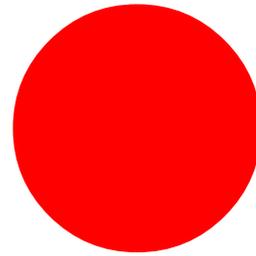


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*Concept Note for MFC Annual Meet 2010*

## **Moving Towards Universal Access to Health Care: Gaps and Barriers in Existing Health System**

*- Anant Phadke, Rakhal Gaitonde, Abhay Shukla\**

In all developed countries, except the USA, practically all citizens have access to health care, with token or no payment to be made at the point of service. At the beginning of the twenty first century, why can't India achieve a similar Universal Access to Health Care for its' citizens?

During the MFC mid-annual meet on July 9-10, 2009, it was decided that we should discuss the theme of an Universal Access System over a two-year period with the Annual Meet of 2011 being planned as a larger meet on the subject. As a build up to that it was decided to discuss the present situation of the health system in India during the Annual Meet of 2010. Through this initial work it is hoped that we can clearly map out the situation and identify key areas that we need to work further on in the build up to the Annual meet of 2011. In the mfc annual meet in 2001, we had discussed the issue of whether health insurance can be a means to achieve universal health care. This time we would discuss the issue of universal access in its totality; not limiting ourselves to health insurance.

### **Definitions**

We may use the definition formulated by the Health Systems Knowledge Network (HSKN).

**Universal coverage (UC):** this is situation where the whole population of a country has access to good quality services according to needs and preferences, regardless of income level, social status, or residency. It is an absolute concept in relation to population

coverage (100%) with the same scope of benefits extended to the whole population (but the range of benefits varies between contexts); and it incorporates the policy objectives of equity in payments (the rich should pay more than the poor), financial protection (the poor should not become poor as a result of using health care) and equity of access or utilisation (implying distribution according to need rather than ability to pay, and requiring equity in the distribution of spending and resources).<sup>1</sup>

Health systems are seen to include *all activities whose primary purpose is to improve health.*<sup>2</sup>

### **Background**

There is a specific national context to revisiting the issue of Universal Access. Some of these major points include:

1. There is a significant shift of the Government's stand from the "universal provider" to an "enabler in a market". This of course is a macro trend with a worldwide unquestioning acceptance (by IFIs and Governments at least) of privatization and large scale outsourcing of health services as an acceptable and welcome solution. In India this has led to a huge explosion in the number and types of PPPs the Government is getting into.

2. Since 2007-08, the Central Government has launched the Rashtriya Swasthya Bima Yojana (RSBY). Through this Yojana the hospital bills of Below Poverty Line card holders would be paid by the Government upto Rs 30,000/- annually. The budgetary allocation for RSBY is too meager and its implementation is still quite limited. There is no likelihood that RSBY would cover all the even

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‘officially poor’ people in India. However, RSBY inaugurates a chapter in the health care policy in India because this is the beginning of use of public money to pay for the bills of private hospitals for people not employed in the Government. In principle, this provision can be modified, expanded and extended to all the citizens.

3. Similarly after a gap of about 15 years, after the 2004 Lok Sabha elections, the Central Government’s health budget started rising by about 20% every year as the relatively farsighted section of the Congress leadership realized that the poor would not vote for them unless some beneficial programmes are launched for them. Thus the Government has started responding, albeit in a measly fashion to the pressure from below of voters. The budgetary allocation for NREGA, supplementary nutrition programmes including ICDS, and rural health services has comparatively increased substantially in the last 4 budgets. This rise has been made possible by an increase in tax collections due to increased growth rate. The Government can now spend more money for social welfare measures to render a “human face” (rather mask) to its Globalization, Privatization, and Liberalization (GPL) agenda.

4. In addition, the peculiar dynamics of demographic transition has meant India currently has a comparatively larger proportion of adult, working population compared to the paediatric and ageing population. To make this adult population healthy and trained for rapid economic growth and hence to increase profits, one section of the rulers want to spend more money on education and public health.

5. A very bad Human Development Index is internationally quite embarrassing for the Government of India which is now becoming a “world player”. It is said that in a major international meeting to consider India’s membership of the UN Security Council, Dr. Manmohan Singh was sharply questioned about India’s very poor HDI and this has been partly responsible for renewed emphasis on increased public expenditure on social sectors.

6. Increased public funding for health care is a welcome trend, though it is grossly inadequate, as of now. However a new danger is that public spending may lead to a mere increase in the bulk market for medical-industrial complex. Pushing vaccines of low public health value into National Programmes is one example. Hence, while clamouring for more public funds for health care, we need to strongly advocate for its proper, rational utilization.

Given this background, in the People’s Health Movement in India, there is a need to discuss these newer trends in health care policy. Since JSA (Jan Swasthya Abhiyan) is an action forum, in JSA meetings there is not much time for a detailed, in depth discussion about strategies for Universal Access to Health Care to achieve the goal of “Health care for all”. Mfc is one appropriate National Forum, which is sufficiently broad based and has a tradition for in-depth, open-ended brainstorming discussions and hence it was decided that in the coming couple of years we would discuss this issue of Universal Access to health care in the annual meets. During the forthcoming meet on January 8-9, 2010 we would focus on the existing scenario of health care system in order to identify the gaps and the barriers (along with its dynamics) while considering a process of moving towards universal access to health care. Then in the next annual meet (2011) we can discuss the concrete outline for achieving the goal of ‘Health care for all’. (These discussions would be a small contribution to JSA by mfc as one of its constituents). If the rulers go in a different direction that would speak for itself and the contrast between what is possible and what is happening can be used by the health movement including JSA to mobilize public opinion about it.

We have flagged below some issues that need to be discussed to have more clarity about gaps in and barriers to achieving the goal of Universal Access to Health Care in India.

### **What is Universal Access to Health Care?**

While the definition of universal coverage is fairly well developed in the HSKN report, its actualization needs a lot of clarity. Some basic sub-headings that need to be clarified include:

- *The logic and rationale behind Universal Access* – this is especially relevant in the context of increasing withdrawal of the state, increasing privatization and the fancy with the “targeted” approaches the Government seems to have.

- *Content:* What services will be available in such a system? While the UN Special rapporteur on Right to Health and the UN CESCR General comment 14 have made some very broad, preliminary listings these need to be worked on further. The content also needs to be looked at in terms of curative components, preventive components and promotive components. How will these components be defined, who will define them, on what basis?

- *Quality:* how does one maintain quality in

such a system? How does one define quality? [For e.g., who would attend to a new-born baby immediately after birth? A dai or a doctor or a paediatrician? How would information be provided to the patient: by a paramedic, or by a doctor or through a brochure/leaflet or through an interactive source on the internet including audio-visual method? Answers to such questions depend upon the availability of resources along with considerations of rational use of these resources.]

- *Distribution and equity:* The unequal distribution of health services is well documented, however this needs to be conceptualized further and studied to come up with solutions. A preliminary working out of the cost of such a system needs to be worked out.

What are the concrete implications of universal access to healthcare? Does it mean that all citizens will have access to all kinds of health interventions at every level? No! For example, we can not expect CT scan machines to be available in every PHC. Is it because there would not be enough work for the radiologist using this machine? Or is it because we do not have enough money and human power? Or is it because we do not actually need to have a CT scan machine in every PHC because now we can transfer patients from PHC to a district hospital within a couple of hours? (In a suspected case of thrombo-embolic stroke, if the condition can be diagnosed with certainty within a couple of hours, the person can be saved from paralysis or from death. Such strokes do occur amongst the rural poor also.) Or is it a combination of all these factors?

As a nation shall we have to make a distinction between what is ideal, desirable and what is optimally possible in provisioning of various health care services? Ideally facilities for all life saving measures must be made available within the critical period for respective emergencies; generally a couple of hours. But do we have the resources to ensure that each citizen has equal access to such facility? If not, would it be necessary for some period to have a two-tier system in which 'free essential services' are equally and universally available to every citizen and some services which can not be made equally available to every citizen free of charge are available on payment in a different, 'fully private system'? (Fully private means both the provider and the source of payment to this provider are private.) As we make further progress, would the domain of the 'fully private system' keep shrinking further?

Does universal access essentially have the aspect of equity? Does it mean that we as a nation will have

to decide that whatever service that is provided through public funds, all citizens should have equal access to it? People's participation based on health awareness, and availability of choices is one more dimension of provision of health services. Choices between systems of medicine are a related consideration. Whether or not is not an issue, but how much and how needs to be debated.

Based on some clarity regarding various issues mentioned above, related to the concept of universally accessible health care, we need to identify the gaps, barriers and resources required to achieve this goal. These gaps, barriers need to be analysed further under all the three aspects –provisioning (human power, infrastructure), financing and governance (including regulation of private providers) as well as the systemic interaction between the three.

### Provisioning of Health Care

One of the most important issues is to first come to terms with the "ground situation". Although the existing public health system in rural areas is nominally a 'universal access system', what is the actual accessibility and quality of services being provided? When we say provisioning of services (from institutions especially) what really happens, how many PHCs actually often have dais conducting deliveries? How many PHCs have pharmacists or paramedics often functioning as the doctors? How many people access "doctors of the informal sector"? How do we see the new move of having AYUSH doctors in charge of PHCs with no Ayurvedic or homeopathic drugs in stock?

Do we have/can we develop appropriate norms about various types of medical personnel (ranging from Community Health Worker to super specialists required per say one million population) and for equipments for providing universal health care for primary, secondary and tertiary level care? Based on the available norms, what gaps emerge about which aspects and where? Why have these gaps remained and what is the direction, dynamics as regards these gaps, barriers? For example, there is dearth of postgraduate, specialist doctors in Rural Hospitals, district hospitals and in rural, poor areas. Though the number of such doctors passing out of medical colleges has increased substantially, most of them graduate from the private medical colleges and their fees have galloped. Given this dynamics, what are the chances of closing this gap through 'filtering down/trickling down' effect? Apart from the fees we also need to look into the content of the medical education that these

students get. Postgraduate doctors are now available in private sector much more in district town, block headquarters compared to say 30 years back. But has this improved accessibility of the expert services to the poor? How much? Assuming a norm of one bed per 500 population, rural areas have up to 20 times less per capita hospital beds compared to urban areas. How can this deficit in rural areas be overcome?

If norms have not been worked out, can we compare availability across countries, regions to get some idea about the gaps we need to overcome? In 1946, the Bhore Committee had recommended levels which at that time were about half that of the levels in developed countries to be achieved for a national health service. For example, one doctor per 1600 population and one nurse per 600 population. What norms do we take now at the beginning of 21<sup>st</sup> century in India?

Why has increasing the availability of nurses been neglected? There has been stagnation and a decline in Nursing Schools in the public sector. What has been impact of encouraging the private sector in nursing education? How do we address large efflux of nurses abroad?

Now anganwadi workers, ASHAs are being increasingly employed to do certain functions at the community level. But ASHAs are expected to do more of demand generation of health services than to provide health services. What is the likely total impact of ASHAs as regards availability of health services at the community level?

What is the potential of revolution in communication technology in availability of health services? Telemedicine need not be an esoteric idea. Why can't the PHC doctor or the family physician consult an expert through fax/phone/email and reduce the gap in availability of expert opinion? Are things likely to improve on this front during the forthcoming decade? Have there been any experiments so far in this regard? Have these experiments identified problem areas which would require further work?

To achieve Universal Access, private practitioners and public health services will have to work in unison. What will be the basis to create the publicly managed comprehensive health care system with an appropriate mix of private and public health personnel?

### **Financing of Health Care**

Average health care expenditure in India is about Rs 3000/- per capita annually. Out of this private, out of pocket expenditure accounts for about Rs 2600/- , i.e., more than 80%. The WHO has

recommended that the Government should spend 5% of GDP on health care. In India, State and Central Governments together spend about Rs 52000 crores annually, i.e., 1% of GDP and the commitment by the UPA Government through the Common Minimum Programme, to increase it to 2% to 3% of GDP is still a distant goal, although the central Government's health budget has increased by about 20% each year for the last four years. In his paper "Financing Strategy for Operationalising Right to Healthcare in India", Ravi Duggal by doing some systematic exercise had estimated that in 2005-06 for a population of 1 billion, the cost of Universal Primary Health Care would be Rs 450 per capita, i.e., 1.50% of GDP of Rs 30,000 billion and the total cost of Universal Health Care would be per capita Rs 670, i.e., 2.3 % of GDP. This expenditure is to be met through tax-based public funds and contribution by the employers and employees in organized sector. These calculations need to be revisited, updated. How can the public health expenditure be increased to three times its current level? Health is a State subject and 80% of health expenditure is done by the States. States do not have much power to collect taxes, except sales taxes and sundry. How do we foresee states contributing say thrice as much as they are doing currently? If Central Government contributes to most of the increase, would not it lead to total domination of the centre over the States in policy making?

This mind boggling increase that is needed cannot of course be spent wholly on public health facilities; even if we assume that there will be substantial rise in the public health facilities from their current share of about 20% of outpatient services and 40% of indoor services. To reach the goal of "Health care for all", a significant portion of public health expenditure will have to be spent on paying the bills of regulated private providers, who will have to provide health care of standard quality at standard rates to be paid through public funds - as is being done in many developed countries. Today less than 5% of the population is under private health insurance. The newly launched Rashtriya Swasthya Bima Yojana (RSBY) would, at its best, cover all officially poor people (about 20%). The provision for RSBY in the 2009-2010 central budget of Rs 350 crores is tokenistic; it is less than 10% of the requirement to cover all the 25 crore officially poor people. How do we envisage the transition from this scenario to have public funds for a non-contributory, tax-based universal, social insurance?

What is the evidence and experience regarding various

forms of insurance (need to draw upon discussions of the 2001 MFC meet) while moving towards universal access? What are the relative strengths and weaknesses of mandatory, social insurance (with contribution from employers and State), community-based insurance (based on voluntary group contributions) and State-subsidised individual insurance? How do we look at the social insurance model in a country where 93% of the workforce is in the informal sector, often with no clear employer? What are the issues and concerns regarding different models of community based insurance?

Developed capitalist countries keep struggling for sparing adequate funds to cover all citizens and all types of health care, though they are spending much more than 5% GDP on health care through public funds. Health care cost seems to be a bottomless pit. The US health care system has been caught up in the trap of private health insurance fuelling “legally safe” medical practice by doctors. This along with high overheads and profiteering of insurance companies and HMOs has resulted in a never ending chain of spiraling costs, wastages and dissatisfaction amongst all stakeholders. Other developed countries are using funds much more economically, though they too are haunted by the problem of ever rising health care expenditure. How can India avoid this problem?

### **Governance Including Regulation of Medical Practice and Creation of Comprehensive System of Health Care**

Right at the outset it is important to highlight two broad perspectives on governance: The currently popular “World Bank” perspective is conceptually positioned on a corporate model of development in which the action of the state is judged by whether or not it facilitates the interests of capital in economic growth. Here, the market provides the barometer for efficacy of state action and, therefore, of good governance. The second perspective, emerging from traditional political theory, progress made with distributional objectives in pursuit of economic advancement characterises the model of development in a democratic polity. The capability to manage social and political processes to subserve this goal constitutes the tool of scrutiny for judging the state’s performance.”<sup>3</sup>

Today’s scenario is characterised by a “dominant paradigm of health care shifting from accessibility, affordability and equity to efficiency of investment (maximum results from least inputs), effectiveness of the output through quality of care (coming from consumer choice) and differentiated systems of health

care (shared cost) where the consumers pay and receive care according to their means. It is important to note also that the new SAPs have led to the loss of inter-sectoral support for health.”<sup>4</sup>

India has one of the most privatized health care systems in the world that too mostly unregulated. Examples of bad quality, negligence, incompetence, cheating, and exploitation are more common than exceptions. Large part of sub-standard care is due to irrational practice by allopathic practitioners, cross practice by non-allopathic practitioners and lack of compulsory Continuing Medical Education. Non-allopathic practitioners do less investigation than necessary whereas the allopaths, especially the experts indulge more in overuse of investigations, medication, and other interventions. Patients do get relief, cure at the hands of these experts but at an exorbitant cost and patients also pay in terms of damage to health through unnecessary medication, and other unnecessary interventions. This description can go on. The need for regulating the content of medical practice is quite clear to any critical observer. However there are nagging issues which require further discussion: The routinization and bureaucratization of all efforts at increasing accountability and participation needs to be seriously looked at. Does the answer lie more in efforts at democratizing communities as a whole rather than issues that are purely health system specific? If yes, what are the prospects of such democratization in the immediate future?

Experience the world over shows that if doctors are paid by a third party payment system which pays doctors at defined rates for defined interventions, the content of medical practice can be controlled by employing mechanisms to monitor whether doctors are following protocols, standard practices. India may have to follow this route, without making a fetish of evidence based medicine. There is a huge gap in preparing Indian standards and protocols. Hence we need to go into some detailed exercise to identify the gaps and the kind and extent of work that is needed to overcome these gaps. Secondly when the state pays the bills, there is a tendency not to economize on costs while preparing standards, even when commercial interests pushing more interventions or jacking up costing are absent. Similarly, wastages tend to occur in public health facilities when nobody cares or wants to take responsibility of taking decisions in broader public interest. Plugging wastages, economizing is important in developing countries like India, when financial resources are quite limited. What mechanisms would be required to achieve

economizing in face of limited financial resources?

Lastly, especially in a post-colonial society like India with a very strong tradition of Inspector Raj and corruption at every level, any regulatory mechanism raises the spectre of Babu Raj with dominance of bureaucrats and greasing of their hands replacing effective regulation. How do we reduce this risk? What are the examples of social regulation with participation of community members? Given the so far dismal record of self-regulation by the private medical sector, would there be some place for self-regulation within the larger system of regulation of medical practice?

While creating a comprehensive, universal health care coverage system, a lot of dovetailing and coordination would be required. Dovetailing would be necessary between paramedics and doctors, experts; between public and private providers; between allopathic and non-allopathic systems. This would require a lot of coordination, management and system building. What is the state of affairs currently and experience so far about this dovetailing? What kinds of gaps exist and

why? This issue will also need a detailed deliberation.

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<sup>2</sup> Gilson, Lucy et al. (2007), op.cit.

<sup>3</sup> Saxena, K.B. "Governance in the Health Sector", in *Securing Health for All: Dimensions and Challenges*. Edited by Sujata Prasad and C. Sathyamala, Institute for Human Development, New Delhi, 2006.

<sup>4</sup> Qadeer, Imrana. "Health Care Systems in Transition III - India, Part I: Indian Experience", *Journal of Public Health Medicine*, Vol 22, No. I, 2000. Quoted in Saxena, K.B., op.cit.

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## Protection and Utilisation of Public Funded Intellectual Property Bill: A Wrong Prescription for Public Sector R&D

-K.M. Gopa Kumar<sup>1</sup>

*The Ministry of Science & Technology and Earth Sciences introduced a Bill titled Protection and Utilisation of Public Funded Intellectual Property Bill (Bill), in the last session of the Parliament (December 2008). Then the Bill was to be referred to the Standing Committee on Science and Technology and the standing committee was expected to submit its report within three months.*

The Statement of Objects and Reasons provide following reasons for the Bill. Firstly, the Bill is introduced to provide incentives for creativity and innovation. Secondly, to encourage innovation in small and medium enterprises, and promote collaboration between Government, private enterprise and non-Government organisations. Thirdly, to encourage commercialisation of intellectual property created out of public funded Research and Development and culture of innovation in the country. Fourthly, to increase the awareness of about intellectual property in the country. Fifthly, to increase the responsibility of universities,

academic and research institutions to innovate. Lastly, to help Universities and research institutions to achieve financial self-reliance and minimise the dependence on Government funding. In short the Bill has been projected as a panacea for all issues related to commercialisation of public funded R&D outcomes and financial self-reliance of Universities and R&D institutions.

To achieve these objectives the Bill contains the following prescriptions:

The Bill proposes a legal obligation on the part of the recipient of a grant from the Government for Research and Development to disclose to the Government regarding the intellectual property created out of the grant within 60 days of the actual creation of such property. Then the recipient is expected to inform the Government within 90 days from the date of the disclosure regarding the intention to keep to retain the title of the publicly funded intellectual property. A failure to disclose or communicate the intention to retain title would make the Government the owner of the intellectual property. The Bill obligates the recipient to create

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an intellectual property management committee within 180 days from the date of receiving the grant. And within a further 180 days of the constitution of the IP management committee shall “establish mechanism to promote the culture of innovation and public funded intellectual property generation within the organisation!” The recipient is obliged to give exclusive license only to such persons who manufacture products using such intellectual property substantially in India. According to the Bill, the royalty or income arising out of publicly funded intellectual property will be divided between the IP creator and the recipient of the grant. The Bill proposes a minimum 30 per cent share to the creator of such intellectual property. Another 30 per cent to fund created by the intellectual property management committee. The Bill sets legal duties on recipient as well as the creator of intellectual property. The Bill imposes penalties on intellectual property creator and recipient in case of failure to discharge their duties. In a nutshell the Bill proposes a compulsory intellectual property creation whenever there is an involvement of public funds. This type of legal prescription does not reflect the reality and suffers from the following defects.

Firstly, the Bill is based on a wrong assumption that creation of intellectual property is the only answer to the problems faced by the Research and Development sector especially the public sector R&D. For instance, according to the objects and reasons of the Bill states that “provides incentive to create intellectual property and the mechanism for its protection and utilisation, encourages innovation in small and medium enterprises, promotes collaboration between Government, private enterprises and non-government organisations, commercialisation of intellectual property created of public funded research and development and the culture of innovation.” All these assumptions are contested in policy circles. There is no concrete evidence to support the role of intellectual property as an incentive for research and development. Thus the undue importance to intellectual property as a law and policy tool to incentivise R&D and innovation in India under the Bill is based more on fiction than reality.

Secondly, the Bill is based on a similar US piece of legislation known as Bayh-Dole Act 1980. There are many studies now available on the outcome of

this legislation. These studies clearly show that there is no evidence to conclude that the Bayh-Dole legislation contributes substantial revenue to universities. Only 5% of total research grant is generated as revenue through license fee. Except two to three universities, most of the technology transfer offices of Universities are functioning on a deficit budget. Further there is a serious move to restructure the Bayh-Dole legislation in the US. Therefore it is not a good idea to adopt a model, which has failed in its place of origin.

Thirdly, the Bill does not reflect Indian reality. There is serious concern about the quality of R&D happening in India and its commercial value. Intellectual property is not a good yardstick to gauge the quality of R&D. There are certain fundamental issues, which affect the quality of R&D in India. Various committees including the Planning Commission have dealt this issue in detail. There is a serious concern regarding the commercial quality of R&D outcomes from India. However, the Bill assumes that all IP created under the public sector R&D institutions are of commercial quality.

Fourthly, apart from the above-mentioned fundamental issues, the proposed Bill imposes penalties on the researchers and institutions for not complying with the legislation. In other words it means the Bill makes it compulsory for the recipients engaged in public fund R&D to protect the IP coming out of R&D. There are many other ways of commercialisation of R&D without protecting IP. However, the Bill rejects all these options and prescribes IP as the only route for commercialisation. This would create further bureaucracy and red tapism in public sector R&D institutions and probably would result in the opposite of what is intended.

Fifthly, the Bill covers not only patent but also all forms of IP including trademark and copyright. Such a broad coverage especially the inclusion of copyright would prevent access to knowledge by preventing free access to publications comes out of public funded R&D.

In the light of the above discussion, a serious rethinking is required on the viability of the Bill. The Standing Committee should examine the viability of the Bill and its implications for public policy before proceeding to examine the Bill clause by clause.

## Willing Participants and Tolerant Profession: Medical Ethics and Human Rights in Narco-analysis

- Amar Jesani<sup>1</sup>

(This paper is an abridged version of the twenty second Dr Ramanadham Memorial Lecture delivered by the author in a meeting organised by the People's Union for Democratic Rights at the Indian Law Institute, New Delhi on September 15, 2007. It is published with the permission of the PUDR.)

I did not know Dr Ramanadham personally, though he was active at the same time when I was also very active in the trade-union and human-rights movements. His work inspired many of us, for the involvement of medical professionals in doing something progressive is quite rare in India. Amongst such rare doctors today, we have Dr Binayak Sen, a friend of ours who has used his professional skills only for the poor and involved himself in human-rights work. The Chhatisgarh government has imprisoned him on false charges. Incidentally, both Dr Ramanadham and Dr Binayak Sen specialized as paediatricians.

Participation of some doctors in the violation of democratic rights, or in conservative and anti-people activities is not new in India as was discovered by the Medico Friend Circle in its investigation of carnage in Gujarat in 2002 (1). In 1995, Indian Medical Association (IMA) had done a survey of medical persons to find out what they knew about torture (2). They found that almost 60 per cent of the doctors believed that torture was justified in certain circumstances and saw no harm in doing it!

Historically, medical professionals have always been involved in designing techniques for torture as well as death penalty all over the world. Most of the time, doctors cheerfully participate for two reasons or, should we say, due to two *misconceptions*. One, that when these things are inevitable, the argument goes, doctors should do something to make them humane. And, two, to make the method more efficient so that quicker would be the result and, hence, the less would be the pain and suffering.

When I was working for human rights organisations, we used to take up campaigns when somebody died in police lock-ups. Immediately, there would be a small committee of journalists, lawyers and doctors like me,

<sup>1</sup>The author is thankful to the persons who transcribed and copy edited this lecture.

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and we would go around doing the investigation and then come out with a report. Normally, our scrutiny was focused on the conduct of the police because the police was the culprit in the killing. But I found that in all these cases, even if a doctor was not directly involved in carrying out the torture, often the tortured person would have been brought for treatment to the medical personnel in a public hospital. Doctors would treat them and then allow them to be taken back to the police lock-ups for more torture. The doctors restore a tortured person to health so that that person can be interrogated again in the same manner and information or confession extracted. The aim of torture is not to kill, often killing is regarded as failure and so medical help may be needed to keep the tortured person alive. It is in this cycle of torture - torture, treatment, torture - that there is intentional or unintentional involvement of doctors.

The involvement of doctors in carrying out death penalty is well documented. In India, even the judiciary forces doctors to participate in these executions. In 1995, the Supreme Court struck down a provision in the Punjab and Haryana Prison Manual related to hangings (3). The prison manual said that a person who is hanged should be kept hanging for half an hour. The reason was very simple. It was in the nineteenth century, in colonial times, that hanging had emerged as a more efficient and *humane* method of judicial killing. In hanging, the knot and its placement is required to be such that the impact of hanging breaks a vertebra in the neck, which leads to severe injury to a crucial part of the brain, thus killing the person instantaneously. However, sometimes there is no instantaneous death, and the person has to be kept hanging so that death is caused by asphyxia. So the colonial administration had this half-an-hour rule. But the petitioners argued that such practice was barbaric. And our court agreed and passed the order that a doctor should be called upon to examine soon after the person is hanged. And, as soon as the doctor found the person dead, the body should be brought down. So, since 1994, the doctor is supposed to examine every few minutes the person who is hanging and if the person is found alive, is supposed to give instructions to keep him hanging! Now, this makes the doctor barbaric. The doctor, whose job is to heal, to give life, to resuscitate, is made to collude in the actual judicial killing by playing the role of assisting the hangman. This is a travesty of

the fundamental principles of the professional ethics of doctors. Unfortunately our medical associations have allowed this judgment to go unchallenged (4).

The process in which a bulk of any profession turns against humanity does not happen overnight. The Nazi physicians, who used their medical skills to participate in atrocities, did not become inhuman overnight. It took years to learn to become inhuman by *adjusting* their ethics to the demands of the Nazis, before eventually participating in the inhuman acts of the state. That is the reason why such *adjustment* of ethics, the slippery slope, must be nipped at the every outset.

### Examining the Science of Lie Detection and Narco-Analysis

Are the techniques used for lie detection and narco-analysis scientific? Two aspects of any science are important. One is validity: Is it a scientifically validated method? To what extent does it measure what it claims to measure? And another is reliability: Is it really a reliable method? How consistently can it be reproduced across time, persons involved, and situations?

When I examine the science of a method, it does not mean that I give less importance to human rights and ethical content or to the use of that method. Both scientific and unscientific methods can be used for violating human rights. Because a method is scientific, its use does not automatically become ethical or humane. Good scientific methods and devices have often been used for very bad purposes. But an examination of science is necessary to engage with those medical scientists, who are otherwise neutral, but get swayed by the claim to scientific validity of such methods. Besides, an unscientific method deceives and does not serve even its basic purpose of finding out what it intends to find, and, in the process, punishes the innocent. A review of scientific literature on the use of lie-detection and narco-analysis *for establishing crime* shows there is not enough researched material to assure us that these are scientifically researched methods (5). Moreover, not much of the inconclusive literature available on the subject is from scientific journals. Most research on the subject is sponsored or conducted by people in the security, intelligence, police and military agencies. So there is a major conflict of interest.

### Lie-Detection Methods

**Polygraph:** Lie detection is separate from narco-analysis - the former is not invasive but the latter is, as it introduces drugs in the body system. But, in

practice, there is a big connection between the two and they complement each other. The polygraph is a lie-detection method in which it is assumed that when you are telling a lie, that is, when your mind is trying to deceive, it has a direct physiological impact, i.e., your physiological response changes - breathing pattern, pulse rate, the way one sweats changes, and so on. These physiological changes are used in the polygraph method to detect lies. They ask you questions and electrodes attached to your body record changes in your pulse rates, breathing rate, blood pressure, etc. They compare changes or lack of changes when you lie or do not lie. The lying is found out by asking questions – the *control* questions (those for which true answers are already known) and the *relevant* questions (relevant to the investigation of crime).

**Computer Voice Test Recorder:** A voice recorder is attached to a computer having certain specialised programmes and functions, and like physiological changes recorded in the polygraph, this device records changes in voice, which is supposed to have a different character when one is lying from when one telling the truth! The sophisticated computer eventually pronounces whether the person was lying in response to the *relevant* questions. I looked up court judgments from the US on the use of this device, and came across cases where the computer had erred, leading to the incarceration of innocents. In one case, the person later got compensation from the manufacturer of the machine.

**Brain mapping/brain finger-printing:** The new technique of *brain mapping* and *brain finger-printing* is used not only for lie detection but also as the basis for undertaking narco-analysis. It uses well known diagnostic instruments, the Electro Encephalogram (EEG) and the functional Magnetic Resonance Imaging (fMRI). Such machines are now used on a regular basis in forensic laboratories in Bangalore, Bombay and Ahmedabad. These are also the places where narco-analysis is carried out.

This method shifts attention from the physiological response of the body to the electrical responses in the brain itself. This supposedly takes care of limitations of measuring physiological response in the polygraph. Besides, the person is not made to say anything; he or she is only made to hear something and the rest is done by the machine to find out how the brain is responding. They say that the knowledge of what you know about persons, places, events, etc, is stored in your mind. If asked, I may say the truth or lie about them. Or I may prefer to stay silent, saying

that to keep silent is my right. But once this method is employed, we no longer have the right to our silence. Technically, one may stay *silent* in the sense that one has said nothing. And yet, the machine attached to my skull provides my interrogators the information. Let us see how this is done.

The person is connected to the EEG or fMRI, and not required to talk. They use auditory stimuli of name(s), place(s), event(s), etc., that are heard by the person. Now, there is something called the P-300 brainwave. According to their theories, this brainwave is not under person's volition, or control. In a fraction of a second after hearing stimuli, if stimuli are recognised, this brainwave spikes. This electrical *spark* in specific areas of brain, is recorded in the fMRI or the EEG machine. And that way, according to them, they can get the *content* of the brain - not details of what person knows, but whether s/he knows about certain specific things that they are interested in finding out. In short, they get this information without person's active participation, without ever verbally answering any question, without having any control over what they found out from brain's electrical activities.

Now, whether this interpretation of the P-300 brainwave is scientific or not, and whether it is based on evidence, I have no idea. But it is on this basis that they believe you know something, and then they have to *persuade* you to bring it out of your mind. And it has to be brought out in such a manner that you are unable to exercise any control over what you say. Because, if you are allowed to use your mind to control what you say, then you may lie or filter out what you do not want them to know. So, having seen the contents page of your mind, as they believe, they follow it up with narco-analysis to read the remaining pages.

Before I deal more with narco-analysis, it may be useful to discuss what independent scientists have to say about the lie-detection techniques. In the last few years, two major scientific or professional committees evaluated lie-detection techniques. Lie-detection methods are used in screening applicants for sensitive jobs. It was in this context that the US Department of Energy requested the National Research Council (NRC) for an evaluation of these techniques. The NRC appointed an expert committee that brought out a report in 2003 (6). The second review was done by a Working Party of the British Psychological Society in 2004 (7). Both committees concluded that lie detection techniques were not scientific, or were based on dubious science.

The assumption that there is always a mutual

correspondence between psychological and physiological states is wrong. I also feel the assumption that P-300 brainwave provides accurate information on whether the brain knows something is a highly mechanical understanding with doubtful scientific validity. Another important issue is the fear of being labelled a *liar*, which can create physiological responses that may actually lead to totally erroneous conclusions about the information obtained. Thus, in all these techniques, the possibilities of, what we call, the false positives and the false negatives are very high.

The **false positives** are those who are telling the truth but are wrongly judged liars. (Even if the judgment of the machine, or one derived by the investigator on the basis of data provided by machine, needs corroboration, the person is doomed as a suspect.) The **false negatives**, on the other hand, are those judgments where a person is actually lying, but the machine and the investigators judge him or her as telling the truth. The false negatives can also be achieved by what is called **countermeasure**, by training oneself to misguide the interrogator or the machine. There is a very interesting case described in one of these two reports (8). A person called Floyd "Buzz" Fay, was falsely convicted of murder in the USA. He was actually judged as a criminal and a murderer simply because he failed a lie-detection test. He was sentenced to life. But, after he had spent two-and-a-half years in prison, the police found the real murderer and Fay had to be released. But, when he was in prison on such grave but false charges, he started training the inmates of the prison how to beat the lie-detection test and he did it very well. He provided training for duration of 20 minutes to those who had told him that they had committed the crime for which they were supposed to go through the lie-detection test. He gave this training to 27 persons, among whom 23 beat the machines and came out scot-free!

### Narco-Analysis

Now, let us look at narco-analysis, which is fast replacing lie detection techniques as the preferred method of making a person say the truth and nothing but the truth. I started with lie detection and brain mapping because the faith in narco-analysis is part of the same mindset that believes there is a technology (or the possibility of one) to recognise truth from a lie or to get to the truth against a person's wishes. It is also one of the latest in a chain of attempted technological fixes, and has the best so-called scientific look to it. So its importance lies in its capacity to seduce scientists into believing that it is scientific and free of the short-comings of the lie-detection

techniques mentioned earlier, and, of course, that it is something *less than torture*. That is why it is more important and, of course, so much more dangerous.

From what I have learnt, narco-analysis, as a procedure of using some drug to facilitate the extraction of relevant information from a person's mind, has a history of more than 80 years. But I do not know much about its early history. Currently, the drug used for narco-analysis is called Sodium Pentothal. This is a trade name given by a company, Abbot Laboratories, which discovered it in 1935. Its real name is Thiopental Sodium, which is a thiobarbiturate, a part of the barbiturate group of drugs. But before this became the drug of choice, doctors undertaking narco-analysis for treating patients had used several other drugs like sodium amytal, scopolamine and nitrous oxide. Apart from drugs, hypnosis was also used in psychiatry. All these procedures were designed to help patients suffering from certain mental illnesses.

The use of drugs by security agencies happened along with their medical use. For instance, the CIA had done covert experiments with LSD – causing death of one unsuspecting participant - during the cold war in order to use its *mind-altering* properties to its advantage. During the cold war period it was believed that the Soviet Union knew some method to brainwash people. And I remember in the 1970s, if a person became Marxist, we were told that person had been *brainwashed*. This term *brainwash* was used very commonly at that time, but at present it is hardly heard, though a different kind of ideology is washing the minds of a large number of people. The death in covert LSD experiment became a scandal, leading to senate hearings. These hearing also revealed that the CIA was also experimenting with the sodium pentothal. Some of the documents of the senate hearings are available on the Internet (9).

**Sodium Pentothal:** Sodium pentothal has another interesting history. It was developed and tested as an anaesthetic agent. Sodium pentothal is given intravenously and is an ultra-fast-acting anaesthetic. It acts within 45 seconds of being introduced into the bloodstream. Almost 60% of it concentrates in the brain and the person immediately starts losing consciousness. It can also be given for a relatively longer period of time. So the surgery can be commenced immediately, and person can be kept under anaesthesia for the duration of surgery. After one stops giving it, it takes 15 minutes to three hours to wear off, and so the recovery from the anaesthesia is also relatively fast. Thus, it is a very useful drug. After it was developed, they used it as an anaesthetic agent in an emergency situation during the Second

World War: the famous Pearl Harbour attack. When it was bombed, the injured persons were given sodium pentothal while being provided surgical care. Several persons died due to the overdose of this anaesthesia. This information was not made available to the public till in 1990s when the freedom of information legislation helped to get it out. The point I am trying to make is that this very useful drug can kill if it is not used judiciously. Its proper use requires the services of a doctor whose sole aim would be to care for the person and not just to extract information by any means.

Sodium pentothal is also famous for its use in other areas like euthanasia. Voluntary euthanasia is where the doctor helps a patient, who is suffering from irreversible, debilitating illness that would surely lead to a slow death, to die. One of the drugs injected in order to hasten death is sodium pentothal. The lethal injection that is used in the USA for executing the death penalty has also been using sodium pentothal.

**Sodium Pentothal in Narco-Analysis:** Now let us understand the assumptions underlying the use of sodium pentothal, an anaesthetic drug, for its intended forensic use in narco-analysis. There are four different stages of anaesthesia. The first stage is called induction. The second stage of anaesthesia is a phase of excitement and the beginning of the loss of consciousness, when the person is partly conscious or semi-conscious, or is in a trance-like state. As one continues to give the anaesthetic substance, the person goes into the third stage of anaesthesia, the surgical plane, when a person loses sensation and is totally unconscious. The loss of consciousness in this stage is reversible. However, the higher dose than this stage leads to the last and fourth stage, the coma or overdose, and is often irreversible due to depression of the brain stem and medullary regions, and it can lead to death as happened at the Pearl Harbour.

In narco-analysis, a person is kept at the second stage of anaesthesia. The hypothesis is that, at this dose and stage of anaesthesia, the sodium pentothal produces not only an effect similar to hypnosis (trance-like state) but, by its interaction with certain chemicals of the brain, it also makes the person to speak the truth. So the hypothesis governing the forensic use of narcoanalysis is that the activity of the upper or cortical part of the brain is required in order to filter or alter a person's response to stimuli. Another assumption is that, compared to telling the truth, lying demands more complex processing in the brain in order to decide how to lie and what to say as a lie. And this complex processing takes place in the upper or cortical portion of the brain. And the final assumption

is that, if the above hypothesis is true, then the expert needs to have only a mechanism or a drug that can stop or reduce the influence of the upper or cortical part of the brain whose role is critical in forming a lie. Once that is achieved, the brain's capacity to lie is altered or controlled by the investigator. And the hypnotic effect produced by the drug would ensure that the person tells the truth and nothing but truth, when asked a question.

Now, have the scientists found in the sodium pentothal such a drug and in narco-analysis such a mechanism that can alter the brain in the manner required? They claim that it is so. In the October 2006 issue of the *Indian Journal of Medical Ethics*, I wrote an editorial (10) disputing the *science* of narcoanalysis and criticised its practitioners for violation of ethics and human rights. The top-most forensic practitioner of narco-analysis in India responded (11) to the editorial. Accordingly, the sodium pentothal has a property of inhibiting the working of a neurotransmitter inhibitor in the brain called GABA or Gamma Amino Butyric Acid. The assumption is that this neurotransmitter inhibits the way the brain controls the response a person gives, and, by inhibiting this neurotransmitter at a certain depth of anaesthesia, the sodium pentothal removes or reduces the inhibitory powers of the upper or cortical brain.

Is there any sound scientific proof for such a series of assumptions? The medical journals are silent on this. On the contrary, there is more evidence, both empirical and otherwise, to argue that full-proof assumptions of such kind are not possible.

As I said earlier, it is known that second stage of anaesthesia produces excitement and the person is not fully unconscious but in a trance-like state. The psychiatrists, who have used this drug, have thus talked of patients being very lucid in narco-analysis and have also talked about narco-hypnosis. Under such assumption, for decades they used this drug to help victims of trauma, whose minds had suppressed their memories of the trauma or were reluctant to describe their trauma as in doing so they were re-living their painful experience. All of which, however, were causing them psychological problems. After writing that editorial I interacted with a few psychiatrists to understand their viewpoints. I found some very good support, though many of them have still not written publicly on this issue. I also interacted with a psychiatrist from the armed forces, who said that he had used this drug for narco-analysis to help his patients. He also told me that he discontinued the use of this drug as well as narco-analysis because while patients gave information in the hypnotic trance

induced in the process, they also gave lots of misleading information. His contention, thus, was that the method was not reliable. However, at the same time, I must add, he said that he had full faith in the security agencies and contended that, in any case, the security of the nation was more important than human rights!

**Narco-Analysis and Hypnotic Suggestions:** While I was giving a public lecture in Mumbai on narco-analysis, a person from the audience said that forensic experts planted ideas in the mind of his relative accused of a crime, while he was undergoing narco-analysis. His question was whether it was possible to plant information through suggestion during narco-analysis. I am not a scientist, and least of all an expert on this subject, to give a definitive answer. However, it is known that the trance-like state of hypnosis was used in psychoanalysis and as the person was also considered more prone to suggestions it was also used in psychotherapy.

I have no scientific evidence, but common sense says that if the sodium pentothal produces a trance-like hypnotic state at second stage of anaesthesia, making a person talk with less inhibition in giving or recollecting information, then perhaps the reverse could also be true. Therefore, the scientists, who are confidently using sodium pentothal to make a person speak the *truth*, have an obligation to provide evidence that their very assumptions and hypotheses do not work at all in reverse. Unless that is done, there will always be a suspicion that the *truth* found in narco-analysis could also be *manufactured truth*, planted by the interrogators themselves.

### **Narco-Analysis and Torture**

Is narco-analysis a type of pharmacological torture? The United Nations' definition of torture (12) has four components. The first, torture produces physical/mental suffering and is a degrading treatment. The second, it is always intentionally inflicted. The third, it is inflicted for certain purposes such as getting information, confession, etc. And the fourth, it is inflicted by an official actor or an actor acting on behalf of an official. Narco-analysis satisfies all four components.

It is degrading because it deliberately uses a drug that attempts to alter the state of mind of a person against his/her wishes. It produces mental suffering in an individual, more so if he or she discovers that some of his or her fantasy revealed in the procedure is used to make accusation of real crime. In the present Indian

condition it is even more so because the police or forensic laboratory have released video clips of the actual narco-analysis of a person to the media, the same getting played out on the TV repeatedly when the same is not even admissible as evidence in a court of law. Thus, it inflicts a high level of mental suffering and stigmatisation of the individual by the society. The rest of the components of the definition are easily satisfied. Indeed, it is deliberately inflicted - so deliberately that it is systematically done in an operation theatre and not in a prison or police lock-up. It is also a method not only to extract information but also to force confessions. And it is always done by police through its forensic laboratory and personnel employed there, along with the doctors in a hospital who are specifically appointed by the police to do the procedure (13).

We always thought of torture as a gory, blood-soaked and barbaric way of treating a person. So we are often misled into believing that anything, which does not look gory, spill blood or break bones, cannot be barbaric and a form of torture. Torture, in fact remains torture even if it does not spill blood, break bones and is done in sterile, air-conditioned operation theatres. What is true of the procedure for death penalty, which moved from gory and bloody firing squads and the guillotine to electric chair and sterile lethal injects, holds true for torture as well. Narco-analysis produces torture as clearly as the lethal injection produces death.

#### **Doctors, Ethics and Narco-Analysis**

The last point that I want to make is regarding the relationship of narco-analysis to doctors and their medical ethics. As I said earlier, Sodium Pentothal is a very dangerous drug if not judiciously used. It needs to be tested in small dose to rule out the possibility of producing shock, or the allergic anaphylactic reaction. The anaesthetist also needs to know how to identify any bad effect that jeopardises person's life. It can suddenly lower the blood pressure, or cessation of respiration or apnoea, or unexplained constriction of the larynx, or a laryngeal spasm (needing emergency surgery); and it can also cause delirium, nausea and headache. But it is also used very commonly in surgeries simply because it is used very carefully by properly trained anaesthetists in the setting of an operation theatre in a hospital. That is why you will find that, although a Forensic Laboratory will claim that it did narco-analysis, it was actually

performed in an operation theatre of a hospital, mostly in a public hospital. The Godhra accused were narco-analysed not in a laboratory but in the SSG Hospital in Baroda, a public hospital with a medical college (14).

That means narco-analysis is a method that cannot be carried out without the assistance of doctors. Indeed, this is also not disputed, that one or more doctors directly participate in it, are continuously present during the interrogation, and the work these doctors do is nothing but assisting the interrogators. And they just not assist, but are actually responsible for creating the conditions for the interrogation to proceed, continue and conclude as desired by the interrogators. Clearly, doctors are directly involved in this procedure, or pharmacological torture. Besides, since there is a possibility of a series of life-threatening adverse outcomes; some other doctors, including a surgeon, have to be available on call, at a very short notice. And above all, there is also the association of the hospital and its head, who is normally a doctor, with the procedure. He/she not only allows but also makes all critical facilities of the hospital – physical as well as human resources, which includes doctors and nurses - available to the interrogators to conduct this torture in the name of scientific medical procedure.

What does this mean to human rights and human-rights defenders? All exemplary work that was done by the human-rights activists and all the gains of human rights in relation to medicine that were achieved in 1970s and 1980s are being thrown out of the window. The achievement and gains of human rights were these: the doctor, himself or herself, will not participate in torture, will not remain present anywhere where torture is carried out, and, not only that, if he or she comes to know about such torture as a doctor, he or she will immediately report it.

Health professionals must recognise that they are being forced or persuaded under various pretexts to violate their own professional ethics. Their participation is giving out a message to society that the medical profession tolerates those members, who are doing medical procedures in violation of wishes of individuals, on whom they are carried out, thus also violating the ethical principle of informed consent (15). This is also an important issue even in terms of the history of the medical profession. For instance, during the nineteen months of emergency in the 1970s,

we all know about the forced vasectomy performed on men. But who performed those vasectomies? Doctors did! They willingly participated in the name of a top-priority national programme, they felt an urgency or emergency to sterilise people without consideration of whether the persons brought by the police and other government officials were anyway coerced, forced or, for any other reason, were unwilling to undergo the family-planning operation.

This is a very important issue for associations of various health professions. The World Medical Association (WMA) issued the Tokyo Declaration against torture and on doctors' role in torture way back in 1975. In response to events that followed 9/11 in 2001, it also revised this declaration recently to ensure that there was absolutely no ambiguity in the prohibition on doctors' participation in torture (16). The Indian Medical Association, as a member of the WMA is signatory to the declaration, and thus has moral obligation to stop doctors from participating in torture and death penalty.

To conclude, participation of doctors in narco-analysis and death penalty; and the tolerance of the medical associations for their unethical acts, are indeed eroding the very ethical core of the medical profession. It is in the best interest of the health-care professions, the human rights movement and society in general that doctors and nurses are immediately removed - completely and unequivocally - from participation in narco-analysis, from police interrogations of all kinds, and also from their participation in death penalty.

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## What's Wrong With CSI: Forensic Evidence Doesn't Always Tell the Truth

- Roger Koppl<sup>1</sup>

Forensic evidence is foolproof, right? It's how those clever cops on *CSI* always catch the killer. DNA evidence springs innocent men from prison. Fingerprints nab the bad guys.

If only forensics were that reliable. Instead, to judge by the most comprehensive study on the reliability of forensic evidence to date, the error rate is more than 10% in five categories of analysis, including fiber, paint and body fluids. (Meaning: When the expert says specimen X matches source Y, there's a 10% probability he's wrong.) DNA and fingerprints are more reliable but still not foolproof. The 1995 study, in the *Journal of Forensic Sciences*, looked at proficiency tests labs take to see whether their work is sound.

More recent studies have also shown problems. Though a 2005 study in the *Journal of Criminal Law & Criminology* suggests a fingerprint false-positive rate a bit below 1%, a widely read 2006 experiment shows an alarming 4% false-positive rate.

Yet the public sees errors as gross anomalies. Like the time the FBI wrongly linked an Oregon attorney named Brandon Mayfield to the 2004 Madrid commuter train bombing that killed 200 people. The FBI had claimed a 100% match between fingerprints found at the scene and Mayfield, who was held for two weeks in federal custody. When the Spanish National Police got the real perpetrator, an Algerian named Ouhmane Daoud, the FBI had to admit its mistake. Mayfield accepted a \$2 million settlement from the government.

Another debacle, this time involving DNA testing: Josiah Sutton served four and a half years for rape after the Houston Crime Lab tied him to crime-scene DNA. The lab was later found to be rife with problems, including a leaky roof that let rainwater contaminate evidence. Sutton was proclaimed innocent in 2004 and awarded \$118,000 in reparations the next year.

Forensic evidence is also used in white-collar cases.

In the Martha Stewart trial, government forensic scientist Larry F. Stewart (no relation to Martha) testified that he had performed incriminating tests on the famous "@60" written next to "ImClone (nasdaq: IMCL - news - people)" on a worksheet used to record Martha Stewart's securities positions. The notation suggested that she had a long-standing agreement to sell ImClone should the price hit \$60, which would have cleared her of insider trading. Larry Stewart said his tests showed the potentially exonerating notation was made with different ink, thereby suggesting that it might have been added later.

When the court learned that someone else performed the tests he claimed to have done himself, Larry Stewart was tried for perjury. The tester had done an incomplete job, failing to compare the "@60" ink to all the other ink on the page. (Larry Stewart was acquitted.)

How can we preserve the usefulness of forensic evidence while protecting the public when it breaks down? The core problem with the forensic system is monopoly. Once evidence goes to one lab, it is rarely examined by any other. That needs to change. Each jurisdiction should include several competing labs. Occasionally the same DNA evidence, for instance, could be sent to three different labs for analysis.

This procedure may seem like a waste. But such checks would save taxpayer money. Extra tests are inexpensive compared to the cost of error, including the cost of incarcerating the wrongfully convicted. A forthcoming study I wrote for the Independent Institute (a government-reform think tank) shows that independent triplicate fingerprint examinations in felony cases would not only eliminate most false convictions that result from fingerprint errors but also would reduce the cost of criminal justice if the false-positive error rate is more than 0.115%, or about one in a thousand.

Other reforms should include making labs independent of law enforcement and a requirement for blind testing. When crime labs are part of the police department, some forensic experts make mistakes out of an unconscious desire to help their "clients," the police and prosecution. Independence and blind testing prevent that. Creating the right to a forensic expert for the defense would help restore the imbalance in scientific firepower that too often exists between prosecution and defense. Private labs are subject to civil liability claims and administrative fines, giving them financial incentives to get it right.

<sup>1</sup>This article is reproduced in public interest from Forbes Magazine dated June 02, 2008. *CSI: Crime Scene Investigation* is an American crime drama television series. *CSI* premiered on CBS on October 6, 2000. The show was created by Anthony E. Zuiker and produced by Jerry Bruckheimer. It is filmed primarily at Universal Studios in Universal City, California. See also the author's *CSI for Real: How to Improve Forensic Science* at <<http://reason.org/news/show/csi-for-real-how-to-improve-fo>>. Roger Koppl is a Professor of Economics and Finance at Fairleigh Dickinson University's Silberman College of Business and a Director of the Institute for Forensic Science Administration.

## An Epistemologist in the Bramble-Bush: At the Supreme Court with Mr. Joiner

- Susan Haack, University of Miami

*Think before you think!* [Stanislaw Lec]<sup>1</sup>

“Judges Become Leery of Expert Witnesses,” ran a headline in the *Wall Street Journal* a couple of years ago; they are “Skeptical of Unproven Science” - the “Testimony of Dilettantes” (Schmitt 1997). Intrigued, I began to struggle through thickets of details of exploding tires, allegedly poisonous perfumes, leaking and bursting breast implants, contaminated insulating oil, etc., etc., and through legal developments from *Frye* through the Federal Rules of Evidence to *Daubert*, until eventually I found myself at the U.S. Supreme Court with Mr. Joiner, eavesdropping as the justices - for all the world like a conclave of medieval logicians - disagreed among themselves about whether there is a Categorical Distinction between methodology and conclusions.

Now *that*, I thought, certainly sounds like the kind of question to which an epistemologist or philosopher of science ought to be able to make a contribution; and, in due course, I shall have something to say about it. But I soon realized it was only the tip of a very large iceberg.

By now, scientific evidence of just about every kind (from DNA fingerprinting to battered-wife syndrome, from studies of mice injected with potentially carcinogenic chemicals to recovered memories) plays a large and apparently ever-growing role in both criminal and civil cases. The long and tortuous history of efforts to ensure that when the legal system relies on scientific evidence it is not flimsy speculation but

decent work, suggests that this interaction of science and the law raises some very tricky problems. And to judge by how often, in that long and tortuous history, explicit or implicit assumptions about the nature of scientific knowledge and the character of scientific inquiry are crucial, those problems are in part epistemological.

The epistemological issues intersect, of course, with problems of other kinds. Peter Huber is preoccupied with greedy tort lawyers hoping to earn huge contingency fees by winning cases with “junk science,”<sup>2</sup> Kenneth Cheseboro with heartless corporations hoping to avoid compensating the victims of their profitable but dangerous products (Cheseboro 1993). I’m afraid both have a point. Both are well aware, however, that there is something about scientific evidence that encourages and enables the operation of such unsavory motives.

Almost a century ago, Learned Hand argued that the role of the expert witness - who not only may but must offer his opinion, draw conclusions - is anomalous, for if each party presents its own expert witness(es), the jury must decide “between two statements each founded upon an experience foreign in kind to their own” - when “it is just because they are incompetent for such a task that the expert is necessary at all” (Hand 901: 54). Only a couple of years ago, Justice Breyer - concerned with scientific evidence specifically rather than with expert evidence generally, and focused less on the jury than the judge, on whom a significant gatekeeping burden now falls - suggested an essentially similar diagnosis. Reflecting that *Daubert* requires judges “to make subtle and sophisticated determinations about scientific methodology,” he observes that “judges are not scientists, and do not have the scientific training that can facilitate the making of such decisions.”<sup>3</sup>

In 1901, Hand had suggested court-appointed experts; in 1997, in his concurring opinion in *Joiner*, Justice Breyer urged that judges make more use of their power under Federal Rule of Evidence 706 to appoint scientists to advise them. But, as Hand himself had observed earlier in his article, when there are expert witnesses on both sides we ask the jury to decide

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1. Gross 1983: 262.

2. Huber 1991, 1992; Huber and Foster 1997.

3. General Electric Co. v. Joiner, 522 U.S. 136, 148, 118 S. Ct. 512, 520 (1997) (Breyer, J., concurring).

"where doctors disagree" (ibid.: 154; emphasis mine). And now it begins to appear that there is a problem beyond judges' or juries' inability fully to understand scientific evidence. Many scientific claims and theories, at some point in their career, occupy that large grey area of the somewhat-but-far-from-overwhelmingly warranted; so sometimes the scientific determinations that judges or juries are asked to make may be so subtle and sophisticated, so manifold and tangled, that even those competent in the relevant area of science may legitimately disagree - or may agree that there is too little evidence, that they just don't know.

Legal efforts to winnow decent scientific evidence from the chaff, I shall argue, have often been based on false assumptions about science and how it works. It doesn't follow, unfortunately, that if we had a better understanding of science, all problems could be easily resolved. A better understanding of scientific evidence and inquiry will reveal why it has proven so difficult to find a legal form of words that will ensure that only decent scientific evidence is admitted, or a simple way to delegate some of the responsibility to scientists themselves; but rather than suggesting any easy solutions it accentuates the need to think hard and carefully about what goals we should be trying to achieve, and what kinds of imperfection in achieving them we are more willing, and what we are less willing, to tolerate.

Here I can offer only some preparatory steps toward such re-thinking: a brief account, first, of scientific evidence and its special complexities; and then - as I cautiously approach that bramble-bush with my philosophical pruning-shears - a brief epistemological commentary on the legal mechanisms that have been devised to handle scientific evidence in court. But I hope, by cutting away some overgrown epistemological deadwood, to clear the way for potentially healthier new growth.

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In their descriptive use, the words "science," "scientific," etc., refer to a loose federation of disciplines including physics, chemistry, biology, and so forth, and excluding history, theology, literary criticism, and so on.

But they also have an honorific use; "scientific," and "scientifically," especially, are very often all-purpose terms of epistemic praise, vaguely conveying "strong, reliable, good." They play their honorific role when the credulous are impressed by actors in white coats assuring them that new, scientific Wizzo will get

clothes even cleaner, or that new Smoothex is scientifically proven to get rid of wrinkles faster; and no less so when, skeptical of some claim, people ask: "Yes, but is there any scientific evidence for that?"

Unfortunately this dual usage, descriptive and honorific, has encouraged a damaging preoccupation - especially in Popper and among his admirers - with the "problem of demarcation," of distinguishing *real* science from pretenders.<sup>4</sup> It has distorted our perception of the place of the sciences within inquiry generally, and disguised what would otherwise be obvious facts: that neither all nor only scientists are good, honest, thorough inquirers; and that scientific claims and theories run the gamut from the thoroughly speculative to the very firmly warranted.

Natural-scientific inquiry is continuous with other kinds of empirical inquiry. The physicist and the investigative journalist, the X-ray crystallographer and the detective, the astronomer and the ethnomusicologist, etc., etc., all investigate some part or aspect of the same world. And scientists, like detectives, or historians, or anyone who seriously investigates some question, make an informed conjecture about the possible explanation of a puzzling phenomenon, check out how well it stands up to the available evidence and any further evidence they can lay hands on, and then use their judgment whether to give it up and try again, modify it, stick with it, or what.

Nor is there any "scientific method" guaranteeing that, at each step, science adds a new truth, eliminates a falsehood, gets closer to the truth, or becomes more empirically adequate. Scientific inquiry is fallible, its progress ragged and uneven. At some times and in some areas, it may stagnate or even regress; and where there is progress, it may be of any of these kinds, or it may be a matter of devising a better instrument, a better computing technique, a better vocabulary, etc.

As human cognitive enterprises go, natural-scientific inquiry has been remarkably successful. But this is not because it relies on a uniquely rational method unavailable to other inquirers; no, scientific inquiry is like other kinds of empirical inquiry - only more so. As Percy Bridgman once put it, "the scientific method, so far as it is a method, is doing one's damndest with one's mind, no holds barred" (Bridgman 1955: 535).

Scientific inquiry is "more so" in part because of the

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4. For a brief summary of controversies in recent philosophy of science, see Haack 1995 and Haack 1996. McErlean 2000 is a useful anthology.

many and various helps<sup>5</sup> scientists have devised to extend limited human intellectual and sensory powers and to sustain our fragile commitment to finding out: models, metaphors, and analogies to aid the imagination; instruments to aid the senses; elaborate experimental set-ups to aid in testing and checking by flushing out needed evidence; mathematical, statistical, and computing techniques to aid our powers of reasoning; and a tradition of institutionalized mutual disclosure and scrutiny that, at its best, enables the pooling of evidence and helps keep most scientists, most of the time, reasonably honest.

E. O. Wilson describes his work on the pheromone warning system of red harvester ants: collect ants; install them in artificial nests; dissect freshly killed workers, crush the tiny gobbets of white tissue released, and present this stuff, on the sharpened ends of applicator sticks, to resting groups of workers: they “race back and forth in whirling loops.” Enlist a chemist, who uses gas chromatography and mass spectrometry to identify the active substances, and then supplies pure samples of identical compounds synthesized in the laboratory. Present these to the ant colonies: same response as before. Enlist a mathematician, who constructs physical models of the diffusion of the pheromones. Then design experiments to measure the rate of spread of the molecules and the ants’ ability to sense them (Wilson 1999: 69-70).

This illustrates both the continuity of scientific inquiry with other kinds of inquiry, and the remarkable persistence with which good scientists go about solving one problem with the help of solutions to others.<sup>6</sup> Of course, that carries risks as well as rewards; the earlier results on which a scientist builds could turn out to be mistaken, and possibly in ways that undermine his work. Scientific helps depend on substantive assumptions, and our judgments of their reliability depend on our background information - e.g., our reasons for thinking that gas chromatography reliably indicates chemical composition.

Still, fallible and imperfect as they are, by and large those helps *have* helped, enormously: helped to stretch scientists’ imaginations, to enable their powers of reasoning, to extend their evidential reach, and to stiffen their respect for evidence. Almost every day, it seems, the natural sciences come up with new and better technical helps (from chemical assays through statistical modeling to computer programs). But there are no grounds for complacency. As science has become so expensive that only governments and large industrial concerns can afford to support it, as career pressures grow, so too does the temptation to

exaggerate results or ignore awkward evidence for the sake of money, prestige, or an easy life.

Like the evidence with respect to any empirical claim, the evidence with respect to a scientific claim includes both experiential evidence (someone’s seeing, hearing, etc., this or that) and reasons (background beliefs) ramifying in all directions; and, as “with respect to” was chosen to indicate, normally includes both positive evidence and negative. But, again, it is “more so” - in the complexity of its ramifications, in the dependence of its experiential components on instrumentation, in the pooling of evidential resources within a scientific community, etc.

A press report describes a meteorite found in Antarctica which when heated gives off a mix of gases unique to the Martian atmosphere - it was part of the crust of Mars about four billion years ago. Lasers and a mass spectrometer reveal that it contains polycyclic aromatic hydrocarbons (PAHs); this residue closely resembles what you have when simple organic matter decays, and might be fossilized bacteria droppings. David MacKay of the Johnson Space Center argues: “We have these lines of evidence. None of them by itself is definitive, but taken together, the simplest explanation is early Martian life” (Rogers 1996: 56-57). Other scientists, however, suggest that the PAHs might have been formed at volcanic vents; others agree that they are bacterial traces, but believe they were picked up while the meteorite was in Antarctica; and some think the supposed bacterial traces might be nothing more than artifacts of the instrumentation (Begley and Rogers 1997).

This illustrates both the continuity of scientific evidence with everyday empirical evidence, and the complexities that can make it so strong - or so fragile. All of us, in the most ordinary of everyday inquiry, depend on learned perceptual skills like reading, and many of us rely on glasses, contact lenses, hearing aids; in the sciences, observation is often highly skilled, and usually mediated by sophisticated instruments themselves dependent on theory. All of us, in the most ordinary of everyday inquiry, sometimes depend on what others tell us; a scientist virtually always relies on results achieved by others, from the sedimented work of earlier generations to the latest efforts of his contemporaries - though there is virtually always some disagreement within the relevant scientific community about which results are to be relied on, and which shaky. A firmly anchored and tightly woven mesh of evidence can be a strong

5. The term, and the idea, come from Bacon 1620.

6. I borrow this happy phrase from Quine 1995: 16.

indication of the truth of a claim - that is partly why “scientific evidence” has acquired its honorific use; but where anchoring is iffy, where some of the threads are fragile, where different threads pull in different directions, there will be ambiguity, the potential to mislead.

The structure of evidence, to use an analogy I have long relied on, is more like a crossword puzzle than a mathematical proof.<sup>7</sup> Einstein, I recently learned, once described a scientist as like a man “engaged in solving a well-designed word puzzle.”<sup>8</sup> I will add that scientific inquiry is a deeply and unavoidably social enterprise (otherwise, each scientist would have to start the work alone and from scratch); so that scientists, in the plural, are like a bunch of people working, sometimes in cooperation with each other, sometimes in competition, on this or that part of a vast crossword - a vast crossword in which some entries were completed long ago by scientists long dead, some only last week; some are in almost-indelible ink, some in regular ink, some in pencil, some heavily, some faintly; and some are loudly contested, with rival teams offering rival solutions.

The degree to which a scientific claim or theory is warranted, at a time, for a person or group of people, depends on how good that person’s or that group’s evidence is, at that time and with respect to that claim or theory. When there is relevant disagreement within the group - as with several people working on the same crossword and disagreeing over certain entries - the group’s evidence should be construed as including the reasons on which the group is agreed, and the disjunctions of those about which there is dispute. Talk of the degree of warrant of a claim or theory at a time, simpliciter, can be construed as shorthand for the degree of warrant of the claim for the person or group of people whose evidence, at that time, is best.

“Person or group” because, while usually the pooled evidence of a group is better than that of its members, sometimes a single person has learned something which has not yet been shared with other members of the relevant community: the results of his experiment have not yet been published, or have been published in a journal too obscure to reach others in the field, or, etc.

Though the warrant of a claim at a time depends on the quality of the evidence possessed by some person or persons at that time, the quality of evidence, its strength or weakness, is not subjective or community relative. How reasonable a crossword entry is depends on how well it is supported by the clue and any already

completed entries, how reasonable those entries are, independent of the entry in question, and how much of the crossword has been completed. Analogously, how warranted an empirical claim is depends on how well it is supported by experiential evidence and background beliefs, how reasonable those background beliefs are, independent of the belief in question, and how much of the relevant evidence the evidence includes.

The meteorite example also illustrates the connection between supportiveness of evidence and explanatoriness. Briefly and very roughly, how well evidence supports a claim depends on how well the claim is explanatorily integrated with the evidence. Explanation requires the classification of things into real kinds; so supportiveness, requiring kind-identifying predicates, is vocabulary-sensitive. That is why, though there is supportive-but-not-conclusive evidence, there is no syntactically characterizable inductive logic. Most importantly for our purposes, it is also why scientists so often need to introduce new terms, or to adapt the meaning of old terms, as they try to match their language to the real kinds of thing or stuff. (Friedrich Miescher first found a nonproteinaceous substance in the nucleus of cells and dubbed it *nuclein* in 1856;<sup>9</sup> now molecular biology has refined its classifications over and over: DNA, with its A, B, and Z forms; messenger RNA, transfer RNA, etc.)

Truth-indicative is what evidence has to be to be good; the better-warranted a claim is, the likelier that it is true.<sup>10</sup> At any time, some scientific claims and theories are well warranted; others are warranted poorly, if at all; and many lie somewhere in between. When no one has good enough evidence either way, a claim and its negation may be both unwarranted (so degrees of warrant don’t work just like mathematical probabilities). Most scientific claims and theories start out as informed but speculative conjectures; some seem for a while to be close to certain, and then turn out to have been wrong after all; a few seem for a while to be out of the running, and then turn out to have been right after all. But, as scientific inquiry has proceeded, a vast sediment of well-warranted claims

7. See for example Haack 1990 and Haack 1993. I am also drawing, in this section, on Haack 1995, Haack 1996, and Haack 1999.

8. Einstein 1936, in Einstein 1954: 295; drawn to my attention in 1996 by John Norton.

9. For the relevant history (up to the date of its publication, naturally) see Portugal and Cohen 1977.

10. Readers who have reservations about the concept of truth are referred to Haack 1998b: 7-30 and Haack 1999.

has accumulated.

Ideally, the degree of credence given a claim by the relevant scientific sub-community would be appropriately correlated with the degree of warrant of the claim. The processes by which a scientific community collects, sifts, and weighs evidence are fallible and imperfect, so the ideal is not always achieved; but they are good enough that it is a reasonable bet that much of the science in the textbooks is right, while only a fraction of today's speculative frontier science will survive, and most will eventually turn out to have been mistaken.<sup>11</sup> *Only* a reasonable bet, however; all the stuff in the textbooks was once speculative frontier science, and textbook science can occasionally be embarrassingly wrong (e.g., the arbitrary tautomeric forms in the chemistry texts on which, before Jerry Donohue set him straight, James Watson relied).<sup>12</sup>

The quality of evidence is objective, depending on how supportive it is, how comprehensive, and how independently secure the reasons it includes; but judgments of the quality of evidence are perspectival, i.e., they depend on the background beliefs of the person making the judgment.

If you and I are working on the same crossword, but have filled in the much-intersected 4 down differently, we will disagree about whether the fact that an entry to 12 across ends in an "F," or the fact that it ends in a "T," makes it reasonable. Similarly, if you and I are on the same hiring committee, and you believe that handwriting is an indication of character, while I think that's all nonsense, we will disagree about whether the fact that a candidate loops his *fs* is relevant to whether he should be hired. Whether it *is* relevant, however, depends on whether it is *true* that handwriting is an indication of character.

If, as I have maintained, the standards of strong evidence and well-conducted inquiry that apply to the sciences are the very same standards that apply to empirical inquiry generally, doesn't it follow that a lay person should be able to judge the worth of scientific evidence as well as a scientist? Unfortunately, no - far from it; for every area of science has its own specialized vocabulary, dense with theory, and judgments of the worth of evidence depend on substantive assumptions. Very often, the only alternative to relying on the judgment of scientists competent in the relevant field is to acquire a competence in that field yourself.

When a lay person (or even a scientist from another specialty) tries to judge the quality of evidence for a scientific claim, he is liable to find himself in the

position of the average American asked to judge the reasonableness of entries in a crossword puzzle where, though some of the clues are in pidgin English, the solutions are all in Turkish and presuppose a knowledge of the history of Istanbul, or are all in Bengali and require a knowledge of Islam, or, etc.<sup>13</sup> Similarly, to know what kinds of precaution would be adequate to ensure against experimental error requires substantive knowledge of what kinds of thing might interfere. To judge the likelihood that you are not dealing with a real phenomenon but with an artifact of the instrumentation requires substantive knowledge of how the instrument works. And so on.

Still, can't we at least assume that competent scientists in the relevant field will agree whether this is strong or flimsy evidence, whether that experiment is well- or ill-designed, etc.? Unfortunately, no - not always. At the textbook-science end of the continuum, where claims and theories are very well-warranted, competent scientists will agree. But the closer scientific work is to the frontier, the less comprehensive the evidence so far available, the more room there is for legitimate disagreement about what background information is reliable, hence about what evidence is relevant to what, and hence about the warrant of a claim. Even the most competent scientists may be in something like the position of people working on a part of a crossword in which, so far, only a few entries have been completed, leaving open more than one reasonable alternative solution to others. As Crick and Watson began work on the structure of DNA, some scientists in the field still believed that protein was the genetic material. As the work proceeded, Crick and Watson were sure DNA was helical; Franklin remained for a good while unconvinced. Crick and Watson thought the backbone was on the inside of the molecule; Franklin suspected it was on the outside. As soon as he learned of Chargaff's discovery of approximate equalities in the purine and pyrimidine residues in DNA, Watson was convinced of its importance; Crick still had to be persuaded.<sup>14</sup>

For most of what follows, the epistemological points that will most concern me are negative, identifying deadwood in need of pruning, misunderstandings

11. Bauer 1993 chapter 3 is good on this.

12. Watson 1968 chapter 26.

13. This puts me in mind of geneticist S. C. Harland's comment on trying to talk about biology with Trofim Lysenko: "it was like discussing the differential calculus with a man who did not know his 12-times table" (Gardner 1852: 147, referring to Huxley 1949).

14. Again, I rely on Watson 1968.

about science and how it works which have hampered legal efforts to distinguish decent science from junk: In the descriptive sense of “science,” there is bad science as well as good. There is no peculiar method which distinguishes genuine science from impostors. Usually there is no way of judging the worth of scientific evidence without substantive knowledge of the appropriate field. There is no guarantee that specialists in a scientific field won’t sometimes legitimately disagree. And there is no guarantee, either, that at any given time and for any legitimate scientific question, a warranted answer will be available.

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Once upon a time, in cases where expert knowledge was required, jurors with the necessary expertise were specially selected - e.g., a jury of butchers when the accused was charged with selling putrid meat; and sometimes specially qualified persons would be summoned to help determine some matter of fact which the court had to decide - e.g., masters of grammar for help in construing doubtful words in a bond. Learned Hand reports that the first case he can find of “real expert testimony” - expert testimony as exception to the rule that the conclusions of a witness are inadmissible - was in 1620.<sup>15</sup> But now, of course, when specialized knowledge is needed, the usual method is calling expert witnesses.

Though it was not cited in a federal or state ruling for a decade, the *Frye* case (1923) gradually began to set the standard of admissibility of scientific evidence, at first mainly in criminal cases but later in civil cases too. Mr. Frye was charged with murder, and had confessed. Later, however, he repudiated the confession; and took, and passed, a polygraph test (or more exactly, a discontinuous test of systolic blood pressure changes under questioning; the technology was in an early and primitive stage).<sup>16</sup>

But the trial court judge excluded this evidence, taking the view that deception tests were inadmissible unless there is “an infallible instrument for ascertaining whether a person is speaking the truth or not.”<sup>17</sup> On appeal, the D.C. Court confirmed the exclusion of this lie-detector evidence, ruling that novel scientific evidence “crosses the line between the experimental and the demonstrable,” and so is admissible, only if it is “sufficiently established to have gained general acceptance in the particular field to which it belongs.”<sup>18</sup> This is the “*Frye* rule” or “*Frye* test.”

As the *Frye* rule was applied and contested in the courts, the effect was sometimes more and sometimes less restrictive. Voice-print evidence, for example, was

sometimes admitted under the *Frye* test, sometimes excluded.<sup>19</sup> In *People v. Williams* (1958), the prosecution’s own experts conceded that the medical profession was mostly unfamiliar with the use of Nalline to detect narcotic use, but the court upheld the admissibility of its evidence all the same; the Nalline test was “generally accepted by *those who would be expected to be familiar with its use*,” and “in this age of specialization more should not be required.”<sup>20</sup> In *Coppolino v. State* (1968), the prosecution was allowed to introduce the results of a test (for the presence of succinylcholine chloride or its derivatives in human tissues) devised by the local medical examiner specifically for this trial - and so not known to, let alone generally accepted in, any scientific community. The appellate court cited *Frye* but, ruling that the trial judge did not abuse his discretion, nevertheless upheld the admissibility of this evidence (Giannelli 1980: 1222 ff.).

The epistemological assumptions behind the *Frye* test are quite crude; and, while it seems overly restrictive in principle, it is indeterminate in ways that made it nearly inevitable that in practice its application would be, not merely variable in borderline cases, but systematically inconsistent.

15. Hand 1901: 40-49; the date (1620) is given on p. 45.

16. “The defendant in *Frye* was subsequently pardoned when someone else confessed to the crime,” writes Paul Giannelli 1980: n. 42. Giannelli cites Wicker 1953; Wicker, he says, cites Fourteenth Annual Report of Judicial Council of the State of New York, 265 (1948). But according to the most complete account I have been able to find of the many twists and turns of Mr. Frye’s story-Starrs 1982-none of this is true.

17. My source in Starrs 1982: 694; he refers to Transcript on Appeal, File 3968, retired files, National Records Center, Suitland, MD.

18. From Judge Van Ordsel’s opinion for the appellate court in *Frye*. At the time, the D.C. Court offered little in the way of rationale for its ruling. Much later, however, when the influence of *Frye* was waning, the same court argued that “[T]he requirement of general acceptance in the scientific community assures that those most qualified to assess the validity of a scientific method will have the determinative voice” (United States v. Addison; my source is Giannelli 1980: 1207).

19. See Black, Ayala, and Saffran-Brinks 1994: 735 ff., listing *Reed v. State* and *United States v. Addison*, excluding voiceprint evidence under the *Frye* test; and *Commonwealth v. Lykus*, admitting voiceprint evidence under the *Frye* test. There is a useful summary of relevant cases in the Symposium on Science and Rules of Evidence, 99 *Federal Rules Decisions* 188 (1983).

20. Giannelli comments: “if the ‘specialized field’ is too narrow . . . the judgment of the scientific community becomes, in reality, the opinion of a few experts” (1980: 1209-1210).

Rather than requiring the trial judge to determine in his own behalf whether scientific evidence proffered is solidly established work or unreliable speculation, the *Frye* test had him rely obliquely on the verdict of the appropriate scientific subcommunity. Three assumptions seem to lie behind the test: that there is a definite point at which scientific claims or techniques cease to be “experimental” and become “demonstrable”; that a claim or technique has not achieved this “demonstrable” status unless it is generally accepted in the relevant community; and that only “demonstrable” claims and techniques should be admitted. The first two assumptions are at best oversimplifications. Rather than a sharp line, there is really a continuum from the unwarranted through the poorly-warranted to the well-warranted; and the degree of credence given a claim in the relevant scientific community is only an imperfect indicator of its degree of warrant (which is only an imperfect indicator - albeit the best we can have - of its truth). Sometimes - perhaps in the case of the medical examiner in *Coppolino* - one person has better evidence than the community. General acceptance in the relevant community is only a very rough-and-ready, and a quite conservative, guide to what is well-warranted at the time in question.

The third assumption - that only “demonstrable” scientific evidence should be admitted - seems extremely restrictive. Precluding the possibility that there should be scientific witnesses who disagree but both of whose testimony is admissible, it seems to confine the courts, in effect, to textbook science. A physicist colleague tells me he once testified that the hypothesis was consistent with the laws of mechanics that the deceased wasn’t pushed, but fell; but very often, surely, the relevant science will be quite far from the textbook stage.

However, it takes only a moment’s reflection to realize that how restrictive the *Frye* test would be in practice depends on what exactly was required to be accepted by what proportion of what community. The narrower and more homogeneous the relevant community is taken to be, the likelier it is that there will be agreement; the broader and more heterogeneous the community, the likelier that there will be disagreement. (Unlike the Verification Principle, which is broader if “verifiable” is construed broadly and narrower if “verifiable” is construed narrowly, the *Frye* test is broader if the community is defined narrowly and

narrower if the community is defined broadly.) No wonder, then, that, though often criticized as overly restrictive, in practice the test was far from consistent.

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The Federal Rules of Evidence (1975) encapsulate a (less ostensibly restrictive) relevancy approach. Rule 104 (a) affirms the gatekeeping role of the court in ruling on admissibility of evidence. But Rule 401 states that relevant evidence - evidence which has any tendency to make the existence of any fact of consequence to the determination of the action either more or less probable than it would otherwise be - is admissible unless otherwise provided by law. Rule 702 states that expert evidence, including but not restricted to scientific evidence, is admissible subject to exclusion under Rule 403. Rule 403, specifying the grounds for exclusion, mentions the danger of unfair prejudice, confusion of the issues, or misleading the jury, but does *not* mention any requirement of general acceptance in the appropriate scientific community. Rule 706 allows the court to appoint expert witnesses of its own selection.

The *Frye* rule didn’t wither away immediately. Scholars debated whether the Federal Rules were compatible with the *Frye* test: some arguing that they weren’t, because they didn’t mention consensus in the relevant community; and some arguing that they were, because they didn’t mention consensus in the relevant community (!).<sup>21</sup> The 1987 edition of a textbook on the Federal Rules suggests irenicly that the *Frye* test be reconstrued under Rule 403 as “an attempt to prevent jurors from being unduly swayed by unreliable scientific evidence” (Graham 1987: 92).

Most to the point of the present narrative, in *Daubert* (1993) the trial court relied almost exclusively on *Frye* in ruling the plaintiff’s expert evidence inadmissible. The plaintiffs were two minor children and their parents, and the claim was that the children’s birth defects were caused by their mothers’ having taken the morning-sickness drug Bendectin during pregnancy. But the plaintiffs’ expert evidence (based on animal studies, pharmacological studies of the chemical structure of Bendectin, and an unpublished “re-analysis” of previously published human statistical studies) was disqualified under the *Frye* test.

21. I rely on Giannelli 1980: 1229–1230. He mentions Saltzburg and Redden 1977: 426 as holding that the Federal Rules are compatible with the *Frye* test because they don’t mention general acceptance; and Wright and Graham 1978: 92, as holding that the Federal Rules are incompatible with the *Frye* test because they don’t mention general acceptance.

The Ninth Circuit confirmed the trial court's decision to exclude.

But in 1993, reversing the exclusion of Daubert's expert testimony, the majority of the U.S. Supreme Court repudiated the *Frye* test as an "austere standard, absent from, and incompatible with, the [Federal Rules]. . . . [U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."<sup>22</sup> Jurors, whose job it is to determine sufficiency, are to concern themselves with expert witnesses' conclusions; but judges, whose job it is to determine admissibility, must focus "solely on principles and methodology" to make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and . . . properly can be applied to the facts in issue."<sup>23</sup>

In determining whether what is offered is really scientific knowledge - *knowledge*, not mere opinion, and genuinely *scientific* knowledge, "with a grounding in the methods and procedures of science" - a key question will be "whether it can be (and has been) tested."<sup>24</sup> Justice Blackmun's opinion for the majority quotes Green: "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry',"<sup>25</sup> and refers to Popper and Hempel. Retaining something of the *Frye* test in the liberalized form of indications, rather than necessary conditions, of admissibility, the *Daubert* ruling also mentions peer-review, a "known or potential error rate," and "widespread acceptance."

However, dissenting in part from the majority, after pointing out that there is no reference in Rule 702 to reliability, and urging that the question of expert testimony generally not be confused with the question of scientific testimony specifically, Justice Rehnquist remarks:

I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its 'falsifiability,' and I suspect some of them will be, too. . . . I do not think [Rule 702] imposes on them either the obligation or the authority to become amateur scientists.<sup>26</sup>

Those reservations are well-founded; for the epistemological assumptions on which the *Daubert* ruling rests are badly confused.

Unlike the *Frye* test, the Federal Rules as interpreted

in *Daubert* require the trial judge to make determinations about scientific methodology in his own behalf. But what the *Daubert* Court has to offer by way of advice about how to make such determinations is - well, a little embarrassing.

The justices are apparently unaware that Popper gives "falsifiable" a very narrow sense, "incompatible with some basic statement" (a basic statement being defined as a singular statement reporting the occurrence of an observable event at a specified place and time); and that according to Popper no scientific claim or theory can ever be shown to be true or even probable, but is at best "corroborated." In Popper's mouth, this is not equivalent to "confirmed," and does not imply truth or probable truth, but means no more than "tested but not yet falsified."<sup>27</sup> If Popper were right, no scientific claim would be well-warranted. In fact, it is hard to think of a philosophy of science less congenial than Popper's to the relevance-and-reliability approach (or to the admissibility of psychiatric evidence, but that is a whole other can of worms). And if the reference to Popper is a *faux pas*, running Popper together with Hempel - a pioneer of the logic of confirmation, an enterprise the legitimacy of which Popper always staunchly denied - is a *faux pas de deux*.

In and of itself, of course, the *Daubert* Court's mixing up its Hoppers and its Pempels is just a minor scholarly irritation. A more serious problem is that neither Popper's nor Hempel's philosophy of science will do the job they want it to do. Popper's account of science is in truth a disguised form of skepticism; if it were right, what Popper likes to call "objective scientific knowledge" would be nothing more than conjectures which have not yet been falsified. And, though Hempel's

22. *Daubert*, 509 U.S. at 598, 113 S. Ct. at 2794.

23. *Daubert*, 509 U.S. at 580, 113 S. Ct. at 2790.

24. *Daubert*, 509 U.S. at 593, 113 S. Ct. at 2796.

25. Green 1992: 645. A footnote (12) refers to Popper, but I can find no reference to Hempel.

26. *Daubert*, 509 U.S. at 600-601, 113 S. Ct. at 2800.

27. In ordinary speech, of course, *corroborated* usually means "confirmed by another witness," but Popper has given the word a quite different, technical meaning. Black, Ayala, and Saffran-Brinks 1994: 750 ff. seem to have confused *corroboration*, in Popper's sense, with *confirmation*. Green-who, incidentally, introduces Popper's philosophy of science in Kuhnian terms, as "the existing paradigm under which scientists work"! -acknowledges that Popper holds that "[t]heoretically... hypotheses are never affirmatively proved" but continues, "of course, if a hypothesis repeatedly withstands falsification, one may tend to accept it, even if conditionally, as true" (1992:645-646).

account at least allows that scientific claims can be confirmed as well as disconfirmed, it contains nothing that would help a judge decide either whether evidence proffered is really scientific, or how reliable it is.

And the most fundamental problem is that the *Daubert* Court (doubtless encouraged by the dual descriptive and honorific uses of “scientific”) is preoccupied with specifying what the method of inquiry is that distinguishes the scientific and reliable from the nonscientific and unreliable. There is no such method. There is only making informed conjectures and checking how well they stand up to evidence, which is common to every kind of empirical inquiry; and the many and various techniques used by scientists in this or that scientific field, which are neither universal across the sciences nor constitutive of real science.

The *Daubert* Court runs together (1) the tangled and distracting questions of demarcation and scientific method with (2) the question of the degree of warrant of specific scientific claims or theories and (3) the question of the reliability of specific scientific techniques or tests - which is different again, for the claim that this technique is unreliable may be well warranted, the claim that this other technique is reliable poorly warranted. Unlike determining whether a claim is falsifiable, however, determining whether a scientific theory (e.g., of the etiology of this kind of cancer) is well warranted, or whether a scientific test (e.g., for the presence of succinylcholine chloride) is reliable, requires substantive scientific knowledge. Justice Rehnquist is right: the reference to falsifiability is no help, and judges are indeed being asked to be amateur scientists. Furthermore, despite the majority’s reassuring noises to the effect that juries can handle scientific evidence well enough, and can always be directed by the judge if they look like going off the rails, one is left wondering: if judges need to act as gatekeepers to exclude scientific evidence which doesn’t meet minimal standards of warrant because juries may be taken in by flimsy scientific evidence, how realistic is it to expect juries to discriminate the better from the worse among the half-way decent?

One of the many subsequent cases<sup>28</sup> in which the Federal Rules as interpreted in *Daubert* are applied to the question of the admissibility of scientific evidence is the one that first drew my attention - the case of Mr. Joiner.

Robert Joiner had worked for the Water and Light Department of the City of Thomasville, Georgia, since 1973. Among his tasks was the disassembly and repair of electrical transformers in which a mineral-based

dielectric fluid was used as a coolant - dielectric fluid into which he had to stick his hands and arms, and which sometimes splashed onto him, occasionally getting into his eyes and mouth. In 1983 the city discovered that the fluid in some of the transformers was contaminated with PCBs, which are considered so hazardous that their production and sale has been banned by Congress since 1978.

In 1991 Mr. Joiner was diagnosed with small-cell lung cancer; he was thirty-seven. He had been a smoker for about eight years, and there was a history of lung cancer in his family. He claimed, however, that had it not been for his exposure to PCBs and their derivatives, furans and dioxins, his cancer would not have developed for many years, if at all. On this basis he sued Monsanto, which had manufactured PCBs from 1935 to 1977, and General Electric and Westinghouse, which manufactured transformers and dielectric fluid. His case relied essentially on expert witnesses who testified that PCBs alone can cause cancer, as can furans and dioxins, and that since he had been exposed to PCBs, furans, and dioxins, this exposure had likely contributed to his cancer.

Removing the case to federal court, GE et al. contended that there was no evidence that Mr. Joiner suffered significant exposure to PCBs, furans, or dioxins, and that in any case there was no admissible scientific evidence that PCBs promoted Joiner’s cancer. The district court granted summary judgment, holding that the testimony of Joiner’s experts was no more than “subjective belief or unsupported speculation.”<sup>29</sup>

The court of appeals reversed. Federal Rule 702, governing expert testimony, displays a “preference for admissibility,” and in the present instance, the question of admissibility was “outcome-determinative”: if the scientific evidence offered were excluded, Mr. Joiner would simply have no case. So a “particularly stringent standard of review” should apply to the trial judge’s exclusion of expert testimony.<sup>30</sup>

But in 1997, reversing the admissibility of Mr. Joiner’s expert evidence, the U.S. Supreme Court held that the

28. By January of 1998, according to Frankel 1998: 3, there had been more than eleven hundred such cases.

29. General Electric Co. v. Joiner, 522 U.S. 136, 136, 118 S. Ct. 512, 514 (1997), citing Joiner v. General Electric Co., 864 F. Supp. 1310, 1326 (N.D. Ga. 1994), which in turn cites *Daubert*, 509 U.S. 579, 113 S. Ct. 2786 (1993), where the phrase occurs three times: at 597 and 2786; at 590 and 2795; and at 599 and 2800.

30. See General Electric Co. v. Joiner, 522 U.S. at 140, 118 S. Ct. at 516.

appeals court erred in applying an especially stringent standard of review. The appropriate standard was abuse of discretion; and it was *not* an abuse of discretion for the district court to have excluded Mr. Joiner's experts' testimony.<sup>31</sup>

And now it begins to appear how the question of the legitimacy of the distinction between methodology and conclusions came to be a hotly contested issue. The *Daubert* Court, taking the distinction for granted, had interpreted the gatekeeping role of trial judges as requiring them to focus solely on methodology, not conclusions. But, Mr. Joiner's lawyers argue, the District Court had no objection to the methodology of the studies cited, only to the conclusions that their experts drew; and this was a reversible error.

GE's brief argues that the court of appeals treated *Daubert*'s requirement of scientific methodology "at such a superficial level as to leave it meaningless - calling for no more than the invocation of scientific materials."<sup>32</sup> Mr. Joiner's experts rely on the "faggot fallacy": the fallacy of supposing that "multiple pieces of evidence, each independently being suspect or weak, provide strong evidence when bundled together."<sup>33</sup> Mr. Joiner's lawyers reply that his experts "were applying a methodology which is well established in the scientific method. It is known as the weight of evidence methodology. . . . There are well-established protocols for this . . . published as the EPA's guidelines. There are similar guidelines for the World Health Organization."<sup>34</sup> GE's lawyers never challenged Mr. Joiner's experts' methodology before; indeed, they use the "weight of evidence" methodology themselves.

Rather than challenging Mr. Joiner's claim that the District Court failed to restrict its attention to methodology as *Daubert* requires, the majority of the *Joiner* Court sustains its ruling that there was no abuse of discretion by holding that "*conclusions and methodology are not entirely distinct from each other.*"<sup>35</sup>

Justice Stevens, however (concurring on the question of the correct standard of review but dissenting from the majority's ruling on whether the district court erred) protests that this is neither true nor helpful. "The difference between methodology and conclusions is just as categorical as the distinction between means and ends." The district court ruling on reliability in *Joiner*, in particular, is "arguably not faithful" to the statement in *Daubert* that the focus must be on methodology rather than conclusions. The majority "has not adequately explained why its holding is consistent with Federal Rule of Evidence 702 as interpreted in *Daubert v. Merrell Dow Pharmaceuticals.*"<sup>36</sup>

In the *Joiner* ruling, *Daubert*'s epistemological chickens come home to roost: with the references to falsifiability gone and the distinction between methodology and conclusions dropped, it is starkly obvious that judges will sometimes be obliged to determine substantive scientific questions.

Given the difficulties with the *Daubert* Court's efforts to specify what makes evidence genuinely scientific, perhaps the knots in which everyone ties themselves in *Joiner* (not to mention the absence from the ruling of any reference whatever to falsifiability, testability, Hepper, Pompel, etc.)<sup>37</sup> are not so surprising. What is surprising, to me at any rate, is that the *Joiner* Court should offer, as an interpretation of *Daubert*, a ruling that denies the legitimacy of a distinction *Daubert* presupposed. I have no difficulty with the idea that a later ruling may make an earlier ruling determinate in respects in which it was formerly indeterminate (which, incidentally, explains why the *Daubert* Court could *rule* that the *Frye* test is incompatible with the Federal Rules, which at first raised my logical eyebrows quite far). But the idea that a later ruling which flatly denies a clear presupposition of an earlier ruling could qualify as an interpretation, rather than a revision, of it, still strikes me as very strange indeed.

However. What about the distinction between methodology and conclusions presupposed in *Daubert*, but repudiated in *Joiner*? In these cases the concept of **methodology** (never exactly well-defined in the philosophy of science) seems to have turned into an accordion concept,<sup>38</sup> expanded and contracted as the argument requires. Is the judge, in determining the validity of experts' "methodology," to decide whether the mouse studies on which Mr. Joiner's

31. But the question with regard to furans and dioxins, according to the Supreme Court ruling, remained open.

32. Brief for Petitioners, General Electric Co. v. Joiner, 47.

33. Brief for Petitioners, General Electric Co. v. Joiner, 49, citing Skrabanek and McCormick 1997: 35, quoted in Huber and Foster 1997: 142. I notice that on the same page, Skrabanek and McCormick refer to what they call the "weight of evidence fallacy"; this, they claim, is not scientific because science, according to Popper, focuses on negative evidence (which cannot be outweighed by confirming instances). While I am noting that GE's lawyers cite Peter Huber, I will also note that Kenneth Cheseboro was one of Mr. Joiner's lawyers.

34. Oral Argument of Michael H. Gottesman, General Electric Co. v. Joiner, 43-44. Mr. Gottesman was also one of the attorneys for Mr. Daubert.

35. General Electric Co. v. Joiner, 522 U.S. at 155, 118 S. Ct. at 523 (emphasis mine).

36. General Electric Co. v. Joiner, 522 U.S. at 151, 118 S. Ct. at 521 (Stevens, J., dissenting).

37. And of any reassuring noises about jurors' ability to assess the weight of scientific evidence.

38. The term, and the idea, come from Sellars 1965: 172.

experts in part relied were well-conducted, with proper controls and good records, using specially bred genetically-uniform mice, etc., etc.; or what weight to give mouse studies with respect to questions about humans; or what weight to give those mouse studies in the context of other studies of the effects on humans of PCB and other contaminants; or what? There are so many ambiguities that everyone is right - and everyone is wrong.

Mr. Joiner's lawyers are right to suggest that drawing the reasonable conclusion from a conglomeration of disparate bits of information (mouse studies, epidemiological evidence, etc.) requires, well, weighing the evidence. But of course it matters whether you weigh the evidence *properly*; and GE's lawyers are right, too, when they complain that Mr. Joiner's attorneys use "methodology" so loosely as to make *Daubert's* requirements practically vacuous.

But GE's accusation that Mr. Joiner's experts commit the "faggot fallacy" relies on an equivocation. There is an ambiguity in the reference to "pieces of evidence, each independently . . . suspect or weak": this may mean *either* "pieces of evidence each themselves poorly warranted" (which seems to be the interpretation intended by Skrabanek and McCormick, to whom the phrase "faggot fallacy" is due), *or* "pieces of evidence each by itself inadequate to warrant the claim in question" (which seems to be the interpretation most relevant to the case). True, if the reasons for a claim are themselves poorly warranted, this lowers the degree of warrant of the claim itself. But GE's brief offers no argument that the reasons based on the studies to which Mr. Joiner's experts refer are themselves poorly warranted. True again, none of those reasons by itself strongly warrants the claim that PCBs promoted Mr. Joiner's cancer. But GE's brief offers no argument that they don't do so jointly.

Sometimes bits of evidence which are individually weak are jointly strong; sometimes not - it depends what they are, and whether or not they reinforce each other (whether or not the crossword entries interlock). Chargaff's discovery that there are approximate regularities in the relative proportions of adenine and thymine, guanine and cytosine in DNA is hardly, by itself, strong evidence that DNA is a double-helical, backbone-out macromolecule with like-with-unlike base pairs; Franklin's X-ray photographs of the B form of DNA are hardly, by themselves, strong evidence that DNA is a double-helical, backbone-out macromolecule with like-with-unlike base pairs. That the tetranucleotide hypothesis is false is hardly, by itself, strong evidence that DNA is a doublehelical, backbone-out macromolecule with like-with-unlike

base pairs; and so on. But put all these pieces of evidence together, and the doublehelical, backbone-out, like-with-unlike base pairs, structure of DNA is very well-warranted indeed (in fact, the only entry that fits).

Neither party seriously addresses this question of interlocking. But in the very complex EPA guidelines to which Mr. Joiner's attorneys so causally refer, I find this: "Weight of evidence conclusions come from the *combined strength and coherence* of inferences appropriately drawn from all of the available evidence."<sup>39</sup>

Justice Stevens is right to say that there is a difference between methodology and conclusions, as there is between ends and means; there is a difference, certainly, between a technique and its result, or between premises and conclusion. But on a more charitable interpretation, the majority's point is not that there is literally no distinction, but that it is impossible to judge methodology without relying on some substantive scientific conclusions. And this is both true and important.

To determine whether this evidence (e.g., of the results of mouse studies) is relevant to that claim (e.g., about the causes of Mr. Joiner's cancer) requires substantive knowledge (e.g., about the respects in which mouse physiology is like human physiology, about how similar or how different the etiologies are of small-cell lung cancer and alveogenic adenomas, etc.). And to determine the reliability of a scientific experiment, technique, or test, it is necessary to know what kinds of thing might interfere with the proper working of this apparatus, what the chemical theory is that underpins this analytical technique, what factors might lead to error in this kind of experiment and what precautions are called for, or to possess a sophisticated understanding of statistical techniques or of complex and controversial methods of meta-analysis pooling data from different studies. And so on.

Which takes us back to that old worry of Justice Rehnquist's of which Justice Breyer's observation that judges are not scientists reminds us: judges are neither trained or qualified to do this kind of thing.

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Already at the time of *Joiner*, the *Daubert* ruling, requiring judges to make a preliminary evaluation of scientific evidence proffered, had prompted wider use of Rule 706, allowing judges to appoint their own experts.

In 1992, the FDA had banned silicone breast implants,

39. 61 *Federal Register* 19,760-1: 17972 (1996) (my italics).

formerly “grandfathered in.” They were not known to be unsafe; but manufacturers had not, as required under FDA regulations, supplied evidence of their safety. Understandably, the ban caused a good deal of anxiety, and provoked a wave of fear, greed, and litigation. In 1996, Judge Sam Pointer of the U.S. District Court in Birmingham, Alabama, who had been in charge of all several thousand federal implant cases for more than six years, convened a panel of four scientists - an immunologist, an epidemiologist, a toxicologist, and a rheumatologist - to review evidence of the alleged connections between silicone implants and various systemic and connective tissue diseases.

Judge Pointer’s carefully phrased remit asks: “to what extent, if any and with what limitations and caveats do existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone-gel breast implants cause or exacerbate any . . . ‘classic’ connective tissue diseases [. . . or] ‘atypical’ presentations of connective tissue diseases. . . . To what extent, if any, should any of your opinions . . . be considered as subject to sufficient dispute as would permit other persons, generally qualified in your field of expertise, to express opinions that, though contrary to yours, would likely be viewed by others in the field as representing legitimate disagreement within your profession?”<sup>40</sup>

Two years and (only) \$800,000 later,<sup>41</sup> after selecting from more than two thousand published and unpublished studies those they thought most “rigorous and relevant,” in December 1998 the panel submitted a long report. Their conclusion was that the evidence studied and reanalyzed (apparently the forty or so studies submitted by each side plus about one hundred others, including unpublished studies, Ph.D. dissertations, and letters) does not warrant the claim that silicone breast implants cause these diseases. They add, however, that in some respects “the number and size of studies is inadequate to produce definite results”; that animal testing “may not fully predict the human effects”; that some evidence suggests that silicone implants are not entirely benign (they can cause inflammation, and droplets can turn up in distant tissues); and that while most people in the field would agree with their conclusions, a few might not.<sup>42</sup>

Despite Judge Pointer’s efforts to ensure that his experts were unimpeachably neutral, the plaintiffs’ lawyers objected that the rheumatologist on Pointer’s panel had undisclosed connections with one of the defendants, Bristol-Meyers Squibb (BMS), while a member of the panel: in August 1997, apparently, he signed a letter soliciting up to \$10,000 in support

of a rheumatology meeting he co-chaired, stating that “the impact of sponsorship will be high, as the individuals invited for this workshop, being opinion leaders in their field, are influential with the regulatory agencies”; in October 1998 he signed a \$1,500-a-day fee arrangement with BMS, and in November 1998 he received \$750 for participating in a company seminar.<sup>43</sup>

In April 1999, averring that there was no actual bias, though acknowledging that there might be a regrettable appearance of bias, Judge Pointer ruled against the plaintiffs’ motion that the panel’s report be excluded. The members of the panel will give videotaped sworn statements that may be used as evidence in courts nationwide. The bramble-bush, of course, is alive and well, growing new fruit, and new thorns, almost every day.<sup>44</sup> In *Kumho* (1999), considering judges’ responsibility for making a preliminary reliability assessment of the testimony of engineers and other non-scientific experts, the Supreme Court stressed that *Daubert*’s test of reliability is “flexible,” and that its list of specific factors (falsifiability, peer review, etc.) “neither necessarily nor exclusively applies to all experts or in every case”; thus partially addressing the issues about the place of scientific evidence within expert evidence generally raised by Justice Rehnquist’s dissent from the *Daubert* ruling.<sup>45</sup>

40. Submission of Rule 706 National Science Panel Report: 2, In re: Silicone Gel Breast Implant Products Liability Litigation (N.D. Ala. 1998) (No. CV 92-P-10000-S), available online at [fjc/BREIMLIT/SCIENCE/report.htm](http://fjc/BREIMLIT/SCIENCE/report.htm).

41. “Only” not only because the sum is trivial relative to the compensation awarded in some implant cases, but also because the amount is quite modest relative to the task undertaken.

42. Submission of Rule 706 National Science Panel Report: 8.  
43. Pointer Rules Federal Science Panel Report Not Tainted by Payments to Panelist, 7.5 *Legal Aspects of Breast Implants*: 4 (April 1999). I conjecture that the discrepancy between reports about the sum of money involved-plaintiffs say \$750, court says \$500-may be a matter of Canadian versus U.S. dollars. Plaintiffs also object that a colleague who had assisted Dr. Tugwell in his work for the panel had received support from a company wholly owned by BMS.

44. It is just this that, as a philosopher, I find most disturbingly unfamiliar when I tackle legal matters. Perhaps that is why, though Karl Llewellyn can write (1930: 141), “To me there is more joy than pain, by a good deal, in the thorns of such a thicket as that through which I have just dragged you,” I am starting to feel as if I have been dragged through a hedge backwards!

45. And *United States v. Starzecpyzel* (880 F. Supp. 1027 [S.D.N.Y. 1995]) raises some interesting epistemological issues about learning and skill in perception, the relation of knowing-that and knowing-how, etc. But I shall have to set these aside.

There have also been some efforts to educate judges scientifically. In April 1999 about two dozen Massachusetts Superior Court judges attended a two-day seminar on DNA at the Whitehead Institute for Biomedical Research. A report in the *New York Times* quotes the director of the institute: in the O. J. Simpson trial lawyers “befuddle[d] everyone” over the DNA evidence; but after this program, “I don’t think a judge will be intimidated by the science.” Judges will “understand what is black and white . . . what to allow in the courtroom” (Goldberg 1999: 10).

And in May 1999 the American Association for the Advancement of Science inaugurated a five-year project to make available to judges “independent scientists who would educate the court, testify at trial, assess the litigants’ cases, and otherwise aid in the process of determining the truth” (Bandow 1999).

Disentangling “reliable” from “scientific,” as *Kumho* begins to do, is certainly all to the good. But a bit of scientific education for judges is at best a drop in the bucket; and court-appointed panels of experts, though potentially helpful, are no panacea.

Not that educating judges about DNA or whatever mightn’t do some good. But a few hours in a science seminar will no more transform judges into scientists competent to make subtle and sophisticated scientific determinations than a few hours in a legal seminar would transform scientists into judges competent to make subtle and sophisticated legal determinations. (“This kind of thing takes a lot of training,” as Mad Margaret sings in *Ruddigore*.) And, to be candid, that *New York Times* report has me a little worried about the danger of giving judges a false impression that they are qualified to make those “subtle and sophisticated determinations.”

“[N]either the difficulty of the task nor any comparative [*sic*] lack of expertise can excuse the judge from exercising the ‘gatekeeper’ duties that the Federal Rules impose,” Justice Breyer avers.<sup>46</sup> More directly than the *Frye* test, calling on court-appointed panels of scientists turns part of the task over to those who are more equipped to do it. Isn’t this a whole lot better than asking judges to be amateur scientists? Sometimes, probably, significantly better - the more so, the closer the work at issue is to black-letter science; not, however, as straightforwardly or unproblematically better as some hope.

As Judge Pointer’s panel’s report was made public, an optimistic headline in the *Washington Times*<sup>47</sup> proclaimed “Benchmark Victory For Sound Science”; and under the headline “An Unnatural Disaster,” an editorial in the *Wall Street Journal* announced that

“reason and evidence have finally won out.”<sup>48</sup> ABCNEWS.com’s “Health and Living” was considerably more cautious: under the headline “No Implant-Disease Link?” a sideline adds, “The panel found no definite links, but it also left the door open for more research.”<sup>49</sup> Neither quite captures my reaction.

I should be quite surprised if it turned out that silicone implants do, in fact, cause the various diseases they have been alleged to (so far as I can tell it isn’t just, as the panel’s report says, that there is no evidence that they do; but that there is pretty good evidence that they don’t).<sup>50</sup> And I don’t think it very likely that that \$750 seriously affected Dr. Tugwell’s opinion (though I must say that - even if this kind of thing is routine in funding applications, as for all I know it may be - that letter boasting of the applicants’ influence with regulatory bodies leaves a bad taste in my mouth).

I don’t feel equally confident, however, that a really good way has yet been found to delegate part of the responsibility for appraising scientific evidence to scientists themselves. Besides the worry about ensuring neutrality, and the appearance of neutrality,<sup>51</sup> there is the worry about how much responsibility falls on how few shoulders - just four people, in the case of Judge Pointer’s panel, all of whom combined this work with their regular full-time jobs, each of them in effect solely responsible for a whole scientific area; and the worry about what jurors will make of court-appointed experts’ testimony. The history of the *Frye* test should warn us,

46. *General Electric Co. v. Joiner*, 522 U.S. at 148, 118 S. Ct. at 520 (Breyer, J., concurring).

47. *Washington Times*, 11 December 1998, byline by Eric Peters.

48. *Wall Street Journal*, 10 December 1998, A22.

49. Jay Reeves, No Implant-Disease Link? ABC News online at [www.abcnews.go.com/sections/living/DailyNews/breastimplants981201.html](http://www.abcnews.go.com/sections/living/DailyNews/breastimplants981201.html) (visited 8 July 1999).

50. I note that in June 1999, a thirteen-member committee of the Institute of Medicine also concluded that “silicone breast implants do not cause chronic disease, but other complications are of concern.” News from the National Academies on-line at [www.nationalacademies.org/news.nsf/isbn/0309065321?opendocume](http://www.nationalacademies.org/news.nsf/isbn/0309065321?opendocume). June 21, 1999 (visited 10 August 1999).

51. Dr. Diamond, one of the members of Judge Pointer’s panel, acknowledging that she knows X, Y, and Z, who turn out to be connected in some way with the defendants, remarks that she feels “extraordinarily naive.” Transcript of Rule 706 Panel Hearing: 91, available on-line at [womnhlth.home.mindspring.com/706/transcript\\_of\\_rule\\_706\\_panel\\_hear.htm](http://womnhlth.home.mindspring.com/706/transcript_of_rule_706_panel_hear.htm). February 4, 1999 (visited 9 July 1999). I suspect that the involvement of large industrial concerns in the funding of scientific research is at this point so ubiquitous that it may be quite difficult to find scientists who are both competent to the task required and without such associations as Dr. Diamond acknowledged.

also, of potential pitfalls in determining the relevant area of specialization.

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Here is Justice Blackmun, struggling valiantly if not quite successfully to articulate the mismatch between science and law that lies at the root of the trouble: [T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final and binding legal judgment - often of great consequence - about a particular set of events in the past.<sup>52</sup>

Yes, we want the law to settle disputes in a timely manner, while scientific inquiry takes - well, it takes the time it takes. Of course, we want cases settled not just promptly but rightly: Mr. Frye to be acquitted if and only if he didn't do it, Mr. Coppolino to be convicted if and only if he did do it, Mr. Joiner to be compensated if and only if his cancer was promoted by his exposure to PCBs, and so on. When scientific evidence is pertinent, we want scientific evidence which is probably right.<sup>53</sup> As Justice Breyer reminds us, one of the goals that the Federal Rules of Evidence set themselves is "that the truth be ascertained."

I don't mean to suggest that juries can never (perhaps with the help of a cross-examining attorney) spot inconsistencies in scientific testimony, realize that a scientist's credentials are dubious, notice that the studies relied on were not controlled, or form a reasonable suspicion that a scientific witness is stretching the facts for the sake of a large fee, or, etc.;<sup>54</sup> nor, of course, that mistakes are only made where scientific witnesses are involved. But as I have been maintaining all along, scientific evidence is "more so" - complex, esoteric, often expressed in an unfamiliar and deeply theoretical vocabulary, and hence unusually difficult for a jury or a judge adequately to assess. (On average, that is; nothing I have said implies that it is more difficult for a judge or jury adequately to assess relatively simple scientific evidence than, say, extremely complicated evidence about accounting procedures.)

No legal form of words can come close to ensuring that only the probable-enough is admitted. *Of course* we want relevant and reliable scientific evidence; but

that form of words doesn't tell a judge anything about what, specifically, to exclude and what to admit (as Peirce might have put it, it reaches only the second grade of clarity, not the third, pragmatic or operational grade). *Of course*, also, scientists in the relevant field are nearly always better judges of the quality of scientific work than the rest of us; but finding a good way to delegate some of the responsibility isn't trivial, and nothing can ensure that even the most competent and honest scientists will always agree about what is probably right, or that they won't sometimes agree that, at the moment, they just don't know.

No wonder scientific evidence provides so many opportunities for opportunism! Often, we are trying to arrive at justice on the basis of imperfect and imperfectly understood information; and not so rarely, we are trying to create justice out of ignorance.

I'm afraid I have been something of an epistemological wet blanket - so much so that by now you may think me an incurable pessimist. So I had better remind you of that nice old Leibnizian joke: "What's the difference between an optimist and a pessimist? They both think this is the best of all possible worlds" - and assure you that in my opinion this is quite far from the best of all possible worlds.

There are no easy answers; but there are, certainly, better questions and worse. Rather than worrying fruitlessly about the problem of demarcation or the distinction of methodology versus conclusions and all that, we would do better to turn our attention to questions of other kinds - and to keep firmly in mind that, though perfection is impossible, better is better than worse; that the cumulative effect of small improvements can be quite large; and that it is inadvisable to restrict our attention too exclusively to issues and strategies internal to the legal system.

Some of the fruitful-looking questions are practical in orientation: What could be done to help jurors deal better with scientific evidence: e.g., consistent with filtering out legally unacceptable questions, to allow them to ask for clarification when they can't follow an expert witness? What could scientists' professional associations do to help serious scientific witnesses communicate better with judges and juries, or to

52. *Daubert*, 509 U.S. at 596-97, 113 S. Ct. at 2798.

53. While according to Popper, remember, no scientific claim is ever probable.

54. The truthfulness of a witness is a matter of (1) whether what he is saying is what he believes to be true and (2) whether what he believes to be true is true. Where scientific testimony is concerned, in general I would think juries are more likely to be able to judge the former than the latter.

discourage those who abuse their expertise? Could the legal profession and legal educators do more to discourage unscrupulous witness-shopping and related abuses? What could we learn from the experience with Judge Pointer's panel about bridging some of the gaps between the folkways of science and of the legal system? What advice might best be given to court-appointed scientists about what connections should be disclosed, or what kinds of record-keeping will be expected of them? (Should we consider asking court-appointed scientists to provide details of the qualifications and affiliations of any assistants on whom they relied; of which studies they decided to look at in detail, and why; of which studies seemed most strongly to indicate the contrary conclusion to theirs, and why, in their opinion, those studies were flawed?)

Could we make the legal system more responsive when new evidence comes in to the scientific community?<sup>55</sup> Could the scientific community be more responsive when legal disputes turn on scientific issues irresolvable by the presently available evidence? Can we think of ways to provide incentives for scientists to study such issues even when they are of much less scientific than practical interest?

Other fruitful-looking questions are more policy-oriented: How significant a gatekeeping role is it appropriate for judges to take? (What exactly do we value about trial by jury, and why?) Given that mistakes are inevitable, should we be more willing to tolerate some kinds than others - not forgetting that scientific evidence plays a role both in civil and in criminal cases, and on both sides?<sup>56</sup> Do we think it appropriate for policy considerations about, for example, how to manage the risks inherent in our reliance on synthetic materials, chemicals, drugs, etc., also to determine what evidence is admissible in criminal cases? (What exactly do we value about uniformity in the legal system, and why?) Are the problems of scientific evidence significantly exacerbated by the contingency-fee system? If so, is it worth the price - presumably, more limited access to the legal system for those without large resources - of changing it? What, ideally, would be the role of tort litigation vis à vis other means of ensuring that, when there is a question about the safety of this or that product, it is carefully looked into, and appropriate action taken?<sup>57</sup> - a question prompted in part by the singularly unfortunate interaction of the FDA and the tort litigation system in the silicone-implant affair. And, of course: Are these things done differently elsewhere, specifically in the legal systems of other scientifically and technologically advanced

countries? If so, what are the benefits, and what the drawbacks?

But it might be prudent, before I begin to tackle such questions, to take Mr. Lec's very shrewd advice, and Think Before I Think . . .

Dedicated to the memory of Richard A. Hausler

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55. Michael Graham observes: "Once [the status of this or that scientific evidence] is set in appellate concrete, a long time might be required to change it when scientific skepticism begins to overtake the original scientific optimism about the validity of the principle or procedure." 99 *Federal Rules Decisions* 188: 222-23 (1983). Or vice-versa.

56. In the same 1983 Symposium on Science and Rules of Evidence (99 *Federal Rules Decisions* 188: 206), Paul Giannelli writes: "For me *Frye* functions much like a burden of proof. . . . If [in criminal cases] we are going to make mistakes in assessing the validity of a novel technique, they should be mistakes of excluding reliable evidence rather than mistakes of admitting unreliable evidence." Ironically enough, however, in *Frye*, where the novel scientific evidence was proffered by the defense, Giannelli's argument would go exactly the other way.

57. In his concurring opinion in *General Electric Co. v. Joiner* (522 U.S. at 148, 118 S. Ct. at 520), Justice Breyer remarks shrewdly on our ubiquitous dependence on synthetic substances and the importance of ensuring that the "powerful engine" of tort litigation discourages the production only of the harmful stuff (though it spoils the effect somewhat that the case in question concerns PCBs, so dangerous that they have been banned for decades!).

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## On Evidence, Medical and Legal

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### Introduction

Medicine, like law, is a pragmatic, probabilistic activity. Both require that decisions be made on the basis of available evidence, within a limited time.

In contrast to law, medicine, particularly evidence-based medicine as it is currently practiced, aspires to a scientific standard of proof, one that is more certain than the standards of proof courts apply in civil and criminal proceedings.

But medicine, as Dr. William Osler put it, is an “art of probabilities,” or at best, a “science of uncertainty.”<sup>1</sup> One can better practice medicine by using other evidentiary standards in addition to the “scientific.” To employ only the scientific standard of proof is inappropriate, if not impossible; furthermore, as this review will show, its application in medicine is fraught with bias.

Evidence is information. It supports or undermines a proposition, whether a hypothesis in science, a diagnosis in medicine, or a fact or point in question in a legal investigation. In medicine, physicians marshal evidence to make decisions on how to best prevent, diagnose, and treat disease, and improve health. In law, courts decide the facts and render justice. Judges and juries assess evidence to establish liability, to settle custody and medical issues, and to determine a defendant’s guilt or innocence.

### Legal Standards of Proof

Law applies well-defined evidentiary standards. In British and U.S. common law systems, differential standards of proof are set according to the consequences of the decision, with life and liberty prized most highly. Legal standards of proof range from the lowest, the Precautionary Principle, to the criminal standard (see Table 1).<sup>2</sup>

In 38 States, the highest, criminal legal standard of “beyond a reasonable doubt” can result in the defendant being put to death. Where criminal penalties are not in issue, courts resolve disputes at a lower standard. Civil cases that follow an evidentiary standard of “more likely than not” require only that the balance of probability be greater than 50 percent to support, or undermine, a disputed proposition.

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U.S. courts, unlike those of the UK at present, use a higher civil standard of “clear and convincing.” This standard is applied when settling disputes involving child custody, involuntary commitment, withdrawal of life support in comatose patients, and determination of a “punishable frame of mind” driven by malice, oppression, or fraud. It is also used in some administrative disciplinary proceedings for attorneys, medical professionals, and other cases.

### The Scientific Standard of Proof

Science prizes objective certainty. For a hypothesis to be proved, or a theory to become theorem, the evidence supporting it must be irrefutable. But science does not uniformly adhere to this standard. Subjective opinions and consensus among scientists often supersede the stricture of irrefutability.

Hence, scientific standards of proof are not uniform and well defined, in contrast to legal standards.<sup>3</sup> Standards of measurement, ways of reporting and evaluating results, and particular types of experimental practices vary.<sup>4</sup> As a result, there is no simple and reducible algorithm against which “good” science can be evaluated.<sup>5</sup>

There is another aspect of the scientific standard of proof that particularly impacts medicine. Science’s quest for objective certainty admits only a narrow range of evidence.

### The Precautionary Principle

The Precautionary Principle is derived from the 1990 Bergen Declaration, which states, “Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.”<sup>6</sup>

As currently practiced, governments implement policies and regulations based on what “might” cause harm, even if there is little or no evidence that a hazard exists.<sup>7</sup> This principle increasingly governs state regulatory policy and international environmental law; and regulators employ it to ban DDT, reduce supposedly harmful CO<sub>2</sub> emissions, and bar planting of genetically engineered crops.<sup>8</sup> It is broadly analogous to “probable cause,” and thus a lower standard than for a prima facie case. In the European Union, under this standard a decision is taken on the “available” evidence: “the real risk alleged for public

health appears sufficiently established on the basis of the latest scientific data available.”<sup>9</sup>

Like requiring medical evidence to meet a scientific standard of proof, rendering regulatory decisions based on the Precautionary Principle, without requiring any evidence on their risk and benefits, must

**Table 1. Legal and scientific proof**

Standards of Proof		
Kind	Level of Evidence	Standard
Regulatory, Legal		Precautionary Principle
Legal - Civil	*	More likely than not
Legal - Civil	**	Clear and convincing
Legal - Criminal	***	Beyond a reasonable doubt
Scientific	****	Irrefutable

be questioned. The benefits achieved from having banned DDT are disputed; and, not having access to this pesticide, 50 million people have died from DDT-preventable malaria.<sup>10</sup>

### Randomized Controlled Trials

Evidence-based medicine (EBM) promotes the “...use of current best evidence in making decisions about the care of individual patients.”<sup>11</sup> Only well-designed, randomized controlled trials (RCTs) produce medical evidence that can meet the scientific standard of proof.<sup>12</sup> Systematic reviews (“meta-analyses”) of multiple RCTs are even better. Meta-analyses are the “gold standard” of scientific medical evidence, and EBM proponents put them at the top of the EB Mevidence pyramid.<sup>13,14</sup>

Investigators have carried out seven randomized controlled trials on transmyocardial laser revascularization (TMR).<sup>15-21</sup> In this procedure the surgeon burns 1-mm full-thickness holes through the heart muscle with a laser, 1 cm apart in a line from the base to the apex, and then in other lines 1 cm from each other, for a total of 20 to 40 channels. These channels and the capillaries that grow out from them provide a way for blood being pumped out of the left ventricle to nourish the myocardium. The channels seal over on the epicardial side and mimic the sinusoids in a reptile’s heart, which has no coronary arteries.

These RCTs prove beyond a reasonable doubt, if not irrefutably, that TMR relieves angina, improves myocardial perfusion, and reduces the need for subsequent angina-related hospitalizations. Accordingly, ACC/AHA guidelines now recommend TMR as a “Class IIA” therapy for intractable angina,

which means the “weight of evidence is in favor of usefulness/efficacy,” with a “Level of Evidence: A,” i.e., “data derived from multiple randomized clinical trials.”<sup>22</sup>

These ACC/AHA guidelines apply to the average patient in the population with intractable angina. Medicine endeavors to make decisions for individual patients in the context of population-based information like this. Data from these TMR trials do not provide information the surgeon needs to treat a specific patient. Some patients with small coronary arteries might benefit from TMR done in conjunction with coronary bypass surgery, since graft patency rates are low in these patients. The operative mortality for TMR is higher in patients with poor ventricular function. Should the surgeon use an intra-aortic balloon pump in these patients? These trials do not provide answers to treatment questions like this.

With regard to Alzheimer’s disease, Saver and Kalafut calculate that 127 RCTs would have to be done in 63,500 patients over a 286-year period to determine the optimal combination of agents to treat this disease.<sup>23</sup>

### Meta-Analyses

Systematic reviews combine trials that address similar questions, like whether albumin or crystalloid is better for volume expansion, in order to achieve a statistically more certain conclusion. The Cochrane Injuries Group Albumin Reviewers in Britain performed a meta-analysis in 1998 of 30 RCTs on volume replacement in critically ill trauma victims, and they found that the risk of death was 6 percent higher in patients given albumin rather than crystalloid.<sup>24</sup> It is notable that none of the study’s seven analysts had experience working in an intensive care unit.

When the study was published, the *Times* (London) reported that it “suggests that up to 30,000 patients in Britain alone have died because they were treated with human albumin solution.” The director of the Cochrane Centre in Oxford said that he would sue any doctor who gave him an infusion of albumin and that patients should seek redress in the courts for clinical negligence if the guidelines based on this analysis were transgressed.<sup>25</sup>

Another systematic review on this subject, published in 2001, analyzed 55 RCTs, including ones that had a lower mortality with albumin than the first meta-analysis left out. This 2001 study concluded that albumin has no adverse effect on mortality.<sup>26</sup>

Analysts employ statistical techniques in their

systematic reviews that include a numerical scale for weighting the quality of each trial. Juni and colleagues show how analysts can obtain diametrically opposing results depending on which of the more than 25 scales they use to distinguish between high- and low-quality RCTs.<sup>27</sup>

Another source of bias is the study's sponsor. The UK's National Health Service (NHS), which stocks albumin and crystalloid in its hospitals, funded the 1998 albumin meta-analysis. Albumin is 30 times more expensive than crystalloid, and the study's sponsor would save a lot of money if it only had to purchase crystalloid. Other meta-analyses suffer similar flaws, such as a recently published one claiming that high-dose vitamin E supplements increase mortality.<sup>28</sup> Critics have exposed the methodological flaws in this study.<sup>29,30</sup>

### Epidemiologic Evidence

Randomized trials provide epidemiologic evidence framed in terms of statistical significance. Epidemiology examines the incidence of disease and the effects of therapeutic interventions at the population level. It cannot answer the question of whether causes in a specific individual. The U.S. Federal Judicial Center's *Reference Manual on Scientific Evidence* states: "Epidemiology... does not address the question of the cause of an individual's disease. This question... [of]... specific causation is beyond the domain of the science of epidemiology... [It] addresses whether an agent can cause a disease, not whether an agent did cause a specific disease."<sup>2, p381</sup>

Epidemiology can show that an association exists between the agent in question and a given toxicity or disease, at the population level. Epidemiologic evidence cannot establish a causal association unless other biological evidence backs it up. The Bradford Hill criteria spell out what that evidence needs to be.<sup>30,31</sup> Regardless of these criteria, some U.S. courts will admit epidemiology as evidence justifying an inference of causation in toxic tort litigation on a "balance of probability" when the relative risk is shown to exceed 2.0. U.S. courts also admit studies with a lower relative risk while recognizing that such studies may be insufficient proof of specific causation.<sup>2, p384</sup>

Evidence from epidemiologic RCTs does not necessarily meet a scientific standard of proof. Indeed, biases in methodology can generate evidence that does not even meet the lowest legal-civil standard of proof. These include faulty trial protocols, reporting outcomes in terms of relative risk without giving

absolute risk of all-cause deaths, and justifying interventions on surrogate outcomes (e.g., cholesterol level) when the primary outcome (freedom from myocardial infarction and survival) is not improved.<sup>33</sup>

The investigator's interpretation of the trial's results is especially prone to bias.<sup>34</sup> And, as seen in the NHS albumin meta-analysis, a study's source of funding can affect its results.<sup>35, 36</sup> Als-Nielsen and colleagues found that RCTs funded by pharmaceutical companies are significantly more likely to recommend the experimental drug as the treatment of choice than are studies funded by organizations that have no financial stake in the outcome.<sup>37</sup>

Chan and Altman reviewed 519 RCTs that were published in December 2000 and indexed in PubMed. They found that incomplete reporting of outcomes (described in the methods section but not in the results section) was common, and conclude that the medical literature of randomized trials represents a selective and biased subset of study outcomes.<sup>38</sup> As one observer put it, "Epidemiological analysis is notoriously susceptible to misinterpretation, and even manipulation. Two sets of researchers can extract diametrically opposed results from the same data."<sup>39</sup> The pharmaceutical and biotech industries now fund more than 60 percent of the RCTs that medical journals publish, which raises the concern that supposedly objective science is being turned into a marketing tool.<sup>40</sup>

### Eyewitness Testimony

EBM protagonists place case reports near the bottom of the medical evidence pyramid alongside editorials and opinions. They call this eyewitness-like testimony "anecdotal." Nevertheless, like witness testimony in the courtroom, the most essential evidence in medicine is the patient's story.<sup>41</sup>

In a court of law, eyewitness testimony is often the primary source of information that the court must use to reach a verdict. Prosecutors and defense attorneys cross-examine witnesses to plumb the evidentiary reliability of their testimony and introduce, when available, more scientific, "hard" evidence, such as DNA hair analysis, that can corroborate it.<sup>2</sup>

### Case Reports

Most medical evidence does not meet the scientific standard of proof; and, as in law, it should be judged by a standard of proof appropriate to the fact or point in question.<sup>42</sup> An "anecdotal" case report can provide evidence of probative value, just like eyewitness testimony in a murder trial. And it can be similarly

tested, by second opinions, re-examination, laboratory tests, and follow-up.

### Specific Causation

A single case report can prove that a drug causes an adverse reaction. Three events related to administration of the drug prove specific causation: 1) *challenge* - the reaction occurs after the drug is given; 2) *de-challenge* - "it resolves when the drug is discontinued; and 3) *re-challenge* - the adverse event recurs when the drug is given a second time.<sup>43</sup> Causation is judged to be certain owing to this "double hit" of challenge and re-challenge.

The U.S. Food and Drug Administration (FDA) and pharmaceutical companies acknowledge that just one challenge/de-challenge/re-challenge (CDR) case proves causality.<sup>44</sup> The FDA states, "Even a single well-documented case report can be viewed as a signal [of causation], particularly if the report describes a positive re-challenge."<sup>45</sup> In another report, the FDA notes that determining causality includes "assessment of temporal relationships [and] de-challenge/re-challenge information...which is usually considered your strongest evidence of a causal association."<sup>46</sup> And as *Stephens' Detection of New Adverse Drug Reactions* puts it, a positive re-challenge is "probably the strongest proof of a causal relationship."<sup>47</sup> If giving the drug a second time is not done, owing to ethical considerations, three cases of challenge/de-challenge (CD) can prove causality.

Heparin causes thrombocytopenia in a small percentage of patients (2-3 percent). In one patient, after a 10-day course of heparin the platelet count dropped from 200,000/mm<sup>3</sup> to 60,000. Over the next 20 days, off heparin, it returned to normal (179,000). A second bolus of heparin was then given, which promptly dropped the platelet count to 49,000. No other causes for thrombocytopenia were evident, and the presence of heparin/platelet factor 4 antibodies provides biologic plausibility on how heparin can cause this adverse effect.<sup>48</sup> This single case proves that heparin causes life-threatening thrombocytopenia in some people. Likewise, one CDR case of suicide ideation after taking flouxetine (Prozac) is sufficient to prove that the drug causes this reaction.<sup>49</sup>

With regard to drugs and vaccines, the Institute of Medicine (IOM) acknowledges that "[t]he recurrence or nonrecurrence of the adverse event will often have a major impact on the causality assessment."<sup>50</sup>

### Similar Fact Evidence vs. Case Series and De-Challenges

The judiciary follows well-developed rules on

admissibility of evidence. Hearsay evidence is not admissible (except for civil cases in the UK and certain well-defined areas such as business records in criminal cases) nor is opinion evidence (except for expert opinion on technical and scientific matters). "Similar fact evidence" is normally inadmissible in English law criminal proceedings unless its value as proof outweighs its prejudicial effect. In the *Brides in the Bath* case, the defendant, George Smith, was accused of drowning his bride in the bathtub.<sup>51</sup> No physical evidence implicated him in her death, but she had signed over her estate to him on their betrothal.

Evidence was admitted at trial that this person, using different names, had married two other women who also drowned in their bathtubs. They too had made financial arrangements from which he would benefit. This evidence was strong proof that outweighed its prejudicial effect. It was sufficient to find Smith guilty as charged, and he was executed in 1915.

This early English law example shows that similar fact evidence is analogous to challenge/de-challenge/re-challenge evidence in medicine. Both are capable of demonstrating causality to the highest standards of proof. In *Brides in the Bath*, their deaths precluded a de-challenge, but such evidence is essentially the same as three CD cases in proving causation. This also demonstrates that the plausibility of a single case report can be reinforced by each subsequent report, whereby a case series taken together can provide a substantially higher degree of proof than each report taken individually or isolated spontaneous reports of adverse events. One such case series is that of Wakefield et al., which shows a possible association of autistic regression, intestinal complaints, and ileal lymphoid-nodular hyperplasia following MMR vaccination in 12 children.<sup>52</sup>

### Medical Evidence in Autism

An epidemic of autism afflicts children today. Fifty years ago fewer than one in 10,000 children had this devastating malady, but today, with a prevalence of one in 166, one in every 68 American families has an autistic child.<sup>53,54</sup> A number of parents with autistic children and some investigators believe that the measles-mumps-rubella (MMR) vaccine and/or vaccines that contain thimerosal, especially in combination, can cause autism. Indeed, the director of the Autism Research Institute states, "Thousands of parents report - and demonstrate with home videos - that their children were normal and responsive until suffering an adverse vaccine reaction."<sup>55</sup>

Medical practitioners first inject the MMR vaccine

into American children at age 12-15 months, and then a second time when they are ages 4 to 6.<sup>56</sup> Injecting two widely separated doses of this vaccine constitutes a challenge/de-challenge/re-challenge in susceptible children. A valid way to test the hypothesis that MMR vaccine causes autism is to adopt the methodology that the FDA and pharmaceutical companies use to show that a particular drug causes an adverse reaction—a CDR case report or CD case series. One well documented case of a normally developing child who becomes autistic after being given the MMR vaccine, improves with therapy, and then regresses following the second dose (re-challenge) would be strong proof that this hypothesis is true.

Public health officials and their respective medical establishments in the United States and United Kingdom will not accept this kind of evidence with regard to vaccines, stating: “The weight of currently available scientific evidence does not support the hypothesis that vaccines cause autism.”<sup>57</sup> For them, only epidemiologic evidence is sufficiently “scientific.” But epidemiologic evidence, as an application of statistics, is open to manipulation and bias. Since it does not meet the scientific standard of irrefutability, it is not per se “scientific.”

The chairman of the IOM Committee on Immunization Safety Review acknowledges that “[the Committee] does not exclude the possibility that MMR vaccine could in rare cases contribute to autistic spectrum disorders ... because epidemiological evidence lacks the precision to assess rare occurrence and the proposed biological models, although far from established, are nevertheless not disproved.”<sup>58</sup>

Absence of evidence is not evidence of absence. Clinical importance is not equivalent to statistical significance. With rare and uncommonly occurring diseases, a nonsignificant finding in a randomized trial does not necessarily mean that there is no causal association between the agent in question and the disease.<sup>59</sup> Such trials are subject to a false-negative Type II error, which incorrectly supports the null hypothesis that agent does not cause disease.

### Commonality of Medical and Legal Evidence

In a legal case, lawyers organize the evidence they obtain to create a “factual matrix.” Elements of information are corroborated and cross-correlated to present a consistent, linked set of facts. Law tests the reliability of the sources of information, in addition to testing the information the sources supply. It admits evidence from a broad range of sources, which include human witnesses, documents, and machine

“witnesses” (material on computers, audio, and video).

Courts tend to exclude information, like hearsay evidence, if the court lacks the means to test its reliability. Medical evidence is the same. It begins with admitting (of necessity) the patient’s oral account. Labeling witness testimony “anecdotal” does not render it inherently unreliable. Oral or eyewitness evidence and “anecdote” are not synonymous. Eyewitness evidence can be tested.

In a medical case, physicians also marshal evidence from a variety of sources to create a factual matrix. They include, in addition to statistical epidemiologic evidence, case reports, case series, their own clinical experience and judgment, the opinions of others.<sup>60</sup> And medicine, like law, has various means for testing and assessing evidence, which include reproducibility and predictability in addition to statistical significance. Medical evidence spans the gamut of proof, from “more likely than not” to “irrefutable”.

In writing “evidence-based” testing and treatment guidelines, EBM advocates make recommendations based only on evidence obtained from controlled trials and meta-analyses. Considered “best practices,” such guidelines are now used by government agencies, third-party payers, and managed care organizations to decide coverage and track physicians’ “quality of care.”<sup>61</sup> But the factual matrix in each patient, which includes genetic and biologic variations and coexisting diseases, renders application of these epidemiologically based guidelines problematic. There are often special circumstances in a particular patient, described by Welsby as “Type 3 complexity,” that guidelines do not address.<sup>62</sup> The commonality of medical and legal evidence helps expose the inherent flaw in these EBM two-dimensional, reductionist flowcharts.

### Dealing with *Daubert*

In scientific and technical matters, judges and juries rely on the testimony of individual experts. The U.S. legal system has rules of evidence that regulate the admission of such testimony. But these rules of evidence do not question or regulate the rules, methods, procedures, and evidence generally accepted in medicine. Expert testimony based on flawed medical evidentiary practices will continue to fail courts and litigants and result in unreliable and unjust court decisions.

U.S. courts always have had power to exclude or admit medical, scientific, or other technical evidence. In 1923 the U.S. Circuit Court of Appeals laid down a “general acceptance” test for the admission of novel

scientific opinion testimony in *Frye v United States*, which stated: “The thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field to which it belongs.”<sup>63,p1014</sup> The Court affirmed the trial judge’s refusal to admit evidence of the results of a “systolic blood pressure deception test” (a predecessor to the polygraph).

Following the 1975 enactment of new Federal Rules of Evidence, and particularly Rule 702 dealing with scientific evidence, in 1993 the U.S. Supreme Court, in *Daubert v. Dow Merrell Pharmaceuticals, Inc.*, for the first time obliged federal judges to be proactive and screen the medical scientific evidence of individual experts in toxic tort litigation to ensure it is relevant and reliable.<sup>64</sup> *Daubert* makes judges “gatekeepers” of medical/scientific expert testimony measured against the benchmarks of existing knowledge and practice.<sup>65</sup>

A judge must now ascertain whether scientific evidence is grounded “in the methods and procedures of science....” The Court emphasized that the “inquiry envisioned by Rule 702 is...a flexible one.” It then identified four factors to consider when assessing whether a theory or technique is derived scientifically. These include its methodology, testability, subjection to peer review, and general acceptance by the scientific community.

In practice, *Daubert* is vulnerable to manifold corruptions resulting in relevant reliable evidence being systematically excluded in favor of the less reliable. *Daubert* rules do not correct erroneous theories that have become accepted medical thinking, including theories about what evidence is reliable. Editors can subvert peer review by selecting only reviewers who will reject papers that run counter to or praise papers that support - the interests of journal’s advertisers or its owners. Lines of independent research contradicting conventional wisdom can systemically remain unpublished.

Such hard-to-publish research may prove that what the scientific community generally accepts as correct is, in fact, wrong. Research follows the funding, resulting in a wealth of publications favoring the funding interests. This can have a disproportionate effect on the “weight” of evidence, especially for epidemiologic evidence in court.

According to some leading trial lawyers, plaintiffs now have to demonstrate near certainty before a court will allow a novel scientific theory to prevail (Waters CA of Waters & Kraus, personal communication, 2004).

Following the lead of evidence-based medicine, U.S. courts place a premium on epidemiologic data.<sup>66</sup>

Before a U.S. judge will allow the plaintiff to prove specific causation, epidemiologic evidence that a causal association exists between the agent in question and a given toxicity or disease must normally be presented first. The *Reference Manual on Scientific Evidence* states: “[A]n agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general.”<sup>2, p385</sup> After jumping this hurdle, the judge will then admit other medical evidence for proving specific causation, such as CDR case reports and CD case series, pharmacological research on mechanisms of toxicity, and animal and *in vitro* tissue studies. In U.S. federal courts and in an increasing number of state courts that have adopted *Daubert*, this epidemiologic prerequisite has blocked litigation on harm done by mercury amalgams, thimerosal, and MMR vaccine.<sup>67</sup>

With regard to uncommonly occurring and rare events like adverse drug reactions and vaccine-induced autism, judges need to realize that a CDR case report and CD case series alone can prove causation to a very high standard. Courts will be informed of apposite evidence of this kind if, and only if, evidence in medicine and medical science does the informing.

Moreover, *Daubert* aside, for this to happen, medicine needs to develop a better understanding of the nature of evidence and of evidentiary proof, by emulating law’s approach to evidence. Law in turn needs a better understanding of the shortcomings of medicine’s current approach to evidence.

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## Too Good to Be True - but True

*Retail Sale of Generic Drugs at Low Prices by the Govt in Chittorgarh Dt*

-S.Srinivasan<sup>1</sup>

We all know that one of the solutions for making medicines affordable to people is to make available only essential generic drugs at lower prices, that is if your doctor prescribes them in the first instance. Procurement prices of generic drugs by Governments like that of Tamil Nadu and Delhi have revealed that prices of generics<sup>1</sup> are 1.5 % to 10 % of the MRP of branded equivalents at the retail level. However to get a retail pharmacist to stock these low priced generics is easier said than done because in the private sector no trader wants to forego margins (profits); low priced generics have low profits; and of course there is a 4 lakh-strong retail pharmacists lobby in India. And also since high-priced brand name drugs sell more, a retail pharmacist will most likely hand you the costliest brand of a medicine.

Patients and end-users too are persuaded by doctors, drug companies, the pharma industry and trade, and by the general discourse in the media and amongst the public, that a costlier version of the same drug is of better quality and good quality drugs cannot come low-priced. But what if the same 'good quality' drug manufacturer makes the same drug and sells it at a costlier price for a branded version and much cheaper for the generic version? Even then prescribers would not be convinced and therefore they would not prescribe. Even if prescribers do, where can they direct the patient to buy them?

There have been few solutions for this dilemma in this vast country. Some few modest examples of *retailing* low-priced generics abound however: the organization Lokayat in Pune stocks medicines from LOCOST, the Vadodara-based low priced generic manufacturing NGO, and makes available these medicines when Lokayat's in-house GPs prescribe them to OPD patients. Rayat pharmacy in Nanded and Meera Medicals in Kolhapur Dt cater to GPs prescribing low-priced medicines from LOCOST.

This writer is glad to report of a relatively recent

<sup>1</sup>The author visited Chittorgarh during last week of July 2009 and this is his report. Author's email: <sahajbrc@youtele.com>. A version of this article appeared in the September 2009 issue of *Health Action*.

innovation in the public sector at Chhitorgarh District of Rajasthan and one that is of a much bigger scale. It is the public sector that is in some senses as difficult, if not more difficult, to get things done as compared to say the voluntary health private sector. We give details in the box *Low Cost Medicines Initiative Chittorgarh District Level Interventions: the Model*.

For the purpose of procurement and supply, the management of the entire effort is done by a specially established government cooperative. Rajasthan Government itself has a history of starting such initiatives: "In Rajasthan the life-line fluid stores run by RMRS in government hospitals are already providing cheap injections and IV fluids. In 2004, the government instructed to upgrade these fluid stores to life-line drug stores, i.e., apart from fluids they will also sell other drugs as well but these drug stores have come up only in few cities. Moreover, these are procuring and supplying medicines by brand names which are costly."

But the fallout envisaged by the current effort is what is interesting: "If such stores are opened in all government hospitals and they procure and provide all essential drugs by generic name, then it will improve the supply of low cost medicines to the patients. Rates must be displayed prominently outside the stores. If these low cost generic medicines are made available at government stores counters the cost of medicines can be reduced to more than half in most cases and this price fall will come down to the extent of one tenth of the prevailing market rate in certain cases, like cetirizine and nimesulide. Once choice of low cost drugs is available to the consumer, market competition will ensure that private medical shops also reduce their prices."

### **Generic Medicine Retail Shop of the Govt Coop Store, Chittorgarh**

The table below gives a sample list of price reductions achieved. For a complete list of comparisons and price reductions achieved, the reader is encouraged to see: <<http://chittorgarh.nic.in/generic/Drugs23.03.2009.xls>>.

### Low Cost Medicines Initiative Chittorgarh District Level Interventions: The Model

We knew that the actual cost of most of the drugs is very low. But, these were not available to patients at low rates because of three obstacles:

1. The doctors prescribe medicines by brand name of a particular drug company. This prevents competition and creates monopoly in the drug market and enables the drug company to put a very high MRP.
2. As very high MRP is printed on the drugs, the chemists charge the same amount from the patient.
3. Consumers are not aware that the actual cost of production of most of the drugs is very low. Moreover, once doctor has prescribed a particular brand, the patient has got no option, but to buy it, even when other low cost brands are available in the market. For example if doctor has prescribed a brand Glivec to a patient of blood cancer, a months course will cost Rs.1,14,400/- to the patient. Whereas, the same anti cancer drug, but with a different brand name Veenet costs just Rs.11,400/-. And Cipla supplies the generic equivalent of this drug (imitib) at Rs. 8,000/- & Gelmark supplies it for Rs. 5,720/-!!!!

So, the district administration adopted the following strategy to provide **low cost medicines** to the patients. Generic medicines are on an average 5 times less the cost of branded medicines. We broke the monopoly of drug manufacturers by pursuing doctors to prescribe by the salt name and we made arrangements to sell medicines below the MRP at government drug counters and made consumer aware. This was done in **three steps**:

1. Ensuring that doctors prescribe drugs by generic (salt) name, as directed by the state government

The state government has issued various circulars/orders, which directs all government doctors to use generic names, instead of brand names.

The following issues were addressed before the project could take off.

- A. Quality?

A team of doctors was constituted to suggest the companies, which they believe, produce good quality drugs. Only these were procured and supplied at co-op. stores.

- B. Combination preparations?

Commonly used combination generic drugs were made available at co-op. stores.

- C. Chemists will give brand of his choice and will charge the printed MRP?

If the patient gets medicine from hospital supply or is educated to buy low cost drugs from co-op. store, the problem is no more. Once, patients understand that the same drugs are available at co-operative store at much cheaper rate, market competition ensures that the chemists also sell at lower rates. Eventually the patient benefits.

- D. Government can put a ceiling on MRP?

This cannot be done at the state government level. Central government can do it using the provisions of Essential Commodities Act and Drug Price Control Order. Doctors were convinced that by the time a ceiling on MRP is put by the central government they should not wait and start helping their patients, specially the poor.

#### Government Cooperative Medical Stores and Life-line drug stores (run by RMRS) provide low cost medicines of well reputed companies

- Medicines which are commonly used by the patients and prescribed by Doctors were **listed** after discussions with various medical specialists.
- A committee of doctors was consulted which recommended that drugs of **reputed companies** like Cipla, Cadila, Ranbaxy, German Remedies, Alembic, etc. can be purchased. (Initially 22 and now 57 companies are approved)
- Finally, the **tender** was floated for these medicines. The tender included 564 generic medicines and more than 100 surgical and I.V. fluids. Cooperative store invited bids to purchase the drugs of these companies from the local stockists at competitive prices, after preparing comparative statement and finding out the most economical company (L1).
- The medicines are then sold at **20% profit** margin to the patients. This money goes to the coop. deptt. and will make the project self sustainable.
- Thus, medicines of reputed drug manufacturers (which are unthinkableably cheap) were made available at government co-op. medical stores for **sale**.
- **Pricelists are displayed** outside the coop. stores to advertise the rates and educate the patients.
- Once choice of low cost drugs is available to the consumer, **market competition** will ensure that private medical shops also reduce their prices.
- **Awareness generation.** Doctors were sensitized by organizing discussions. Training of co-op. pharmacists was carried out. The consumers were made aware by displaying boards showing comparative price lists and positive use of local electronic and print media.

#### Quality Control and Audit

The quality control Officer is Dr. Dinesh Vaishnav who is assisted by Drug Inspector Sh. Jain. This team ensures that the drugs of the companies approved by the committee of doctors only are available. So far 33 samples of generic drugs from various shops have been tested and all of them have been found to be of standard quality.

Source: *Making Medicines Affordable: Reaching the Unreached*. Documentation by Dr. Samit Sharma, Collector & District Magistrate, Chittorgarh, Rajasthan. See also: <[http://chittorgarh.nic.in/Generic\\_new/generic.htm](http://chittorgarh.nic.in/Generic_new/generic.htm)>.



Photo Source: DM Sharma's Presentation

**Table 1: Sample List of Price Reductions Achieved by the Chittorgarh Model**

Generic Name of Drug	Chittorgarh Bhandar Rate* (Rs.)	Unit	MRP Printed on pack/strip (Rs.)
Albendazole Tab IP 400 mg	1.37	1 tablet	25.00
Alprazolam Tab IP 0.5 mg	1.75	10 tablets	14.00
Arteether 2 ml Inj	11.72	1 Injection	99.00
Amlodipine Tab 5 mg	3.12	10 tablets	22.00
Cetirizine 10 mg	1.50	10 tablets	35.00
Ceftazidime 1000 mg	64.90	1 Injection	370.00
Atorvastatin Tab 20 mg	22.59	10 tablets	170.00
Diclofenac Tab IP 100mg	2.75	10 tablets	25.00
Diazepam Tab IP 5 mg	1.90	10 tablets	29.40
Amikacin 500 mg	8.67	1 Injection	70.00

Source: Making Medicines Affordable: Reaching the Unreached, op.cit.

Obviously, treatment cost of most illnesses fall with an increase in number of patients getting free drugs from hospital supply. A byproduct is decrease in expenditure for the Rajasthan Pensioners Medical Fund (RPMF), so more patients are now benefited. All these of course depend on rational prescription and correct diagnosis by prescribers and as far as possible as per Standard Treatment Guidelines brought out by the Rajasthan Government.

This writer was most glad to see all the prices of the major drugs, about 200 in number, put upfront in the cooperative shop – so that no body is left in doubt. The cooperative runs at least 6 such stores in the Chittorgarh town, supplies to government public health facilities of several neighbouring districts as well as CHCs of Chittorgarh District. The drugs at

these prices are also available for the indoor and outdoor patients of the Sanwaliyaji Government District Hospital at Chittorgarh town – at this hospital, medicines and investigations are free for BPL and other deserving groups like single women, orphans, aged persons, etc. The charge list of investigations even for paying patients are very nominal – starting at Rs 5 for an Hb (iron content of blood) or an Malarial Parasite test and going up to Rs 300 for a total lipid profile (the only such test costing Rs 300). The laboratory and the X-Ray Unit function 24x7 and reports are made available at 12 noon and 5 pm. OPD/ IPD registration charges are Rs 2 and Rs 10 respectively and there are no other charges for beds and treatment and surgery.



Source for Photos: Making Medicines Affordable: Reaching the Unreached, op.cit.

Photos Above: The Positive Effect of the Government Initiative on Private Retailers: Even Private Medical Shops Announce Availability of Low Priced Generics!

### Enabling Factors

The Chittorgarh model could not have been a success but for the dynamic leadership of the District Collector Dr Samit Sharma, a qualified pediatrician, a person quite sanguine of the political economy of medicines and medical practice; and with of course the cooperation and efforts of senior medical doctors of the district administration who saw wisdom in Dr Sharma's initiatives. Will this outlast Dr Sharma's inevitable transfer, sooner or later, as he is an IAS officer? Well we hope so - with the amount of awareness and consciousness among the local politicians, the media and the general public, it may be difficult to undo these gains. It is heartening to see advertisements by the District Collectorate at several places in the town – so much so 'generic dawaiyan', or generic medicines, has passed into common parlance of even

the ordinary people of the town, this writer talked to. As also in the media discourse (see for examples cartoons below).



Of course if the Rajasthan government would adopt this model all over Rajasthan – that is if generic drugs are procured and made available at these prices to all users of the Government’s health facilities *plus* made available through a chain of retail stores, a revolution in drug pricing as if people mattered is in the offing and one which pharma industry wallahs would ignore only at their peril.

Dr Narendra Gupta of Prayas, Chittorgarh and colleagues have calculated that if all the OPD patients of Rajasthan Government health facilities were to be given free medicines, the cost would be only Rs 493 crores per year – the order of expenditures for the NREGA scheme per district!

(All unreferenced quotes are from *Making Medicines Affordable: Reaching the Unreached*, op.cit.)

## Bayer to Stop Selling Endosulfan

The multinational chemical company Bayer has committed to end distribution of the pesticide endosulfan in 2010, and to replace the toxic pesticide with safer alternatives. The decision follows an innovative action in 16 countries, led by Panta to Poverty, the organic and Fairtrade underwear company, and its coalition of partners including Pesticide Action Network, Fairtrade Alliance Kerala and Zameen Organic.

*In a letter addressed to Coalition Against Bayer Dangers, Bayer said: “We plan to stop the sale of the substance endosulfan by the end of 2010 in all the countries where it is still legally available.” The letter, signed by Bayer CropScience’s head of investor relations, Judith Nestmann, said endosulfan would be replaced by alternatives “with a significantly better risk profile”.*

Bayer’s decision comes after years of global campaigning against this persistent pesticide, which is linked to autism, birth defects and male reproductive harm, as well as deaths and acute injuries to farmers through direct contact. It is banned in over 60 countries including those in the European Union. In the United States endosulfan is used primarily on cotton in the state of California and tomatoes in Florida. Several lawsuits and legal petitions have been filed by groups concerned about the chemical’s health effects.

In this latest action, in 16 centres around the world, people exchanged their conventional undies for a free pair of organic underwear, and signalled their commitment to cotton production without the use of endosulfan. The conventional undies were sent to Bayer’s HQ with a demand that it ceases to distribute endosulfan.

Linda Craig, Director of Pesticide Action Network UK, said, “We are pleased that Bayer has committed to stop selling endosulfan. There are many proven alternatives to its use that do not have the deadly side effects of this pesticide”.

Staff scientist Karl Tupper of PAN North America said “With Bayer stepping out of the picture, this leaves just handful of generic manufacturers selling this poison. We call on these companies to put health and the environment ahead of the meagre profits they earn pushing this antiquated pesticide, and stop their sales. It’s the only

responsible thing to do.”

“Nine countries in West Africa have taken the resolution to ban the use of endosulfan in agriculture because of the serious effects observed on farmers and their families, and on the environment. It is necessary to continue to push for the total ban of this product around the world” indicated Dr. Abou Thiam, regional coordinator of Pesticide Action Network Africa.

At the international level, endosulfan is being scrutinized at the Rotterdam Convention for stricter regulation and at the Stockholm Convention for an international ban due to its adverse effects on human health and the environment. PAN will continue to work to ensure that endosulfan is included in the list of chemicals that are banned globally.

However, progress is obstructed by the Government of India, as Dr. Meriel Watts, Coordinator of PAN Aotearoa New Zealand observes: “In India, the Government itself manufactures endosulfan - it owns Hindustan Insecticides which manufactures endosulfan, and then the Indian Government acts in the international conventions to stop endosulfan’s listing. It has members on both the Stockholm Convention’s POPS Review Committee and the Rotterdam Convention’s Chemical Review Committee. This is a “clear conflict of interest”, she says, “a manufacturer is using its power to veto international agreements on a chemical.”

“Chemicals like endosulfan that are toxic, bioaccumulative and so persistent that they contaminate our bodies, our babies and the environment have no place in agriculture. We are calling on all governments and industries that still use, manufacture or trade in endosulfan to follow Bayer example and cease to profit from this toxic poison,” said Dr. Mariann Lloyd-Smith, Co-Chair of the International POPs Elimination Network.

July 23, 2009, Press Release PAN North America (PANNA)

### More information:

Coalition against BAYER Dangers (Germany)

[www.CBGnetwork.org](http://www.CBGnetwork.org)

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## Minutes of Meeting of the Mid-Annual Meet of mfc, July 10-11, 2009, Pune

*Participants: Manisha Gupte, Jenny Liang, Ramesh Awasthi, Rakhal, Anant Phadke, Chinu Srinivasan, Nilangi Nanal, Abhay Shukla, Bharat, Sarika, Mira Sadgopal, Amar, Neha Madhivala, Sarojini, Aastha, Ankur and Sandeep of Swasthya India, Shashikant Ahankari, Tejaswini, Abhijit, Dhruv Mankad, Anant Bhan.*

### July 10, Day 1: Pre-Lunch Session

At the outset it was decided that on the first day, the group would focus on the annual meet content, time table, papers as well as discuss some of the issues about mfc's overall strategy/work, etc., to be raised by the new convening team, and then the second day will be used to come to a consensus on it, after which organizational issues that were identified during the last AGBM will also be taken on.

The context in which the mfc started, nearly 36 years ago defining itself as a thought current, has changed quite drastically. These changes have occurred at the micro-level (at the level of the individual, family and community) where there have been huge challenges to the very concept of community and family, and at the macro-level where corporate agendas seem to have taken over all policy making in almost all sectors. Accompanying this is a significant shrinking of spaces for discourse and especially dissent. Linked to this is the increasing non-visibility of any debate or alternative discourse vis-à-vis the dominant paradigm of development.

One of the recurrent themes of the mfc has been how we are addressing the 'mainstream': at present we do it (to a limited extent) through the - egroup, the *mfc bulletin*, our publications, and the website. We need to assess these and come up with comprehensive plans for more effective use of these spaces and thus reinventing the role of mfc as a thought current in the current scenario.

Rakhal brought up the issue of the lack of a set of alternative resource material in community health and discourses around development. A set of alternative writings, updated anthologies would be a possibility. Original authors in dialogue with another commentator: original author looks back on twenty years since they wrote the article, and another younger mfc friend looks at the next twenty years. Get a collection of case studies in a particular area could be included in such an exercise. Output would be a set of debates and learning from experiences. It was argued that while this is certainly desirable, it would be a task to get all the authors to reflect on the topic they wrote about many years back. It was felt preparing, publishing a new anthology of the articles published in the last 10 years or so would be a more realistic objective. (Any offers?)

A paper summarizing the debates in the past many years would be useful in this context: a sort of review of the debates over the years. [The paper could inter alia contain: Proactive agenda: based on our understanding - commercialization, health systems deterioration, contradictions of corporatization versus inclusive growth call of the new government; emergence of dissent of various kinds; health implications of that – looking beyond healthcare; JSA: talking about role of increased public health expenditure, criticizing its weakness; now is the time to launch an attack on the unregulated private sector (it cannot be wished away)- tame the animal- lay a framework in which they can operate.]

One of the more recent initiatives in which many of us both individually and as mfc got involved was the campaign around the release of Binayak Sen. It was noted that it is important to document and discuss the various streams of energy that were activated during the campaign. In fact it was quite enthralling to see the large number and wide ranging nature of groups which came forward in support of the campaign over the last two years. It seemed more a support of someone who dared to challenge boundaries (now more and more being laid down by the state). In fact what happened to/is happening to Binayak is merely a reflection of the shrinking space for dissent and an alternative discourse. It is important to understand and effectively use the energy as well as the spaces opened up during this campaign.

The convening group pointed out that there was a lack of a set of alternative resource material in community health and discourses around development. It was suggested that a set of alternative writings, possibly in the form of updating creatively the original mfc anthologies, creating new sets of anthologies from the published bulletins, scanning the original anthologies and putting them on the website, working on a paper/booklet summarizing the various debates that have occurred in mfc over the years, and working out methods to regularly post responses of mfc to the present situation be worked out, with an idea to crystallize some of these debates into easily accessible alternative literature.

It was pointed out that the role of mfc is to analyze and understand the existing situation and to look at

the future drawing on the ingredients present today. Closely linked to this is the need to also project options for the future. It was thus felt that we needed to proactively look at some of the major developments in the health field and base our analysis on the experiential learning of the individual members of mfc. Unlike JSA and AIDAN which are action groups where there may not be enough time for in-depth discussion, mfc should provide that forum for detailed discussion and analysis to the extent possible.

It was felt that there needs to be a deeper understanding of things playing out at multiple levels. One set of forces were the macro policy environment which favors commercialization and privatization with a concomitant deterioration of the Public Health System and other inter-sectoral supports to health like water, housing, sanitation, etc. The other set of contradictions is that of the government encouraging various policies for inclusive growth like social security, NREGA etc. while at the same time refusing to regulate the private medical sector. Thus on the one hand it actually increases budgetary allocation while on the other it seemingly reduces public sector capacity to absorb this budget by encouraging privatization or PPPs (Public Private Partnerships).

It was stressed that there was a need to pose positive alternatives – while mfc as a body may have limited capacities; it was urged that we look at health systems and the issue of multiple determinants impacting on people's health in a direct and serious way. It was suggested that we review and respond to the various new developments. It was further suggested that we as a group take on a few issues and systematically pursue it over couple of years and try to come up with some clear/objective output/responses.

At this juncture it was pointed out that in mfc we have already done some substantive work on the theme of structural violence and violations. This was following the meeting on Gujarat where it was decided to come up with a comprehensive curriculum etc. Similarly there has been a lot of effort around the Bangalore meet on public health education which needs to be taken to its logical conclusion. It was suggested that these two major themes find place in the work of the mfc over the next few years, and the efforts already made by brought to a logical conclusion.

### Themes of Crucial Importance

There then followed a discussion during which various themes/issues that were felt to be of crucial importance were identified.

- Increased allocation to NRHM and the parallel

inability of states to absorb the money; and the capacity of the systems to deliver.

- ANMs: in many states are aging. How they are visualizing their future is changing; we need to study this. Things sometime become vague on the ground; ANC and PNC often in the public sector and deliveries in the private sector
- Role of CHWs in an area where there is conflict;
- Who are the people getting into the medical profession? What kind of resources and economic criteria play a part in their decision making
- Our health system is semi-privatized in various ways with a whole range of private interests; difficult to extricate. Cannot look at the public and private in compartments, e.g., government doctors doing private practice.
- The other challenge besides PPP is insurance and the way it is panning out in India. It may be noted that RSBY allocation is being increased this year again. However RSBY is under the labor ministry now.
- Education/trajectory and role of medical professionals; trajectory of medical professionals, career paths. Then see how certain sub-groups can take responsibility on some of these themes.
- Take the health workers into the movement; there are groups coming up of health professionals who might have some ideas which map out to our thoughts. However it was cautioned that sometimes the unions are more worried about privatization and their jobs rather than peoples health.
- Keeping our eyes and perspective open about how post 2012 things will be given the context of NRHM officially ending that year.
- Debate around NUHM: would it be based on PPPs or strengthening public healthcare institutions; a consensus is not emerging much; urban areas- difficult to move ahead without addressing the private sector. The health movement: JSA/mfc has not been able to evolve a comprehensive response to this issue.
- Regulation of health sector, especially private sector: there is a deep divide. Key to it is targeting regulation at all levels- from technicians to providers. Regulation at all levels should be demanded as this will help manage the damage.
- NHRC and dialogues: interest in being part of

the process and following up- trust, audit, addressing private sector. Public hearing linkages to getting health rights recognized.

### Theme Meet on Health Systems

There then followed an intense discussion on the actual functioning of mfc and the planning of the meets etc. This was followed by some specific suggestions for a proposed theme meet on health systems.

A series of questions/issues were posed to the group by different members present:

- Do we look at issues in an intellectual manner with a futuristic perspective in mind?
- Since we are examining issues in a disjointed manner, how are we going to examine some of the contradictions? We need to reflect on the entire health system.
- Conflict on determinants of health; very few of us are involved with the non-health movements like labor movement, right to food (are we focused too much on disease/public health).
- Need for reform in the urban system- cannot just address rural system in isolation.
- Need to work on a good referral system.
- Need to focus our energies, and adapt to the realities of today.
- Are we intellectually progressing through the meets?

Based on a discussion around the above set of questions the following suggestions emerged:

- Crystallize ideas for the next couple of meetings. Need to focus consistently on a set of topics. Need to synthesize our themes for the next few years: Health systems. Take a thrust area and try to focus on it.
- It was suggested that we plan for a series of interlocking meets so that there can be a systematic follow up of issues from meet to meet. It was suggested that interlocking meets be planned for a 3 to 5 year cycle. It was also suggested that satellite meetings / cell meetings be revived. It was also stressed that flexibility also needs to be maintained to respond to sudden situations like the Gujarat carnage.
- Need to go forward and focus on areas/ dimensions of healthcare systems. Anthology as a starting point is a good idea.
- Proactive agendas and looking ahead is important but this will mean a lot of people might not feel involved or excited; hence we need to

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take areas which others might be interested in.

- Use the model of the National Bioethics Conference: involve those interested in ethics and also be able to do outreach with institutions that had no interest in ethics earlier. Work with institutions in preparing themes. Change the organization of at least one annual meeting and let us learn from that experience.
- Nov 2010: governance of health systems- National Bioethics Conference (New Delhi); will be organized with AIIMS as host; will provide an opportunity to dialogue with the mainstream; mfc could combine its annual meeting with this event.
- There was a discussion trying to find the balance between the need for a space for 'friends' to have intense debates, and learn from each others experiences versus involving larger number of people (with its own dynamics) in an effort to 'reach the mainstream'.
- One way to do this is to redefine the MAM as a meeting strong on content and not only organizational work thus giving more space for sharing and debate. Again the two to five year cycle of themes will enable this to happen.
- Need to reflect back on what mfc has done in the past and on issues such as whether there is something sacrosanct in things like individual contribution and insistence on non-organizational contribution or do we need to evolve further modalities.
- There is a need to continue to balance the 'evocative' idea of a friends circle and the rigor that we need to put together if we hope to have an impact.
- One opinion was that we should be able to involve other organizations and not be bogged down by negativities. While mfc meet needs to remain an mfc event, an organization should sponsor its employees in participating in the meeting and contribute to it (as is already happening in many cases).
- Need for CORE GROUP of 10-15 people who will commit to mfc.
- What do we gain by involving organizations formally: Resources and People. Mfc has been always subsidized in various ways by Masum/ Sangitha, Chinu, etc.
- We need some kind of structure. If the convener and a certain number of the EC decide to represent mfc into something, it would be a

problem. They could be questioned and decisions ratified in the annual meet. *Transparent formality is better than opaque informality.*

#### Suggestions for Proposed Meet on Health Systems

- Four areas:
  - a) Healthcare and the hospital system/industry: universal access to health Vs access to healthcare in a hospital where catastrophic expenditures take place
  - b) Human resources for health
  - c) Health financing: health insurance – user fee, price control, fee for services; doctor income disparity
  - d) Governance of health systems in a background of poor regulatory structures.
- Regulation of health industry: context of responding to emerging needs like rise of PPPs, RSBY.
- Community health: we are not rejecting the hospital industry; need to have a concrete response to the hospital industry (confronting the challenge of the hosp industry instead of merely outright rejecting / ignoring the impact it has on all aspects of health care). Similarly community health, community monitoring etc. also needs to be brought in so that it does not get lost in the discussion around hospitals and health systems

It was decided that provisioning, financing, and governance can be the broad areas to focus on.

#### July 10, Day 1: Post-Lunch Session

The afternoon discussion started with the issue of whether the group felt the need to re-look at the theme of the proposed annual meet at Bhopal. This was especially in light of the discussions during the morning and earlier discussions between some of the members.

There was a call for more discussion before deciding to change the topic. After a discussion during which various opinions were expressed including the fact that while involvement in Bhopal had been a historical fact, the present involvement was certainly patchy at best and that having the meeting in Bhopal to show symbolic solidarity may not necessarily serve its purpose, as shown by the experience of 5 years ago when we had a meeting in Bhopal to commemorate 20 years and despite efforts by many had very little involvement of local groups. Others also felt that we can show solidarity without actually being there and

in other forms. While there were some logistic problems to be expected. At the end of this discussion it was decided to go ahead and change the proposed topic of the annual meet to be more in line with the discussions of the morning.

It was suggested that we can have “*Changing Health Systems*” as the theme for the next two years and also we can focus on one part of it for the annual meeting. Various options regarding how to map out the various interlocking themes for the next few years were discussed.

At the end it was agreed that we would plan a large scale meeting in 2011 titled “Towards a Universal Access Health Care System.” For the 2010 annual meet we can map out the present situation. At that meet we can chalk out the topics where we need more information, understanding etc. which will help us focus for the 2011 meeting.

During the afternoon and evening of the first day there was a rough roadmap to the Annual meet 2010 chalked out. This was further discussed in detail and refined on the morning of the second day. The final structure that emerged is being reported.

(The discussion on organizational matters that took place on the evening of the first day and later part of the morning of the second day is again reported together after the discussion of the Annual Meet 2010.)

#### Annual Meet Jan 8-10, 2010

It was then decided to have the 2010 Annual Meeting on the theme “Mapping out the Current Situation of Health Care in India” to have clarity on the gaps and barriers to Universal Access to Health Care. The dates would be January 8-10, 2010. Venue: Yatri Nivas, Sewagram (*both dates and venue have been since confirmed – editor*)

Anant Bhan took responsibility to contact Subodh and find out about their participation; and also do an outreach if local hostel facilities or rooms/ auditorium spaces can be arranged for people to stay within medical college. Other mfc friends will follow up with their contacts in Sewagram to increase local participation.

It was proposed that the annual meet will have three major sessions covering the broad topics of (a) Provisioning/Delivery of Health Care; (b) Financing; (c) Governance and Accountability and will be held over a period of one and a half days. It was suggested that one individual each can take responsibility of putting various material that is suggested (by

discussants) and collected and of making an overarching presentation on the issue (for each session). Another presentation can be on field level experiments / initiatives that have taken place in the field. The rest of the time may be spent on discussion and inputs from others including the invited discussants. At the end we can have a half day session on mapping out the issues for the Annual Meet of 2011. This can be followed by a full day AGBM on day 3 where these issues are finalized and fine tuned.

The 2010 meet will be treated as landscaping of the health system and then it would give leads for future areas of enquiry. The theme 'mapping' would mean description of functioning, collection of case studies and experiences in totality and looking at how all of these themes contribute to the way we want to see impediments to universal access. Mention was also made about the following: need to get models and cases in the mapping exercise; need to look at large scale unnecessary medical interventions (rationalization of healthcare); need to look at how this has been done in countries like Thailand and Brazil; addressing rationality at various levels, etc.

The overall concept note, laying out the scope and framework, would be developed by Abhay, Anant and Rakhal.

#### **Details of Sessions**

- For each of the three sessions of 3-hours each, we will have two lead presentations (landscape presentations) which would be based on the background papers. After this initial lead presentation there will be detailed discussion either in groups or in plenary.
- To organize these sessions three teams will work on one session each, with each team having one convener with other mfc members as team members.
- Need to formulate key questions for each session Systems for accountability - presenters can address key questions accordingly.
- Need to keep both rural and urban areas in mind, but urban healthcare needs to be in focus comprehensively because so far MFC has focused mainly on rural areas.
- Take a test state like Maharashtra, and then focus on different indicators, and try to give a realistic picture of how things are at the ground level ( detailed information and analysis is needed at these levels).
- Inputs needed from micro level studies to look at a map/system of provisioning.

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- However it would be good to have people who might have done other studies.
- Look at quantitative differences and diversities and how these emerge

#### **Time Table and Related Tasks**

- Concept note: end of July '09/first week of August (Anant Phadke, Abhay Shukla and Rakhal).
- Letters to invitees: second week of August (Renu and Manisha to draft)
- Collection of existing material: end of August
- Reminders: end of September
- New material: end of October.
- With reminders: mid-November
- Circulate annual meet material: mid-December

Half day each for all 3 sessions and half day for pulling things together; devise group work if there are more than 30 participants

Annual meet announcements to be made in:EPW, IJME, NMJI, Down to Earth, mfc bulletin, websites.

#### **Organizational Issues**

##### **Membership**

- mfc membership: After much discussion it was decided to offer yearly membership for members attending annual meets for the first time; 2-3 timers and regular attendees may be offered two yearly, 5 yearly, or 10 yearly memberships. There will be no life membership. This needs to be ratified in the AGM.
- mfc membership form: members went through the form and made suggestions It was decided to charge Rs 200 as the fee for membership. This is including a complementary mfc bulletin subscription, for new members. Thus all members will be subscribers, however all subscribers need not be members.
- It was suggested that the list of annual meet attendees from the past 15 years should be scanned, the concerned individuals contacted and asked to register/pay membership again to build up a stable membership base. They will be given Option of joining the e-group in case they are not already members.

##### **Role of the Executive Committee**

- EC is the support body for conveners in between the meetings.
- EC members can take up responsibility of coordinating paper-writing and other responsibilities towards the annual meets.

Section	Sub-theme/Discussant	Person who will contact	Section Convener/ cell
Provisioning	● Health delivery status in northeast - government & private sector also – <i>Jenny Liang</i>		Abhay (Convener) Sarojini Jenny
	● Hosptial industry in private sector - McKinsey report – <i>Ankur / Sandeep</i>		
	● Private sector / Private sector provisioning. - <i>Rama Baru</i>	Sarojini	
	● Private sector / Private sector provisioning. - <i>Kabir Sheikh</i>	Renu	
	● Private sector / Private sector provisioning. - <i>Muralidharan</i>	Rakhal	
	● Public health sector : Case study of Maharashtra - <i>Nilangi</i>	Abhay	
	● Public health sector – Provisioning – <i>Prof. Nagarajan</i>	Rakhal	
	● Human Resources – <i>Neha</i>		
	● Human Resources – <i>Thamma Rao</i>	Rakhal	
	● Irrational practice - <i>Anurag</i>	Anant Phadke	
	● Essential drugs and vaccine policy- <i>Madhavi and Chinu</i> with <i>Abhay/Nilangi</i> giving Maharashtra status update on healthcare provisioning and utilization	Chinu	
Financing	● Insurance schemes-landscape: <i>Deva</i>	Rakhal	Anant Phadke (Convener) Ravi Duggal
	● Insurance schemes – landscape – <i>Murali Iyer (NIA)</i>	Ahankari	
	● Community health insurance/RSBY: <i>Denny John</i>	Abhay	
	● Community health insurance: <i>Ahankari</i>		
	● Community Health insurance – case study – <i>Ulhas / Anant Bhan</i>	Anant Bhan	
	● Overall critiques – <i>Ravi Duggal</i>	Anant Phadke	
	● Sources of financing: <i>Ravi Duggal</i>	Anant Phadke	
	● User fee: <i>Bijoya Roy</i>	Chinu	
	● PPP: <i>Rama Baru</i>		
	● Cehat case studies - <i>Padma Deosthali</i>	Anant Phadke	
	● PPP case study – <i>Sarika / Bharat</i>		
	● OVERVIEW PAPER (PPP) - <i>Sundaraman</i>	Abhay	
	● OVERVIEW PAPER (PPP) – <i>Padma Deosthali or Saktivel (Chinu to contact)</i>		
Governance	● Issues in health governance: <i>KB Saxena (background paper)-</i>	Rakhal	Rakhal (Convener) Renu, Anant Bhan
	● Community Based Monitoring – overview of nationwide process – <i>Renu / Rajani / Ram</i>	Renu	
	● CBM – Case study of Maharashtra - <i>Dhananjay</i>		
	● Overview of Regulation : <i>Sunil/ Amar</i>	Amar	
	● Maharashtra experience on non-regulation: <i>Anant</i>		
	● Process of Gujarat public health act : <i>Renu</i>		
	● Decentralization Kerala: <i>Joy Elamon/Ekbal</i>	Renu	
● Governance / regulation - <i>Muralidharan</i>	Rakhal		

- If the need is felt, EC members can address relevant issues by issuing statements on behalf of mfc. A detailed consultation with other members may delay the issuing of such letters. If some immediate action has to be taken, convener may take it and inform EC about it.
- They may also help in raising subscriptions / membership / distributing brochure and generally representing mfc in meetings they attend etc.
- While it was reiterated that mfc is an organization and a 'friend circle', it was pointed out that with visibility comes responsibility. Thus there was an obligation to address issues, organize ourselves etc.

There was some discussion on using mfc's name in signing a petition, showing solidarity etc. It was felt that if a few members felt strongly about an issue, they can initiate in a quick e-mail consultation with the EC and convenors and based on the response, they can go ahead and sign or show solidarity. Each of these instances can then be reviewed in the subsequent MAM or AM.

Current EC members: Sarojini, Jenny, Chinu, Rakhil, Sukanya, Eddie, Meera, Manisha, Anant Phadke, Raju, Ravi D'Souza.

#### **Thematic Cells**

There was a brief discussion on the various thematic cells. They were clearly not functional. Some ideas for revival were suggested including getting each cell to guest edit one issue of the bulletin, come up with yearly position statements etc. However after discussion it was felt that the present cells that have been non-functional may be considered scrapped. It was decided that while in principle the cells were a good idea, they were not working presently. In case they become more active at a future point in time they can be supported and discussed.

#### **Discussion Regarding the Bulletin**

Number of published copies: 400-500; Deficit last year for bulletin: Rs 13000. The present situation of the cost of publishing as well as the financial aspects of running the bulletin was presented. While numerous ways of overcoming the deficit were discussed it was finally decided that we first need to try to raise more subscriptions, send out subscription forms to all subscribers, check out the period of subscriptions for all life subscribers (and change to 10 years) and basically build up the individual subscriber base

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before thinking of alternative financial models (see below for a report).

It was also suggested to increase the rate for annual subscription to Rs 150 (minimum), or Rs 200 (proposal). This can be ratified at the AGM.

It was opined that the home page of the mfc website can be the bulletin. This will increase its visibility. It was also decided that the mfc website needs comprehensive redesign. Neha on behalf of CEHAT/CSER offered to undertake this exercise.

Anthologies - can be revisited and older anthologies can be scanned and put up on the website

#### **Discussion on Various Financial Models**

- It was calculated that the interest from a Rs 5 lakh FD at present interest rates will suffice to make up the deficit.
- Bulk purchase of issues by organizations to distribute to their contacts may be another option to cover the costs.
- Organizations picking up tab per issue.
- It was reiterated that to rejuvenate organization, maintaining a bulletin is important as a mouth-piece
- The editor in consultation with the editorial committee will come up with a financial plan for the bulletin.
- State wide lists of mfc bulletin subscribers can be generated. It was requested that individuals follow up in that state to ensure more subscriptions.

#### **Other Bulletin-Related Issues**

- Chinu will send PageMaker and PDF files to Neha for upload.
- Page numbers can be given continuously for a year with one volume per year. This is a basic requirement now for getting the bulletin to be registered with many indices.
- Strategise why people read or do not read it (the *mfc bulletin*); need to reflect on the readability.
- Mira Sadgopal will join the editorial committee

#### **Role of Editorial Committee (suggested)**

- Writing at least one article per year
- Eliciting at least two articles per year
- Helping and editing one issue per year
- Encourage subscriptions and following up/ promoting the bulletin. Associate editors can be appointed to do specific work

## Merck Published Fake Journal

Merck paid an undisclosed sum to Elsevier to produce several volumes of a publication that had the look of a peer-reviewed medical journal, but contained only reprinted or summarized articles - most of which presented data favorable to Merck products - that appeared to act solely as marketing tools with no disclosure of company sponsorship.

"I've seen no shortage of creativity emanating from the marketing departments of drug companies," Peter Lurie, deputy director of the public health research group at the consumer advocacy nonprofit Public Citizen, said, after reviewing two issues of the publication obtained by *The Scientist*. "But even for someone as jaded as me, this is a new wrinkle."

The *Australasian Journal of Bone and Joint Medicine*, which was published by Excerpta Medica, a division of scientific publishing juggernaut Elsevier, is not indexed in the MEDLINE database, and has no website (not even a defunct one). *The Scientist* obtained two issues of the journal: Volume 2, Issues 1 and 2, both dated 2003. The issues contained little in the way of advertisements apart from ads for Fosamax, a Merck drug for osteoporosis, and Vioxx.)

The claim that Merck had created a journal out of whole cloth to serve as a marketing tool was first reported by *The Australian* about three weeks ago. It came to light in the context of a civil suit filed by Graeme Peterson, who suffered a heart attack in 2003 while on Vioxx, against Merck and its Australian subsidiary, Merck, Sharp & Dohme Australia (MSDA).

In testimony provided at the trial last week, which was obtained by *The Scientist*, George Jelinek, an Australian physician and long-time member of the World Association of Medical Editors, reviewed four issues of the journal that were published from 2003-2004. An "average reader" (presumably a doctor) could easily mistake the publication for a "genuine" peer reviewed medical journal, he said in his testimony. "Only close inspection of the journals, along with knowledge of medical journals and publishing conventions, enabled me to determine that the Journal was not, in fact, a peer reviewed medical journal, but instead a marketing publication for MSD[A]."

He also stated that four of the 21 articles featured in the first issue he reviewed referred to Fosamax. In the second issue, nine of the 29 articles related to Vioxx, and another 12 to Fosamax. All of these articles presented positive conclusions regarding the MSDA

drugs. "I can understand why a pharmaceutical company would collect a number of research papers with results favourable to their products and make these available to doctors," Jelinek said at the trial. "This is straightforward marketing."

Jelinek also pointed out several "review" articles that only cited one or two references. He described one of these articles as "simply a summary of an already published article," and noted that they were authored by "B&J Editorial."

"It appears that 'B&J' (presumably *Bone and Joint*) refers to the Journal, and B&J editorial presumably to the publishers or owners as there is no editor of the journal," Jelinek said in his testimony. "This is a subtle attribution, and many readers may not realise that the paper was written by the owners or publishers of the journal, presuming that is who would write under the heading of 'editorial'."

Lurie, in examining two of the issues for *The Scientist*, agreed that one particularly strange element of the *Australasian Journal of Bone and Joint Medicine* is that it contains "review" articles that cite just one or two references. "I've never seen anything quite like this," he said. "Reviews are usually swimming in references." For example, one article on osteoporosis labeled above the title as a "meta-analysis" cites two references - one itself a meta-analysis. "To the jaundiced eye, [the journal] might be detected for what it is: marketing," he said. "Many doctors would fail to identify that and might be influenced by what they read."

Lurie noted that the *Australasian Journal of Bone and Joint Medicine* is akin to other publishing strategies employed by drug companies; paying for supplements to existing journals or publishing compilations of original research articles that tend to lack scientific rigor (so-called "throwaways"). "It's kissing cousin to two other tricks that the [drug] companies pull."

In response to several questions about the publication posed by *The Scientist*, an MSDA spokesperson wrote in an email: "MSDA understood that Elsevier envisaged the complimentary publication would draw on the vast resources of Elsevier, publishers of many leading peer-reviewed journals including *Lancet*, *Bone*, *Joint Bone Spine* and others, to deliver novel and timely full text articles and abstracts to physicians." Many of the articles appearing in the *Australasian Journal of Bone and Joint Medicine* were in fact reprints or summaries of studies that originally appeared in other Elsevier journals.

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Posted by Bob Grant in <<http://www.the-scientist.com/blog/display/55671/>>

[Entry posted at 30th April 2009 04:27 PM GMT]

A spokesperson for Elsevier, however, told *The Scientist*, “I wish there was greater disclosure that it was a sponsored journal.” Disclosure of Merck’s funding of the journal was not mentioned anywhere in the copies of issues obtained by *The Scientist*.

Elsevier acknowledged that Merck had sponsored the publication, but did not disclose the amount the drug company paid. In a statement emailed to *The Scientist*, Elsevier said that the company “does not today consider a compilation of reprinted articles a ‘Journal.’”

“Elsevier acknowledges the concern that the journals in question didn’t have the appropriate disclosures,” the statement continued. “It is worth noting that project in question was produced 6 years ago and disclosure protocols have evolved since 2003. Elsevier’s current disclosure policies meet the rigor and requirements of the current publishing environment.”

... One of the members of *Australasian Journal of Bone and Joint Medicine*’s “Honorary Editorial Board,” Peter Brooks, a rheumatologist in Australia, said he didn’t recall who asked him to serve on the

board, but noted that he was on Merck’s Asian Pacific and international advisory boards from the mid 1990s until about 2004, as well as the advisory boards of other pharmaceutical companies, including Pfizer and Amgen. “You get involved in a whole bunch of things at this level,” Brooks said, adding that he had put his name on “a few advertorials” for pharmaceutical companies about 10 years ago.

As for the *Australasian Journal of Bone and Joint Medicine*, he said, “If it would have been put to me that [the journal] was just sort of a throwaway, then I would have said ‘no’” to serving on its editorial board. He said he was never paid for his role, adding that he “didn’t ever get [manuscripts] to review or anything like that,” while on the board, because the journal did not accept original manuscripts for review.

“Having looked at one issue, it actually had some marketing studies,” Brooks said. “It also had papers that were excerpted from other peer-reviewed journals. I don’t think it’s fair to say it was totally a marketing journal.”

## 10 Amazing Facts About Pfizer’s \$2.3B Bextra Settlement

By Jim Edwards | Sep 2, 2009

The Department of Justice made official today its \$2.3 billion settlement with **Pfizer** over its illegal marketing of **Bextra** and other drugs.

... here are 10 interesting facts about the case:

In addition to the fines, six whistleblowers will receive more than \$102 million in the recovery, the DOJ said.

“This case alone impacted more than 10,000 postal employees on workers’ compensation who were treated with these drugs,” said **Joseph Finn**, Special Agent in Charge for the Postal Service’s Office of Inspector General.

Whose brand name will be tarnished by the company pleading guilty to a crime? Not Pfizer’s. Rather, it’s “**Pharmacia & Upjohn Company**,” which will cop to felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. P&U is, of course, a Pfizer acquisition.

In what must be the dumbest act of off-label drug promotion ever, Pfizer once put out a press release touting Bextra as an effective morphine-sparing analgesic after knee surgery. Bextra was not approved for post-surgery pain.

Former sales manager **Thomas Farina**, who led a team of sales reps in Brooklyn who promoted Bextra off-label, is about one and a half months into a six-month sentence of home confinement with an electronic ankle bracelet for his role in the case.

Farina’s team was called “the Highlanders” — a reference to a movie and TV show about a cult of immortals living secretly among us who must kill or be killed. Farina signed his emails, “There can be only one,” a reference to the motto of the show.

Farina became tangled in the probe when he was caught changing the timeclock on a computer in order to back-date certain documents. Farina did this after showing his team a compliance training video informing employees that they were under investigation on Pfizer.

At one point, about 100 reps were focused on selling Bextra off-label. Their boss was **Mary Holloway**, who paid a \$75,000 fine and is currently on two years’ probation.

At the time, Pfizer’s medical directors thought Holloway’s handling of the Bextra business was “awesome.”

Pfizer first disclosed the \$2.3 billion fine on the same day it announced its merger with Wyeth and released its Q4 earnings. Most media missed the settlement because of they were focused on the merger. Pfizer also detailed the investigation in several of its quarterly SEC filings, but gave less detail in its quarterly earnings press releases, which come out before the SEC filings. Because people read the press releases first, and they tend to be similar to the SEC filings, no one noticed the settlement until BNET pointed it out on the morning of the Wyeth merger.

[Source : <http://industry.bnet.com/pharma/10004048/10-amazing-facts-about-pfizers-23b-bextra-settlement/>]

## Letter on HPV Vaccine

Date: September 29, 2009

Shri Ghulam Nabi Azad,  
Union Minister for Health and Family Welfare,  
Ministry of Health and Family Welfare,  
Nirman Bhavan, Maulana Azad Road,  
New Delhi 110 011

**Subject: Concerns around Human Papilloma Virus (HPV) vaccine**

Sir,

We, the undersigned, public health organizations, health networks, medical professionals and women's groups, write to express our concern with regard to the introduction of Human Papilloma Virus (HPV) vaccine, Gardasil, to young girls in the country.

On July 9th, 2009 under the demonstration project being implemented by the Union Ministry of Health and Family Welfare in association with Indian Council of Medical Research (ICMR), PATH International and State government, the Andhra Pradesh Minister for Health and Family welfare launched a pilot program for vaccination against cervical cancer. The three doses of HPV vaccine are to be administered to 16,000 girls between 10 and 14 years in the mandals of Bhadrachalam, Kothagudem and Thirumalayapalem in Khammam district in Andhra Pradesh. The vaccine will be administered in 3 doses at the interval of 0, 2 and 6 months.

Similarly, on August 13, 2009, the Gujarat government launched a two-year 'Demonstration Project for Cancer of the Cervix Vaccine' in three blocks of Vadodara District - Dabhoi, Kawant and Shinor - to immunize 16000 girls between 10 and 14 years with three doses of Gardasil. The Gujarat State Minister for Health and Family Welfare claimed that this demonstration project will help the Centre to examine the possibility to introduce the vaccination project across the country.

We are alarmed by this decision by State and Union Governments and we oppose the introduction of the vaccine on the following grounds:

### **Efficacy of the Vaccine**

- Information about the efficacy of Gardasil remains uncertain. The current HPV vaccine prevents infections, resulting from just two of the HPV subtypes (16 and 18)

that may cause cervical cancer, and also HPV subtypes 6 and 11 that can lead to genital warts. The subtypes 16 and 18 account for 70% of the cases of invasive cervical cancer globally.

But there are over 100 HPV subtypes and one of the main concerns is that if the vaccine was to work and indeed 'block' subtypes 16 and 18 then the other carcinogenic subtypes may become dominant.

- There is lack of conclusive data regarding the length of immunologic protection the vaccine confers against HPV subtypes 16 and 18. Studies so far have followed up with the vaccinated 'subjects' for 5 years and have shown that it offers protection only for 5 years. Thus it is not clear whether protection lasts longer than this time period. Since the long term efficacy and protection by the vaccine is unknown we can not claim that even 60-70% protection will be achieved. Moreover, since the highest incidence of cancer of the cervix in India is in women above 35 years of age, it is not clear whether a 3-dose schedule will provide long lasting immunity or if boosters will be required.

- If booster doses are needed, and it is not known how frequently, what will be the impact of the booster doses on the safety of the vaccine? Moreover, booster doses would certainly increase the cost of vaccination per woman as many times as the booster would be given.

- HPV vaccination is not a substitute for cervical cancer screening. All women, including those who are vaccinated, should continue to have regular Pap test screening and also HPV test as the preventive effect of the vaccine on cervical cancer has not yet been demonstrated.

- HPV Infection rarely leads to progression to cancer. Only a minority of infections persist for several years, and only about 10% of low-grade lesions progress to a higher grade. About 5% of high-grade lesions progress to invasive cancer.

### **Side-Effects**

1. The Federal Vaccine Adverse Event Reporting System (VAERS) in the US has logged a total of 12,424 of adverse events following HPV vaccination, according to the US Centre for Disease Control and Prevention. Between June 2006 through December 2008, more than 23 million doses were administered in the US alone. Of these, 772 were reports of serious events (6.2 % of the reports) including 32 deaths and the remaining 11652 (93.2%) were classified as non-serious.

The most common events reported were, Syncope, Local reactions at the site of immunization (pain and redness),

Dizziness, Nausea and Headache. Venous thromboembolic events, autoimmune disorders, Guillian Barre Syndrome, motor neuron disease, anaphylaxis, transverse myelitis, pancreatitis and death were amongst the serious adverse events reported. Amongst reports of autoimmune disorders to the VAERS system, 88% were associated with the HPV vaccine alone.

2. In Australia, the rate of anaphylaxis shock after Gardasil injection has been reported as 2.6 per 100,000 doses.

3. The official Gardasil website itself clearly mentions, "GARDASIL may not fully protect everyone, and does not prevent all types of cervical cancer, so it's important to continue routine cervical cancer screenings. GARDASIL does not treat cervical cancer or genital warts". The side effects listed include, pain, swelling, itching, bruising, and redness at the injection site, headache, fever, nausea, dizziness, vomiting, and fainting. Sometimes fainting is accompanied by falling with injury, as well as shaking or stiffening and other seizure-like activity.

4. The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) in their recommendations mentions that, the vaccine is contraindicated in those with history of previous hypersensitivity to any vaccine and should be avoided during pregnancy.

Moreover, while this data is mostly sourced from US based research and trials conducted in other countries, the adverse reactions in the Indian context are unknown. Thus, the approval of a vaccine that claims to prevent a sexually acquired infection that sometimes causes cancer of cervix, and that too only if vaccination is completed before exposure, is highly questionable.

#### Cost Effectiveness

1. The current cost of the vaccine is Rs. 3000/- per dose (approximately USD 60) per dose. So for every 10-year old girl, 3 shots initially, and 8 shots (assuming the need for a booster shot every 5 years) over the next 40 years [until she becomes 50]. This would amount to Rs. 33,000/- by present estimate. Can the Ministry afford an injection that costs Rs 9,000 for every woman in a country where we cannot give DPT (costing Rs. 3) to 50% of children of the country?

2. In a recent study from India, published in the New England Journal of Medicine (NEJM), 31,488 women (30 to 59 years old), were followed up over 8 years with no intervention (in the control group). 64 died of cervical cancer. The absolute risk of cervical cancer was 2.5/10,000/year. If we optimistically assume that every case of cervical cancer will be prevented by the vaccine, the absolute risk reduction is 0.00025 and the numbers of women needed to be

vaccinated to prevent one death is 4000. So the cost per life saved is Rs. 75 million.

3. A cost effectiveness study published in the NEJM in 2008 concluded that if the vaccine provided protection against HPV for only ten years, then vaccinating preadolescent girls would only provide a "2% marginal improvement in the reduction in the risk of cervical cancer as compared with screening alone." Moreover, it would cost \$144,100 for each healthy year of Life Saved, instead of the \$ 43,600 estimated for a vaccine providing life-long protection. Most researchers believe that even in the US, interventions costing more than \$50,000 per quality-adjusted year of life (QALY) saved, are not cost-effective, while others use a higher ceiling of \$100,000.

4. Looking at our public health system, no government in India can afford this expense. The average per capita annual income in India in 2009 is Rs.38 000 and, while the current per capita annual public health expenditure in India is about USD 10.

5. Given this totally unfavorable cost-efficacy in the Indian context, we see no chance that this vaccine can be included in the Indian National Immunization program. Hence conducting such a demonstration project in India would mean using Indian people as mere guinea pigs.

#### Aggressive Marketing

- Merck Sharp & Dohme (MSD) India Pharmaceuticals Private Limited, which is the Indian subsidiary of Merck & Co. Inc., the manufacturers of Gardasil, has also recently started a Cervical Cancer Prevention Program that informs Indian Women to help protect them against cervical cancer and related HPV infections. The program's tagline, "What will I do to save my daughter from cervical cancer? - Everything that I can!" is uncannily similar to Gardasil's tag line - "We chose to help protect ourselves against cervical cancer and other HPV infections: Now the choice is yours." Similarly, PATH, that supported the formative research for the HPV vaccine Gardasil in India, highlights the demand for the vaccine through quotes like "Our granddaughters' generation should be a generation without cancer." In this way a false signal is sent out that claims that the vaccine can prevent cancer although Gardasil prevents cancer of cervix associated with just 2 types of HPV.

- These advertisements induce fear with regard to HPV and cervical cancer and thus create an inaccurate impression of a "public health emergency".

- A 15-second commercial on Indian television urges parents to get their young girls inoculated with the vaccine Gardasil to protect against cervical cancer, Advertising prescription drugs on television is unethical enough, but using fear and

inaccurate claims to sell them is worse.

**We urge that:**

1. The Government should review the decision to conduct a demonstration project of HPV vaccine in the mass immunization programs in the absence of sufficient long-term evidence of its effectiveness complete and unbiased information, and without any prior public debate. The huge cost incurred in this mass immunisation even if the current price of the vaccine is reduced substantially should be seriously considered.

2. The state initiates comprehensive access to reproductive and sexual health programs / services for adolescents, women and men.

- The focus should be on increasing access to preventive health care services such as pap screenings, visual screening of the cervix with acetic acid (VIA) and Visual Inspection of cervix with Lugol's Iodine (VILI).

- Screening programs should be augmented with newer technologies such as the use of liquid based pap testing in women, who have abnormal pap test results.

- Provide population-based outreach pap screening services for Cancer of cervix, particularly for women from the tribal and rural areas.

- Undertake special measures towards promoting awareness among women and community so that they come forward without any inhibitions to undergo such screening tests.

- Instead of an expensive vaccination strategy, monitoring measures should be made available to detect Cervical Cancer at a very early stage.

Treatment of all women with the diagnosis of Cervical Cancer in situ is likely to cost the public health care system much less, than buying the vaccine.

- Public health services be made available to all, with special emphasis on women's health, by filling in the vacancies of the gynaecologists and para- medical workers, by providing basic screening facilities.

3. As mentioned earlier the current vaccines target only 2 oncogenic types:

HPV-16 and HPV-18. Secondly, the relationship between infection at a young age and development of cancer 20-40 years later is not known. So how should a parent, physician, politician, or anyone else decide whether it is a good thing to give young girls the vaccine that partly prevents infection caused by a sexually transmitted disease that in a few cases will cause cancer 20-40 years from now?

4. It is learnt that the Union Health Ministry has signed

a memorandum of understanding (MoU) with the US Company Merck, covering the entire gamut of the trial and the launch in the country. As per the MoU, the pre introductory trial will be carried out at several centres in the country, including Institute of Cytology and Preventive Oncology (ICPO) ([www.icpo.org.in](http://www.icpo.org.in)) for a duration of 6 months. What is the status of these trials and if they have been completed, what are the results/findings?

5. Financial support from industry or from an international organization should not be the criteria to introduce any vaccine in pilot phase or in universal immunization program.

6. The role of PATH is not very clear. It appears that PATH is trying to find ways of influencing policy makers through its formative research.

**Our Demands**

*1. All trials and studies to be immediately brought to a halt till in an open forum questions relating to safety, efficacy and cost effectiveness of the planned intervention can be justified.*

*2. To place before the public: - All the documents pertaining to the agreement with vaccine manufacturers and all other bodies regarding the government's plan to introduce the HPV vaccine. The list of all trials planned, proposed, approved and completed, the agencies involved, the donors involved and proposed locations and all the results of the pilot phase trials as well as clinical trials.*

*- The status of approval accorded to the vaccine and the data which has been submitted by the company (vaccine manufacturer) for the purpose.*

*- The estimated total cost, as per the government's assessment, of purchase of the vaccine and its administration.*

*3. A vaccine policy to be formulated based on public health needs.*

*4. Open up the issue for public debate and the opinion of health groups, women's groups and other civil society members to be actively sought.*

*We urge you to consider these demands very seriously and act upon this matter in the larger interest of the health and well-being of the women and adolescent girls of this country. We ask you to provide the information and documents that we have requested within a month of the receipt of this letter.*

Yours Sincerely,

Signed by: Sama, New Delhi; Medico Friend Circle: All India Drug Action Network; and over 60 civil society organisations and individuals across India.

## Annual Meet

### Theme

“Mapping out the Current Situation of Health Care in India” to have clarity on the gaps and barriers to Universal Access to Health Care.

### Dates

January 8-10, 2010.

### Venue

Yatri Nivas, Sewagram

For more details, see pages 47-49.

### Subscription Rates

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