

HAI AP News

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Health Action International Asia-Pacific (HAIAP) is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAIAP is an informal network of non-governmental organisations and individuals in the Asia-Pacific Region committed to strive for health for all now. HAI AP News is the organ of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' work.

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Message from the Coordinator

I have often wondered how ideas are created, catch fancy, take a foothold and gain currency in the international health and development community. For a space of time an important idea reigns high, then maybe recedes, and makes way or joins with a new important idea. Some years ago, country ownership for health information system strengthening was a hot topic of conversation in the global health community. Then the idea of sustainability became paramount, with an emphasis on countries taking responsibility for funding and staffing while transitioning from donors.

Today's important idea is resilience. Resilence became an important focus in many communities ravaged by

HIV infection and the need for resilience has been strengthened by the challenges that West African governments experienced in responding to Ebola. It is vital that communities and health systems build and maintain resilience to withstand further health shocks.

Is the global health community as fickle as the fashion industry? I readily admit to regular changes in my wardrobe: I observe new fashion trends, participate in some and am known to criticize fashion faux pas in celebrities! But I have a stash of classic clothes which I can depend upon for any occasion because I know they will never go out of fashion. They have stood the test of time.

The problem is that ideas can come and go in the health and development community without being given enough time to develop fully. Country ownership, sustainability and resilience all require long term commitments and collaboration. Building resilient and sustainable systems involve slow processes that are fundamental for all that follow.

Which brings me to our first feature article by Dr Mohammad Barzgar and Ms Beverley Snell on how Iran has been able to sustain and strengthen its Primary Health Care Program for 45 years now; an idea that the country committed to and maintained through good planning, review, reform and implementation. Iran's success with its PHC Program prompted policy makers in the US to consider the potential implementation of a similar program in the Mississippi Delta, in view of

Mississippi's rating as having the poorest health system in the country.

Dr Ken Harvey has done us proud by winning the ANZAAS Medal for 2016 awarded by the Australian and New Zealand Association for the Advancement of Science. The medal is awarded annually for services for the advancement of science or administration and organisation of scientific activities, or the teaching of science throughout Australia and New Zealand and in contributions to science which lie beyond normal professional activities. HAIAP is proud of its illustrious membership and Dr Ken Harvey has consistently demonstrated resilience with his dedication to good medicine and health activism in the many years that he has been a part of HAIAP. Resilience was exemplified in Ken's stand in the face of legal action during the SensaSlim debacle. http://tinyurl.com/j7hxbyk

http://www.haiasiapacific.org/?p=1356

Congratulations Ken! And we look forward to many more good years of healthy activism from you.

While it is easy to mouth the cliché: An organization is more than the sum of its parts, I must say that HAIAP would be an empty mouthpiece if not for the continued display of integrity, expertise, leadership and resilience or its members.....who in their own right are more than the sum of the roles that they play in society. PHM India through its consitutents demonstrates this clearly. PHM has been engaged in a long battle with the pharmaceutical industry which is described in this issue: Fiasco of marketing code for the pharma industry in India.

As I write this, Amitava Guha and Dr Mira Shiva are at a meeting with the National Pharmaceutical Pricing Authority of India. In the words of Amitava, 'A huge racket mostly led by American companies fleecing money from people is dominating our market. We are expecting a tough battle with them.' We do the work that we do because it is a part of who we are......and so much more.

Cheers!

Shila

ANZAAS Medal For Ken Harvey

The Australian and New Zealand Association for the Advancement of Science has awarded Dr Ken Harvey the 2016 ANZAAS Medal.

The medal is awarded annually for services for the advancement of science or administration and organisation of scientific activities, or the teaching of science throughout Australia and New

Zealand and in contributions to science which lie beyond normal professional activities.

Dr Harvey is one of Australia's leading campaigners against non-science based medicines and a critic of pharmaceutical marketing. He has been described by The Age newspaper as an 'anti-quackery crusader', and by CHOICE as a 'serial complainer'. CHOICE made him a life member for services to the consumer movement in 2012. Australian Skeptics awarded him the Thornett Award for the Promotion of Reason in 2011, and made him a life member in 2013.

Among the wide range of his campaign activities, he is particularly well known in Skeptical circles for his fight against the SensaSlim 'diet' product, where the company took him to court in a SLAP suit. Australian Skeptics organised a public fund-raising exercise to cover his legal expenses. He won the case.



Dr Harvey was a member of the expert group that drafted the World Health Organisation *Ethical Criteria* for *Medicinal Drug Promotion* and also the Commonwealth Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee that formulated the Quality Use of Medicines (QUM) pillar of Australian Medicines Policy.

He has recently served on the Therapeutic Goods Administration (TGA) Transparency Review Panel, the Working Group on Promotion of Therapeutic Products, Medicines Australia Code Review Panel and the Australian government's Natural Therapy Review Advisory Committee.

Ken has been a HAIAP member for 25 years and was the Chairman of the Governing Council from 2010 to 2014

The Lancet: Physical Activity 2016

http://www.thelancet.com/series/physical-activity-2016

In 2012, The Lancet published its first Series on physical activity, which concluded that physical inactivity is as important a modifiable risk factor for chronic diseases as obesity and tobacco. Four years later, the second Series presents an update of the field.

Homeopathic vaccine peddlers

Jane McCredie in MJA Insight Issue 30 / 8 August 2016 http://tinyurl.com/jduhs62

News broke recently that the 'homeopathic vaccines' being sold by a Brisbane (Australia) homeopath were made of nothing but refined sugar.

Cyena Caruana, whose website is no longer publicly viewable, was apparently selling vaccines purported to protect against pertussis, measles, polio, meningococcus and malaria. According to the *Courier Mail*, a post on her Facebook page had also claimed to have sold 'homeopathic prophylaxis medicines' against the Zika virus.

The newspaper arranged for vaccination and booster pilules from Caruana's business, *Homeopathy at Home*, to be tested by scientists at the Queensland University of Technology, who found they were simply refined sugar.

Very expensive sugar – the total cost of the products was more than \$250.

That homeopathic preparations might be found to have nothing in them is hardly a surprise. After all, the principle of homeopathy is that the 'active' ingredients are diluted to a point where there may no longer be a single molecule present in the final preparation.

It does seem surprising, though, that businesses continue to get away with this kind of misleading advertising despite repeated attempts to rein them in (see this 2015 Federal Court judgment about vaccination on the Homeopathy Plus website, for example).

It's not as though the claims being made for the sugar pills are consequence-free. If a pregnant woman believes she is protected from the Zika virus by one of these magic potions, she might well be more willing to engage in behaviours that could put her baby at risk.

Parents of a homeopathically 'immunised' child might likewise be less worried about exposing their child to infection or, worse, about putting a newborn at risk by allowing their unimmunised child to visit.

Not all homeopaths endorse the practice of 'homeoprophylaxis' against infectious disease, but Caruana is certainly not alone. Victorian homeopath Dr Isaac Golden (he gained a PhD from Swinburne University in 2004 for his homeopathic research) is something of an international celebrity in the field.

Many of those offering homeoprophylaxis in Australia, and elsewhere, base their services on his approach.

'I use the immunisation protocol developed by Dr Golden as it has been rigorously tested and verified over a 20-year study as being currently the most effective and safest method of providing homeopathic immunisation,' writes one practitioner from Sydney's eastern suburbs.

'His results have found that those children who were immunised with homeprophylaxis have a similar rate of incidence of childhood disease as those who have been vaccinated, and a lower rate of incidence than those who used no form of immunisation.'

Oh, well, if it's a protocol, it must work.

One of the stated purposes of Dr Golden's research has been to provide governments with data showing that 'vaccination is not the only valid option to prevent targeted infectious diseases'. Parents, he believes, should be able to freely choose between two apparently equal options: vaccination or homeoprophylaxis.

Dr Golden writes ... Such a dual system would 'increase the national coverage against targeted diseases (increase herd immunity), and lower the national incidence of certain chronic illnesses, such as asthma and eczema, as well as reduce behavioural problems associated with vaccination'.

The research underlying this claim (that 20-year study) was based on questionnaires completed by Dr Golden's clients, the parents following his homeoprophylactic program.

It's perhaps not surprising these true believers reported excellent health outcomes in their children.

You'll be relieved to hear that Dr Golden's rigorous research found homeoprophylaxis was not only non-toxic (well, of course it is, there's nothing in it) but also 'energetically safe' (whatever that means).

The internet is hard to police: it's a vast and sprawling beast, and one that is constantly changing. Maybe it's inevitable that the peddlers of miracles so often seem to act with impunity.

Under Australian law, 'businesses are not allowed to make statements that are incorrect or likely to create a false impression'. Now that would be a true miracle.

The Trans Pacific Partnership trade pact: update

After more than three years the text of the Trans Pacific Partnership agreement was released and proved to be even more worrying than expected. The TPP permits corporations to sue governments in international tribunals if they can argue that a change in law or policy at national, state or local level "harms" their investment. There are increasing numbers of cases against health, environment and even minimum wage laws.

Key issues in the text are:

- Foreign investor rights to sue governments over domestic laws (Chapter 9)
- Stronger monopoly rights for pharmaceutical corporations and medicine price rises (Chapter 18)
- Weak and non-enforceable environmental protections despite promises (Chapter 20)
- Weaker and more difficult to enforce Labour rights than promised (Chapter 19)
- Copyright monopolies (Chapter 18)



After consistent opposition from rights based groups and individuals all 12 countries involved in the development of the TPP signed the Agreement. However, before becoming accepted, it still has to be ratified by the governments of all involved countries. So there is still time to educate politicians about the real impact of the TPPA and to get them to refuse to sign it.

Following the Federal election in Australia activists are now taking the opportunity to make demands about the TPP hearing with a new Shadow Trade Minister.

In July, US Vice President Biden was in Australia 'talking up' the TPP during his speeches. But US Senate Republican Majority Leader Mitch McConnell, who controls the numbers in the US Senate, had declared the previous week in the Washington Post that the TPP legislation is unlikely to pass Congress this year. He said that the new President should reject or renegotiate the deal in 2017.

http://thewire.org.au/story/joe-biden-uses-australia-shore-us-support-tpp/

http://aftinet.org.au/cms/sites/default/files/160718%20TPP%20media%20Biden.pdf

Dr Patricia Ranald, Convener of the Australian Fair Trade and Investment Network said that opposition from presidential candidates Trump and Clinton had made it virtually impossible to pass the Trans-Pacific Partnership after the November elections. Most Congressional Democrats are opposed, Hillary Clinton has strengthened her opposition, and it will not pass without Republican support.



Also in July, Republican Senate Finance Committee Chair Orrin Hatch launched 'a torpedo' by accusing Australia of 'stealing' from US Pharmaceutical companies. He called for even stronger monopoly rights for life-saving but costly biologic medicines, which would further delay access to more affordable versions of those medicines.

According to Dr Ranald the Australian Trade Minister Ciobo's visit to Washington the previous week to get support for the TPP showed desperation in the face of Australian election results where a record number of minor party and independent candidates opposed to the TPP were elected. She explained that the TPP is so unpopular in the US that Australian Ministers are being recruited to lobby for it there, while US officials are talking it up here, urging the Australian Parliament to pass it before the US does. 'But this game of double dare will not work. The terms of the TPP require the US as the largest economy to pass the TPP implementing legislation, or the deal will collapse.'

Dr Ranald believes smaller countries like Australia would be very unwise to proceed with their implementing legislation before the US has passed its own legislation. It would put the Australian government in a weak and embarrassing position if an incoming US government rejected or sought to renegotiate the terms of the agreement.

The Australian government has refused to commission any independent studies of the economic, health, environment or other impacts of the TPP for this Inquiry.

The Opposition parties and other minor parties which form a majority in the Senate are called to conduct a Senate inquiry, which can commission independent studies into the TPP's impact on future government regulation. It could investigate major concerns about foreign investor rights to sue governments, stronger medicine monopolies and limits on local content in government purchasing rules in the TPP.

US Secretary of State John Kerry and others have described the TPP as a Foreign Policy Tool.

'We must make the best use of every foreign policy tool, from multilateral institutions to the selective and necessary use of force, to uphold democratic principles and strengthen the rule of law. And we must be willing to invest in American leadership like the richly blessed nation we are.'

In his own blog John Kerry said:

'Today, 70 per cent of US imports cross our borders tariff-free. That's not the case with all our trading partners. In fact. America's exporters face a wide range of high tariffs in many TPP countries. That's what we have to gain from this deal; it will eliminate over 18.000 foreign taxes on 'Made in America' products and help our manufacturers, farmers, and small businesspeople to compete and win in fastgrowing markets. By voting for this trade agreement, the US Congress can reinforce the message that the United States is – and will remain – a leading force for and security throughout the prosperity Pacific. That will be welcome news for our allies and friends, a huge boost for stability in a region vital to our future well-being, and glad tidings for American companies and workers.'

https://blogs.state.gov/stories/2015/10/17/us-foreign-policy-changing-world



NAFTA = The North American Free Trade Agreement

Marianne Schneider-Petsinger, a Geo-Economics Research Fellow for *Chatham House* published her own views in collaboration with Chatham House.¹ http://www.realclearworld.com/articles/2016/07/01/fighting_the_myth_of_the_multi-

headed trade monster tpp ttip 111932.html

'First, these agreements are a US foreign policy tool to bolster American partners and allies. In the case of the TPP, the United States' desire is to strengthen political and strategic ties with many of the 11 countries along the Asia-Pacific rim (such as Japan, Vietnam, and Malaysia) at a critical time for a region in flux.

'A second strategic aspect of TPP (and similar agreements) is maintaining western leadership in the international economic space. Through these new



trade deals, Washington will lead efforts to write the rules of the road at a time when there are competing visions for the global economy.

'With a role in all agreements, the United States (which accounts for roughly 10 per cent of global trade) would be at the centre of a hub-and-spoke trade system that covers more than 70 per cent of the global economy.

'The TPP can take effect only if the US Congress approves it, and its fate in Congress is uncertain at best. Fast Track trade authority only passed through Congress by the narrowest of margins after a series of legislative manoeuvres, with reluctant support from some key swing members contingent upon certain provisions being in the final TPP. The released text shows these concerns have been largely ignored.'

An unprecedented array of organizations have joined together in a powerful and diverse coalition to stop the TPP. Groups united on this extend well beyond labour unions and include consumer, Internet freedom, senior, health, food safety, environmental, human rights, faith, gender-based, student and civil rights organizations. Opposition to the TPP is growing at home and in many of the other countries involved.

http://aftinet.org.au/cms/trans-pacific-partnership-agreement
and https://stoptpp.org/ http://tinyurl.com/j9rzbjc

http://www.citizen.org/TPP several videos and other resources.

¹Chatham House, is a non-profit, non-governmental organisation based in London whose mission is to analyse and promote the understanding of major international issues and current affairs.

News from India

Driven to Suicide by an 'Inhuman and Unnatural' Pressure to Sell

On August 11 the New York Times printed a distressing report by **Geeta Anan**d and **Frederik Joelvingaug** concerning the suicide of a young salesman who could not meet the performance goals of his employer Abbott laboratories.

http://tinyurl.com/zzdyamp

Leaving his wife and two young children home on a recent Sunday, a 27-year-old salesman for Abbott Laboratories' operations in India rode his motorcycle to a remote railroad track and jumped in front of a train.

In his pocket, a note in blue ink, handwritten in a mix of Hindi and English, said, 'I'm going to commit suicide because I can't meet my company's sales targets and my company is pressuring me.'

Ashish Awasthi's death resonated across India and through the halls of the health care giant. More than 250 fellow Abbott drug representatives in India walked off the job for a day, protesting what some called the company's overly aggressive sales policies. A national union of drug sales workers called for new government rules to rein in sales practices industry-wide, saying they compromised patient health.

A six-month investigation by The New York Times found that in the push to win customers in India's chaotic and highly competitive drug market, some Abbott managers instructed employees to pursue sales at virtually any cost — in violation of Indian law, professional medical standards and the company's own ethics guidelines.

Sales jobs with global powerhouses like Abbott are highly prized positions in India. But they can also be extremely demanding, putting employees under inordinate pressure to cut corners, according to interviews with more than a dozen current and former sales representatives and managers and a review of internal Abbott communications provided by two of them.

In one of the most common practices, The NYTimes found, Abbott managers told sales staff to hold what the company called health camps, where representatives would perform tests on patients for various ailments in an effort to drum up business for doctors, who would then prescribe Abbott drugs. The camps were typically held at doctor's offices or as community events.

Vivek Gupta, a former manager of a sales team in northern India, said he was fired last year under pressure to make his sales representatives do more screenings of patients to promote a new Abbott multivitamin for nerve damage. He tried to resist, he said, out of respect for the national rules and the company's

own policies, which prohibit the use of health camps to influence which medicines are prescribed.

India's health camps were described in

HAIAPNewsDecember2015

The Indian Pharmaceutical Industry Marketing Code fiasco

Amitava Guha, National Coordinator, Jan Swasthya Abhiyan (PHM- India)

The long standing campaign by Jan Swasthya Abhiyan (JSA) (Peoples Health Movement - PHM India) pushing for a legal code of marketing of medicines by the pharmaceutical industry of India eventually compelled the Government to develop a code. In the first attempt, the government called all industry associations to a meeting and asked them to prepare a voluntary uniform code. Organisations led by foreign multinationals and large Indian companies prepared and submitted a code which they claimed had unanimous industry approval. But the small scale industry protested on the basis that it carried out little or no promotional activity and that there was no prior discussion with it. Thus this move towards developing a code was shelved.

Meanwhile, media exposed the failure of government in regulating malpractices of industry by highlighting evidence of unethical practices, collected by JSA.

The Medicine industry in India comes largely under the purview of the Ministry of Chemicals and Fertilisers. On 13 January 2009, the Ministry of Chemicals and Fertilisers called a meeting of industry associations. The government expressed concern that several disturbing reports in the media exposed substantial spending by industry on doctors; which ultimately has direct implication on prices of medicines. The meeting resolved to prepare another code of marketing practices.

Much later, in April 2011, the Government circulated a draft code for discussion; but never took up the issue until December 2014 when it circulated another draft code. JSA submitted severe criticism of the draft and the Government sent a slightly modified code to the industry in January, 2015, saying that it will remain as a voluntary code for six months and after review if it is found to have no opposition, the code will be made statutory.

A year later a meeting was called by the government in November 2015 with industry, JSA, All India Drug Action Network and other health activists. Four persons from Civil Society faced 26 persons from industry in the discussion. JSA submitted a strong note explaining that the Code circulated by the Government was prepared by the industry and therefore could not serve the purpose of regulating its marketing practices, to which

the government agreed. Industry vehemently opposed the proposal to make the code statutory.

JSA then submitted several cases of evidence of how the industry is directly bribing doctors. It was also mentioned that the recipient doctors had grossly violated the Code of Ethics formulated by the Medical Council of India.

JSA also proclaimed that the industry is spending lavishly on promotion while earning tax exemption for these unethical expenses. There had been an amusing proposal that industry representatives would judge violation of the code by another industry partner. That again is an unethical proposal. In any case penal provision is so trivial and ineffective that it cannot prevent even gross violation. In the discussion, when the Minister asked for comments from the industry, it remained silent and later told the Ministry that it would have separate discussions with the Government without the presence of civil society.

In the mean-time, JSA prepared a comprehensive ethical code of marketing and asked the Government for a meeting. In an exclusive meeting held on 17 February, 2016, JSA explained the code before the Secretary and other officials. It is learnt that the Government also met with industry later. The Government has remained silent since February and no further notice on the marketing code has been issued. This situation gives the industry unbridled scope to proceed vigorously with unethical practices.

However recently, a Member of the Parliament discussed his concern with the Minister and wrote him giving a number of instances of unethical practices by pharmaceutical industry. He also raised the question about Government decision on framing a legal code of marketing. This gives hope to civil society that movements such as JSA can significantly oppose attempts by the industry to enact an industry-friendly marketing code.

HAI ACCISS Study

http://haiweb.org/what-we-do/acciss/

Diabetes and the Need for Insulin

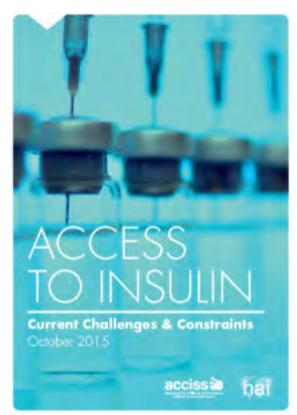
Insulin is a naturally occurring hormone that converts sugar, starches and other food into needed energy. People living with diabetes either no longer produce insulin (type 1 diabetes) or their bodies have become resistant to it (type 2 diabetes). For over 90 years those living with type 1 diabetes have relied on external insulin (currently available in bovine, human and analogue forms) to survive. Today, around 100 million people around the world need insulin, including all people living with type 1 diabetes and between 20-30 percent of

people with type 2 diabetes. But globally, more than half of these people cannot afford and/or access this much-needed medicine. Without access to insulin, people living with type 1 diabetes will die. Many more will suffer from diabetes-related complications, like blindness, amputation and kidney failure, and, ultimately, premature death.

The ACCISS Study

A solid understanding of what is causing the barriers to insulin access is needed so inequities and inefficiencies in

the



global insulin market can be addressed. A global study, called Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS), sets out to do this and more. ACCISS is being co-led by Margaret Ewen at Health Action International, David Beran from Geneva University Hospitals and the University of Geneva and Richard Laing from Boston University. It involves a unique group of leading international experts as members of the study's <u>advisory and technical groups</u>. ACCISS is being funded by a US\$1.25 million grant from The Leona M. and Harry B. Helmsley Charitable Trust. The three-year study is being conducted in <u>phases</u> and a virtual advocacy network will be developed over the course of the study.

Videos, fact sheets and the latest reports are available here

http://haiweb.org/what-we-do/acciss/research-finding

Feature: Iran's Primary Health Care Program – 45 years

Compiled by Beverley Snell and Mohammad Ali Barzgar

Iran's health program recognised with the 2016 Dr Lee Jong-wook Memorial Prize for Public Health

At the World Health Assembly in May 2016, WHO Director-General Dr Margaret Chan and President of the Sixty-ninth World Health Assembly Dr Ahmed Mohammed Obaid Al Saidi awarded the 2016 Dr Lee Jong-wook Memorial Prize for Public Health to Dr Alireza Mesdaghinia, Department of Environmental Health Engineering, School of Public Health, Tehran University of Medical Sciences, Iran.²

Dr Alireza Mesdaghinia was still studying medicine in Iran when the country's public health system was awakening in the country. After his 28 years as Dean of Pubic Health at Tehran University of Medical Sciences, Dr Mesdaghinia notes that life expectancy has risen from 52 to 74 years. But, he says, 'It's not my credit; it's the whole country's credit.'

Today, almost all Iranian children are fully vaccinated; 87% of the country's rural population and 98% of the country's urban population has access to safe drinking water. And there are 20,000 Health Houses, staffed by *Behvarzan* — trained Community Health Workers (CHWs).

In April 2012 the HAIAP News featured a story by HAIAP member Dr Mohammad Ali Barzgar about the evolution of the Primary Health Care program in Iran that began in 1971. See HAIAPNews2April2012.pdf

The program began with a joint Health Services Research Development (HSDR) project by the School of Public Health, University of Tehran, Ministry of Health and WHO. In 1971 a survey was undertaken to assess the health needs of the population, the efficiency of health services system dealing with the health problems and the behavior of the population in relation to the health services.

Dr Mohammad Ali Barzgar believes there is no doubt that introduction of *Behvarzan* and the needs oriented *Block* system training was the most significant initiative of the program. But the importance of the situation-analysis or survey undertaken prior to establishment of the PHC network cannot be over-emphasised. He explained:

²http://www.who.int/mediacentre/events/2016/wha69/prizes-lee-jong-wook/en/

'The situation analysis in 1971 had shown us the health and health services needs of the people and their expectations; and identified the shortcomings and the missing parts of the existing system, ie the Primary Health Care level. The results of the situation analysis also guided the proper and relevant development of the training program of the Behvarz, based on the needs of the community.

'The situation analysis revealed an Infant Mortality Rate of 131 per thousand live births and a Maternal Mortality Rate of 400/100,000. Therefore we decided that the first subject that Behvarz should be taught is Child Care and that was included in the First Block of the Behvarz training materials; and the second Block was Maternal Health Care.

'Furthermore we found that 70% of the population were living in rural areas, but there weren't any health facilities in rural areas except Rural Health Centres which were located on the roadside far from the villages. Therefore we proposed the establishment of Health Houses in villages and recruitment of local CHWs residing in the same village. Now, on average two out of three villages are covered by Health Houses, based on population of the villages (average 1500); and one hour walking distance from central populated village, where a Health House is located.

We linked the rural people to the health system and the health system to the 70% of disadvantaged population of the country. While the initiative at primary level significantly changed the functions of the Ministry of Health, I agree that we failed to develop a good referral system.

'After establishment of the system, we brought the health cluster universities under the authority of the Ministry of Health and renamed the Ministry of Health as the Ministry of Health and Medical Education. The purpose of the integration was to make the curriculum of the medical schools a community oriented one based on PHC on one side and on the other making the academicians aware of the real health needs of the country; rather than concentrating on rare syndromes taught to the medical students in the teaching hospitals of the schools of medicine.

'For example, I, as National Scientific Director of PHC was appointed the Vice Dean and Head of the Community Medicine of a new established School of Medicine and Nursing in West Azerbaijan (the same province where Iran's first Behvarz and first Health House were established), in order to orient the

students of School of Medicine and Nursing to PHC from the first day of their course. The faculty members were exposed to PHC too. As their training had been classic hospital based and curative it was hard to change their behavior. We can conclude that the PHC changed not only the health services system, it also integrated medical education into Ministry of Health and somewhat changed it's curative nature to the preventive one.

'I would like to again emphasize the importance of operational research (Situation analysis of the program and the PHC Field Laboratory), which guaranteed the appropriate implementation and the sustainability of the program for 45 years under two different governments. I am honored that I was involved from it's conception for 15 years until the program was accepted as a National program and the base for the country wide health system.'

(Dr Barzgar was involved in situation analyses and evaluations throughout the 1970s that informed the ongoing direction of the program.³)

In 2016 several papers referred to the Iran Behvarzan. Most notably, in January 2016 the Archives of Iranian Medicine published a detailed analysis of the Iranian Behvarz program that had been undertaken by Moshiri, Rashidian, Arab and Khosravi.⁴ The writers consulted and quoted people at all levels, including politicians, program implementers, health workers and community members.

'When the scheme was operating in an area of a district, local experts felt proud of it believing that they were involved in changing the situation.' (A former senior health policy maker)

'The network setup was very successful in the first year because parliament allocated enough budget to develop the network in two new districts of each province, while we had asked budget for one new district of each province for the next year. '(A former senior health policy maker)

'Every year, we went to the PBO to determine the number of Behvarz for each province according to the expected development.' (A former deputy minister)

Two significant aims of the program were justice and access and many interviewees believed the program had made important steps towards access:

³Barzgar MA, Djazayery A. 1981. Evaluation of Rural Primary health Care Services in Iran: Report on Vital Statistics in West Azarbaijan. *AJPH*, Vol 71, no 7.

⁴: Moshiri E, Rashidian A, Arab M, Khosravi A. 2016. Using an analytical framework to explain the formation of primary health care in rural Iran in the 1980s. *Arch Iran Med.* 19(1): 16 – 22.

'A father could bring children for vaccination even after daily work. He did not have to go to the city or wait until the vaccination team came from the city. This event means improving rural people's access to health care. (A former deputy minister)

During the war between 1980 and 1988 Iran was subject to air strikes, diminished oil export and scant income. Health services could have suffered severely but there was motivation to continue the PHC program despite the difficulties.

'... the active war and even the vast bombardments on the cities of Iran (especially Iran's capital) couldn't impede the PHC movement ahead. We designed the health care network of the country with consideration of all its aspects and dimensions.' (A former senior health policy maker)

'During the war, although the country had many problems, a considerable amount of money was secured for the [PHC] network expansion through negotiations with the Parliament.' (A senior provincial health manager)

'Former UNICEF president, Mr. James P. Grant, had a prominent role in introducing Iranian PHC to the world. Once at the height of the war, I accompanied him to visit Hamadan [province] villages. He was impressed by Health Houses' performance and quality of services. Then he traveled to China where he held a press conference and stated: - I'm coming from a country that is engaged in social activity during the war, the country in which health is not neglected even at war.' (A former deputy minister)

The writers in the Archives of Iranian Medicine acknowledged the outstanding achievements of the PHC network but noted it had not been entirely successful. The plan had been to cover urban as well as rural areas and the urban areas had been neglected and a network of PHC posts had not developed.

'One of our ideals was that hospitals accept no one except for emergency patients [or after referral]. But PHC coverage was too low in cities and people had no other choice. (A former senior health policy maker)

The results of the study showed that

'Talented actors, clear content with agreed objectives and a top-down approach to the implementation in a special socio-political context were the main influential factors for fulfilment of the PHC policy in Iran. However full implementation of the policy was hampered by failure of some main components of the referral system.'

It was recognised that the top down approach and insufficient communication between all levels had contributed to the weaknesses in the referral system but when it was decided later to introduce the family

physician program and the rural insurance program in rural areas, the PHC network provided a strong infrastructural framework for implementation.

Some Features of the Program

Women's Health

In January 2016, Hassan Joulaei described the impact of Iran's PHC program on women's health⁵.

He commented on the active collaboration between community members that strengthens the cultural links and delivery of immunisation services, antenatal care, prevention of epidemics and promotion of healthy life-

General Practitioner (GP)

Laboratory Technician

Health Technician

Midwife

Pharmaceutical technician

Rural Health Center

community styles. Local health volunteers work with trained Behvarzan to enhance the delivery of health Hassan care. Joulaie concluded that

'... the active delivering of healthcare by well-trained Behvarzan via Health Houses is the leading factor for contributing improvina the health situation of the rural community. specifically amongst women children. Overall. Iran's health network system with focal point of Behvarzan has incredible achievements, so it should be reinforced by health policy makers; and each reform in Iran's health system has to be in line with this approach.'

A study by Nadery and Bahrampour (2000) of the sensitivity of screening for breast tumours by female Behvarzan found 95% accuracy so concluded that screening for breast tumours by Behvarzan should be recommended.6

Treating Tuberculosis

The Global Fund and the Centres for Disease Control have been supporting Direct Smear laboratory work and diagnosis of TB within Iran to reduce the time lag between testing, diagnosis and treatment. The TB

⁵Joulaei, Hassan. The Miracle of the Behvarzes' Efforts on Women's Health; Iran's Experience. Women's Health Bull. inpress(inpress):e41021. Published online 2016 January 19.

⁶Nadery T., Bahrampour A. 2000. Determination of sensitivity and specificity of breast tumor diagnosis by health care auxiliaries (Behvarz). Journal Of Kerman University of Medical Sciences Spring 2000, Volume 7, Number 2; Page(s) 73 To 78.

management and treatment program could not operate without the Behvarzan who are linked with the program and who provide follow-up and support for patients at all stages of the program, including daily administration of DOTS.

Diabetes and NCDs

Researchers at the Institute of Health and Medical Education. Harvard University had studied 'Effectiveness of diabetes and hypertension management by rural primary health-care workers (Behvarz workers) in Iran and published the findings in 2012.8 They had noted the specific role of the Behvarzan.

Rural Health Houses Behvarz City hospital Para Clinic hospital Subspecialty Province

'Concentrated most heavily in poorer districts, Behvarz workers are educated to identify individuals at high risk for diabetes, refer them to physicians at local 'Health Houses' for testing, and follow up with treatment and lifestyle quidance. No specific training program is in place for Behvarz workers manage high pressure. An increase of one Behvarz worker per 1.000 residents was associated with 0.09 mmol/L reduction in fasting blood glucose.The difference in diabetes treatment effects of Behvarz workers versus physicians can be attributed to the fact that Behvarz workers

regularly follow up with diet and lifestyle education and check patients' adherence to treatment'.

In Chronic Non-communicable Diseases in Low and Middle-income Countries (2016)9-the Iranian example is used to illustrate the optimal use of resources by Behvarzan in the PHC system for identifying high risk patients for referral to physicians at community health centres for testing for diabetes and other NCDs and for treatment with subsidized drugs.

www.ir.undp.org/content/iran/en/.../treating_tuberculosis_gorgan.ht

8Farzadfar F, Murray C, Gakidou E, Bossert T, Hengamah N, Alikhani S, Moradi G, Delavari A, Jamshidi H, Ezzati M. 2011. Effectiveness of diabetes and hypertension management by rural primary health-care workers (Behvarz workers) in Iran: a nationally representative observational study. The Lancet Volume 379, No. 9810, p47-54, 7 January 2012

⁹Chronic Non-communicable Diseases in Low and Middle-income Countries. 2016. EdsAma de-Graft Aikins, Charles Agyemang... Oxfordshire UK CABI group

⁷Kummer, Tamara. Treating Tuberculosis in Gorgan. UNDP in Iran. 2016

The *Behvarzan* visit patients monthly to monitor drug adherence, provide ongoing medication and provide supportive education and information. Diabetes management was found to be more effective in rural areas than in urban areas.

Factors influencing burnout among rural health workers

In March 2016 the Razi Journal of Medical Sciences published a study by Mohammad Amiri *et al* of *Factors influencing the intensity of burnout among rural health workers* (Behvarzan) in Northeastern Provinces of Iran.¹⁰

Although burnout among the health workers was found to be low, significant relationships were observed between burnout and factors including satisfaction with income and essential facilities, interest in job, gender, and place of residence. The authors concluded that the intensity of emotional exhaustion and lack of feelings of personal accomplishment in health workers with experience of over 10 years was high. They recommended transfer of highly experienced workers to Health Houses closer to city centres, together with opportunities for continuing education, academic support and job promotion to improve the situation.

A description of the evolution of the Primary Health Care program over 30 years has been published by the Kermanshah University of Medical Sciences (August 2016). 11 The role of the Universities of Medical Sciences that exist in each province is crucial with the Chancellor of the University as Executive Director of the Provincial Health Services and the University in charge of all district health centres and hospitals together with its provision of medical education and overseeing delivery of health services. The Behvarzan and the Health Houses are the axis of the village. The program has evolved from provision of health education with antenatal care, prevention of communicable diseases and provision of crucial data for the Ministry of Health to now include the management of chronic diseases like diabetes and hypertension, and improving nutrition, control of iodine disorders, iron-deficiency anaemia and fluoride treatment within an effective referral system.

Review of the Iran program for possible implementation in the Mississippi Delta

In 2009, Mississippi health care pioneer Dr Aaron Shirley and James Miller of the Oxford International Development Group, with Dr. Mohammad Shahbazi of Jackson University and originally from Shiraz in Iran,

¹⁰Amiri M, Chaman R, Arabi M, Ahmadinasab A, Hejazi A, Khosravi A. 2016. Factors influencing the intensity of burnout among rural health workers (Behvarz) in Northeastern Provinces of Iran. Razi Journal of Medical Sciences Vol. 22, No. 141, Feb-Mar. conducted a review of the organization and effectiveness of the Iran program with a view to potential implementation of a similar program in the Mississippi Delta in the USA. 12 Mississippi was judged to have the worst health system in the country. The review indicated that the Health Houses and activities of the *Behvarzan* were the basis of an appropriate and sustainable health service program in Iran. The impressive achievements were noted including lowering the IMR from 131 to 13 per thousand live births and the MMR from 400 to 25 per 100,000; together with 96% immunization coverage.

The results of the review provided a number of takeaway lessons for US policy. ¹³ Mississippi's challenges were similar to those of Iran and the success of the *Behvarzan* in a program administrated by nonphysicians shows that dedicating funding to primary care and public health results in significant health gains for the population.

It was acknowledged that the political environment in the USA would not be aligned with implementation of such a model. The Iran PHC reforms were a conscious top-down commitment by the Iranian government to a Primary Health Care system while in the USA commitment to public health was marginal and only a fraction of the amount recommended by the Institute of Medicine. Only 30% of Iranian government revenue is from taxation and 70% is derived from the sale of natural resources making Iran's generous PHC support difficult to replicate. Iran was able to bypass the protests of the medical community against the *Behvarzan* and that would not be possible in the USA where the physician community would be likely to lobby against CHWs as they do against nurse practitioners.

The recommendation from the reviewers for policymakers in the USA was to prepare for an opportunity to implement a Health House inspired program by developing health worker certification curricula that could be quickly adopted.

According to Dr M A Barzgar, Iran Ministry of Health and University of Shiraz staff were involved in implementing a pilot project in Mississippi and a mission from Mississippi visited the Iran PHC program. Apparently CNN correspondents criticized the Mississippi officials - asking why are they considering adapting a program from an enemy country. A wise Nurse Practitioner answered: 'No matter if it is an enemy country, or a friendly one. They have solved their health problems with this strategy and we want to solve our people's health problems too.'

¹¹http://khc.kums.ac.ir/en/net/iphcs

¹²https://www.fic.nih.gov/NEWS/GLOBALHEALTHMATTERS/Page s/1209_health-house.aspx

¹³https://zamishka.com/2016/06/21/primary-care-reform-in-iran-and-lessons-for-the-u-s/

Feature: High medicines prices in Europe – do not Brexit the people

By Ellen 't Hoen, LLM Global Health Unit, University Medical Centre Groningen, Netherlands

What happens in Europe has a major impact on what happens in other parts of the world. We are grateful to Ellen for providing this analysis. - Editor HAIAP News

The issues of high priced medicines and problems with access to medicines have for many years been themes belonging to the realm of global health. We are familiar with images of people in African capitals demonstrating in the streets for access to medicines, such as those to treat HIV and AIDS. Today these images can be shot in the streets of Madrid, London, Bucharest, Athens, San Francisco and Washington DC concerning access to a number of medicines. High-income countries, including those in the European Union, are struggling with the burden of high priced medicines on their health budgets. In some cases this is now leading to rationing of proven effective, essential medications even in high-income countries.

The most notorious examples of high priced medicines are the new direct action antivirals (DAAs) for the treatment of hepatitis C. The DAAs in the Netherlands are priced at 54.000 euro per 12-week curative treatment. In France, Médecins du Monde has calculated that providing DAAs for all people with hepatitis C in France would exceed the annual budget of the public hospitals in Another example is the rising cost of cancer treatment. The increase in price of breast cancer medications has led to crisis situations in the UK, where cancer groups have asked the government to invoke compulsory licensing after the government announced it would not longer pay for the treatment. Compulsory licensing is a well known TRIPS flexibility that was routinely used in the early 2000s for the supply of HIV and AIDS medicines in the developing world. (In the EU a compulsory licence can only be granted by individual EU countries.)

The high price of medicines is generally caused by a monopoly position in the market sustained by patents or regulatory measures that exclude generic competition. Such exclusivity is needed to encourage investment in the development of new medicines. However, these state granted monopolies keep the price of medicines high well after the R&D investments have been earned back. This phenomenon is increasingly recognised as an imbalance in the patent system. The UN Secretary General has established a High-Level Panel on Access to Medicines to address the misalignment between the rights of inventors, international human rights law, trade rules and

public health where it impedes the innovation of and access to health technologies. He asked the Panel to examine issues in high-income as well as low-income countries.

Under the leadership of the Dutch presidency, the Council of the European Union has decided to take action. On 17 June 2016 the Council adopted the following: "Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States". (The European Parliament recently held a workshop on the issue where Ellen spoke that can be watched here.)

The European Union has experience with a variety of market exclusivity instruments for pharmaceuticals in addition to the national patent systems of its member states. Examples include orphan drug regulation offering 10-12 years market exclusivity for a product or indication developed for a rare disease, supplementary protection certificate (SPC) for medicines that gives up to 5 years of additional patent protection over the mandated minimum 20 year period, paediatric exclusivity offering up to 6 months SPC for patented products, and 8-10 years of data exclusivity for the development of paediatric indications of non patented products.

These exclusivity mechanisms were designed to stimulate the development of new medicines and new indications that are neglected by the industry because of lack of profitability. They increase the industry's ability to retain a monopoly position in the market. They have in common that they contribute to high pricing of medicines. There is also growing evidence that the pharmaceutical industry abuses these mechanisms by "salami-slicing" a product in indications for small patient groups in order to obtain orphan drug benefits. Several of the top ten best selling medicines in the world benefit from an orphan drug designation. Annual sales on some of these drugs ranging from 5 to 14 billion USD a year would seem to indicate that the lack of profitability was not the issue. In the face of economic austerity and the pressure on health budgets, the question the Council now has put on the table is, do the benefits of these incentive mechanisms actually outweigh the

The Council has outlined the following actions for the European Commission:

- Streamline implementation orphan regulation; ascertain proper application of the rules, incentives and rewards and revise them if necessary;
- Create an overview of EU pharmaceutical legislation in relation to IP related incentives and their intended purposes;
- Analyse effects of these incentives on innovation, accessibility, availability and affordability of medicines, as well as price strategies of the industry;
- Analyse functioning of the EU pharmaceutical market in terms of transparency, market behaviour, and competition, and strengthen market oversight
- Recommend possible remedies in the context of the agenda 2017-2020.

The question now is how much gusto will the Commission display to grab this opportunity and show it is able to respond to the concerns of the European public about high medicines prices. The European Commission is often seen as too close and too cosy with the industry at the expense of the development of more public interest oriented regulations. The Brexit vote – partly driven by concerns about health care costs - should be a wake up call. The Council has laid out a clear agenda for the Commission. Let's hope the Commission grabs this opportunity to show it can deliver by creating a better balanced pharmaceutical R&D environment that meets people's needs and does not break the bank of national health care systems.

Ellen t'Hoen is the author of

Private Patents And Public Health: Changing Intellectual Property Rules for Access to Medicines.

Published by HAI Europe

http://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf







Ellen says, "I dedicate this book to the memory of Dr Andrew Herxheimer, Dr KumariahBalasubramaniam, and Ms Pat Cody¹⁴ who taught me the meaning of sharing knowledge for action".

About the book

Millions of people around the world do not have access to the medicines they need to treat disease or alleviate suffering. Strict patent regimes interfere with widespread access to medicines by creating monopolies that maintain medicines prices well beyond the reach of those who need them. The magnitude of the AIDS crisis in the late nineties brought this to the public's attention when millions of people in developing countries died from an illness for which medicines existed, but were not available or affordable.

Faced with an unprecedented health crisis — 8.000 people dying daily — the public health community launched an unprecedented global effort that eventually resulted in the large-scale availability of quality generic HIV medicines and a steady scale-up in access to those medicines. This has allowed nearly 13 million people to lead longer, healthier lives. However, trends in international intellectual property law could have an impact on many of the policy tools used to scale up HIV treatment. Developments in global health and specifically access to medicines policies are now at an important juncture. Impressive progress has been made in access to medicines for HIV and many lessons can be learned from that experience. But it is important to examine whether those lessons can be applied for other diseases.

Today's pharmaceutical patent regime affects almost all medicines developed since 1995 in most countries. The high prices of new medicines, such as for cancer, tuberculosis and hepatitis C, cause huge access challenges globally, in both developed and developing countries. These new global challenges pose the question of whether the public health approaches to medicines patents developed in response to the HIV crisis are exclusive to HIV or whether they can be applied more broadly.

This book provides a history of the parallel developments in global public health and international patent laws: detailing the current situation, how we got here, and how we can move forward to best protect the future of medical innovation as well as the lives that will depend on it.

The book is an update of an earlier account that was published in 2009:The Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on

Berkeley Free Clinic to attend to their health needs. Pat became the clinic's treasurer and was intimately involved in making it a viable institution. She started DES Action in 1971 after she learned that the daughters of women who took the antimiscarriage drug during pregnancy developed cancer and reproductive problems. She died in 2010 at 87 years.

 $^{^{14}}$ In 1964, as the Free Speech Movement attracted thousands of young people from across USA, Pat Cody helped start the

TRIPS and Public Health. It is divided into the following chapters:

INTRODUCTION: Patents and patients are today at a critical juncture; the global HIV epidemic and the international response to it is the critical case study to best understand why.

CHAPTER 1: Ending Global Diversity in Patent Laws: The formation of the World Trade Organization (WTO) Trade-Related Aspects ofIntellectual Property Rights Agreement (TRIPS) resulted in the first enforceable international standards for patent protection and, as a result, in problems for public health. This chapter explores how TRIPS came about, and details the growing tensions between the public health community and those looking for greater intellectual property protection.

CHAPTER 2: Turning the Tide: The growing patent/patient tension resulted in the 2001 Doha Declaration on TRIPS and Public Health, the pivotal point in international negotiations about patents and medicines. This chapter details its key provisions, and explains how those provisions should be interpreted.

CHAPTER 3: From Declaration to Application: Since 2001, governments and other actors around the world have used Doha principles and flexibilities to implement key policy changes to improve access to medicines. This chapter presents data and analysis on how these principles and provisions have been used over the last decade and a half.

CHAPTER 4: Closing the Policy Space: TRIPS was meant to strike a balance between protecting innovators and protecting the public interest; it contains several flexibilities to ensure that balance can be maintained. But regional trade agreements and other trends are

shrinking that space by binding countries to more stringent 'TRIPS-plus' rules. This chapter details TRIPS' key flexibilities for public health, and how recent trends threaten to limit their use.

CHAPTER 5: The New Frontiers: The HIV epidemic laid bare the conflicts between patent regimes and a growing need for the life-saving medicines those regimes priced out of reach. But HIV is not the only disease for which high prices are a problem. This chapter details several of the newest frontiers of health needs and high prices: cancer, hepatitis C and tuberculosis.

CHAPTER 6: Fixing the Broken R&D System: At the heart of the price/patent debate is the question of how to support the expensive research and development (R&D) that leads to pharmaceutical innovation, while also guaranteeing access to the products of that innovation. The system as it currently stands is broken and fails to incentivise R&D for diseases that have profound public health impact but little market promise. This chapter outlines international efforts to address this concern, especially the 'delinkage model' and a proposed International R&D Agreement.

CHAPTER 7: Restoring the Balance: There is a crying need to restore the balance in the patent system, and to explore alternative ways to ensure neither new innovation nor the health needs of the global population are ignored. The lessons of HIV can inform this process, but there are other factors at work as well. This chapter evaluates the HIV experience and the extent to which past success can guide future action, as well as details where new strategies are needed.

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