Knowledge Ecology International submission to the World Health Organization
Consultative Expert Working Group on R&D Financing

Innovation Inducement Prizes

June 22, 2011

Introduction

KEI is one of several groups jointly providing a submission on a possible essential health and biomedical R&D treaty. These separate comments address a number of other issues, including in particular, the proposals before the CEWG involving innovation prize funds, and other issues relating to the de-linkage of R&D costs from product prices.

We begin with a discussion of the inequality of incomes among and between countries, and the consequences of those inequalities on pricing and access, and conclude with comments on the possible role of innovation inducement prizes to de-link R&D incentives from product prices.

Income inequality and drug prices

Most of the world's population live in developing countries, where average incomes are low. According to the World Bank, in 2009, 1.117 billion persons lived in high-income countries, or roughly 16.5 percent of the World's population. In these countries, the 2009 per capita income was $37,990. Another 5.659 billion persons lived elsewhere, and had a per capital income of $2,959, just 7.7 percent of the average in high income countries. "Least Developed Countries" are a subset of developing countries, referred to by the UN as the "poorest and weakest" countries. In 2009, these 48 countries had a combined population of 837 million, and an average per capita income of $639, just 1.7 percent of the average in high income countries. Collectively, LDC countries had about 12.4 percent of the global population, but just .9 percent of global income.[1]

Not only are incomes quite different between countries, but they are also very different within countries.

Prices for drugs are set to maximize profits. In the absence of competition, a company will estimate the willingness to pay for various groups, and set prices that maximize profits for the market as a whole. In theory, there are opportunities for price discrimination among consumers of different incomes, and in practice this happens part of the time.

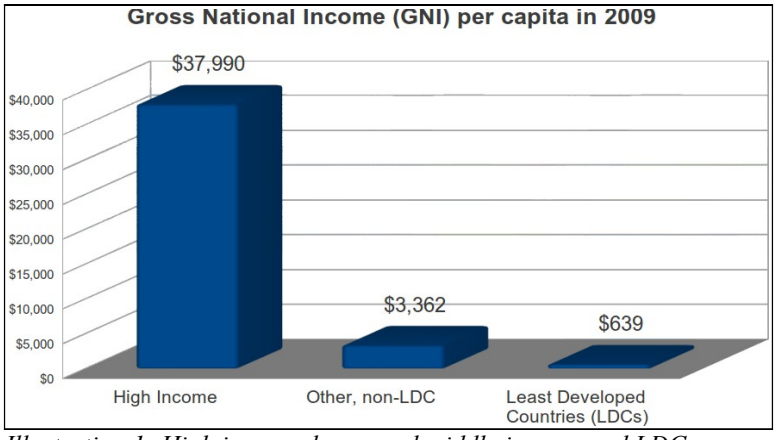

Illustration 1: High income, lower and middle income and LDC country per capita income

1 In May 2011, the United States Trade Representative announced it would require LDC countries to enforce patents and test data protection for pharmaceutical drugs by 2016. See: "White House and European Commission trade official oppose waiver of drug patents for Least Developed Countries (LDCs)," June 11, 2011. http://keionline.org/node/1154

For a variety of reasons, the type of price discrimination that broadens access is limited, particularly for certain products. It may be difficult to charge significantly different prices within the same country, or to maintain different prices between countries. Cross border parallel trade in a handful of markets, formal and informal cross-border reference pricing, and the practical and legal difficulties of price discrimination within countries, create disincentives to lower prices for persons with less capacity to pay. Within many countries, the profit maximizing prices are often those targeted at a small number of relatively affluent consumers. For countries that have universal health insurance, consumers are protected somewhat from differences of income within countries, but still influenced by differences of income between countries.

In *Illustration 2,* national *per capita* income and populations are arranged to show the shape of a global demand curve, in a stylized example of a world with universal health insurance at the national level, and constant global income elasticities of demand.

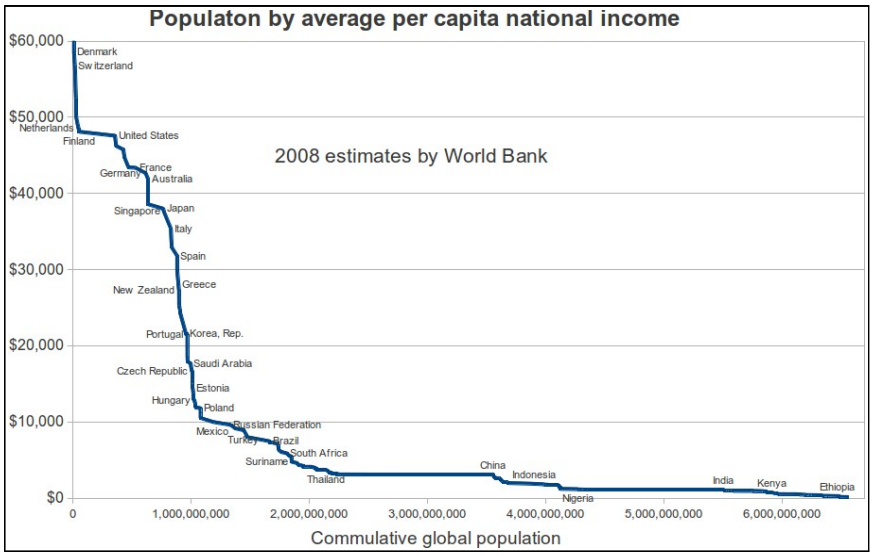

Illustration 2: What the shape of a global demand curve looks like, with constant income elasticities

If a company had to pick a single price, it would be one that was affordable in only a handful of high income countries. A single price that was affordable for most people would not be the profit maximizing price. In this simple stylized case, where insurance was universal within countries, the profit maximizing price would be one affordable to .89 billion persons, and not affordable to 5.68 billion persons – meeting the needs of only 13.5 percent of global population.

In practice, markets are of course more complex, with gaps in health insurance, major differences in reimbursement and distribution practices, lower income elasticities of demand in lower income countries, and a variety of other price determining factors that either increase or decrease access for particular products. In general however, there is not doubt about the central problem created by unequal incomes – a tendency to price products in such a way that products are not affordable for many persons.

Competition plays an important role in lower prices for products

For most products, the creation of market monopolies creates huge differences between costs of product and the prices paid by consumers. These differences can be seen by by comparing prices of Indian generics to prices charged under patent in high income countries, or even by looking at prices within high income countries.

For example, in the United States, IMS estimated that in 2010, generic drugs represented 78 percent of prescriptions by volume, but only 13.4 percent of sales in a market of $310 billion.[2] For the U.S. market, the cost of each one percent of the market was $.53 billion from generic suppliers, and $12.2 billion from patented/brand name suppliers.

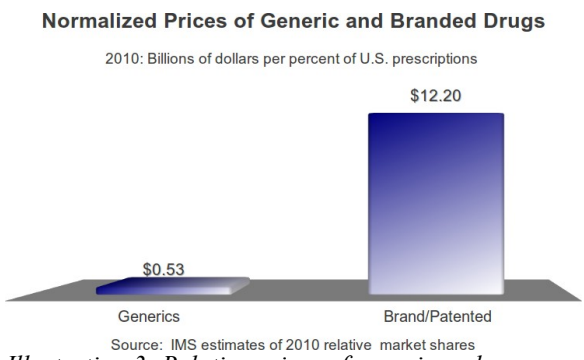

Illustration 3: Relative prices of generic and patented/branded drugs in United States

Generic prices are the most affordable when there is the capacity to manufacture products, and a large enough market to induce entry to multiple suppliers, and sufficient economies of scale and scope to achieve manufacturing efficiencies.

Changes in global international property regimes have reduced the size of generic markets for new drugs in developing countries, and the pressure to extend market monopolies in high income countries through a proliferation of *sui generis* intellectual property regimes for test data, orphan product exclusivity, and other legal barriers to competition, make it challenging to find competitive low cost generic suppliers for many products.

As the committee does its work, it needs to have a strategy to encourage and promote competitive supplies for new medicines.

Prizes that de-link R&D incentives from product prices

KEI requests our presentation to the CEWG on April 6, 2011, titled "De-linking R&D costs from product prices," (attached via email) be incorporated by reference. Rather than repeat that document here, including the rationale for de-linkage or innovation inducement prizes, we add some additional information.

KEI maintains a web page with links to research and analysis of medical innovation inducement prizes here: http://www.keionline.org/prizes

Among the featured articles are following that are relevant to the work of the CEWG:

- March 7, 2008. Selected Innovation Prizes and Reward Programs, *KEI Research Note 2008:1* This paper examines hundreds of innovation inducement prizes over several centuries, addressing a variety of innovation issues.

- James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," *Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer 2009, and "The Big Idea: Prizes to Stimulate R&D for New Medicines," Chicago-Kent Law Review, Volume 82, Number 3 (2007).* These two papers describe the rationale and key design issues for medical innovation inducement prizes that completely de-link R&D incentives from product prices.

- May 26, 2011. Overview of the Medical Innovation Prize Fund Act. This provides a background on S. 1137, a bill recently introduced in the U.S. Senate that would eliminate product monopolies for new medicines in the United States, by creating an $80+ billion

2 The Use of Medicines in the United States: Review of 2010, Report by the IMS Institute for Healthcare Informatics

alternative reward for successful innovations, including an open source dividend and systems for both end product and interim results prizes.

- May 26, 2011. Overview of the Prize Fund for HIV/AIDS Act. This provides an overview of S. 1138, a small more version of the prize fund approach, that targeted treatments for HIV/AIDS. To appreciate the importance of this bill, consider the following.

  - There are more than 1.1 million persons living with HIV in the United States, and an estimated 56 thousand new infections every year.
  - Only 24 percent of persons living with HIV in the United States are estimated to be currently receiving antiretroviral drugs.
  - The average retail price of the most important first line treatment in the United States is about $24 thousand per year.
  - Common four drug protease inhibitor regimes have retail prices that exceed $35 thousand per year. From 2006 to 2010, U.S. Expenditures on antiretroviral drugs for HIV increased from $5.6 to $9.2 billion.
  - From January 2009 to May 2011, the U.S. has seen an explosive growth in waiting lists for government programs that provide ARV drugs.

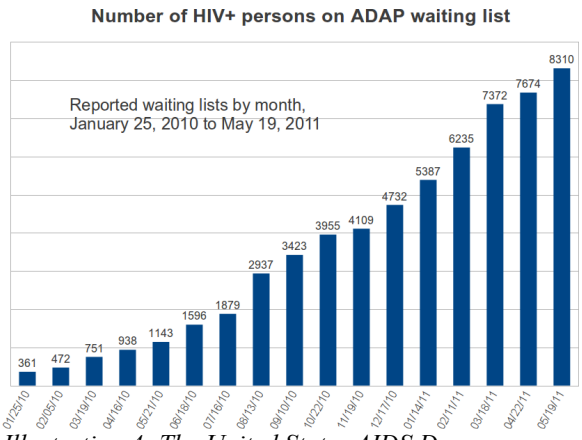

Illustration 4: The United States AIDS Drug Assistance Programs are under funded

The CEWG prize proposals

The CEWG has been asked to evaluate five quite different proposals for innovation prize funds that de-link R&D incentives from final product prices.

In 2009, Bangladesh, Barbados, Bolivia and Suriname (3B+S) provided the following proposals to the EWG on R&D Financing:

- **Chagas Disease:** Chagas Disease Prize Fund for the Development of New Treatments, Diagnostics and Vaccines
- **Donor:** Prize Fund to Support Innovation and Access for Donor Supported Markets: Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Uses
- **TB Diagnostic:** Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis

The 2009 proposal by Bangladesh, Bolivia and Suriname (2B+S) to the EWG on R&D Financing:

- **Cancer:** Prizes as a Reward Mechanism for New Cancer Treatments and Vaccines in Developing Countries

In addition, some submissions to the CWEG have made reference to this earlier 2008 proposal by Barbados and Bolivia (2B) to the IGWG :

- Priority Medicines and Vaccines Prize Fund (PMV/pf)

Each of the 2B, 2B+S and 3B+S prize fund proposals are designed to address different innovation challenges, and have fairly different structures, funding levels and funding mechanisms. I will briefly comment on two – the donor prize fund and the cancer prize fund.

While innovation is a consideration of the donor prize fund and the cancer prize, the benefits of both are perhaps best understood when focusing on the proposals as mechanisms to expand access to products in developing countries. Both were presented to the WHO as possible mechanisms to achieve cost effective and affordable access to medicines within the context of existing and often underfunded mechanisms to buy medicines. Neither proposal received any analysis by the previous EWG or from the recent Results for Development study of innovation prizes, other than the unsupported assertion that the proposals were not acceptable to big pharmaceutical companies, a statement that was certainly not true for the donor prize fund, and not particularly relevant to the cancer prize fund.

The Donor Prize Fund

The donor prize fund is a proposal to set aside a percentage of donor outlays on drugs for HIV/AIDS and perhaps other diseases supported by humanitarian funding programs, for an innovation prize fund – and then link the prize fund money to the licensing of patents and other intellectual property to generic suppliers. It is necessarily a voluntary mechanism, as it would be administered on behalf of more than 100 developing countries – and it in practice be impossible to implement as a non-voluntary mechanism.

In the 3B+S proposal, perhaps 10 percent of money now spent on drug purchases would be set aside into the fund, a figure that could be modified as desired. The rationale for creating the prize fund is to create an incentive for drug developers to negotiate a given fraction of the drug budget as the innovation reward, in return for giving up the monopolies on products, and permitting generic competition. During the Mexico International AIDS Conference and at a meeting on Prizes held at MSF in 2010, Gilead and Johnson and Johnson (J&J), two very important developers of drugs for HIV and other Type II diseases, both said that the donor prize fund approach was a sound basis for a negotiation with drug developers, as regards in particular the objective to obtaining much wider geographic coverage for voluntary licenses for the Medicines Patent Pool. Earlier, at an MSF meeting on TB, Paul Herrling from Novartis agreed that some combination of prize funds and patent pools might work for the developing county implementation of rewards for development of tuberculosis drugs.

Some treatment activists are concerned that the donor prize fund would divert money from treatment. However, this would only be true if the funding of the prize fund was more expensive than alternative ways of obtaining access to newer AIDS drugs. The CEWG might consider requesting the WHO, UNAIDS or the Global Fund to simulate the costs and benefits of the donor prize fund, with regard in particular to efforts to provide sustainable access to newer generation drugs for HIV/AIDS. Would the donor prize fund increase or decrease the cost of acquiring such drugs, and are there really any more promising ways to obtain access to newer HIV/AIDS drugs?

The major advantages of the donor prize fund is that it can be implemented without any new sources of funding, and indeed, is presented as a cost saving measure. If successful as regards efforts to obtain licenses, it would ensure that on the margin, drugs can be purchased at competitive generic prices, something that is not the case today for many newer drugs, in a world with rapidly

expanding intellectual property protections in developing countries (including, by 2016, in LDC countries).

The Cancer Prize Fund

The 2B+S proposal for cancer is somewhat different. There is no tradition of donor funding for cancer drugs – just a very great disparity of access. A game changing cancer drug like Herceptin, which treats HER2+ breast cancer, is essentially unavailable to most people living in developing countries, because of its high price.

Pricing contours for cancer drugs are much flatter than they are for AIDS drugs, where the use of compulsory licenses have been used or threatened to bring prices down in developing countries.

The cancer prize fund proposal is the implementation of changes in patent laws, to eliminate monopolies for cancer drugs, and to implement the innovation reward as a prize fund that is funded by the public and private entities now providing for insurance for cancer treatments.

By radically lowering the prices of cancer drugs, developing countries would have a greater incentive to finance other aspects of cancer treatment, such as diagnostics, surgery, radiation and care. As developing countries become more developed, and outlays on treatment increase, the rewards to drug developers would increase – in some useful relationship to the benefits of the drugs to patients in developing countries.

KEI has a proposed terms for reference for studying of the feasibility of the cancer prize fund approach in both the European market, where there are order of magnitude differences in national per capita incomes, and within developing countries. KEI can provide this to members of the CEWG or the WHO staff.

Both the donor and the cancer prize fund are serious proposals to reconcile innovation and access in countries where resources are scarce and people are poor.

The other 2B and 3B+S prize fund proposals are also worth study, including in particular the TB and Chagas prizes, both of which anticipate and address concerns that in some cases, open licensing alone is not a sufficient access provision.

In addition, and as an overall comment on innovation inducement prize funds, KEI strongly recommends the CEWG examine in detail the open source dividend proposal included in several of the EWG prize proposals, as well as in S. 1137 and S.1138.

Other Prize Proposals.

KEI recommends the CEWG become familiar with S.1138, the Prize Fund for HIV/AIDS Act.

KEI recommends the CEWG reject the Health Impact Fund proposal because it does not targets resources effectively, given the likely amount of money available from new funding sources, and because it will undermine rather than expand the role of generic drug manufacturers in supplying drugs. In this regard, the HIF should be seen as an anti-competitive response to more transformative and pro-consumer and pro-competitive proposals. The HIF is clearly preferred by those who want to protect the status quo and big pharmaceutical company interest, and it is seen by many as a distraction to real reforms. (More comments on this topic at

http://www.keionline.org/hif)

KEI suggests that CEWG be wary of the Advanced Marketing Commitment (AMC) and Advanced Purchase Commitment (APC) proposals, which as currently implemented are largely designed to subsidize a handful of politically well connected vaccine manufacturers, and do not make an effort to overcome barriers to competition in the vaccine market, or build new developing country capacity to manufacture vaccines.

KEI appreciates the fact that the priority review voucher is a prize type mechanism, but it has many implementation flaws, provides no assurances regarding pricing or access, and is difficult to scale.

Appendix

The following are six figures from *KEI Research Note 2010:5* Differences in deaths for 6 cancer types in 14 WHO regions, with reference to income of region. This and other information relating to cancer are available from http://www.keionline.org/cancer

Figure 1. Breast Cancer: Death rates and incomes in 14 WHO regions

Ratio of 2004 breast cancer deaths to new breast cancer cases in the same year

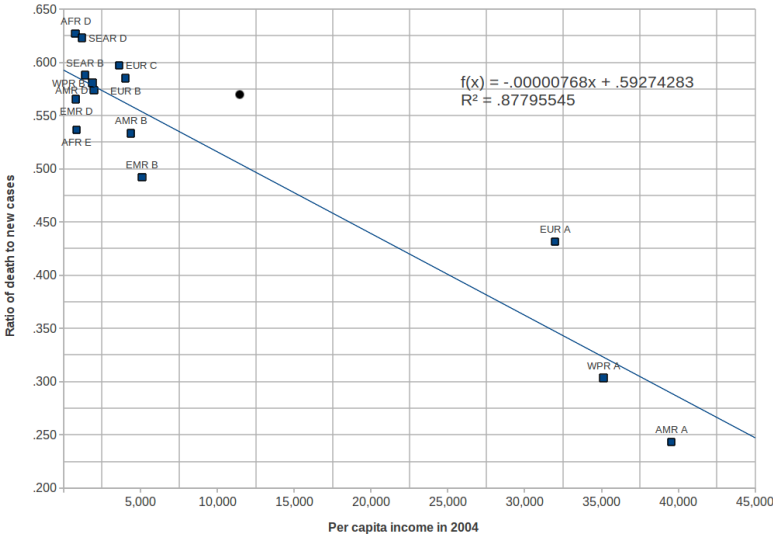

Figure 2. Prostate Cancer: death rates and incomes in 14 WHO regions

Ratio of prostate cancer deaths to new prostrate cancer cases in the same year

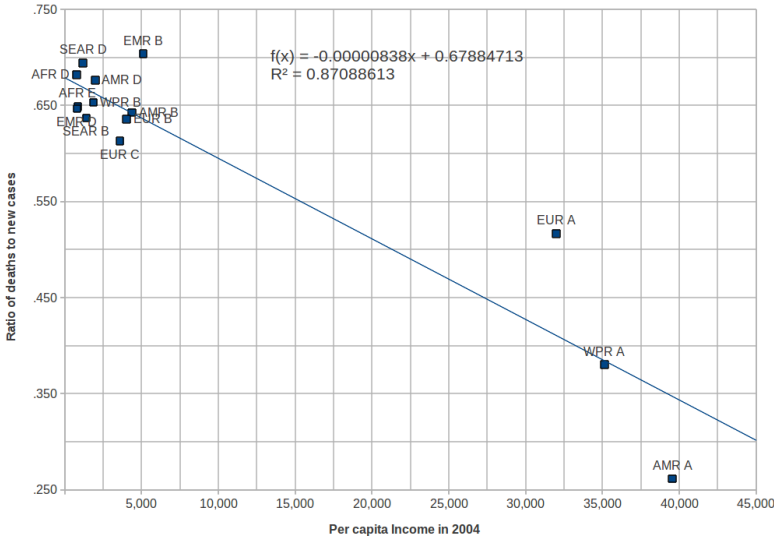

Figure 3. Cervix uteri cancer: death rates and incomes in 14 WHO regions

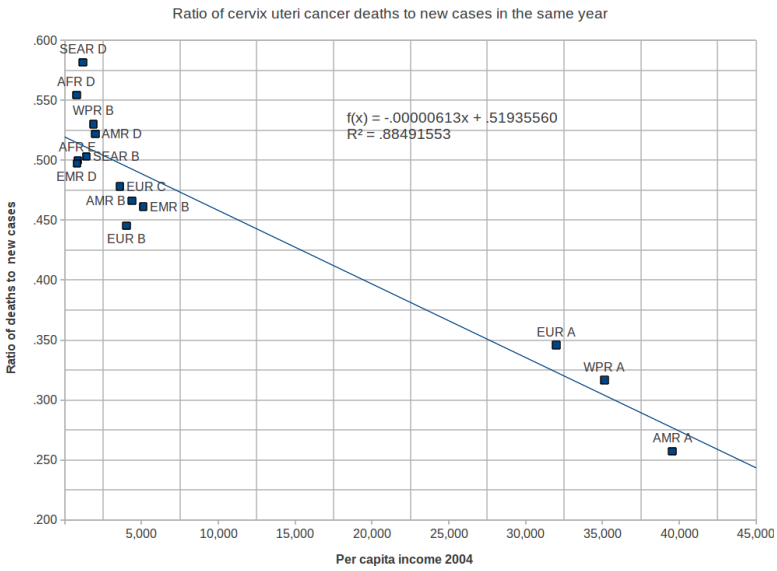

Figure 4. Colon and rectum cancers: death rates and incomes in 14 WHO regions

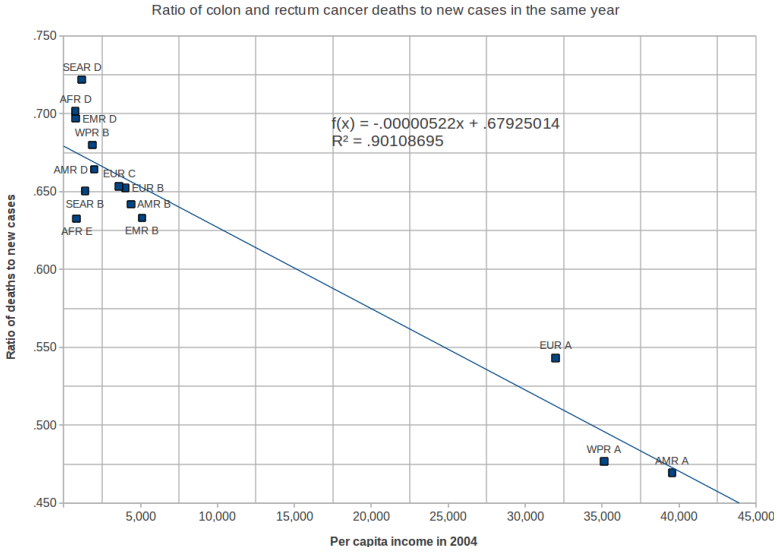

Figure 5. Bladder cancer: death rates and incomes in 14 WHO regions

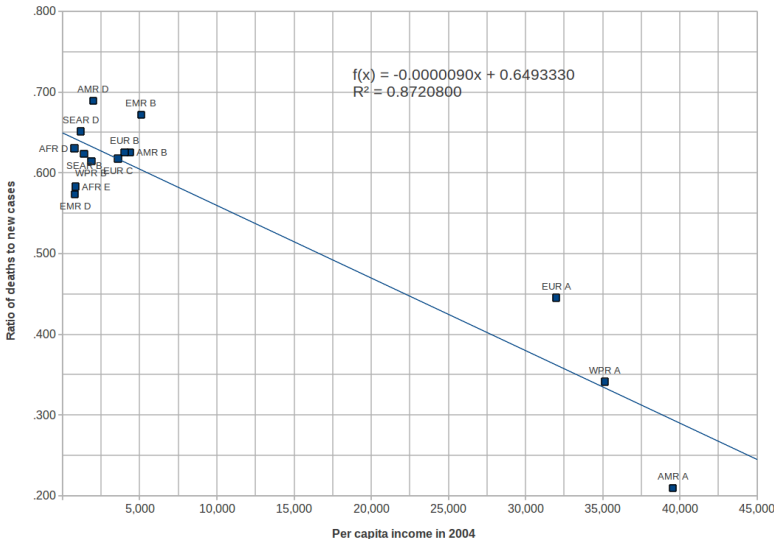

Figure 6. Melanoma and other skin cancers: death rates and incomes in 14 WHO regions