epidemiologist with the division of HIV/AIDS prevention of the Centres for Disease Control and Prevention. "We estimate that 75 percent of these 12 billion injections are not necessary," he added, quoting the World Health Organisation (WHO) figures. "So, 9 billion unnecessary injections are being administered globally at a rough cost of 50 cents a shot," Sabin said. "Some $4.5 billion is being wasted annually on these unnecessary injections." [3]

Injections - a dangerous engine of disease

- Unsafe injection practices are a powerful engine to transmit blood borne pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Because infection with these viruses initially presents no symptoms, it is a silent epidemic. However, the consequences of this silent epidemic are increasingly recognized.

Hepatitis B virus

- HBV is highly infectious and causes the heaviest burden of disease: unsafe injections account for 33% of new HBV infections in developing and transitional countries for a total of 21.7 million people infected each year.

Hepatitis C virus

- Unsafe injections are the most common cause of HCV infection in developing and transitional countries, causing two million new infections each year and accounting for 42% of cases.

Human immunodeficiency virus

- Globally nearly 2% of all new HIV infections are caused by unsafe injections with a total of 96000 people infected annually. In South Asia up to 9% of new cases may be caused in this way. Such proportions can no longer be ignored.

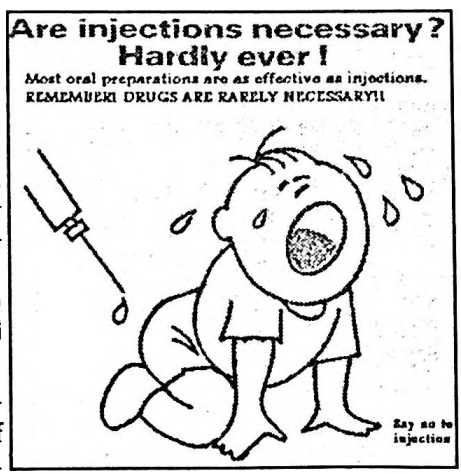
Fear of HIV is a powerful motivation to engage patients and healthcare workers in safer injection practices. [4]

1) Samisen L, Kane A, Lloyd J, Zaffran M, Kane M. Unsafe injections in the developing world and transmission of blood borne pathogens: a review. Bulletin World Health Organ. Geneva, Switzerland 1999;77(10):789-800.

2) David S. MacDougall. International Association of Physicians in AIDS Care. Third International Conference on Therapies for Viral Hepatitis. Monday, December 13, 1999, Maui, Hawaii. http://www.iapac.org/conferences/ictvh91213.html.

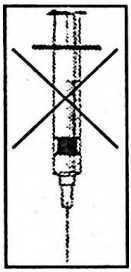
3) The Times of India On Line. Saturday 7 April 2001.

4) Unsafe injection practices - a plague of many health care systems. WHO.



MEDICINES NOT TO INJECT

In general it is better never to inject the following :



1. ***Vitamins*** : Rarely are injected vitamins any better than vitamins taken by mouth. Injections are more expensive and more dangerous. Vitamins taken by mouth as well as injections, cost less and are not dangerous. **Do not inject vitamins! It is better to swallow them – preferable in the form of nutritious foods.**
2. ***Liver extract, vitamin B_{12} and iron injections*** (such as Imferon). Injecting these can cause abscesses or dangerous reactions. Ferrous sulphate pills will do more good for most anaemia.
3. ***Calcium***, injected into a vein is extremely dangerous, if not given very slowly.
4. ***Penicillin.*** Nearly all infections that require penicillin can be effectively treated with penicillin taken by mouth. Use injectable penicillin only for dangerous infections.
5. ***Chloramphenicol or Tetracycline.*** These medicines do as much or more good when taken by mouth.

Intravenous (I.V.) solutions. These medicines be used only for severe dehydration and given only well trained persons. When not given correctly they can cause dangerous infections or death.

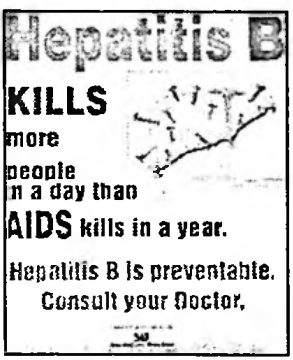
If you want vitamins, buy eggs or other nutritious foods instead of pills or injections

YES NO

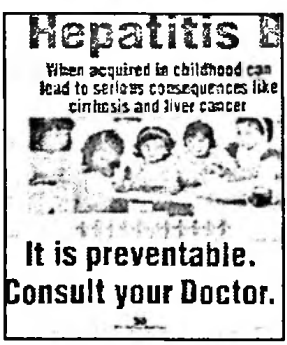
Misleading promotion

Misleading advertisements have flooded the market and only deceived the consumer to undergo hepatitis B vaccination. A certain degree of fear has been instilled in the public mind regarding how important it is for one to get vaccinated or else die of cance of liver. The companies seem to have achieved a great deal of success in inducing fear among the general public. DAF-K has collected some such misleading advertisements. Here are some of them. DAF-K has written to the drug companies and to the Karnataka State Drug Controller, Bangalore. If it does not get a postive reply from the concerned company, then it plans to seek justice in the court of law

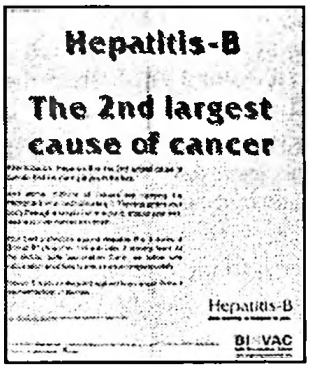
Some examples of such advertisements :



This advertisement by the leading multinational company SKF (now known as Glaxo Smith Kline or GSK) is promoting that hepatitis B kills more people in a day than AIDS in a year. This is totally misleading and unscientific



Another misleading advertisement by the same company. At the out set it is unethical to show pictures of chubby children for such a advertisement. In fact such pictures capture the imagination of parents and almost give them the feeling that there own children may get effected. The use of children for promoting a drug is considered to be unethical as standards set by certain groups campaigning for consumers in Europe.



This is another misleading promotion by the drug company Wockhardt. This company has not replied to DAF-K's letter dated 7th February, 2004.

Letter from Healthskeptism

6th February 2004

Gopal,

Thank you for contacting us!

The advertisement uses an emotive picture that exaggerates the effect of hepatitis B on the liver compared to what happens for many people.

The promotional claim is ambiguous. I can think of 10 possible meanings. (Meanings 1) and 3) below depend on the fact that people sometimes get HIV positive status without signs and symptoms confused with AIDS.)

The promotional claim could be taken to mean that:

1) more people die within a day of being infected by hepatitis B than within a year of being infected with HIV.
2) more people die within a day of being infected by hepatitis B than within a year of developing AIDS.
3) the proportion of people with hepatitis B infection who die is higher than the proportion of people with HIV who die so that if 1,000 people had hepatitis B and 1,000 had HIV then the number with hepatitis B who die each day would be more than those with HIV who die each year.

4) the proportion of people with hepatitis B infection who die is higher than the proportion of people with AIDS who die so that if 1,000 people had hepatitis B and 1,000 had AIDS then the number with hepatitis B who die each day would be more than those with AIDS who die each year.

5) the absolute number of people who die each day from hepatitis B each day is higher than the absolute number who die from AIDS each year.

These claims could be taken as referring to India only or to the world as a whole so that doubles the list of 5 above to make 10 possible meanings.

It would be good to ask GSK which meaning or meanings did they intend and what if there evidence to support those meanings. If there are any meanings that they did not intend do they have any evidence from pre-testing the advertisement to show that people would not interpret the advertisement in that way?

I hope that is understandable and helpful.

Dr Peter R. Mansfield,

Healthy Skepticism,

34 Methodist Street,

Willunga SA 5172 Australia.

www.healthyskepticism.org

peter@healthyskepticism.org

Ph/Fax +61 8 8557 1040

A LETTER TO HEALTH MINISTER FROM DAF-K

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

DRUG ACTION FORUM-KARNATAKA

1 January 2004

To,
Smt Sushma Swaraj,
Union Minister for Health & Family Welfare,
Ministry of Health & Family Welfare,
Government of India,
Maulana Azad Road,
New Delhi 110 011

Drug Action Forum-Karnataka is a committed group of citizens voluntarily involved in bringing awareness among consumer regarding Rational Drugs Promotion and Policy.

We learn from the media reports that Government of India is planning to implement hepatitis B vaccination as a part of its Universal Vaccination Programme in a phased manner in all districts of India. We express our grave concern on this issue because of the following reasons:-

1. ***Lack of resources:-*** To vaccinate all newborn with hepatitis B vaccine and to implement which would cost Rupees 1250 million annually for the hepatitis-B vaccine alone, at the rate of Rupees 50 per new born for the 25 million annual births in India. If this is compared with the budget in the year 2000-2001 of Rupees 1250 million allotted by the Government of India for its National Tuberculosis Programme and Rupees 1050 million for Malaria control. Tuberculosis & Malaria are obviously major killers in India.

   It is necessary to address these questions in a developing country like India, where financial resources is always a constraint. Secondly, in any case, modern health care management should consider cost efficacy and effectiveness of any healthcare intervention paid through public money.

2. ***Absence of epidemiological basis:-*** The quoted study, by medical bodies has been that of S.P.Thyagaran et al, which puts the carrier state in India at 4.7%. This is not acceptable, as it suffers from errors as per Phadke Anant & Kale Ashok. Actually the epidemiological HBsAg carrier rate works out to be 1.42%. Based on low carrier rate alone, it is clear that the Universal Strategy is invalid in India.

Therefore we would like to suggest:-

1. That Government of India take up the Selective Vaccination Strategy, in which the pregnant women be screened for HBsAg and vaccinate such newborn only if mother is positive. It has been observed that the cost efficacy of this Selective Vaccination Strategy, (around Rupees 5227), is much greater, than Universal Vaccination Strategy, (around Rupees 9260) for protection from HBeAg (hepatitis B e antigen). Secondly, to cover all the pregnant women and their newborn in a year, the total annual cost of the programme for Universal and Selective vaccination for a cohort of 10,000 would be Rupees 5,00,000 and Rupees 1,15,000 respectively.

   A detailed write up on the issue titled "Hepatitis B vaccination in India – a controversy" has been enclosed for your kind reference and perusal.

2. That the Government should regulate the promotional material of the vaccine manufacturers, which has been misleading the common man. We enclose one such advertisement from a vaccine manufacturer and we believe that there are several such. Only effective regulation on the part of the Government can stop this.

We hope that you will look into this matter urgently as it is an important public health issue and if you need more information we would be happy to provide you the same.

Yours sincerely,

(Dr Gopal Dabade)

Attachments :

1) Hepatitis B vaccination in India – a controversy.
2) Misleading advertisement by drug company SKF about hepatitis B vaccine.

FIRST LETTER TO THE DRUG COMPANY ABOUT MISLEADING ADVERTISEMENT FROM DAF-K

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

DRUG ACTION FORUM-KARNATAKA

29th December 2003

To,
Smith Kline Beecham Pharmaceuticals,
Devanhalli road,
Off Old Chennai Road,
Post Box Number 2,
Bangalore 560049.

Drug Action Forum-Karnataka is a concerned and committed group of citizens voluntarily involved in trying to bring awareness to the consumer regarding Rational Drugs promotion and policy.

I am here with enclosing advertisements by your company for the vaccine hepatitis B. These advertisements are totally misleading and are an unscientific way of promoting this vaccine. It is unfortunate that such advertisements often lead to gross misuse of a drugs (vaccine in this case) for unnecessary indications.

Drug Action Forum-Karnataka appreciates that hepatitis B vaccine is a useful vaccine for public health problems, as long as it is used properly. But your company has attempted to create a wrong impression that hepatitis B is greater public health problem than HIV/AIDS. It is well know that HIV/AIDS is an important public health problem and your company attempts to belittle it because you have a vaccine for hepatitis B.

We urge you to withdraw the advertisements immediately and seek an public apology (by advertising in popular dailies). We hope to hear from you within a fortnight, if not we will be compelled to take the issue to concerned authorities.

Hoping to hear from you soon.

Yours sincerely,

(Dr Gopal Dabade)

Copy to : State Drug Controller, Palace Road, Bangalore 560001.

REMINDER LETTER FROM DAF-K TO DRUG COMPANY

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

DRUG ACTION FORUM-KARNATAKA

13th January, 2004

By Regd. Post with Acklodgement due

To,

Smith Kline Beecham Pharmaceuticals,
Devanhalli road,
Off Old Chennai Road,
Post Box Number 2,
Bangalore 560049.

Dear Sir / Madame,

Drug Action Forum – Karnataka is a collective action group in raising awareness among the general public on rational use of medicines and vaccines.

We had written earlier to you in our letter dated 29th December 2003 regarding a misleading promotional material from your company addressed to the lay person about vaccine hepatitis-B. In this advertisement you had claimed that hepatitis-B kills more people in a day than HIV/AIDS in a year. We had suggested that you should withdraw the advertisement and seek an public apology for advertising in such a manner.

It is unfortunate matter that you have not bothered even to reply to our letter dated 28th December 2003. This letter dated 11th January 2004 is a final warning to you and if we do not get a suitable reply from you within a fortnight, then we will be compelled to take the issue to court to seek justice on behalf of the consumers. I hope wiser council will prevail upon you and that you will act soon.

Hoping to hear from you soon.

Yours sincerely

(Dr Gopal Dabade)

Copy to : State Drug Controller, Palace Road, Bangalore 560001

REPLY FROM KARNATAKA DRUG CONTROLLER

GOVERNMENT OF KARNATAKA
(DRUGS CONTROL DEPARTMENT)

DCD/23/DMR/2003-04

Office of the Drugs Controller,
for the State of Karnataka,
Palace Road, Bangalore.
Date : 19th Jan, 2004.

To M/s. Smith Kline Beecham Pharmaceuticals,
Devanhalli Road,
Post Box No.2,
Bangalore 560 049

Sir,

Sub : Drugs & Magic Remedies (Objectionable advertisement) Act, 1954 and Rules thereunder.

Ref : Letter dated 15 Dec' 2003 of Drug Action Forum, Karnataka.

With reference to the above, please find herein enclosed a copy of advertisement and letter sent by the Drug Action Forum, Karnataka.

You are directed to submit your comments.

Yours faithfully,

Drugs Controller

Copy to Dr. Gopal Dabade, Drug Action Forum, Karnataka, 57, Tejaswinagar, Dharwad 580 002 for information.

REPLY FROM DRUG COMPANY

GlaxoSmithKline
Pharmaceuticals Limited
Regd. Office: Dr. Annie Besant Road,
Worli,
Mumbai 400030.
Tel: 022-2495 9595
Fax: 022-2495 9494

BY COURIER

30th January 2004

Drug Action Forum

57, Tejaswinagar

Dharwad 580 002 Karnataka.

Dear Sir,

We refer to your letter dated 13th January 2004 received by us in Mumbai on 28th January 2004 possibly because the same is addressed to SmithKline Beecham Pharmaceuticals India Limited [SBPIL] at the Bangalore factory address. You may recall that SBPIL merged with Glaxo India Limited in the year 2001 and is now known as GlaxoSmithKline Pharmaceuticals Limited [GSK].

It is stated in the said letter that you had previously addressed a letter to us on 28th December 2003 regarding 'misleading' promotional material from our Company addressed to lay persons about the vaccine Hepatitis B. We would like to state that we have not received your letter of 28th December 2003 nor have we received from you the 'misleading' promotional material / advertisement referred to by you in your letter under reply. Without being able to refer to the material in respect of which the allegation is made, it is difficult for us to comment in any detail on the same.

Despite the lack of the material referred to, we have investigated the matter and would like to state that no such promotional material/ advertisement as referred by you has been released by SBPIL or GSK during the past five years at least. Unfortunately, we have not been able to confirm whether any such promotional material was issued more than five years ago, since there have been many changes in the erstwhile SBPIL following the merger. It is possible that the promotional material that is being referred to is very old, at least more than 5 years. However, to allow us to comment more in detail, we would request you to forward to us a sample of the said promotional material/advertisement or inform us where the same can be seen so that we can take up the matter at the earliest.

As a responsible Company ethically promoting its products, we do not make any claim that is not factually correct. In the circumstances, we reiterate once again that GSK has made no such claim as mentioned by you in the aforesaid letter and in the event the promotional material referred to by you is in fact issued by our predecessor Company, we will certainly take steps to withdraw the same if they are still in existence.

Yours faithfully,

GlaxoSmithKline Pharmaceuticals Limited

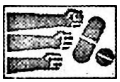
(Mrs. S. Patel)

Senior General Manager

Legal & Secretarial

cc: State Drug Controller, Palace Road, Bangalore 560 001.

AND DAF-K'S REPLY



DRUG ACTION FORUM-KARNATAKA

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

4th February, 2004

To,
Mrs S K Patel
Senior General Manager
Legal & Secretarial
GlaxoSmithKline Pharmaceuticals Limited
Regd. Office: Dr Annie Besant Road, Worli
Mumbai 400 025.

Dear Mrs Patel,

Thanks for your letter dated 30th January 2004, which was received on 2nd February 2004.

Drug Action Forum-Karnataka had earlier written to your company in the address that were mentioned in your web pages. It is only now through your letter we learn about this contact address. So from hence forth all correspondence of Drug Action Forum-Karnataka will be addressed to the same.

Apart from our letter the Karnataka State Drug Controller in letter dated 19th January 2004 number DCD/23/DMR/2003-04 has mentioned about Drug Action Forum-Karnataka's complaint and written to your company to respond to the same. We fail to understand as to how you have not received all these letters.

None of your advertisements mention the date on which it was released. So it is just impossible to know when your company released the grossly misleading advertisement for promoting hepatitis B vaccine. So we from Drug Action Forum-Karnataka suggest that YOUR COMPANY SHOULD MENTION DATE OF RELEASE ON ALL ITS ADVERTISENMTS ATLEAST IN FUTURE, so that consumers would know when it was released.

As per your request I am enclosing the copy of the advertisements. We not only want you to withdraw these advertisements but your company should seek **public apology (by issuing an advertisement in the form of statement) for having advertised the same.**

Yours faithfully

(Dr Gopal Dabade)

cc : State Drug Controller. Palace road, Bangalore 560001

Commissioner Food & Drug Administration, Griha Nirman Bhavan, Bandra (East), Mumbai 400051

SECOND RESPONSE FROM DRUG COMPANY

19th February 2004
Drug Action Forum,
57, Tejaswinagar
Dharwad 580 002
Karnataka.

GlaxoSmithKline
Pharmaceuticals Limited
Regd. Office: Dr. Annie Besant Road,
Worli,
Mumbai 400030.
Tel: 022-2495 9595
Fax: 022-2495 9494

Dear Sirs,

We refer to your letter dated 4th February 2004 forwarding to us samples of material said to have been released by the former Smith Kline Beecham Pharmaceuticals India Limited [SBPIL] in connection with Hepatitis B vaccines.

On examining the material forwarded by you, we would state that it is incorrect to say that the said material is a "grossly misleading advertisement", as the contents of the same were factually and medically correct at the time the said material was released. As mentioned in our earlier letter, the material was probably released by the former SPBIL many years ago. At that time, the statement made in the material was factually correct as can be verified by you. We send herewith copies of material furnished by our Medical Department to substantiate this position.

It is not apparent from the material sent by you as to where the same was "advertised" as mentioned in your letter under reply. Since these materials were released by the former SBPIL several years ago, we are surprised to note that you have been able to obtain the material at this time. We request you to let us know as to where the said material is still available to enable us to take appropriate action.

If the said material is still in circulation, we will make our best efforts to ensure that the same is withdrawn. We once again assure you that as a responsible Company, we do not issue any promotional material that is either false or misleading to our consumers. The question of releasing any advertisement for a public apology therefore cannot arise since the said promotional material has not been released by us and

does not continue to be in circulation. Moreover, as indicated above, the said material is factually correct.

We trust that in the circumstances, you will treat the matter as closed.

Yours faithfully,

GlaxoSmithKline Pharmaceuticals Limited

(Mrs. S. Patel)

Senior General Manager

Legal & Secretarial

Encl:a/a.

cc: State Drug Controller, Palace Road, Bangalore.

REPLY FROM DAF-K

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

DRUG ACTION FORUM-KARNATAKA

8th March 2004

To,

Mrs S Patel,
Senior General Manager,
Legal & Secretarial,
GlaxoSmithKline Pharmaceuticals Limited,
Regd Office: Dr Annie Besant Road,
Worli,
Mumbai 400 030

Dear Sirs/Madame,

This is in reply to your letter dated 19th February 2004, which was received on 26th February 2004.

DAF-K's Scientific Committee has gone through the material

that has been sent by you, which your letter mentions is to substantiates the position that is in the advertisement. Unfortunately in general the material is unscientific. Most of it is correspondence between individuals or some of it even being advertisements. One particular article is from Readers Digest, which you are perhaps aware is not a scientific journal. The lone scientific article from Indian Journal of Medical Sciences, volume 57, number 9 of September 2003 by DD Banker, does not mention that hepatitis B kills more than HIV/AIDS.

It is important to note (as mentioned in your letter dated 19th February 2004) that now your company find the advertisement irrelevant as you want to withdraw the same. One wonders how an advertisement issued by your former company some time ago could turn out into one not so now. How does your company substantiate this?

To sum up we do not find any evidence either then or now to state that the advertisement is correct and we are more convinced than ever that it is a totally gross misleading and unscientific promotional material. The material is thus factually incorrect.

To your specific question as to where we found the advertisement, we admit that it was found in a hospital in our small home town. But that is not the complete picture, as I am sure your company would have distributed this grossly misleading advertisement throughout the country. So this specific question of yours should be directed to your Medical Representatives, who would be in a better position to answer this question.

We are also surprised about the mention in your letter that the "material was probable released by the former SPBIL many years ago". As mentioned in our DAF-K's previous letter dated 4th February 2004, none of your advertisements mention the date on which it was released. So it is just impossible to know when your company released the grossly misleading advertisement for promoting hepatitis B vaccine. So we from Drug Action Forum-Karnataka suggest that YOUR COMPANY SHOULD MENTION DATE OF RELEASE ON ALL ITS ADVERTISENMTS ATLEAST IN FUTURE, so that consumers would know when it was released. Given this state of affairs one would like to know how you derive at the conclusion that it was released "many years ago". Though we raised this issue in our letter

dated 4th February 2004, your letter dated 19th February 2004 unfortunately does not address it.

The claim in your letter that the advertisement was not released by your company, is truly shocking. It is also not clear from your letter if you are making this statement because it was released by your former company SBPIL. But we know that it was issued by SBPIL, with whom Glaxo has got merged now. And needless to point out that the present company GSK is fully responsible for all the previous deeds of SBPIL.

Let us assure you and your company that we are more than eager to close the matter and give it a decent burial, provided your company seeks a public apology **(by issuing an advertisement in the form of statement),** instead of writing endlessly and meaninglessly that your company is a responsible company, and does not issue any promotional material that is false.

We trust that this letter clears your doubts and will put sense in your actions.

Yours faithfully,

(Dr Gopal Dabade)

CC to;-

- Commissioner Food & Drug Administration, Griha Nirman Bhavan, Bandra (East), Mumbai 400 051.
- Karnataka State Drug Controller, Palace Road, Bangalore 560 001

LETTER FROM DAF-K TO ANOTHER COMPANY

57, Tejaswinagar,
Dharwad 580 002
0836-2461554
drdabade@sancharnet.in

DRUG ACTION FORUM-KARNATAKA

7th February 2004

To,

Wockhardt Limited,
Wockhardt Towers,
Bandra Kurla Complex,
Bandra East,
Mumbai 400 051

Sir/Madame,

Drug Action Forum-Karnataka is a concerned and committed group of citizens voluntarily involved in trying to bring awareness to the consumer regarding Rational Drugs promotion and policy.

I am here with enclosing advertisements by your company for the vaccine hepatitis B. This advertisement is misleading and is an unscientific way of promoting this vaccine. It is unfortunate that such advertisements often lead to gross misuse of a drugs (vaccine in this case) for unnecessary indications.

Drug Action Forum-Karnataka appreciates that hepatitis B vaccine is a useful vaccine for public health problems, as long as it is used properly. But your company has attempted to create a wrong impression about hepatitis B.

We urge you to withdraw the advertisements immediately and seek an public apology (by advertising in popular dailies). We hope to hear from you within a fortnight, if not we will be compelled to take the issue to concerned authorities.

Hoping to hear from you soon.

Yours sincerely,

(Dr Gopal Dabade)

CC to : – Commissioner Food & Drug Administration, Griha Nirman Bhavan, Bandra (East), Mumbai 400051

Reproduced from BMJ towards fair use;

Should immunisation against hepatitis B take priority over provision of clean drinking water?(Statistical Data Included)

British Medical Journal, July 17, 1999, by Jacob M Puliyel

EDITOR — The World Health Organisation has suggested universal immunisation with hepatitis B vaccine. [1] The Indian Academy of Paediatrics has recommended vaccination to paediatricians in the country and to the government; paediatricians have in turn been recommending it. The cheapest Indian vaccine costs 360 rupees (5.21 [pounds sterling]) for three doses.

The India Development Report 1997 suggests that a third of the population earn less than 57 rupees (83p) per capita per month. [2] The main causes of death in India are diarrhoea, respiratory infections, and malnutrition.

Does the World Health Organisation really want universal immunisation with hepatitis B vaccine to take priority over the provision of clean drinking water? At what stage of development of a country's infrastructure does the prevention of hepatitis B by vaccination take priority? Is there any study about this? We would like to be rid of this vermin, but the Pied Piper must be paid.

[1] Hoofnagle JH. Towards universal vaccination against hepatitis B. N Engl J Med 1989;321:1333.

[2] Parikh KS, ed. India development report 1997. Delhi: Oxford Press, 1997.

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- Subject: AFRO-NETS> Hepatitis B vaccination or clean water ?
- From: "Jacob M. Puliyel" <puliyel@del6.VSNL.NET.IN>
- Date: Sat, 13 Feb 1999 11:18:11 -0500 (EST)

Hepatitis B vaccination or clean water ?

Source: e-drug@usa.healthnet.org (modified)

Dear everybody,

The WHO has. suggested universal immunisation with Hepatitis B vaccine in countries with intermediate prevalence. The Indian Academy of Paediatrics has dutifully recommended it to paediatricians in the country and to the government. Paediatricians have in turn been advising the vaccine. The vaccine costs about Rupees 750 for 3 doses.

The India Development Report 1997 (Ed. Kirit S Parikh Oxford Press Delhi 1997) suggests that a third of the population earn less than Rupees 57 per capita per month. The major killers here are diarrhoea, respiratory infections and malnutrition. Basic amenities like safe drinking water are not available to the majority.

Does the WHO really want universal immunisation with Hepatitis B as a priority over the provision of clean drinking water? At what stage of infrastructure development in a country does Hepatitis B prevention by vaccination take priority? Is there any study about this?

How does one compute the cost effectiveness of Hepatitis B vaccination. One way to compute cost-effectiveness would be to look at the cost of a liver transplant and the cost of vaccinating n number of people to prevent the need for that transplant. If the cost of the latter is less than the former it can

be called a cost-effective intervention. But surely the WHO is aware of the ground realities in developing countries.

Liver transplant is not an option for 99.99% of the population. For one person dying of liver failure hundreds of others die of diarrhoea. The interventions (like provision of clean drinking water) required to save these hundreds would cost a fraction of what is required for Hepatitis B vaccines.

Is it right that developing countries are advised to spend their meagre resources on this expensive Programme of universal immunisation with Hepatitis B vaccine?

The WHO is manned by the best brains in the world. There must be very sound reasons for their recommendation. I am however curious to know their reasoning. I put my question to them via e-mail. I have not heard in reply. Probably the e-mail did not reach the right person.

I wonder if any one can help with the answers.

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Send mail for the 'AFRO-NETS' conference to 'afro-nets@usa.healthnet.org'.

Mail administrative requests to 'majordomo@usa.healthnet.org'.

For additional assistance, send mail to: 'owner-afro-nets@usa.healthnet.org'.

PLEASE TEAR THE PAPER HERE

Date :

To,

Union Minister for Health & Family Welfare,

Ministry of Health & Family Welfare,

Government of India,

Maulana Azad Road, .

New Delhi 110 011

We learn from the media reports that Government of India is planning to implement hepatitis B vaccination as a part of its Universal Vaccination Programme in a phased manner in all districts of India. We express our grave concern on this issue because of the following reasons:-

- ***Lack of resources:-*** To vaccinate all newborn with hepatitis B vaccine and to implement which would cost Rupees 1250 million annually for the hepatitis-B vaccine alone, at the rate of Rupees 50 per new born for the 25 million annual births in India. If this is compared with the budget in the year 2000-2001 of Rupees 1250 million allotted by the Government of India for its National Tuberculosis Programme and Rupees 1050 million for Malaria control. Tuberculosis & Malaria are obviously major killers in India.
- ***Absence of epidemiological basis:-*** The quoted study, by medical bodies has been that of S.P.Thyagaran et al, which puts the carrier state in India at 4.7%. This is not acceptable, as it suffers from errors as per Phadke Anant & Kale Ashok. Actually the epidemiological HBsAg carrier rate works out to be 1.42%. Based on low carrier rate alone, it is clear that the Universal Strategy is invalid in India.

Therefore we would like to suggest:-

- That Government of India take up the Selective Vaccination Strategy, in which the pregnant women

be screened for HBsAg and vaccinate such newborn only if mother is positive. It has been observed that the cost efficacy of this Selective Vaccination Strategy, (around Rupees 5227), is much greater, than Universal Vaccination Strategy, (around Rupees 9260) for protection from HBeAg (hepatitis B e antigen). Secondly, to cover all the pregnant women and their newborn in a year, the total annual cost of the programme for Universal and Selective vaccination for a cohort of 10,000 would be Rupees 5,00,000 and Rupees 1,15,000 respectively.

- That the Government should regulate the promotional material of the vaccine manufacturers, which has been misleading the common man. We enclose one such advertisement from a vaccine manufacturer and we believe that there are several such. Only effective regulation on the part of the Government can stop this.

We hope that you will look into this matter urgently as it is an important public health issue and if you need more information we would be happy to provide you the same.

Yours sincerely,

( )

Name:-

Address:-

PLEASE TEAR THE PAPER HERE

DRUG ACTION FORUM-KARNATAKA

Drug Action Forum – Karnataka is a registered under Karnataka registration society act and is a group that is committed to Rational Drug Therapy and Policy.

Drug Action Forum – Karnataka believes that drugs and vaccines should be made available to people that:-

- can meet the health requirements,
- are only essential,
- are safe and
- the cost is within the reach of people.

DID YOU KNOW ABOUT THE DRUG SITUATION IN INDIA?

- World Health Organisation's list of Essential Drugs is only 372.
- But there are around 80,000 formulations in our country.
- Most of them are unessential and some even hazardous.
- Common public health problems in India are Tuberculosis, Malaria, HIV/AIDS. But there is no drug price regulation on these drugs for these Public Health problems.
- The Drug policy of our country is prepared by Ministry of Petroleum & Chemicals. The Health Ministry has nothing to do with it.
- The drug price control is by Ministry of Commerce.

OBJECTIVES OF DRUG ACTION FORUM – KARNATAKA

- ❑ Conduct studies on unessential and hazardous drugs in the Indian market.
- ❑ Bring it to the notice of people through various medias.
- ❑ Publish a bulletin three times a year.
- ❑ Bring out publications on such issues.
- ❑ To explain lay person about Indian Drug policy and Health policy.
- ❑ Conduct trainings on such issues.
- ❑ To promote the concept of "Health for All", as stated in the World Health Organization documents.
- ❑ To support and involve in People Health Movements.
- ❑ To collect information on these issues and disseminate it to people.
- ❑ Join hands with like minded national and international organisations.

HOW CAN YOU INVOLVE

- ⏲ Actively involve in all Drug Action Forum – Karnataka's programmes.
- ⏲ Purchase, distribute and sell DAF-K's publications.
- ⏲ Talk to your family doctor and local chemist about the issues involved Rational Drugs.
- ⏲ Donate your time, energy and money for the cause of Rational Drugs campaign.

This booklet **"Instead of looking at the issue of health as a human right it appears to have become an economic asset and the focus appears to be on creating markets for new vaccines."**

– Dr. H Sudarshan, President, Karnataka Society for Rational Drug Use (KSPRUD),

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