Essential Medicines, Intellectual Property and Neglected Diseases:

A Proposal for Reform

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Essential medicines

"Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness.

"Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford."

- WHO Expert Committee 2003:22

Medicamentos esenciales

"Se consideran esenciales los medicamentos que cubren las necesidades de atención de salud prioritarias de la población. Su selección se hace atendiendo a la prevalencia de las enfermedades y a su seguridad, eficacia y costoeficacia comparativa.

"Se pretende que, en el contexto de los sistemas de salud existentes, los medicamentos esenciales estén disponibles en todo momento, en cantidades suficientes, en las formas farmacéuticas apropiadas, con una calidad garantizada, y a un precio asequible para las personas y para la comunidad."

- www.who.int/topics/essential_medicines/es/

WHO Model List of Essential Medicines

18th list

(April 2013)

(Final Amendments – October 2013)

Status of this document

This is a reprint of the text on the WHO Medicines web site

http://www.who.int/medicines/publications/essentialmedicines/en/index.html

Market Failure?

- In 2003, it was observed that "only 5% of the world's people with HIV/AIDS in developing countries who [needed] anti-retroviral treatment ... [actually had] access to it" (Elliott *et al*., 2003).
- Ten years later, "the HIV treatment coverage in low- and middle-income countries represented only 34% (32-37%) of the 28.6 million people eligible in 2013" (UNAIDS 2013, 6).
- Anti-retroviral drugs permit HIV-positive individuals to live productive lives. They do not cost much to manufacture. They are "essential medicines" for many developing countries. And yet...
- They are ***not*** available for 2 out of 3 persons in need of them.

Market Failure?

- The non-availability of essential antiretroviral medications to combat the HIV/AIDS pandemic in developing countries was, and still is, primarily (but not exclusively) one of *price* – the treatments exist, but the majority of those who need them cannot afford them.
- For numerous other diseases constituting serious health-problems in developing countries, the problem is, rather, that remedies do ***not*** exist – or are very inadequate – for the reason that relatively little medical and scientific research is devoted to them.
- Once again, the reason is that the prospective market does not provide an adequate ***incentive*** to have this research done.

Market Failure?

"One of the challenges of development is that technology specifically designed to address the problems of poor countries is not developed, both because the public interest of rich countries in subsidizing such technology is low or heavily discounted and because there are no private incentives, given that the markets in which the technology would be sold are thin and small. This has long been recognized as a problem in terms of health interven-tions, especially medicines and vaccines for diseases that affect developing countries almost exclusively, but it also exists in other areas, like agriculture."

- WHO-EWG 2010:10

¿ Fallo del mercado ?

"Uno de los obstáculos al desarrollo es que aún no se haya creado una tecnología específicamente concebida para resolver los problemas de los países pobres, debido a que el interés público de los países ricos en subvencionar esa tecnología es bajo o muy reducido, y a que no hay incentivos privados, pues los mercados donde se vendería dicha tecnología son pequeños y débiles. Esto ha sido un problema desde hace mucho tiempo para las interven-ciones sanitarias, en especial en lo que atañe a los medicamentos y las vacunas para enfermedades que afectan casi de forma exclu-siva a los países en desarrollo, si bien ese problema también existe en otros ámbitos, como la agricultura."

- WHO-EWG 2010: 11*es*

Before we continue,

a bit of terminology...

Diseases of Type I, II & III

- Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each.
- Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries.
- Type III diseases are those that are overwhelmingly or exclusively incident in developing countries.

- WHO-CEWG 2012:18n2

Neglected Tropical Diseases (NTDs)

(Enfermedades tropicales desatendidas)

- These diseases constitute a group of 17 Type III diseases which have been prioritized by the World Health Organization (World Health Assembly resolutions).
- They include Buruli ulcer disease (*Mycobacterium ulcerans* infection), Chagas disease (American trypanosomiasis), cysticercosis, dengue, dracunculiasis (guinea-worm disease), echinococcosis, endemic treponematoses, foodborne trematode infections, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis (elephantiasis), onchocerciasis (river blindness), rabies, schistosomiasis (bilharziasis), trachoma and soil-transmitted helminthiases.
- Many literate and well-educated North Americans and Europeans will not even have heard of most of these diseases, with the possible exception of rabies, sleeping sickness and leprosy.

Market Failure: Is there one problem, or several ?

There seem to be at least two problems:

- The (artificially?) high price of certain essential medicines of particular importance for developing countries (e.g. antiretrovirals)
- The lack of research on diseases of Types II and III and, as a consequence, the absence of good quality essential medicines (at any price) for diseases of particular importance for developing countries (e.g. dengue, chikungunya, leishmaniasis, etc.)

But these two problems may share at least one common cause (to which we shall return shortly), namely the currently dominant intellectual property regime.

Health Research

The "10/90 Gap" – or is it 5/93 ?

- According to the Global Forum for Health Research (GFHR), in 1998, only 10% of health research in the world is devoted to the health problems of 90% of the world's population.
- The Commission on Health Research and Development (CHRD) proposes a revised calculation which "would suggest a 5/93 gap" whereby only 5% of health research is devoted to the problems of 93% of the world's population.

- Cf. WHO-CEWG 2012:90

Searching for the cause of injustice and of obstacles to development:
How is medical innovation to be paid for?

- The currently dominant model for how medical and, in particular, pharmaceutical research is to be financed is through the system of patents – a form of intellectual property.
- This system is considered by some to be the best way to incentivize scientific and medical innovation.
- Others, however, consider the current system of patents to be ill-adapted to the needs of developing countries (in particular) – or even not appropriate for medicines in the first place!

Patents and TRIPs

- A patent is a form of commercial monopoly restricting, by law, the manufacture, sale, export and import of an invention.
- A patent is granted – and enforced - by a national government.
- Applying patents to *medicines* (and requiring government approval to market the latter) is a relatively new phenomenon, even in advanced, industrialized countries.
- In 1994, member states of the World Trade Organization (WTO), signed the ***Agreement on Trade-Related Aspects of Intellectual Property (TRIPs)***.

TRIPs = ADPIC

- *Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC)*
- Se trata del Anexo 1C del Convenio por el que se creó la Organización Mundial del Comercio (OMC) firmado en 1994.
- En él se establece una serie de principios básicos sobre la propiedad intelectual tendientes a armonizar estos sistemas entre los países firmantes y en relación al comercio mundial.
- Todos los miembros del OMC deben obligatoriamente conformarse al *Acuerdo sobre los ADPIC*.

Joseph Stiglitz on TRIPs
From: *Making Globalization Work* (2007)

- The TRIPs Agreement attempts to impose "on the entire world the dominant intellectual property regime in the United States and Europe".
- This system is "not in the interests of developing countries".
- It is also "not good for the United States and the EU".
- Stiglitz furthermore argues that no one single intellectual property regime can be suitable, simultaneously, "for the least-developed, the middle-income and the advanced industrialized countries".

- "Patents, Profits and People" (ch. 4)

Joseph Stiglitz on TRIPs (cont'd)
From: *Making Globalization Work* (2007)

- Patents restrict the flow of knowledge and technology.
- Patents require a good deal of government intervention in order to enforce them.
- The difference between patent-supported prices and the price of generics in the absence of patents can thus be thought of as a form of "tax" paid by the end-consumer.
- This "tax" is paid in the hope of a presumed benefit conferred by the overall system.
- The promised benefits do not seem to be forthcoming.

- "Patents, Profits and People" (ch. 4)

Market Failure: Is there one problem, or several ?

We recall (as already remarked on an earlier slide) that there appears to be at least two problems:

- The high price of certain essential medicines of particular importance for developing countries (e.g. Antiretrovirals)
- The lack of research on diseases of Types II and III and, as a consequence, the absence of good quality essential medicines (at any price) for diseases of particular importance for developing countries (e.g. dengue, chikungunya, leishmaniasis, etc.)

These two problems may share at least one common cause, namely the currently dominant intellectual property regime.

Solutions ?

- In its 226-page report to the World Health Assembly in 2012, entitled *Research and Development to Meet Health Needs in Developing Countries*, the Consultative Expert Working Group on the question has examined a number of proposals, including the following:
  - Linking research strategies to access considerations and [...] delinking the costs of R&D from the price of products.
  - Innovative sources of funding for the necessary research.
  - The adoption of a binding international agreement based on Article 19 of the WHO constitution – inspired by the already existing Framework Convention on Tobacco Control.

Solutions ?

- Delinking the costs of R&D from the price of products would mean that R&D would mean that R&D would no longer be financed by *charging what the market will bear* for patent-protected products.
- A better principle for fixing priorities for access to treatment and investment in research is the principle of ***triage*** (as used in hospital emergency departments throughout the world).
- The basic criterion for decisions should and could be the *burden of disease* as measured by Disability-Adjusted Years of Life (DALYs) which are currently lost or which can potentially be saved.

Solutions ?

- Part of the solution should include a mechanism for rewarding and incentivizing the developers of useful new medicines, diagnostics and vaccines.
- A model for this mechanism is provided by the Canadian Public Lending Right Program which provides annual payments to the authors of works on loan in Canadian public libraries.
- It is beneficial to the entire community that there be access, free of charge, to books. It is beneficial that authors should receive some compensation for the usefulness of their work.
- Authors' compensation need not be solely a function of sales in bookstores – but can be calculated from an estimate of readership of their works on loan in public libraries.

Solutions ?

- The mechanism for rewarding and incentivizing the developers of useful new medicines, diagnostics and vaccines would not be a function of their readership – but of the health benefits which resulted from their use and application.
- A possible measure of health benefits is reduction in mortality (lives saved).
- A better measure of health benefits is years of life saved. (Saving the lives of 32-year-olds is preferable to saving the lives of 100-year-olds.)
- A yet better measure of health benefits is Disability-Adjusted Years of Life (DALYs) the loss of which can potentially be saved by treatment or prevention.

Solutions ?

- But to offer ***solutions*** is to pre-suppose there is a problem.
- The currently dominant intellectual property regime (under the *TRIPs Agreement*) purports to solve the problem of funding scientific and medical innovation for the benefit of all.
- But does it?

False premises and unkept promises

- (1) Revenue from patent-supported pricing pays for research.
- (2) Patent-supported pricing is the normal, "obvious" way to incentivize innovation: without it, there would be either fewer medical innovations, or perhaps none at all.
- (3) Rich and poor nations alike benefit from health research paid for by patent-supported prices.
- (4) Any hardships and injustices initially associated with the *TRIPs Agreement* regime have been eliminated through "flexibilities" in the form of compulsory licenses and parallel exports, in order to allow member states to deal with public health crises.

(1) How is patent-generated revenue actually used? (a)

- The former editor-in-chief of the *NEJM* writes: "In 2002, when the ten U.S. drug companies in the Fortune 500 list had combined worldwide sales of about $217 billion and spent just over 14 percent of that on R&D (about $31 billion), they had a profit margin of 17 percent ($36 billion). Thus, profits were substantially more than R&D costs. Even more startling is the fact that they spent a walloping 31 percent of sales (about $67 billion) on marketing and administration." (Marcia Angell 2004)
- To summarize:
  - Company profits are higher than expenses claimed for R&D.
  - Expenses identified as marketing and administration were more than twice those claimed as having been for R&D.

(1) How is patent-generated revenue actually used? (cont'd (b))

- Marcia Angell also calls attention to the fact that the figures for amounts spent on "research" by the pharmaceutical companies are provided by the companies themselves, with no detailed breakdown of how this money was actually spent.
- So-called "phase IV trials", for example, are probably budgeted for under "research" – while they are really promotional campaigns in which doctors are paid to try new medications (which have already been approved).
- We are entitled to wonder whether the widespread phenomenon of "medical ghostwriting" paid for by pharmaceutical companies is not also budgeted for under "research".

(1) How is patent-generated revenue actually used? (cont'd (c))

- Most of the time, effort and money of researchers working for the big pharmaceutical companies is spent on the search for a "blockbuster" (like Lipitor or Prozac) – or on producing "me-too" approximations of the block-busters of rival companies.
- Another relatively unproductive research activity is directed at the "evergreening" of existing patents for existing medications.
- Patent-generated revenue also provides both the incentive and wherewithall for pharmaceutical companies to conduct effective lobbying and public relations campaigns against initiatives perceived as threatening this source of revenue.

(1) What proportion of research is actually financed by patent-generated revenue? (cont'd (d))

- In the case of neglected diseases, research expenses claimed by "aggregate pharmaceutical and biotechnology companies" as compiled by the WHO Consultative Expert Working Group in their report submitted in 2012, amounted to 16.4% of the total amount for the year 2010.
- The Bill & Belinda Gates Foundation provided almost as much, at 14.9%.
- The United States National Institutes of Health (NIH) provided an impressive 39.6%.
- All other funders contributed less than 3,3% each.
- The total expenditures on this type of research was only slightly more than $3 billion US (dollars of 2007).

(1) What proportion of research is actually financed by patent-generated revenue? (cont'd (e))

Funder	2010 (US$)	2010 (%)
United States National Institutes of Health (NIH)	1 211 704 054	39.6
Bill & Melinda Gates Foundation	455 832 350	14.9
Aggregate pharmaceutical and biotechnology companies[A]	503 525 794	16.4
European Commission	92 529 756	3.0
United States Department of Defence (DOD)	69 942 925	2.3
United States Agency for International Development (USAID)	85 975 465	2.8
United Kingdom Department for International Development (DFID)	97 229 720	3.2
Wellcome Trust	80 459 662	2.6
United Kingdom Medical Research Council (MRC)	60 857 019	2.0
Dutch Netherlands Ministry of Foreign Affairs	–	–
Inserm–Institute of Infectious Diseases	20 196 417	0.7
Institut Pasteur	45 158 519	1.5
Australian National Medical Health and Medical Research Council	19 464 047	0.6
Subtotal top 12 funders	2 742 875 728	89.6
Total R&D funding	**3 062 669 973**	**100**

[A] Includes new survey respondents in 2009 and 2010

(1) Which "neglected diseases" are investigated?

Table 2.3 Total R&D funding by disease, 2010 (2007 US$)

Disease	2010 (US$)	2010 (%)
HIV/AIDS	1 073 033 520	35.0
Tuberculosis	575,361,902	18.8
Malaria	547 042 394	17.9
Dengue	177 643 516	5.8
Diarrhoeal diseases	158 918 128	5.2
Kinetoplastids	147 867 513	4.8
Bacterial pneumonia & meningitis	92 866 038	3.0
Helminth infections (worms & flukes)	73 685 406	2.4
Salmonella infections	43 982 149	1.4
Leprosy	8 840 532	0.3
Buruli ulcer	5 456 026	0.2
Trachoma	4 507 718	0.1
Rheumatic fever	1 736 877	0.1
Platform technologies	27 358 501	0.9
Core funding of a multi-disease R&D organization	76 884 279	2.5
Unspecified disease	47 485 474	1.6
Disease total	**3 062 669 973**	**100.0**

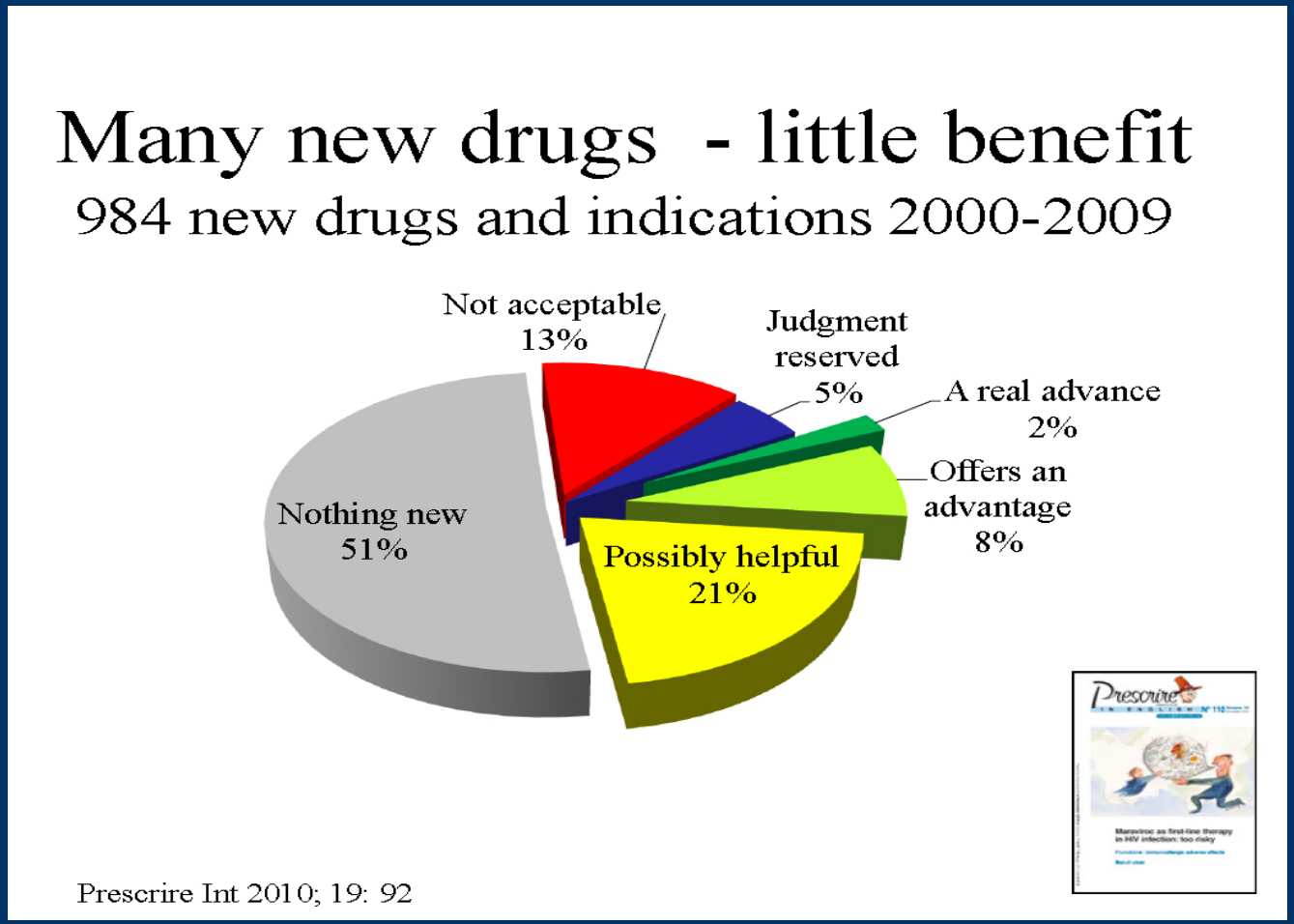
Source: G-Finder Report, 2011.

(2) Does patent-generated revenue effectively incentivize innovation? (a)

- Many extremely important innovations have occurred ***without*** the benefit of patent protection (anaesthetics, aspirin, insulin, penicillin, anti-polio vaccine, etc.).
- Many authors and at least two Expert Working Groups of the World Health Organization have observed that in the period since the inception of the *TRIPs Agreement* in 1994, the pace of innovation has actually slowed considerably (i.e. not accelerated).
- The present system provides more incentive towards the development of "me-too" drugs for the affluent countries than it does towards the development of genuinely innovative medicines useful in developing countries.

(2) Does patent-generated revenue effectively incentivize innovation? (cont'd (b))

This pie-chart – from the French publication *Prescrire* – was presented by Jörg Schaaber of the *International Society of Drug Bulletins* at the "Selling Sickness" conference held in Washington in 2013:



(3) Do the benefits of patent-funded research flow to rich and pour alike ? (a)

In their 2012 report, submitted to the World Health Assembly, the Consultative Expert Working Group note:

"An influential article published [in the *Lancet*] in 2002 estimated that of 1393 new chemical entities (NCEs) marketed between 1975 and 1999, only 16 targeted 'tropical diseases' and tuberculosis" (WHO-CEWG 2012:35).

(3) Do the benefits of patent-funded research flow to rich and poor alike ? (cont'd (b))

Answer: The low level of expenditures from patent-supported and other sources on diseases of particular interest of the developing world indicates that patent-generated revenue is not adequately financing this direction of research.

(4) Do the TRIPs "flexibilities" in the form of compulsory licenses and parallel exports provide a solution to patent-imposed hardships? (a)

- These "flexibilities" were introduced by the *Doha Declaration* of 2001 and the General Council Decision of 2003.
- They allow national governments *under certain conditions* to issue compulsory licenses (even over the opposition of the patent-holders) for the manufacture of medications.
- This can extend to authorizing the manufacture of a product for export to a country with no pharmaceutical industry of its own (parallel export).

(4) Do the TRIPs "flexibilities" in the form of compulsory licenses and parallel exports provide a solution to patent-imposed hardships? (cont'd (b))

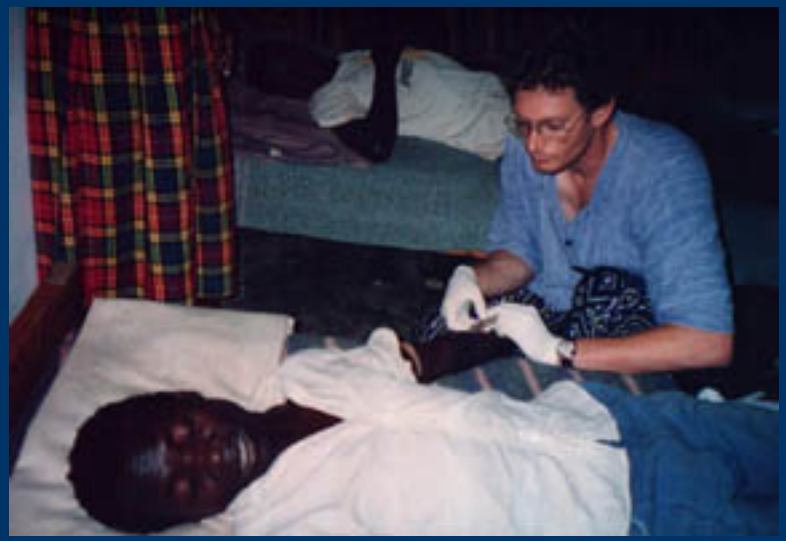
- The first case of such a parallel export was under Canada's Access to Medicines Regime (CAMR) and occurred in 2007.
- 260,000 packs of Apo-Triavar - enough to treat 21,000 AIDS patients for a year - were be delivered to Rwanda (at approx. 4¢ per pill, as opposed to $20).
- The second case occurred in 2008 when India authorized a local company Natco to copy and to export Roche's anti cancer drug, Tarceva to Nepal.
- It is difficult to give a brief account of the numerous restrictions and hurdles associated with these measures.
- CAMR, in its present configuration, is unlikely to be used again.
- Most of the difficulties associated with CAMR are directly attributable to wording in the *TRIPs Agreement*, the *Doha Declaration* and the General Council Decision.

The Eflornithine Affair
(a cautionary tale)

- In addition to simply failing to provide improved medications for important third-world diseases, the current intellectual property regime is also structured in a way as to deprive the world of an existing, effective medication.
- A striking example of this is the Eflornithine Affair.
- Eflornithine was originally developed in the hope it would be a useful cancer drug.
- In 1990, it was registered for use in the treatment of coma associated with sleeping sickness (African trypanosomiasis) - and earned the name "resurrection drug".

The Eflornithine Affair

(a cautionary tale – cont'd)



The Eflornithine Affair
(a cautionary tale – cont'd)

- However "the production of eflornithine was brutally discontinued in 1995 by the pharmaceutical group Hoechst Marion Roussel which held the patent the reason given being that the medication was not generating sufficient profits" (Borch-Jacobsen 2014: 72)
- NGOs like MSF campaigned, but in vain, to have the drug reinstated.
- Then, in 2000, it was discovered that the same molecule was effective in reducing female hirsutism – unwanted facial hair – and the drug Vaniqa was born.

The Eflornithine Affair

(a cautionary tale – cont'd)

Facial hair is unattractive

Vaniqa can remove facial hair in 4 weeks

NDC 67402-040-30

VANIQA®
(eflornithine hydrochloride)
Cream, 13.9%

For topical use only.

Rx only

Net Wt 30g (1.06 oz)

Not for ophthalmic oral, or intravaginal use.

See crimp of tube for Lot Number and Expiration Date.

Warning:
Keep out of reach of children.

Each gram contains:
13.9% (139 mg/g) of anhydrous eflornithine hydrochloride as eflornithine hydrochloride monohydrate (150 mg/g) in a cream base of ceteareth-20, cetearyl alcohol, dimethicone, glyceryl stearate, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, stearyl alcohol and water.

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Do not freeze.

USUAL DOSAGE: Apply to affected area twice daily. See package insert for complete information.

U.S. Patent No.: 5,648,394

Distributed By SkinMedica, Inc.
Carlsbad, CA 92010
Made in Canada
2005419

The Eflornithine Affair
(a cautionary tale – cont'd)

- The discontinuance and refusal to re-commence production of the anti-sleeping sickness medication thus began to assume the dimensions of a public relations disaster.
- The new owners of the patent (Bristol-Myers Squibb and Aventis) had tried to give WHO the right to seek a manufacturer for the anti-sleeping sickness drug – then they relented and resumed production themselves.
- They also tried to "make amends" by contributing $5 million per year for research on sleeping sickness.

The Eflornithine Affair
(a cautionary tale – cont'd)

- The proper reaction here is not to be scandalized at the "evil" actions of the management of BMS and Aventis.
- The proper reaction is to note that they were acting in conformity with the requirements of the system, *as it currently structured*.
- If management does not maximize profits, the shareholders are entitled to fire them – or to take other legal action.
- The proper reaction is to reflect what kind of structure could produce better outcomes. (This is a Spinozistic approach.)
- This also requires us to reflect on what distinguishes a "better outcome" from one which is "less good" – or an "important" health problem from a less important one.

The Eflornithine Affair
(a cautionary tale – cont'd)

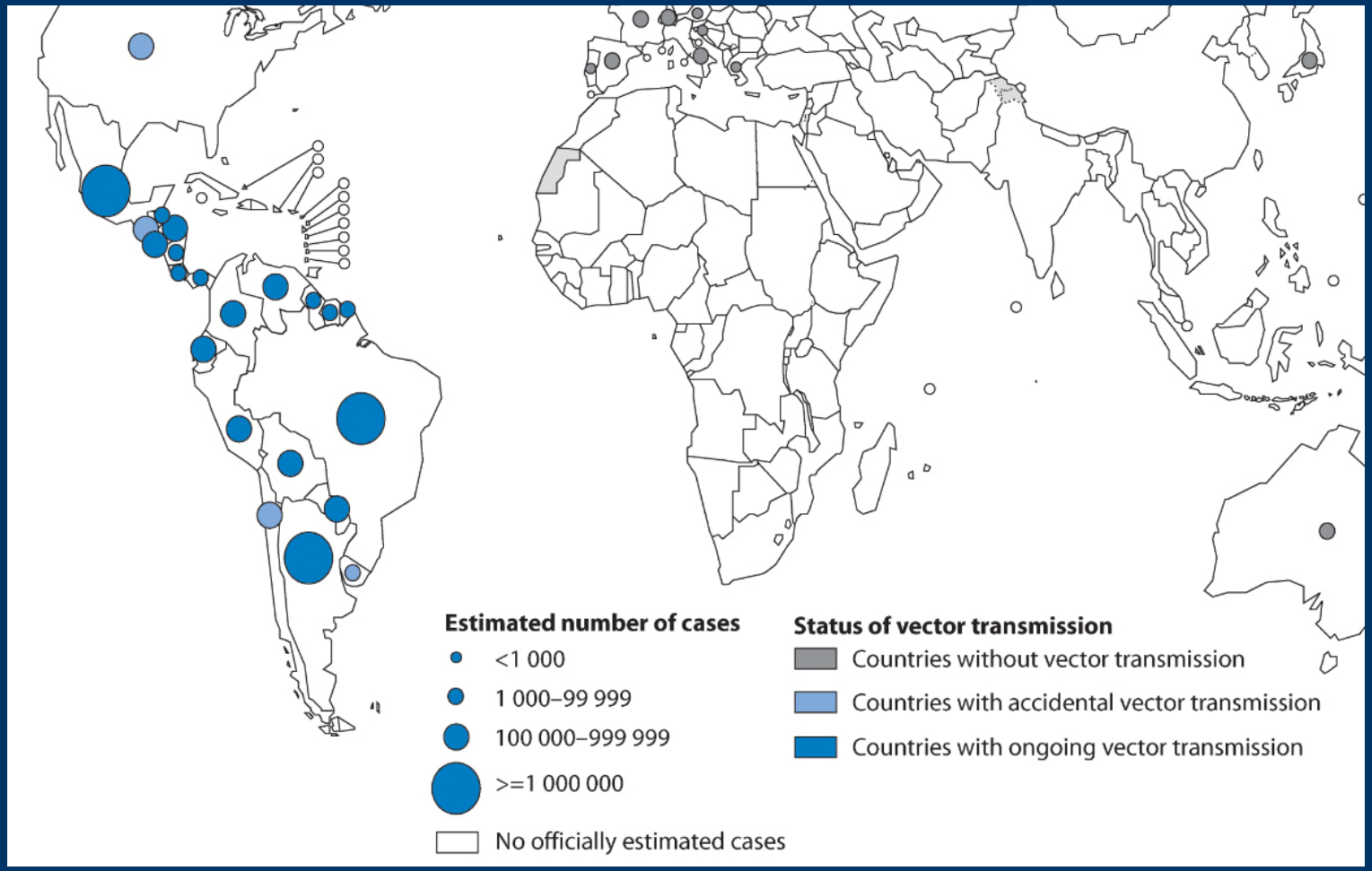
- We may in fact observe that the outcome of this episode has provided us with clues as to what a better structure might look like.
- A WHO-mandated body should be in charge of issuing contracts for the manufacture of other useful medicines (not just eflornithine).
- WHO should perhaps in addition be the sole patent-holder (to the extent that there exists a patent at all).
- WHO could be in charge of compensating the intellectual authors of innovative and useful treatments, diagnostics and vaccines, etc.
- The basic criterion for awarding contracts and for compensating the intellectual authors of treatments should be Disability-Adjusted Life Years saved (DALYs).

Another important but "neglected" disease: Chagas Disease

- Also known as American trypanosomiasis, Chagas Disease is caused by the trypanosoma cruzi parasite – a relative of the trypanosoma brucei which causes sleeping sickness.
- 7 to 8 million people (or more) in 21 countries of the Americas suffer from it.
- It kills more people in the Americas than malaria.
- It affects the productivity of those it hasn't yet killed.
- Less than 1% of those who are affected receive treatment.
- In 2004, the number of Disability-Adjusted Life Years lost to Chagas Disease in the Americas was 426 thousand. saved (DALYs).
- DNDi states that "Chagas disease is a leading cause of infectious cardiomyopathy worldwide".

Another important but "neglected" disease: Chagas Disease

Another important but "neglected" disease: Chagas Disease

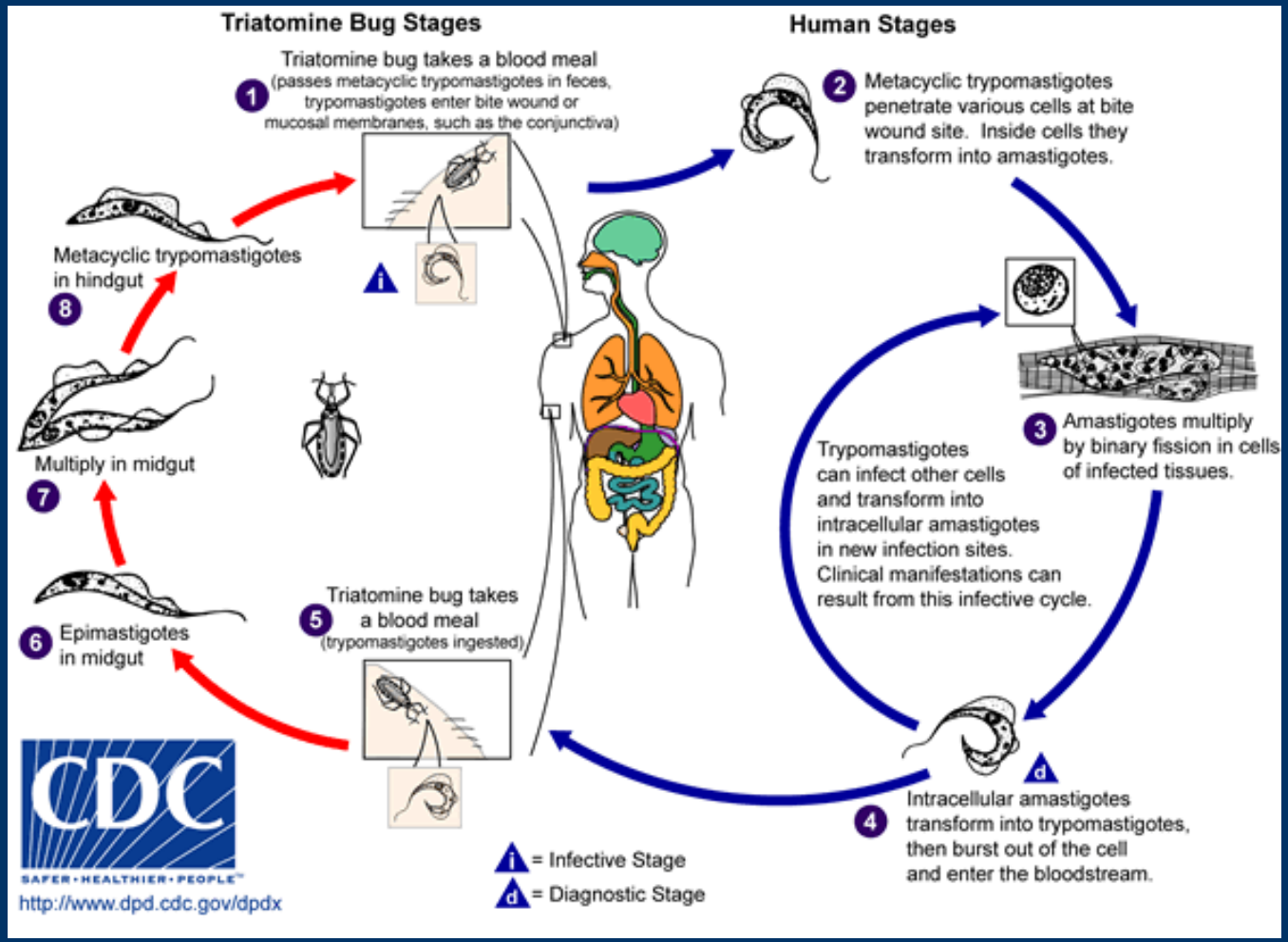


Another important but "neglected" disease: Chagas Disease

The main vector: the "kissing bug", triatomine or ***chinche picuda***.
Also known as *vinchuca* or *barbeiro* and by many other names besides.

Another important but "neglected" disease: Chagas Disease

The life cycle of trypanosoma cruzi



Another important but "neglected" disease: Chagas Disease

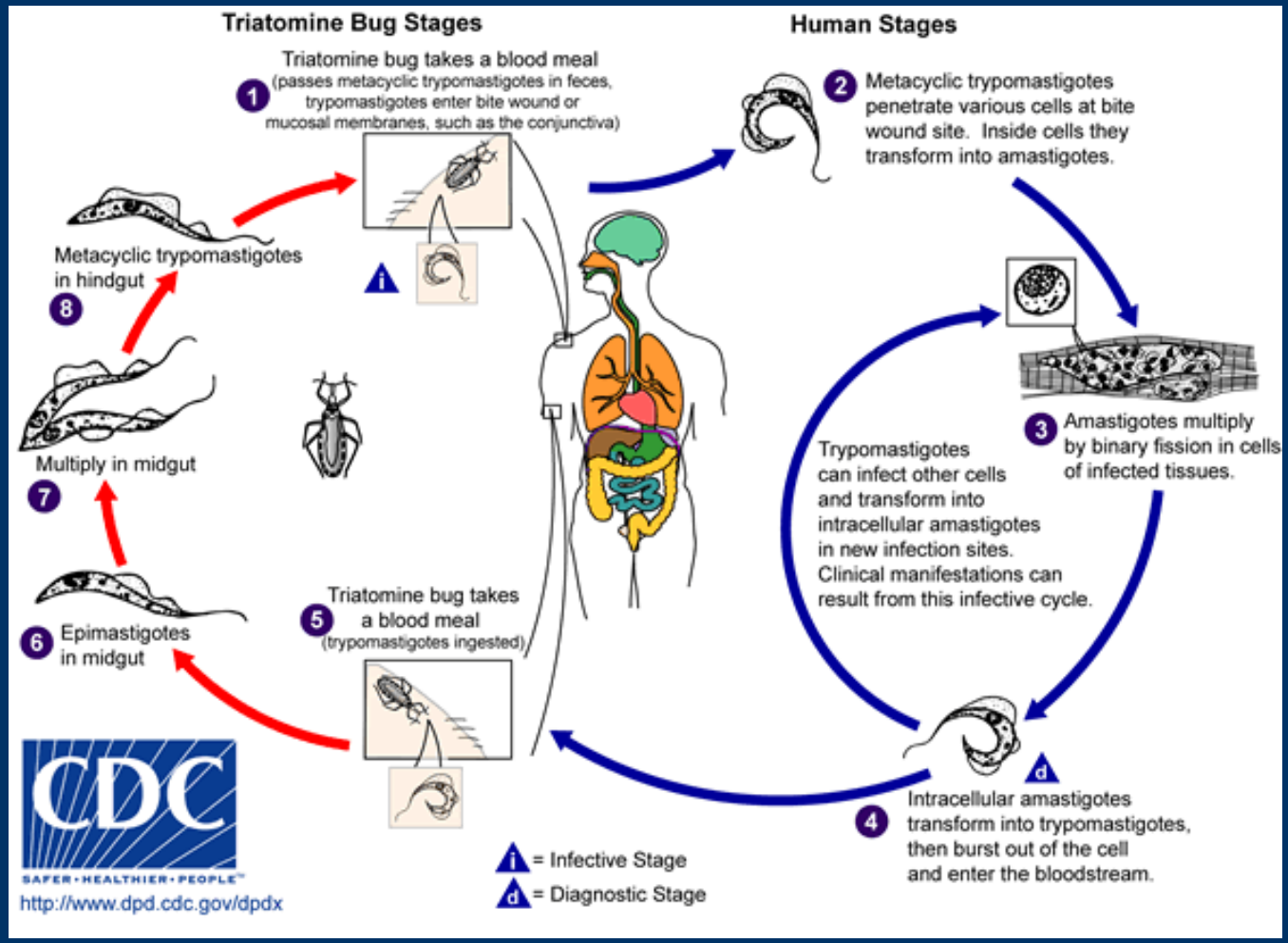
Named after Carlos Chagas (1879-1934)
who discovered the cause of the disease in 1909

Another important but "neglected" disease: Chagas Disease

Carlos Chagas named the parasite responsible for the disease trypanosoma ***cruzi*** in honour of his mentor, the Brazilian bacteriologist and epidemiologist Oswaldo Cruz (1872-1917)

Another important but "neglected" disease: Chagas Disease

The life cycle of trypanosoma cruzi

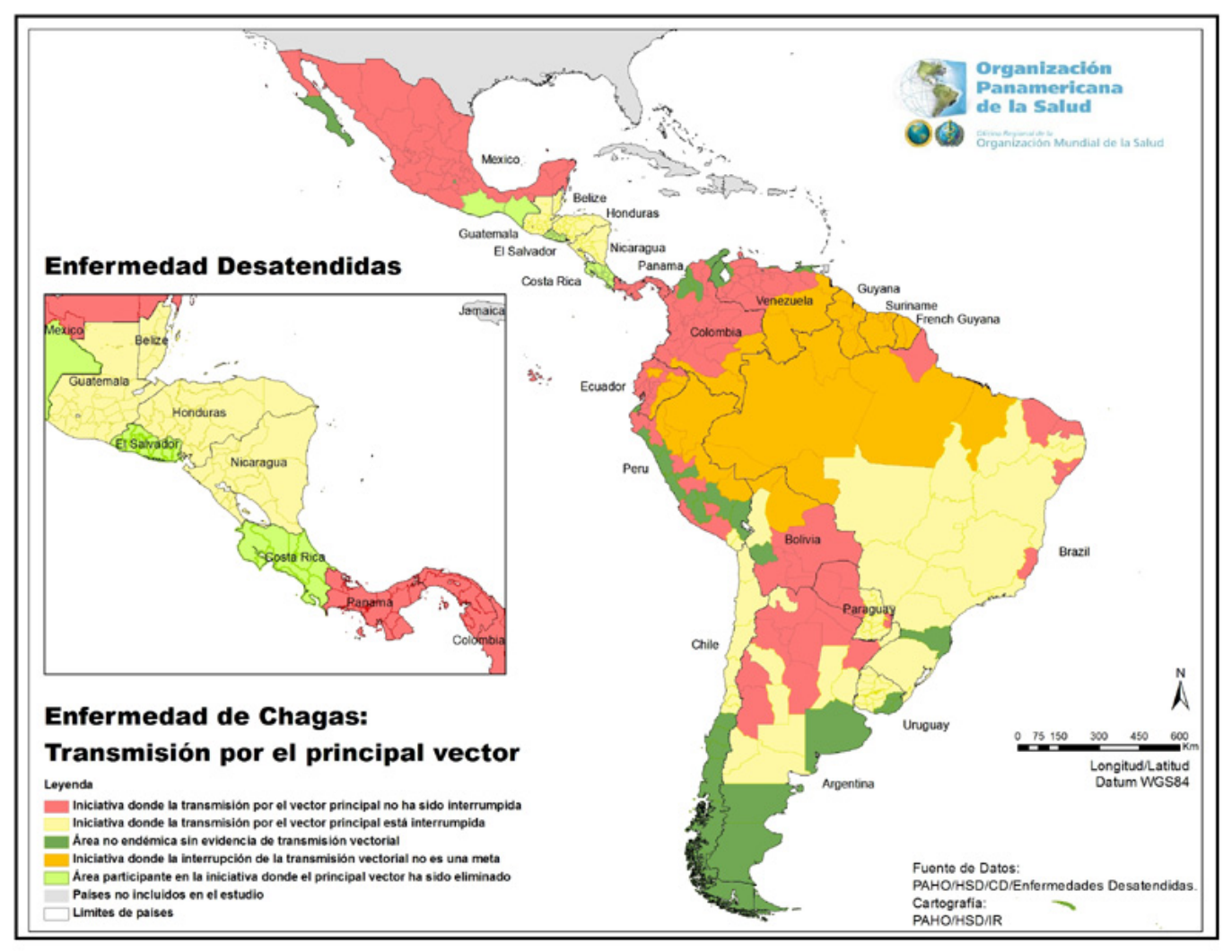


Another important but "neglected" disease: Chagas Disease

Romaña's sign

Another important but "neglected" disease: Chagas Disease

Good news for visitors to Costa Rica – and for Costa Ricans, too!



Another important but "neglected" disease: Chagas Disease

Here's part of how it was done !! With public education campaigns, etc.

Another important but "neglected" disease: Chagas Disease

- The relevant WHO and CDC pages claim there is no vaccine.
- DNDi would like there to be a more suitable medication for children.
- DNDi would like to see developed a new drug for chronic disease "that is safe, efficacious, and adapted to the field".
- The current medications on the World Health Organization's list of essential medicines for the disease have alarming levels of toxicity for the patient and are not satisfactorily effective in treating the later phase(s) of the disease.
- "Doctors and nurses in the field are forced to care for patients with treatments that are largely archaic, toxic, ineffective; some are unaffordable and some are nonexistent" (Sophie Delaunay of MSF, quoted by Voelker 2009: 1755).

Thank you for your attention.

Now it's your turn !

(Comments, questions, debate...)

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