

*Health Law*

**GOVERNMENT PUBLIC HEALTH POLICY: THREE  
CAUTIONARY TALES FROM MALAYSIA, SOUTH AFRICA AND  
THE UNITED STATES**

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**Abstract:** Three authors describe problematic scenarios of health policy in their respective countries. These examples illustrate the role of government influences in determining resource allocation, legislation, health provision and health outcomes in very different situations. These outcomes are affected not only by attitudes to public health, but also by the legal systems in the countries which are the subjects of this study. The authors draw conclusions about the use and abuse of public health regulation.

**Keywords:** Malaysia; South Africa; United States; public health policy; health regulation; AIDS legislation; health care financing.

**INTRODUCTION**

Governments around the globe share common mandates to be engaged in promoting and protecting public health through a broad and complex array of efforts. The law lies at the core of public health policy formulation and implementation, and is rightfully seen as a tool to promote effective regulatory strategies and interventions. A common focus in considering the intersections of law and public health concerns how various legal processes, legislative, administrative and judicial, can be harnessed to facilitate effective government responses. It is not enough, however, to cast the law only as a tool of public health, but the law must also be a mechanism to check abuses of power on the part of regulators and promote public inclusion and responsible decision making. This article presents three portraits from Malaysia, South Africa and the United States respectively, illustrating how legally established government activities in

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public health may be compromised by biases and uncertainties on the part of regulators themselves. In the case of Malaysia the discussion of public health policy concerns how legally sanctioned public participation in the development of key aspects of the country's national health policies, and financing have been minimized in practice. In the South African context, the discussion centers on the issue of public health resource allocation which is underpinned by changes in constitutional law, recognizing access to health care as a fundamental right that requires public actors to make requisite allocation decisions on the basis of reliable scientific knowledge. The government of South Africa has adopted a controversial view of how HIV/AIDS should be treated based on alleged scientific opinion that has pitted government authorities against medical experts, the international public health community, AIDS activists and the public. The behavior of the South African government demonstrates how the misuse of science can circumvent fundamental tenants of law and run counter to a decision of the country's Constitutional Court. The American discussion focuses on issues of risk in public health regulation, highlighting the difficult task of deciphering what type of scientific understandings should drive the actions of government policy makers, including the courts. The U.S. discussion argues for the adoption of more flexible regulatory approaches to public health that would enable regulators to better address complex public health matters.

## **(I) Public participation and its role in the public health setting in Malaysia**

### ***(a) Introduction***

The WHO Constitution states that its mission is “the attainment by all peoples of the highest possible level of health”. In striving to realize this mission it considers as its major task, that of combating disease, particularly key infectious diseases such as SARS and AIDS. Programmes to combat such diseases include the developing and distributing of vaccines.<sup>1</sup> Malaysia being a member country of the WHO Western Pacific Region naturally echoes this mission. The question which arises is - how might this mission be achieved? (Or a skeptic might well ask a further question or two - what constitutes a 'reasonable level of health' and is this mission realistically attainable?)

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1. [http://en.wikipedia.org/wiki/World\\_Health\\_Organization](http://en.wikipedia.org/wiki/World_Health_Organization) (22 March 2006).

*(i) Definitions*

The Constitution of WHO defines health as a state of complete physical, mental and social well-being, and not as consisting only of the absence of disease or infirmity or mental retardation.<sup>2</sup> As far back as 1920, Winslow (a Professor of Public Health at Yale University) defined public health as 'the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene; the organization of medical and nursing service for the early diagnosis and treatment of disease; and the development of the social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health. In short, public health refers to the health or well-being of the whole community.

Public health therefore addresses the health of the population as a whole rather than medical health care, which focuses on treatment of the individual ailment.<sup>3</sup> It is therefore re-stating the obvious that responsibility and provision towards public health may be divided three-ways: the government, the healthcare providers and the public.

*(b) The role of the government and the public*

In the World Health Report 2000 published by WHO, it was unsurprisingly identified that the ultimate responsibility for the overall performance of a country's health system must always lie with the government. In this respect governments should be the stewards of the national resources. Stewardship in health is said to be the very essence of good government. This translates into the government establishing the best and fairest health system possible. This in turn, further translates into the Ministry of Health taking on a large part of stewardship of the health system.

Health policy and strategies should extend beyond state-funded services and activities, covering also, the private provision of services and private financing. Only then can health systems as a whole be oriented towards achieving goals

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2. *Ibid.*

3. [www.phdatastandards.info/knowresources/tutorials/glossary.htm](http://www.phdatastandards.info/knowresources/tutorials/glossary.htm).

which are in the public interest. The vision of the country's health policy must be defined, as does the direction of such policy.<sup>4</sup>

In ensuring that a country's national health policy is reflective of the health needs of that country's population, an integral component in the formulation of such policy is the identification of the population's health needs. This of course requires involvement of the public, be it in the form of identification of their specific health needs, as well as challenges and strengths, within the healthcare system in relation to those needs. (A question which might be posed here is whether involvement must be direct or whether indirect involvement is sufficient; meaning the identification of health needs be made through the collection of available data of illnesses and other health issues or threats in the country).

In any case, it goes without saying that greater public participation would result in more representative policy-making and would translate into, at least theoretically, an enhanced quality of health strategies implementation.<sup>5</sup>

***(c) National Health Policy and public participation in Malaysia***

The National Health Policy is currently in draft form and is due to be finalized this year (2006). At the outset it might be said that the primary goal is to achieve the Vision for Health which reads as follows:

To develop a nation of healthy individuals, families and communities, through a health system that is equitable, affordable, efficient, technologically appropriate, environmentally adaptable and consumer-friendly, with emphasis on quality, innovation, health promotion and respect for human dignity, and which promotes individual responsibility and *community participation* towards an enhanced quality of life. (emphasis added).

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4. see the preamble to Chapter Six, "How is the Public Interest Protected?", World Health Report 2000.

5. In Canada for instance, the public was to be consulted on new health protection laws in the wake of fears concerning the spread of SARS, mad cow disease and West Nile virus. The draft proposal was then posted on the website and in the end, all recommendations would lead to the writing of a draft bill. The bill would also give the federal government more authority to take action to prevent the spread of communicable diseases. See [http://groups.google.com.my/group/alt.support.breast-implant/browse\\_thread/thread/fd2a3da57e549f34/e0796ae431755b26?lnk=st&q=public+health&rnum=4&hl=en#e0796ae431755b26](http://groups.google.com.my/group/alt.support.breast-implant/browse_thread/thread/fd2a3da57e549f34/e0796ae431755b26?lnk=st&q=public+health&rnum=4&hl=en#e0796ae431755b26) (23 March 2006).

Public participation is thus an integral component and requirement within the Vision for Health. The National Health Policy comprises nineteen health policies with the respective strategies of how the policies are to be implemented.<sup>6</sup> The identification of health issues which formed the basis for the formulation of the Policy and strategies were achieved through various consultative meetings of the relevant agencies and technical working groups.

*(i) Selected Health Policies and the element of public participation*

In addition, there are several existing health policies which directly refer to public participation within the policy statement itself. Two examples would be:

- (a) In the National Adolescent Health Policy, the active participation of adolescents in health promotion and preventive activities is a strategy employed to empower them with appropriate knowledge so that they are able to practice healthy behaviors.
- (b) In the National Mental Health Policy, it is stated that the general community would be involved in the planning, organization as well as evaluation of community-based activities. This community involvement would be used to determine rights and the appropriateness or suitability of the activities themselves. The 'community' includes the family members of
- (c) Those suffering from mental illness, who will be directly involved with the introduction and implementation of the community-based activities.

The importance of public participation therefore, is duly recognized at the policy level.

*(d) Public participation in practice?*

In practice however, experience has shown that hitherto, public participation has its own meaning and is rather limited within the Malaysian context. (The

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6. They are : equity, quality, primary healthcare, health promotion, disease control, medical services, urban health, environmental health, oral health, traditional/complementary medicine, pharmaceutical services and industries, human resource in health, health care financing, health information system, health care technology, telehealth, research, role of Ministry of health and intersectoral collaboration.

examples below primarily revolve around environmental issues).

(i) *Case study 1*

One case study relates to development plans which are statutorily governed.<sup>7</sup> As land matters fall under the State Government's jurisdiction, so it follows that planning and development is carried out by local planning authorities who act on the directions of ultimately, the State Government. Public participation is provided for in development plans in two different settings. The first is where the local planning authority prepares a draft structure plan, in pursuance of its duty under the relevant statute. In this structure plan, the overall planning and development of that particular township over a specified period would be laid out. The relevant statute requires that public input be incorporated before the finalization of the structure plan.

However, according to A Harding and A Sharom in *Access to Environmental Justice in Malaysia (Kuala Lumpur)*,<sup>8</sup>

...the practice of this requirement, as illustrated by the experience of the Petaling Jaya (PJ) Residents' Association (in 1995) during the PJ draft structure plan public participation process, leaves much to be desired. The first shortcoming is the lack of efficient publicity to the public. Advertisements are placed in newspapers, but these are small and easily missed.<sup>9</sup> There is also a shortage of time given to the public to prepare their objections and queries. In the PJ example, there were only 30 days to prepare. Furthermore, there was very little useful information about the plan that was provided for public scrutiny before a public meeting with the State Government and the local council. Thus it was difficult to protest constructively and in an informed manner.

Although the TCPA requires public consultation, it says nothing about the extent to which the views of the public should be considered. It would appear that,

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7. Town and Country Planning Act 1976.

8. Chapter 5 of Andrew Harding (ed), *Access to Environmental Justice: A Comparative Survey* (London-Leiden Series on Law, Governance and Development, Martinus Nijhoff, Leiden, 2006, forthcoming).

9. Under the Town and Country Planning Act, (TCPA) the local planning authority is required to advertise in three issues of two national daily newspapers, of which one must be in the national language, Malay.

although there is a right to object to a plan, there is no guarantee that input from the public will be absorbed into the final plan.

The second setting referred to above, in which an avenue is provided for public participation, is the right of adjoining neighbors to make known their complaints over any development projects which might affect them. This applies in situations where say, a shopping centre is to be built near a housing area. The applicable procedure is for affected households to be informed of the proposed development/construction. Notification used to be by way of post. However, the relevant statute<sup>10</sup> was amended and now the local authority need only advertise its intentions in the press. However practice has shown that the tendency is to print the lot number and the district where the house or affected houses are situated, as opposed to the exact addresses of the potentially affected houses. This practice is unsatisfactory since a majority of homeowners are more often than not, unable to instantly identify that they might be those who might be affected.

The relevant statute had in fact done away with the need for consultation. Fortunately, this was not recognized by the courts, which held that the duty to inform remained.<sup>11</sup> This case is authority for the view that “material considerations” which the Mayor must take into account under the particular statutory provision<sup>12</sup> include objections to the proposed development. However, according to another statute<sup>13</sup> the Mayor's decisions regarding planning in Kuala Lumpur are entirely discretionary. There have been no cases as yet of judicial review of the limits of this discretion.

A more recent example of an almost identical discrepancy between legal requirements and practice was highlighted in the national newspapers on 3 April 2006. Interestingly, it is the same municipal area and local council as the case study above.

In accordance with the law, namely the Town and Country Planning Act 1976, the local council is required to consult residents before any changes are to be

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10. Federal Territory (Planning) Act 1983 (FTPA).

11. *Datin Azizah bte Abdul Ghani v Dewan Bandaraya Kuala Lumpur and others* [1992] 2 MLJ 393.

12. Section 22 FTPA.

13. The Federal Capital Act 1960 (Act 90) (Revised 1977).

made to its local draft plan. This consultation session did take place. The Town Planning department officer provided a brief explanation of the twenty-one changes which were being planned. One proposed change was highlighted - the conversion of a car park into a commercial area. An irate resident questioned why the matter seems to have been pre-decided before the consultation process. He pointed out that this project had already been launched by the Chief Minister of the State, with corresponding banners on roads within the area of the local council's jurisdiction, bearing the state government's and local council's crest. He questioned how the council could approve and advertise a project that was just then being tabled for discussion with residents. He also suggested that in proposing a change in status such as this, the local council should provide an impact assessment on traffic for otherwise it would be tantamount to ad hoc planning. The President of the local council responded by saying that the proceedings were a briefing and not a dialogue! He further stressed that although residents may give their comments and views on the proposed plans, but they should not expect immediate responses and reactions to their comments. The session ended with the residents requesting for further briefing sessions, including accusations of impropriety on the part of the local council.<sup>14</sup>

(ii) *Case Study 2*

A second case study revolves around the proposed National Health Financing Scheme. One of the nineteen policies in the draft of the National Health Policy relates to health care financing.

The policy in relation to this is:

the national health financing system shall be affordable and provide universal coverage for comprehensive health care with greater equity and accessibility.

The national health care financing is a tool for the optimization of financial resources for health care. A successful financing scheme will enhance accessibility, achieve equity, improve efficiency and quality and above all integrate and regulate the health care providers from both the public and private sectors. The rising annual population, increase in life expectancy and consumer expectations in quality of healthcare, have all led to a corresponding increased burden on the federal government in financing the public sector health expenditure. The emergence of private health insurance has caused further

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14. *The Star*, (Star Metro) 3 April 2006, pp 1, 3, 4.



inequity in access to healthcare. All these challenges and more were (and are) evidence of the need for a reform of the health financing system. This need has been identified for as long as about 20 years ago. Following that, studies and consultations towards a reform of the system were made. On 19-22 June 2002 a Healthcare Financing Scheme Conference was held, in which more detailed proposals in relation to this proposed changes were highlighted and discussed. In December 2005 it was reported that this Scheme would be implemented in 2006. Since then, a total of about 82 non-governmental organizations have grouped together under the name, Coalition Against Health Care Privatisation Malaysia. According to the Coalition's chairman, who has together with some members met with the Minister; the Ministry of Health has not outlined the mechanics of the Scheme. However, everyone is expected to make a contribution, the exceptions being - civil servants, pensioners, the disabled, the hardcore poor and the unemployed.

The proposed Scheme comprises seven main components:<sup>15</sup>

- i) National Health Fund - this is a Fund which will disburse payments for illnesses listed under the 'Essential Health Benefit Packages'.
- ii) Mandatory monthly contributions - every wage earner is required to make a contribution, except those who are exempted from doing so.
- iii) Essential Health Benefit Packages - there are no details with regards to the illnesses covered under this package.
- iv) Restructured government hospitals and clinics - the end objective is to improve efficiency, affordability and accessibility, but there are no details as yet.
- v) Private sector healthcare - the Fund will also pay for visits to private general practitioners but the ministry has not decided on whether payments will be on a fee-for-service or on a capitation basis.
- vi) Private insurance for extra coverage - those able to afford, may buy additional private insurance packages for treatment of conditions not included in the Essential Health Benefit Package and to fully cover payment of conditions only partially covered by the Fund.

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15. See *The Sun*, Monday 12 December 2005; *The New Straits Times*, Monday 12 December 2005 p 26 and *Aliran* (monthly magazine) 2005:Vol 26(1) pp 4 -17.

- vii) The National Health Financing Authority - this is a new body set up to oversee the overall administration and evaluation of the new health care system. However the constitution of this body is as yet undecided.

Foreign consultants have been appointed to look into the details of the Scheme, such as the quantum, criteria and ceiling of contributions, the collection mechanism, the essential basic health packages and the payment mechanism for the clinics and hospitals.

The Coalition has requested that full and prior consultation be made with the citizens, the unions, consumer groups and health personnel. A consultation would require the Government to scrutinize the proposals made by the people and provide responses as to why (if at all) any proposal might be rejected. There is fear that open consultation and transparency might not be implemented in the process as when the Economic Planning Unit (EPU) was asked in December 2005 about the Terms of Reference for the appointment of the consultant, the EPU responded by saying that the terms of reference were confidential.

It would not be incorrect to say that many quarters are anxious about the details of the Scheme. Collectively and overall, people are anxious about whether they can 'afford' better health care under this new Scheme. For instance The Malaysian Medical Association's initial plan was towards a community-rated insurance scheme to cover all Malaysians, rich or poor. This was based on the concept of universal access of health care to all. However, this concept will not turn into reality as the proposed Scheme does not include the (minimum) 1 million civil servants in the country. Among the many issues raised is that because this would mean that those who are subject to the Scheme must contribute more, the question is how much more? What are the benefits? What does better access mean? It is in view of these and other issues which all need clarification, that the Ministry and government has been urged to have an open and public dialogue and discussion.<sup>16</sup>

It was reported that the consultants would begin work in February 2006.<sup>17</sup> It is also clear to the Ministry of Health that they are expected to have an open consultation with the citizens. All that is left now is to wait - and see whether public participation will become a reality on this national issue.

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16. See article by Dr David KL Quek, Malaysian Medical Association, May 2005 at p 7.

17. see *Aliran* (2005) Vol 26(1) p 14.

***(e) Is public participation a necessarily important element (in public health issues)?***

Public participation is not merely about making one's views known. It is also not merely about complying with the process, legal or policy-wise. Public participation is linked to the concept of accountability to self, of self-determination. It is about awareness and belief that one has a right to put one's views across, and to have that view considered, provided it does not conflict with other interests. In a democratic system of governance where the citizens (usually) demand and exercise their self-determination over specified issues, it falls back on the citizens of that society to insist on their right to participate in issues of public interest. The government may wish to deny or limit public participation for various reasons, but it must be understood by the people that the denial or limitations can be set by the citizens themselves.

***(f) Conclusion***

It is obvious that there seems to be a gap between what the law provides for and actual practice. One might ask why is this so? Is it because practice is slower to adapt to what might be described as idealistic (but correct and proper) legal requirements, or is it because public participation is simply not demanded by the people? It probably is a combination of both factors. There are however other factors at play. One significant factor is culture. The Malaysian culture is such that we are deferential to authority. The government is generally a trusted trustee.

The way forward depends on the people, really. After all, if indeed it is true that healthcare should be acceptable and affordable to all citizens in any country, then surely it must be equally true that the citizens must be able to specify what they deem acceptable, and what they can, or cannot, afford, clearly and openly.

**(II) Perspective on Allocation of resources for the Treatment of HIV/AIDS in South Africa**

***(a) Introduction***

This paper addresses the question to what extent public opinion or scientific expert opinion should be a decisive factor for resource allocation in the public health system in South Africa with specific reference to the allocation of resources for the treatment of HIV/AIDS. Healthcare legislation in South Africa has been overhauled in the wake of the Constitution which guarantees

access to health care to everyone.<sup>18</sup> The question to be assessed is who should dictate what the content and/or quality of the right to access to health care in the public health system should be? This question is explored in context of South Africa which has, with the rest of Sub-Saharan Africa, the most infected populations in the world. Thus far, in an attempt to combat the treatment of HIV/AIDS and curtailing the infection rate thereof, the South African government (and more specifically the South African Minister of Health) has largely been in denial about the causes/treatment/prevention of the disease, as much support for this stance is based on the expert opinion of the controversial vitamin entrepreneur, Dr Matthias Rath.<sup>19</sup> This opinion on which reliance has been placed has been labeled as state-sponsored pseudo-science<sup>20</sup> and is in stark contrast to public opinion, non-governmental organizations, civil society groups and activists such as the Treatment Action Campaign (TAC)<sup>21</sup>, and the scientific evidence of eminent virologists as well as the judgments of the Constitutional Court.<sup>22</sup> The stance taken by the Ministry of Health has serious implications for the public health system in context of HIV/AIDS treatment/prevention in South Africa. This paper will briefly explore and assess these implications/conflicts/tensions in context of resource allocation.

***(b) South African Legal Framework for Resource Allocation in Public Health***

The South African Constitution as the supreme law of the land, dictates in section 27 that everyone has the right to access to health care services; that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of these rights; and that no

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18. Section 27 of Constitution of the Republic of South Africa, Acto 108 or 1996.

19. For the website of the Rath Foundation see <http://www.Dr-Rath-Foundation.org>.

20. Compare Geffen N "Echoes of Lysenko: State-Sponsored Pseudo-Science in South Africa" CSSR Working Paper No 149, Centre for Social Science Research - University of Cape Town (2006), obtainable from their website at <http://www.cssr.uct.ac.za/index.html>. According to this publication about 5 million South African are infected with HIV and over one million have already died of AIDS.

21. For a full discussion of the salient issues see the website of the Treatment Action Campaign <http://www.tac.org.za>.

22. *Hoffmann v South African Airways* 2001 (1) SA 1 (CC); *Treatment Action Campaign v Minister of Health* 2002 (5) SA 721 (CC).

one may be refused emergency medical treatment. It should be noted that these rights are not absolute and may be limited in terms of section 36 of the Constitution if such a limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.<sup>23</sup> The Constitutional Court has limited the right to access to health care services for economic reasons<sup>24</sup>, but has also ordered the Ministry of Health to roll out anti-retroviral treatment specifically to combat mother-to-child HIV- transmission.<sup>25</sup> Despite such an order, a recent United Nations report has showed that at least 85% of South Africans in need of antiretroviral drugs were not yet receiving them by mid-2005. It is clear, based on the Constitution that the State (and more in particular the Ministry of Health) is primarily responsible for resource allocation in public health. Does this mean that the Ministry of Health guarantees a boundless provision to medical services? Clearly not. Access to medical services must be dictated by what is effective, reasonable and necessary. This is the issue: when it comes to resource allocation, whose opinion dictates the content/quality of health care services in order to be *effective, reasonable and necessary*? It has also been stated that the most important criterion is the clinical need of patients, but this must be considered in relation to the severity of the disease or condition, the benefits and the costs of existing/proposed treatment.<sup>26</sup> This consideration particularly rings true in the context of the treatment of patient suffering from HIV/AIDS.

Significant is the fact that the Constitutional Court in the case of *Hoffmann v South African Airways*<sup>27</sup> has accepted the clinical manifestations of HIV/AIDS based on the medical evidence and opinion of an eminent virologist and other medical experts. The Court accepted that the HIV virus causes AIDS and accepted the identifiable stages in the progression of untreated HIV infection namely: the acute stage; the asymptomatic immuno-competent stage; the asymptomatic immuno-suppressed stage; and the full blown AIDS stage.<sup>28</sup>

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23. Act 108 of 1996.

24. *Soobramooney v Minister of Health KwaZulu-Natal* 1998 (1) SA 765 (CC).

25. *Treatment Action Campaign v Minister of Health*, *supra*.

26. Compare the discussion by McLean S & Mason JK *Legal and Ethical Aspects of Health Care* (2003) 15-27; See also in general Currie I & De Waal J *The Bill of Rights Handbook* (2005) 591-595 in context of a discussion of section 27 of the South African Constitution.

27. *Supra* paragraphs [11] - [15].

28. *Hoffmann v South African Airways*, *supra* paragraph [11].

If it is accepted that reliance on scientific expert opinion plays a pivotal role in the allocation of resources, then an assessment should be made of how scientific medical expert evidence is to be assessed. It is submitted that the Ministry of Health or any other public authority should, when an assessment is to be made of the allocation of resources in public health, apply their minds and make an informed decision based on defensible scientific expert opinion. The South African Supreme Court of Appeal<sup>29</sup> has on occasion made a ruling on the assessment of expert medical testimony. Although the assessment was made primarily in context of the proof of medical negligence, it is submitted that the same general principles enunciated by the Court, could be adopted in the assessment of scientific medical expert opinion with reference to resource allocation in public health. The Court formulated some boundaries for expert evidence which could also be utilized to determine the nature and scope of resource allocation in context of the treatment or protection of HIV/AIDS in South Africa. These rules can be summarized as follows:

- Essentially in cases where disputes cannot be resolved extra-judicially, the matter could be resolved by a court to determine the basis of the various and often conflicting expert opinions presented;<sup>30</sup>
- As a rule, that determination will not involve considerations of credibility but rather the examination of the opinions and the analysis of their essential reasoning (inclusive of scientific methods and research);
- The determination should be made whether and to what extent the opinions advanced are founded on logical reasoning, in other words a court must be satisfied that the expert had considered comparative risks and benefits and has reached a defensible conclusion. If a body

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29. *Michael v Linksfeld Park Clinic (Pty) Ltd* 2001 (3) SA 1188 (SCA); See also Carstens PA "Setting the Boundaries for Expert Evidence in Support or Defence of Medical Negligence" 2002 *Journal for Contemporary Roman Dutch Law* 430.

30. Compare McLean S & Mason JK 17 who in context quote the British case of *R v Central Birmingham Health Authority, ex parte Walker* (1987) 3 BMLR 32 where it was stated "It is not for any court to substitute its own judgment for the judgment of those who are responsible for the allocation of resources. This court would only intervene where it was satisfied that there was a prima facie case, not only of failing to allocate resources in the way in which others would think that resources should be allocated, but of failure to allocate resources to an extent which was unreasonable".

of professional opinion overlooks an obvious risk which could have been guarded against, it will not be reasonable, even if almost universally held;

- The assessment of medical risks and benefits is a matter of clinical judgment which a court would not normally be able to make without expert evidence, and it would be wrong to decide a case by simple preference where there are conflicting views on either side, both capable of logical support;
- Only where expert opinion cannot be logically supported at all will it fail to provide the benchmark ;
- Expert scientific witnesses tend to assess the likelihood in terms of scientific certainty and not in terms of where the balance of probabilities lies on a review of the whole of the evidence.

***(c) The South African Government's Apparent Support for AIDS-Denialists***

The response of the South African government to the HIV epidemic has been controversial with specific reference to the views held and expressed by the President and the Minister of Health. These views are well-documented and has led to the inference that they have, since 1997, courted pseudo-scientific theories about HIV/AIDS.<sup>31</sup> The stance by the Ministry of Health is based on and influenced by the expert scientific opinion of Dr Matthias Rath whose expert opinion is indicative that the HIV/AIDS epidemic can be controlled naturally by way of, amongst others, a vitamin enriched diet and in fact that micronutrients can reverse the course of AIDS. This is echoed by the Minister of Health who propagates the use of olive oil, beetroot, garlic, the African potato<sup>32</sup> and lemons as essential ingredients for such a diet. Dr Rath also strongly holds the opinion that the exporting of patented antiretroviral (ARV) drugs to people affected with HIV/AIDS, has become a multi-million dollar business on which the pharmaceutical industry depends and that the international

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31. As stated and documented by Geffen 2006 CSSR Working Paper supra 3 ff.

32. Based on the opinion of Tine Van der Maas, a former nurse, without formal training in scientific method, who provides her patients with a concoction containing very large amounts of raw garlic as well as a product called 'Africa's Solution' which contains hypoxis, an extract from African potato.

drug cartel is abusing/manipulating the United Nations.<sup>33</sup> This stance has been slated by national and international critics and has prompted activists, such as the TAC to accuse the government of state-sponsored pseudo-science being the major factor hampering the rollout of highly active antiretroviral treatment (HAART) for HIV/AIDS in the public health sector. They argue that this support will have many policy implications and will result in many deaths. This response by the TAC prompted Dr Rath to attack the TAC in the public media. This attack, briefly stated, is premised upon the view that antiretroviral drugs are extremely toxic and that in promoting the use of such drugs, the TAC is simply advancing the interests of the pharmaceutical industry. Furthermore it was contended that the TAC is indirectly funded by the said industry. To these allegations the TAC responded by successfully obtaining an interim interdict against Dr Rath and his Foundation in the Cape High Court<sup>34</sup> against the defamatory statements.

What then is meant with “pseudo-science” in context of this paper? According to Geffen<sup>35</sup> pseudo-scientists are those who purport to work within the scientific paradigm, but who ignore or misrepresent accumulated scientific knowledge, fail to adhere to established scientific methods of research and who use scientific rhetoric when promoting their alternative remedies. Unlike traditional healers, who appeal to the knowledge of herbs passed down through generations, or to the advice of ancestral spirits, pseudo-scientists seek to claim the legitimating mantle of science arguing that a corrupted scientific establishment has unjustifiably repressed their correct alternative theories. Debate and argument over alternative theories is undoubtedly the engine that drives scientific discovery and innovation. What distinguishes pseudo-scientists from scientists who are simply proposing new theories or arguing in favour of minority positions is that

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33. Compare website: [http://www4.dr-rath-foundation.org/open\\_letters/img-nyt0506/speech\\_drrath.htm](http://www4.dr-rath-foundation.org/open_letters/img-nyt0506/speech_drrath.htm).

34. *TAC v Matthias Rath and Others CPD*, Case No: 2807/05, judgment delivered on 3 March 2006, as yet unreported - available on website <http://www.tac.org.za>.

35. 2006 CSSR Working Paper supra 2 ff. It should be noted that Geffen draws interesting parallels with state-sponsored support for Lysenkoism in the Soviet Union. According to him both Lysenko and Rath were able to present their marginal status in the scientific establishment as evidence of repression by the bourgeois (in the case of Lysenko) or commercial interests (in the case of Rath - thereby appealing to specific nationalist projects espoused by those in political power. On commonality between Lysenko and Rath is that they both receive state support, with consequent gross injustices.



the pseudo-scientists do not respect the rules that govern scientific research and intellectual engagement, but instead appeal to popular fears and misperceptions and seek support wherever it is offered in order to advance their own interests.

*(d) Discussion*

To state that the HIV/AIDS epidemic in South Africa is acute, would be an obvious understatement. A further reality is the fact that although the State has been ordered by the Constitutional Court to roll out antiretroviral treatment to sufferers of HIV/AIDS, access to this treatment and appropriate health care services seems to be compromised. A recent report by the convener of the Joint Civil Society Monitoring Forum estimates that about 200 000 people are on treatment, of which about 110,000 are treated by state health facilities, but this still leaves a shortfall of about 500,000 people with AIDS who do not receive treatment, of whom over 300,000 are likely to die in 2006.<sup>36</sup> Could this compromised situation be as a result of apparent state sponsored pseudo-science in South Africa? This is ironic if regard is paid to the fact that the Constitutional Court, the highest Court in the country, has judicially recognized and accepted the clinical manifestations of HIV/AIDS! Such judicial recognition is indicative that the treatment of HIV/AIDS should be considered according to defensible medical science and research. It should be noted that defensible medical science and research have always argued that adequate nutrition should go hand-in-hand with any ARV treatment. In this regard the stance of the World Health Organization (WHO) is also clear: adequate nutrition cannot cure AIDS but is essential to maintain the immune system and physical activity and to achieve optimal quality of life. The life-saving benefits of ARV's are clearly recognized and documented. The WHO has also sternly warned that there is a proliferation in the marketplace of untested diets and dietary therapies, which exploit fears, raise false hopes and further impoverish those infected by HIV/AIDS.<sup>37</sup>

It is submitted that the medical opinion of so called pseudo-scientists should be tested against the criteria set by the Supreme Court of Appeal in context of defensible medical and scientific methods and research. It is submitted that it

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36. Statistics provided by Geffen N 2006 CSSR Working Paper *supra* 2.

37. Compare World Health Organization's treatment guidelines and policy statement at websites: (see also Geffen N *supra* 26): [http://www.who.int/hiv/pub/prev\\_care/en/arvrevision2003en.pdf](http://www.who.int/hiv/pub/prev_care/en/arvrevision2003en.pdf); [http://www.tac.org.za/Documents/Durban\\_Participants\\_Statement.pdf](http://www.tac.org.za/Documents/Durban_Participants_Statement.pdf).

is doubtful that the “scientific methods” of these scientists will at present withstand judicial scrutiny. Consequently Courts should be able to intervene where a failure to allocate resources (based on indefensible scientific methods and research) seems to be unreasonable. In this regard one can only but agree with the stance taken by the TAC that state support of AIDS-denialism in South Africa continues to cost lives, undermine appropriate medical care, science and even traditional medicine, and that a major challenge for civil society and researchers is to propose realizable mechanisms for reducing the risk and damage of state-supported pseudo-science. Anything less would amount to the proverbial “fiddling while Rome is burning”!

### **(III) Crafting Public Health Regulations in the Face of Scientific Uncertainties and Unknown Risks**

#### ***(a) Introduction***

It's 6:30 pm in America on any given weekday in 2001, and millions of TVs sets glow with images from national network news programs. Inevitably the news is interspersed with advertisements, many for pharmaceutical products. One ad in particular, featuring Dorothy Hamill, the US skater, presents the picture of a healthy young woman gliding across the ice and extolling the virtues of the anti- arthritis medicine, Vioxx, which has allowed her to skate pain free, years after her 1976 Olympic championship. Jumping ahead to 2004, Dorothy Hamill is no longer on television pitching Vioxx, as its manufacturer Merck in April of that year voluntarily removed the drug from the market in response to strong clinical evidence linking the drug to an increased rate of cardiovascular disease, even though, according to the company, many patients allegedly benefited greatly from the drug. Taking the Vioxx scenario to the present, we find growing concern about the link between certain pain reduction medications and heart disease, and in addition, serious questions have been voiced about the effectiveness of regulation, and influence of economics in the process. Now as many as 6,400 lawsuits have been filed, alleging that Merck bears liability to injured Vioxx users for failure to warn.<sup>38</sup> It is not the intent of this essay to focus on the Vioxx scandal as such; rather the case is a springboard for consideration of critical questions about science policy and the role of regulation in protecting the public's health. This essay will consider the question

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38. Alex Berenson, "Jury Rules Merck Is Not Liable for Heart Attack of Vioxx User" *NYTimes* Nov.3, 2005.

of risk, the legal duty of government in confronting public health risks, and raise the possibility of creating alternative regulatory approaches, better suited to agency operations and current needs for enhanced scientific proof.

***(b) Risk: The Reality of Public Health Regulation***

Risk underlies virtually every human endeavor from rising in the morning to taking a prescription drug, to flying in an airplane near and far.<sup>39</sup> Calculating, accepting and often ignoring risk is part of our daily lives. In the context of public health, risk becomes something quite different, however, in that it falls outside the abilities of the average person to be able to make educated determinations about the nature and scope of a given health issue. It becomes government's role to take the lead in public health in identifying, assessing, and acting on given threats in the interests of safeguarding individuals and populations alike. There is a long tradition in the law, which empowers governments on both a national and international level to exercise police powers to confront public health threats. While there may be problems in domestic and international public health legal structures, as was demonstrated in the U.S. post -Katrina, or internationally in the case of SARS, the core challenges of this area lie in linking science and law together to formulate reasonable and workable policies.<sup>40</sup> Government officials, at the very least, are at the mercy of science and economics in responding to public health risks.

The challenges of risk response in government public health enforcement are triggered at three levels. Initially, public officials must weigh the question of deciphering when something is a risk, as response to threats that pose limited risks may be costly, disruptive and counter productive, particularly if the response undermines public confidence. A good example of an overblown response was the post 9/11 American reaction to the threat of inhalation anthrax, spread by mail, that proved largely unfounded, but generated costly and disruptive policies.<sup>41</sup> The mantra that "it is better to err on the side of caution" may not always be good public policy, if it fails to rest on sound science and reasonable probability. Of course, government regulators run a risk on the side of failing to respond to a potential health threat, if it proves to be serious, even though seemingly slight.

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39. Paul Slovic, *The Perceptions of Risk* (2000).

40. Berggen, Curiel, "After the Storm" 354 *New England Journal of Medicine* 1549 (2006).

41. Steven Milloy, "Concerns v. Chaos in the Anthrax Scare" Fox News Oct. 12, 2001.

Here we may return to the case of Vioxx where subsequent evidence has demonstrated that the regulator, the U.S. Food and Drug Administration had information about a possible link between Cox 2 inhibitors (the class of drugs of which Vioxx was one) and cardiovascular disease, but did not act on it.

The second issue involving risk, beyond identifying a given health problem, is determining how much of a threat the issue at hand really is. The best current example of this dilemma can be seen in the ongoing debates over the appropriate responses to the A/H5N1 bird flu, which causes Avian Flu. To date, 192 human cases (109 of which have caused deaths) of bird flu have occurred in nine countries, and while the virus cannot be transmitted efficiently from human to human, with several genetic mutations it could trigger a global pandemic.<sup>42</sup> Multiple efforts are ongoing across the globe to deal with Avian flu, from creation of a vaccine, to international reporting, to local area emergency response planning, but none of these measures directly answers the question regulators must be concerned with, namely how real a threat is this flu to warrant a large scale response. Here government agencies must deal directly with assessment of scientific information that may be inconclusive and contradictory. It is not only scientific evidence that requires analyses, but also, policy makers must also be aware of the beliefs and biases of the public they are charged with protecting. There are individuals who will never be convinced that fluoridated water is safe or that there isn't a linkage between thimerosal (mercury) in childhood vaccines and autism, and the fact is that current science may never be able to settle either controversy definitively.<sup>43</sup>

The third issue of risk response entails actually crafting a program to meet the challenges of an identified and analyzed health problem. A number of variables come to the forefront here including time, adequacy of supplies, particularly vaccines and prophylactics, availability of institutional and community resources, adequacy of trained personnel, public education and inevitably finances. While it is hard to generalize, and programmatic responses will vary with the problem at hand, it seems clear that beyond broad principles rooted in public health practice, actual responses for identical issues may be quite variable from jurisdiction to jurisdiction. For example, there are some who argue that in the face of novel communicable disease it is helpful to wear face masks to prevent

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42. See [http://usinfo.state.gov/gi/global-issues/bird\\_flu.html](http://usinfo.state.gov/gi/global-issues/bird_flu.html).

43. See, <http://www.flouridedebate.com/conclusions.html>, [http://immunizationinfo.org/thimerosal\\_mercury\\_detail.cfv?id=42](http://immunizationinfo.org/thimerosal_mercury_detail.cfv?id=42).

airborne exposure to a virus, as was widely seen in the case of SARS. Others in the public health community take the position that hand washing and limited personal contact are far more effective than face masks in safeguarding against viral contacts.<sup>44</sup> In the case of the potential hazards nations may face from Avian flu it has been suggested that preventing childhood deaths will require school closures, but critics of that position point out considerable logistical problems with such a measure.<sup>45</sup> Over time experience with a given virus will assist in programmatic response, but in the face of uncertainty, even the relatively straightforward questions of whether to don a mask or close a school may have a profound impact on the success or failure of public health authorities in preventing the spread of disease.

### **(c) Public Health, Science and Law: Vague Legal Standards**

All three of the questions regulators face in dealing with risk, initial identification, assessment and programmatic response, are all tied to an understanding of the science underlying a given public health problem, and the need for a certain level of certainty in decision making processes. Quite clearly views about scientific certainty maybe widely variable, depending upon the novelty or uniqueness of a particular threat. In light of uncertainties, the question arises as to how regulators should approach the science of public health, and what the threshold of scientific proof must be before government regulators take action. The matter of scientific certainty is not just one of public policy and common sense, but must be underpinned by law as well, for the respective authorities engaged in these matters need to take actions that are recognized within the scope of their authority, judged by the application of a legal standard. What then are the legal standards, which dictate how government agencies should behave in reference to dealing with the science underlying public health risks?

In the American context, the issue concerning the adequacy of scientific evidence comes up most frequently in the judicial arena, but is also a matter of concern for the two other branches of government, the executive and the legislative. Under the 1993 American Supreme Court case of *Daubert v. Merrill Dow* there is a requirement in U.S. federal courts that experts testifying about

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44. Clay Chandler, "Masks Can't Stop This Virus", *Fortune Magazine*, April 28, 2003.

45. Martin Croucher, "Schools in Britain To Close if Bird Flu Goes Pandemic" *Epoch Times*, April 13, 2006.

scientific matters must base their opinions on conclusions supportable in recognized research, and not merely based on the opinion of a “earned body”.<sup>46</sup> In the case of the executive branch of American government, administrative agencies are very heavily involved in science policy through both the creation of regulations and the subsequent application of such regulations. Presumably agencies, which deal with public health matters, have sufficient internal expertise and ties to the scientific community to make sound judgments about how best to respond to established and emerging public health issues. Not surprisingly, however, politics, economics, regulatory capture, lack of internal leadership, may compromise regulatory entities abilities to craft science policy, as was seen in the case of the US FDA and Vioxx, previously noted. From a legal standpoint the processes of administrative agency rule making is heavily proscribed, but in areas of substance, agencies tend to have wide discretion and in practical terms are bound only by general principles of due process, and equal protection.

Legal standards for the legislative branch of government in reference to laws involving scientific matters are rather general, originating with the US Supreme Court case of *Jacobsen v. Massachusetts*, now over 100 years old.<sup>47</sup> *Jacobsen* involved a challenge to the legal fairness of a mandatory small pox inoculation requirement by an individual who claimed such mandate posed a distinct health threat and infringed on his individual liberty. The Court disagreed with the claimant and issued a ruling strongly supportive of legislative enactments, which were designed to enhance public good. The *Jacobsen* court did not grant legislatures total discretion in public health, but rather articulated a four point test for evaluating the legality of a given mandate, which requires that a public health law be necessary, reasonable, proportional, (demonstrating a link between the problem and the solution), and not pose serious risks to affected individuals. The four fold test found in *Jacobsen* continues to be applied, and in effect sets a very general, and easily followed legal standard, that could actually support ineffective and, even incorrect, science policies in areas such as public health.

Public health authorities around the globe are all confronted with having to craft policies, which can be supported legally. In Canada, the Supreme Court in the 2000 case of *R. v. J.L.J.* examined the question of scientific evidence, and largely adopted the US *Daubert* standard that requires a more rigorous,

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46. 509 U.S. 579 (1993).

47. 197 U.S. 11 (1905).

measurable process supporting expert testimony.<sup>48</sup> In the UK, the government has created the Office of Science and Technology to coordinate and develop policy guidelines for matters involving scientific analysis and policy making.<sup>49</sup> In addition to national government efforts at forging science policies that have legal foundation, international entities such as the World Health Organization, and regional bodies, like the European Union, also develop policies on public health that rest on their respective legal frameworks. Clearly, without legal authority government public health officials can't act effectively (or at all), but it may seem unrealistic to expect the law to formulate processes and standards that have a positive impact on analyses and decision making in this context. It certainly can be argued that beyond regulatory process, the law's role is to support flexibility and discretion on the part of government officials and deter the formulation of policies, which are discriminatory in nature. Certainly in reflecting on the legal standards for science policy applied in the American context (by the three respective branches of government) the law provides a very broad framework within which a wide and flexible range of public health policies can be created and enforced, but has a rather low threshold when it comes to legal assessment.

***(d) Raising the Bar, New Thresholds for Process and Standards***

Perhaps it's unrealistic to expect that law can do more in dealing with public health risks than provide needed authority for official actions, develop a process for exercising that authority and afford some general limitations on government actions which don't inhibit discretion. It is, however, the conviction of this essay that within the realm of process and in the nature of scientific standards, changes can be made that may make government public health authorities more effective responders. In reference to process there is a demarcation between the U.S. and other countries in that the American public health authorities seem to be far more laden with administrative requirements (rule making) than their counterparts in other parts of the world. But on the other hand, public health agencies in America appear to have greater regulatory powers, which in crisis situations maybe an advantage. It would seem to be most helpful for U.S. health authorities to introduce notions of responsive regulation into public health,

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48. 2 SCR 600 (2000).

49. <http://www.ost.gov.uk/policy/advice/index.htm>.

as has been done, for example, in Europe and Australia.<sup>50</sup>

One area that can be explored in the search for alternative regulatory strategies is the so-called precautionary principle.<sup>51</sup> The precautionary principle comes out of environmental law, but has been expanded to apply to numerous regulated arenas. While characterized in numerous ways, the precautionary principle is essentially a legal concept which shifts the burden of risk assessment, and requisite response, to the actor(s) engaged in an activity which threatens public health. The precautionary principle is in evidence in the European Union and in international law agreements as well as in the laws in individual countries. It is often argued that the United States approach to regulation is inherently opposed to the precautionary principle, but in fact such a generalization can be challenged by far more stringent approaches to public health matters in the American context than in other parts of the world. What is interesting about the precautionary approach from a process standpoint is that it both shifts the regulatory burdens directly to the regulated and expands the boundaries of compliance in a meaningful fashion.

Under the rubric of responsive regulation noted above, the focus of regulators is not so much on format, but rather on designing government requirements that take into account varying contexts, and may result in negotiated and highly tailored requirements. In the American context responsive regulation is often referred to generically as new governance, and encompasses a number of strategies from closer collaborations between regulators and the regulated, to management based regulation, which entails a regulatory planning, implementation and measurement process.<sup>52</sup> While much of new governance is designed around a type of public contract between regulators and a given industry, the same concepts can be applied in creating processes, which engage citizens as stakeholders in a particular problem area.<sup>53</sup> The point underlying

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50. Ian Ayers, John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (1995).

51. Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, 2000, see also, Peter T. Saunders, "Use and Abuse of the precautionary Principle" found at <http://www.i-sis.org.uk/prec.php>.

52. Cary Coglianese, David Lazar, "Management based Regulation: Prescribing Private Management to Achieve Public Goals" 37 *L. & Soc'y Rev.* 691 (2003).

53. Louise Trubek, "Public Interest lawyers and new Governance: Advocating for Healthcare" *Wisconsin Law Review* no. 2 (2002).



the movement to new governance is the need for a regulatory process that can be applied quickly, and creatively, and which is more responsive to needs than rules. This is not to say that adoption of more fluid ways of regulating, that are heavily dependent on the public engagement of those most affected, is a rejection of law, rather it is an attempt to create a more relevant legal foundation, and in fact makes law more meaningful to public health authorities. From the point of view of application, it may actually be more challenging to use a new governance model in public health in that it engages more parties in the debate, and forces a very open airing of relevant issues.

Altering regulatory process, while introducing new difficulties, maybe very helpful in coping with complex risks matters, but in and of itself, does not guarantee a more rigorous approach to questions of science and risk. In recent years public health authorities have benefited from a wider international sharing of the latest data and analyses on public health risks generally, particularly in light of global threats like SARS and Avian flu. No doubt current information on the nature of a given disease is critical to effective regulation, but, in and of itself, fails to establish a legal standard for scientific risk assessment. In the attempt to develop a new legal standard for risk assessment, one that is more current and rigorous, a possible model can be drawn from health care. There is presently an international movement to create medical guidelines in a wide range of practice areas, reflecting the best information available on the processes and outcomes of treatment, referred to generally as evidence based medicine.<sup>54</sup> Under the auspices of the U.S. Agency for Health Care Quality and Research, and the U.K. Cochrane group, a wide range of evidence based medicine standard projects have been launched.<sup>55</sup> Formulating evidence based medical recommendations entails the development and refinement of a set of key practice questions by a group of experts, a systematic review and analysis of studies in the area, and the issuance of practice recommendations. The evidence based medicine standards, which emerge from this rigorous process, reflect the most current and up to date recommendations on how to approach treatment in given areas.

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54. D. Atkins, K. Fink, J. Slutsky, "Using Evidence reports: Progress and Challenges in Evidence Based Decision Making" 24 *Annals of Internal Medicine* 123 (2005).

55. See, <http://www.ahrq.gov/clinic/epc/>, <http://www.cochrane.org/indexo.htm>.

Using the evidence based concept as a legal standard for decisions about public health risk would refine current notions of reasonableness by mandating a much more rigorous scientific process of decision making (which may or may not occur now) and still afford regulators with discretion as such standards would likely offer a range of possible actions. Adoption of evidence-based public health standards would dovetail with changes in regulatory processes toward the more fluid models noted above. There will likely be times when a particular threat is imminent, so an analysis to identify the best practices will need to be expedited, or health threats will manifest themselves in varying ways, depending on location, and exposed population, thus it will be helpful to allow for variable regulatory approaches to given situations. Still, the legal expectation should be that public health authorities will apply evidence based standards to risk assessment and that the requirements for necessary rigor will only be relaxed in special situations. It is also necessary to recognize that it may take time in public health bureaucracies for use of evidence-based standards to reach the field level, as has been the case in the medical area.

*(e) Concluding Thoughts*

The world is increasingly complex and smaller, and risks of all sorts, spawned in far corners of the earth quickly arrive on our collective doorsteps. The case noted in the opening portion of this essay involving the FDA and Vioxx only serves to underscore the complexities, difficulties and uncertainties public health authorities must deal with, as well as the pressures being placed on public authorities. While the task of regulators in public health extends beyond assessing and dealing with risks, that collective function lies at the core of public health operations and is in increasing need of attention. Regulators in all nations are confronted with identifying, assessing and acting on public health threats that predictably will only increase in number, and in their potential to affect more lives. The law can be a benign element, a pro forma reality, a necessary accompaniment to government decision making and actions concerning risk, but hardly a central element. On the other hand, law can be shaped into a more proactive public health tool by modernizing regulatory processes through adoption of new models, in tandem with the development of more rigorous and current methods of scientific assessment. It would be unfortunate if law isn't viewed as a catalyst for addressing global and national public health threats as the structure and standards it can provide will only become more necessary in confronting the health realities in an uncertain world.

*(IV) Observations*

While each scenario depicted in this article details different aspects of public health policy there are three broad observations which can be drawn from the respective country discussions. First, each of the national examples provided, depicts varying degrees of failure on the part of regulators to follow established legal mandates. For instance, in the case of Malaysia, the two scenarios detailed, illustrate the failure of authorities to incorporate meaningful public participation into health policy decision making processes, as required by Malaysian law. In the South African context, the paper points out how the Minister of Health's policies regarding HIV/AIDS are contrary to legally established standards for science policy development, as well as being contrary to the South African Constitutional Court's recognition of scientific and medical evidence concerning HIV/AIDS. The American discussion doesn't focus directly on regulatory failings, but begins with recognition of the U. S. Food and Drug Administration Vioxx scandal, which is rooted in the agency's failures to properly consider critical evidence.

The second observation that can be made from the three country discussions is that legal processes alone guarantee neither effective regulation nor responsible conduct on the part of regulators. In Malaysia there is a public process evident in the two scenarios presented, but what is clear from the discussion, is that the process is a format with little or no meaning in the health policy decisions made by government. In essence the regulators in Malaysia maybe following the letter of the law by including public participation, but the reality appears to be that this participation constitutes form over substance. In South Africa, the Minister of Health undoubtedly possesses legal powers to respond to the HIV/AIDS crises, but does so in a way that is irresponsible, and can be characterized as an abuse of power. American public health regulators exercise their authority in the context of a very structured administrative process, but if the decision making inputs into the process are faulty, the end results maybe less than optimal.

The third and perhaps most significant observation that comes out of the three country discussions is that public health law is most effective when it delineates mechanisms for dealing with short and long term population health issues in a manner that recognizes the rights of individual and population groups to be protected from regulatory abuses. Public health matters occur in varying time frames and increasingly matters of health move rapidly requiring prompt and meaningful responses from government authorities. As all the variables

underlying public health policy formulation come together there are real dangers, even on the part of the most well meaning regulators, that power can be abused in the name of necessary response and this area of regulation may become overly paternalistic. This is not to say that governments shouldn't be empowered to meet their mandates to protect the public but rather that those mandates must include meaningful inputs from constituent groups to safeguard against abuses, and such recognition of rights must be incorporated into public health laws generally.

Finally it appears from the three country discussions presented that public health decision making whether it be about health planning in Malaysia, the appropriate ways to deal with HIV/AIDS in South Africa or how to assess public health risks in America, will be fraught with uncertainties and complexities. Government actors may stumble in tackling health issues for various reasons, including culture and tradition, politics, and scientific uncertainty. Even in the best of circumstances regulators will not always devise optimal strategies for dealing with particular population health matters, and regulations no matter how carefully crafted can't overcome inadequacies in information and judgment. Such an observation does not, however, diminish the importance of law, but only reinforces the need for an affective legal infrastructure in the public health arena as a core element in directing effective regulatory approaches. Sound public health laws within, and across jurisdictions, establish the foundations for transparency, procedural clarity and consistency, and enhancement of human rights, all of which are vital elements in successfully addressing the challenges of population health.