Decision-making and prioritization of vaccines to address public health needs in LMICs

A case study from one company

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CENTER FOR VACCINE INNOVATION & ACCESS

PATH

Workshop 8: Prioritization for Vaccine R&D

The Global Vaccine and Immunization Research Forum, 22-25 February 2021

In theory…

There are several reasons why vaccine companies should sell new vaccines they already produce to LMICs at lower prices

- Make a profit, even if marginal per dose

- Good public relations
- Build markets for the future
- Politically savvy

- Public health value
- Do good
- Internal morale

And yet, in reality

Why *didn't* one industrialized country company sell a new vaccine to LMICs at discounted prices?

A case study of Hib (childhood pneumonia and meningitis) vaccine in the mid-1990s.

Reasons given by different staff at the company

1. **We would lose money. Our cost of goods is higher than the prices UNICEF would pay.**

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On careful investigation with Company Finance, turned out not to be true for this vaccine.

However

- It was true for some other vaccines
- Calculation of COGs may not be straightforward, with no universally accepted method to calculate COGs
  - May depend on what is included besides marginal cost of manufacturing.
    - Clinical and regulatory costs, including registration in each country?
    - Costs of failed lots?
    - Facilities?
    - R&D costs to develop this product?
    - R&D costs to develop other vaccines?
    - Other expenses?

2. **We simply do not have excess production capacity available, because our facilities are sized for a certain (limited) demand.**

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On careful investigation with company Manufacturing, turned out there was excess capacity available.

However:

- It was true in occasional years.
- Need to invest in facilities several years before product licensure—huge risk.
- It is always a guess as to the appropriate size of the facility needed, with major financial implications.

3. There are legal/contractual restrictions in US CDC contracts that prevent us from selling the exact same vaccine cheaper elsewhere.

Note: CDC purchases >50% of vaccines used in US

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After checking with company Contracts, turns out not to be true.

However:

- Some purchasers, e.g., PAHO revolving fund, do have such clauses.

Pan American Health Organization

Regional Office of the World Health Organization

4. **Politically it is just too risky.**

   We will be perceived as overcharging in richer markets; difficult to explain differential pricing

Recommended reading by

Ciro de Quadros
Immunization Champion
Public Health Pioneer

OVERSIGHT OF IMMUNIZATION COST

HEARING

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND GENERAL OVERSIGHT

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

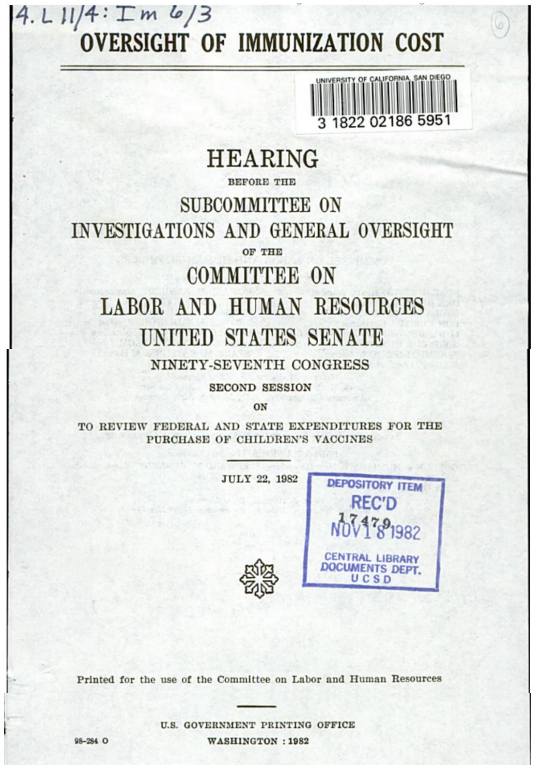
ON

TO REVIEW FEDERAL AND STATE EXPENDITURES FOR THE PURCHASE OF CHILDREN'S VACCINES

JULY 22, 1982

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE
98-284 O WASHINGTON : 1982



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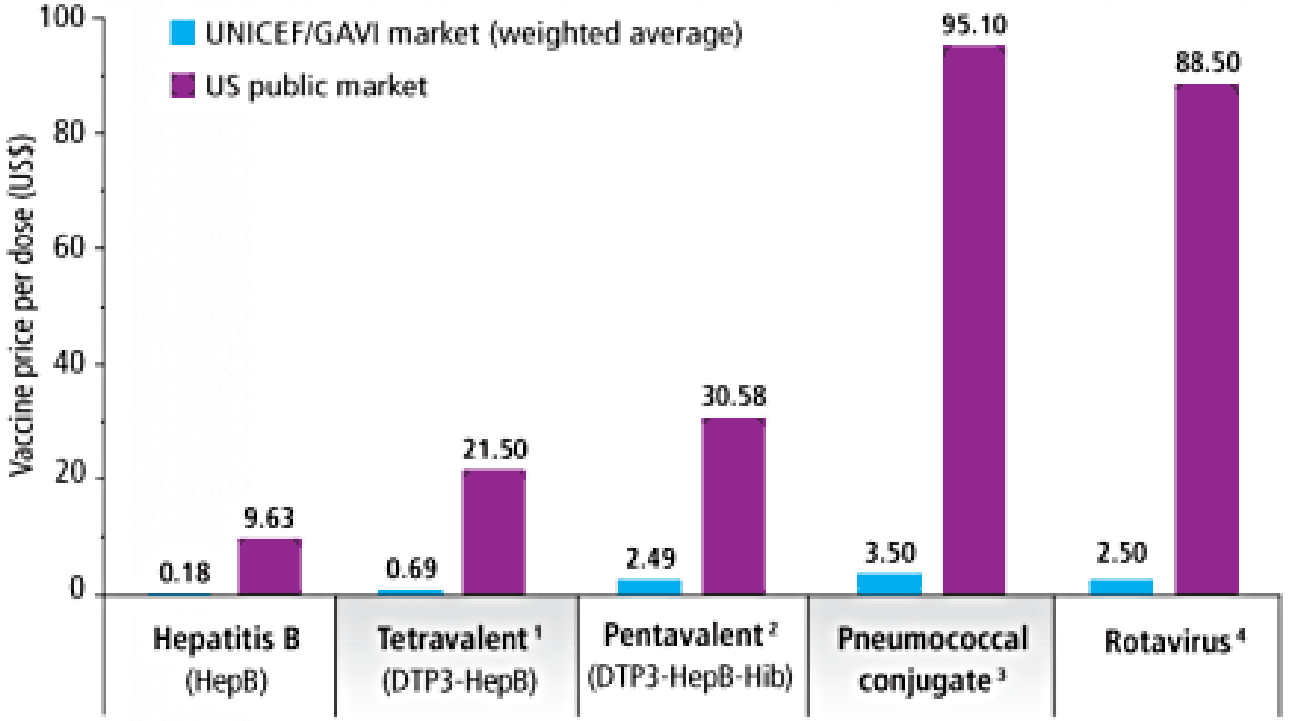
*How can you justify charging nearly **three times** as much for measles vaccine to the US government as you did to foreign countries…?*

U.S. Senator Paula Hawkins [Republican] (1982)—to the heads of the 2 largest US vaccine manufacturers

*I cannot believe that anyone seriously believes that America should manufacture vaccines for the world**, sell them cheaper to foreign countries**, and immunize fewer kids as a percentage of the population than any nation in this hemisphere...*

President Bill Clinton [Democrat] (1993)

Note that the price gap is much bigger today



[1] The combination procured by UNICEF is not provided in the US markets; US prices refer to the sum of a DTaP (diphtheria-tetanus-acellular pertussis) vaccine and a HepB monovalent vaccine.

[2] The combination procured by UNICEF is not provided in the US markets; US prices refer to the sum of a DTaP vaccine, a HepB monovalent vaccine and a Hib vaccine.

[3] 13-valent vaccine (US markets) and tail price cap under the AMC agreement (UNICEF/GAVI market).

[4] Refers to GlaxoSmithKline product procured by GAVI as of 2012.

http://www.gavi.org/library/news/roi/2010/gavi-approach-creates-tiered-pricing-for-vaccines/

4. Politically it is just too risky.

We will be perceived as overcharging in richer markets; difficult to explain differential pricing

After (fascinating) discussion with company government relations/lobbyist, I was told:

"There is that risk, but I am confident we could handle it"

However

- The price differential IS difficult to explain and justify

So that wasn't it

5. **We will lose control of our core business.**

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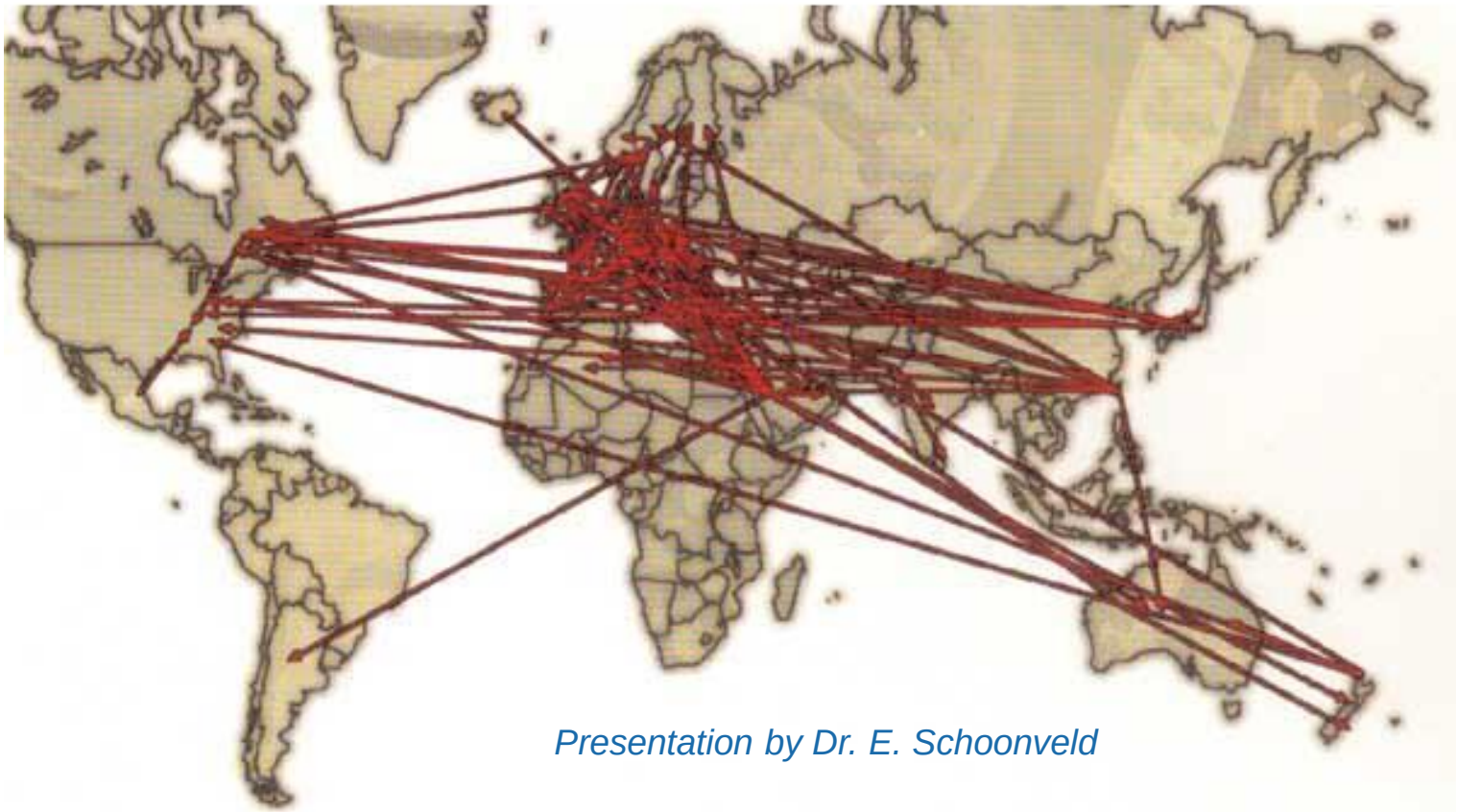
What exactly does that mean?

Fear of losing control of pricing in home markets

Countries which use international price comparisons in their negotiations with manufacturers or which are countries of reference for price purposes



Presentation by Dr. E. Schoonveld

Report of the Workshop on Differential Pricing & Financing of Essential Drugs
A WHO/WTO SECRETARIAT WORKSHOP/GLOBAL HEALTH COUNCIL

http://apps.who.int/medicinedocs/es/d/Jh2951e/2.3.5.html

5. We will lose control of our core business.

Yet some other companies (e.g., SmithKline/GSK, Pasteur-Merieux/Sanofi) had successfully managed this risk.

However, those companies had been in the international business for a long time, and were very familiar with the commercial and political landscape

My conclusions

All of these can, in some cases, be barriers:

- Price margins may simply be too close to COGs
- Production capacity difficult to justify without longer-term purchase guarantees
- Contractual restrictions
- Political pressures

But most important may be

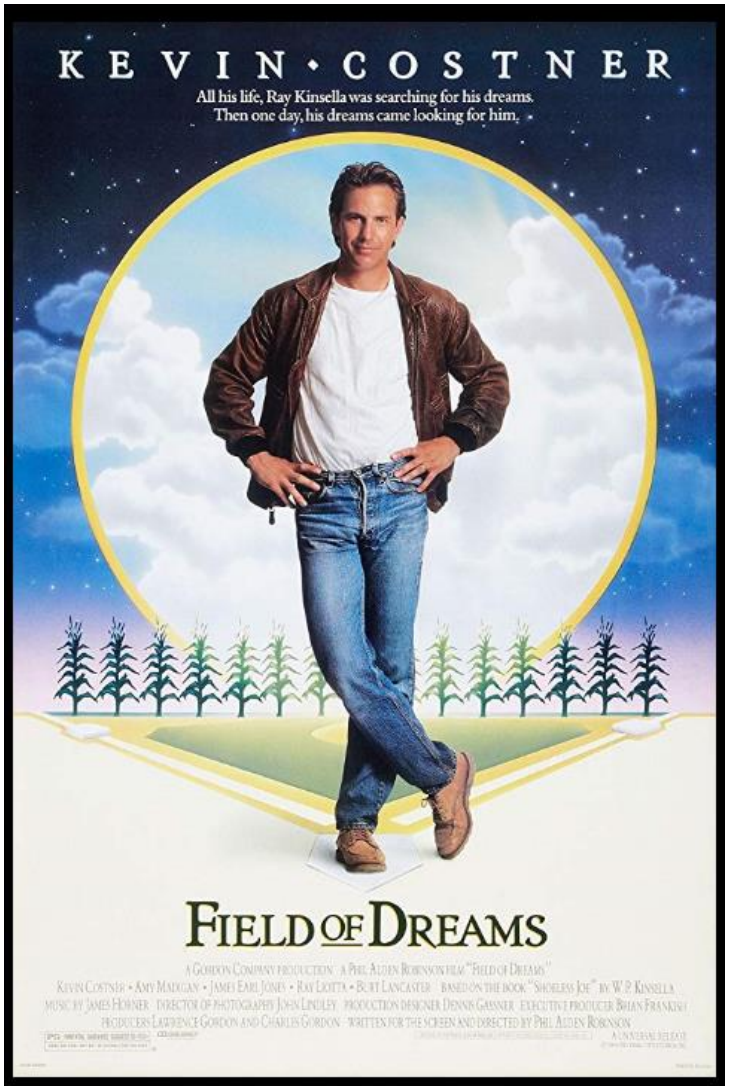
Free-floating (business) anxiety and uncertainty

Compounded by lack of familiarity with LMIC markets

and

Unclear guidance from the public sector

Don’t Say This:



“Build it and they will come”

or, translated into vaccine-ese

“Develop a good vaccine against a disease WHO has identified as a priority and there will be sufficient demand”

This, unfortunately, has too often NOT been true

The more clarity the public sector can provide, the better

"Prices are too high"

- What price range is acceptable, and based on what?

"There will be a high demand for such a vaccine"

- Plausible demand forecasts?
- Who exactly will be buying it, in what quantities and in what price range?
- Multiple year contracts?

"We can give you our preferred levels of efficacy, but of course, we can't guarantee a universal policy recommendation"

- What is the minimum acceptable level of efficacy?
- What other vaccine characteristics and data are considered crucial—as opposed to nice to have--to drive policy recommendations?

"The vaccine regimen should comprise as few doses as possible"

- Given the crowded schedule, when exactly could it be delivered?
- Will introduction depend on combination with an existing vaccine?

Avoiding public sector murkiness will encourage companies in their R&D prioritization efforts

"The Great Smog" of London 1952

https://upload.wikimedia.org/wikipedia/commons/thumb/0/02/Nelson%27s_Column_during_the_Great_Smog_of_1952.jpg/512px-Nelson%27s_Column_during_the_Great_Smog_of_1952.jpg

Especially if you are trying to encourage a vaccine developer unfamiliar with the international vaccine policy and recommendation world

Delhi, 2020

https://www.scidev.net/asia-pacific/news/delhi-smog-can-t-be-blamed-on-punjab-farmers-alone/