

The Eflornithine Scandal

How Pandering to Vanity Resurrected a Life-Saving Drug

by James Crombie

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for presentation at the Launch of the WHO Collaborating Centre for Governance,
Accountability and Transparency for the Pharmaceutical Sector

Location: The Leslie Dan Faculty of Pharmacy, University of Toronto

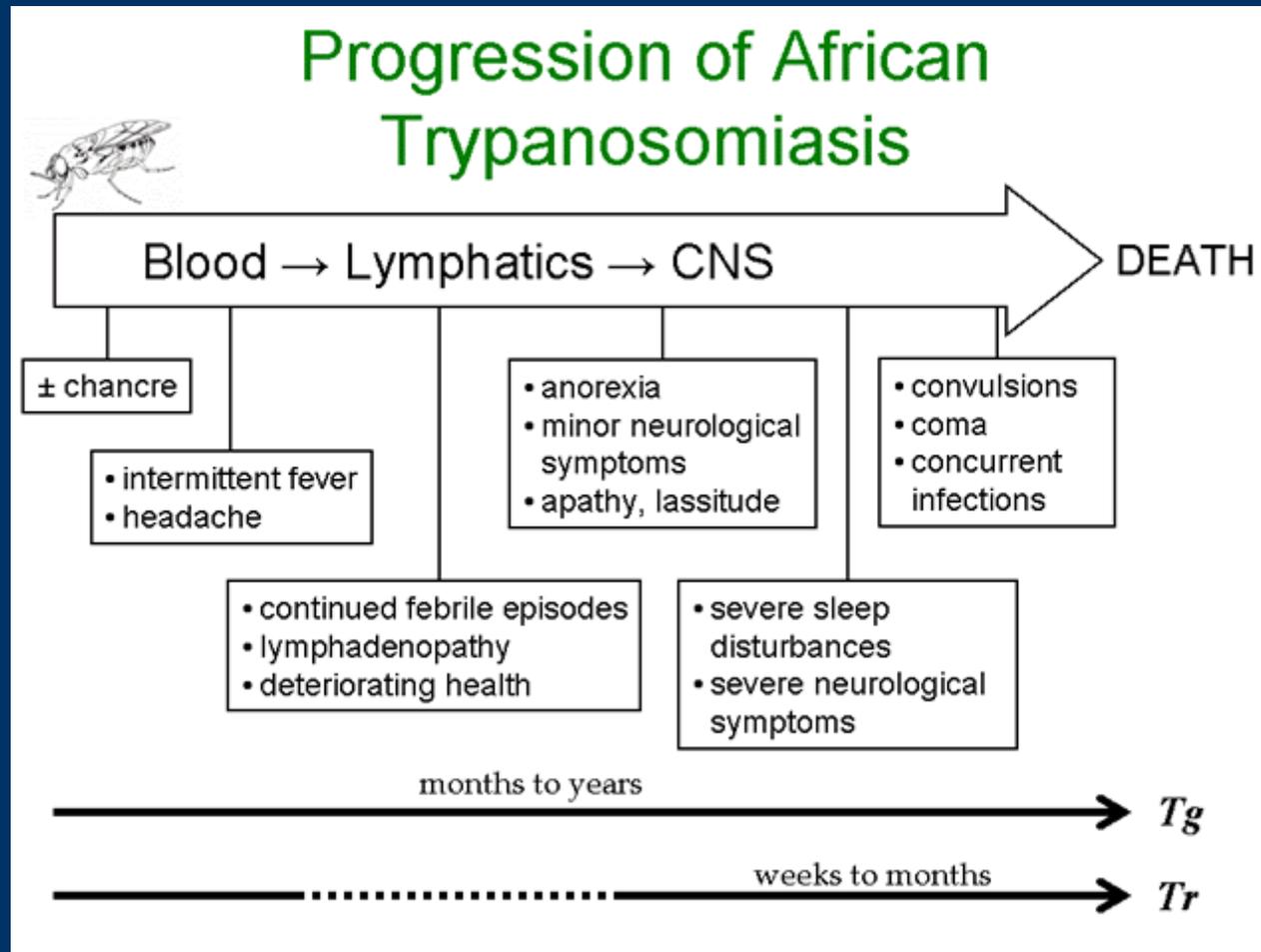
Date: Friday April 29 2016

Theme: “Taking the Pulse of Governance, Accountability, and Transparency in the
Pharmaceutical Sector: Diagnosing the Issues”

Eflornithine – the “Resurrection Drug”

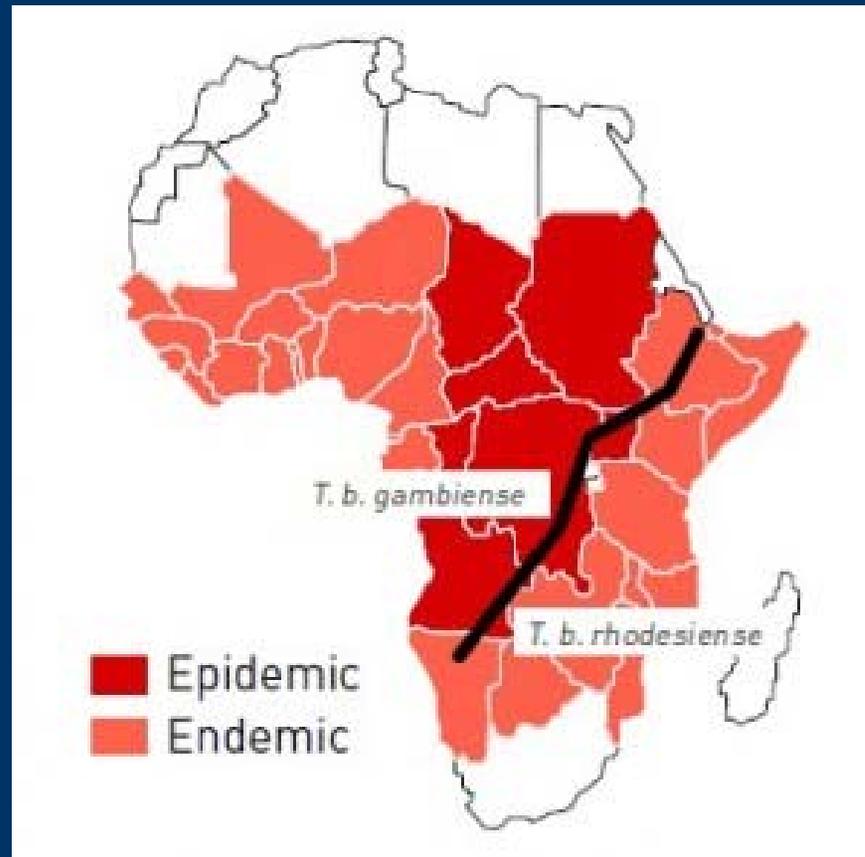
- ◆ "Eflornithine was discovered in 1980 by Dr Cyrus Bacchi through a TDR-supported study on polyamine metabolism in trypanosomes" (WHO 2001).
 - ◆ Peter Gøtsche (2013) mentions that the molecule was first developed by Aventis as a not-very-successful anti-cancer medication.
 - ◆ Eflornithine came into its own however as an effective treatment against Human African Trypanosomiasis (aka "sleeping sickness").
 - ◆ "Known as the ‘resurrection drug’ because of its spectacular effect on comatose patients in late-stage gambiense sleeping sickness, eflornithine is well tolerated in patients" (WHO 2001).
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Eflornithine – the “Resurrection Drug”



Source : Wiser 1999-2013

Eflornithine – the “Resurrection Drug”



Areas affected by Human African Trypanosomiasis aka "Sleeping Sickness" in Africa
Source : Drugs for Neglected Diseases Initiative DNDi 2014

Eflornithine – the “Resurrection Drug”



Patients in an MSF sleeping sickness ward in Tambura, Sudan
Source : www.doctorswithoutborders.org/issue/sleeping-sickness
Photo : Juan-Carlos Tomasi

Eflornithine – the “Resurrection Drug”

- ◆ 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 Médecins sans frontières 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.
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Eflornithine – a depilatory facial cream



Facial hair is unattractive



Vaniqa can remove facial hair in 4 weeks

NDC 67462-040-30

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, cetyl alcohol, dimethicone, glyceryl stearate, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, stearyl alcohol and water.

VANIQA[®]
(eflornithine hydrochloride)
Cream, 13.9%

For topical use only.

Rx only

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

Net Wt 30g (1.06 oz) 2005419

- Source:<http://buyvaniqacream.net/page/2/>

Eflornithine – the “Resurrection Drug”

- ◆ 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) 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.
 - ◆ Eflornithine is on the WHO list of **Essential Medicines** .
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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

Non-Availability of Essential Medicines

The non-availability of essential medicines – in both developed and less-developed countries - can be associated with at least three kinds of problem:

- 1) The (artificially?) **high price** of certain essential medicines (e.g. antiretrovirals in less-developed countries)
 - 2) The **lack of research** on important but 'neglected' diseases – in particular the neglected *tropical* diseases (NTDs) and other diseases of Types II and III.
 - 3) The **discontinuance of production** of proven remedies for important diseases.
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The Eflornithine Affair (considered as a "cautionary tale")

- ◆ 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.
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Need for a better decision-making mechanism

"It should not be necessary for individual doctors or nurses, or non-governmental organisations, to pressure pharmaceutical companies and governments to act. An international mechanism must be put in place to ensure that essential medicines get produced in sufficient quantities".

– Bernard Pecoul, quoted MSF 2001.

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