

# Promises and Realities of the Advance Market Commitment

## Minimizing the number of poor children saved

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- The current donations of \$1.5 bn for new pneumo vaccines is designed so only 99,000 poor children will be saved by 2015. (MGD #4)
- But with a few changes, 965,000 could be saved.

## ■ Outline

- Original AMC Design and its Flaws
- Moral Problems
- Deceptions, Untrustworthy claims
  
- The Pneumo pseudo-AMC
  - Norway takes a stand. Faces down price increase
- Further Deceptions – GAVI raids core funding for AMC
  - Inflates children saved by 10-fold
- Minimizing children immunized and saved
- How to Maximize children saved
  - Partial restitution within the AMC design
  - Full maximization outside the AMC

**AMCs have become the prevailing model for how wealthy nations (the G8) will spend the billions donated to discover an effective vaccine for a neglected disease.**

- **Seen as a brilliant solution to the age-old problems of new vaccines not being affordable to poor countries for 10-15 years. (I.e. during patent-controlled prices)**

## What is an AMC?

- an advanced commitment to motivate companies to discover a new vaccine for a neglected disease by matching the revenues and profits from developing a new medicine for affluent mkts.
- Eg buy millions of doses at a Western price, once a vaccine for malaria is discovered, tested, and approved.  
Eg 200 million doses @ \$15 each = \$3 billion for a malaria vaccine
- Recipient company must agree thereafter to make the vaccine available at a *tail price* close to cost: Eg \$1-2 per dose.
- Recipient countries must want to administer the vaccine and pay a small co-payment.

## AMC Design Flaws

- Based on premise that a large purchase will spawn a plethora of private research that will overcome obstacles to discovering a new vaccine that NIH and university researchers have failed to do.
  - Evidence indicated it would not from the beginning.
- AMC design favors multinational firms: No funding until after 10-15 yrs of research and development of new vaccine.
  - Legal work done by global big-pharma, US firm. Sponsored the AMC launch.

## Further AMC Design Flaws

### *A Donor's Dream, a Developer's Nightmare*

**No funds for research by govt or university labs, nor can they compete for final prize.**

**No funds for smaller firms in developing or wealthy countries.**

**Early focus on nurturing capacity in developing regions – Asia, L.A., Africa – was dropped.**

## Further AMC Design Flaws

**Ignores how daunting scientific obstacles are.**

**Promotes secrecy among competitors.  
Undermines cooperative research efforts.**

**Ties up large funds. Encourages PUSH-funders (grants, contracts) to turn to other priorities.**

## More AMC Design Flaws

- Don't know how complex the vaccine will be to develop or manufacture.
- Hard to set the tech specs right 10-15 yrs hence.
- Hard to set buyout price or post-buyout price realistically 10-15 yrs hence.
  - Package much too large, based on industry, inflated figures for R&D costs and prices needed for profits.
- Why 200 million doses? UK, others have bought 20-50 million at a high price, then offered lower price for next 100 million, then less for next 100 million, because gross average price drops rapidly.

## Still More AMC Design Flaws

- No IP concessions as part of large purchase for the poor.
- Makes enforcing the post-buyout price (eg \$1) and manufacturing enough vaccine difficult.
- Precludes generic price competition – the major way AIDS and other drug prices have plummeted.

## Other AMC Design Flaws

Won't work even for major firms, because big buyout can be split among all who discover a vaccine. This undermines core rationale for AMC approach.

Eg vaccines for rotavirus now: 2 good ones by Merck & GSK, but several second-generation vaccines in development by Asian firms. Any "winner" would receive only part of the AMC buyout.

No funds or consideration of actual delivery.

- Strengthen public health systems
- Improve the cold chain
- Improve monitoring

## Moral Problems

Donors pass over the millions of infants & children who become diseased, hospitalized, disabled, or die now from diseases that current vaccines that could prevent now.

*Let children die now in order to save lives of children in the future, even unconceived beings.*

Far more immunized and saved per \$million at \$1 each or less than costly, future vaccine.

Certain benefit vs possible future benefit

AMC design minimizes children saved

## Initial Deceptions

- Removed names of people who would not support this design of an AMC
- No dissenting votes allowed. No minority report.
- Then presented to G8 Finance Ministers as “unanimously endorsed”
- “Assessments” by Finance Ministers & by World Bank don’t mention any of the concerns or criticisms. Pretend they don’t exist.

## THE Pneumococcal Pseudo-AMC

- Switched AMC from R&D for malaria vaccine to buying extra doses of already developed pneumo vaccines.
- Fundamentally abandoned AMC purpose to develop a new vaccine for a neglected disease
- Has become a *forward surplus contract* on already-developed 10-13 valent world vaccines, but mischaracterized as “motivating innovation.”
- No need for a buyout price vs tail price.

## The Pneumo Pseudo-AMC

- **GAVI & AMC advocates work hard to create new justification for a buyout price – large capital and several years to build mfg capacity**
  - GAVI documents already indicate capacity is there.
  - Companies rapidly expanding capacity already
  - If country co-pay equals mfg cost, *what are the donations for??*  
(--Dr. Tido Schoen-Angerer, the Director of the Campaign for Essential Medicines at Medicins sans Frontieres)

## The Pneumo Pseudo-AMC

- **GAVI, advocates raised buyout price from \$5 to \$7, to \$10.**
  - Little discussion of trade-offs in more children allowed to die.
  - Greatly increases donations going to profits.
- **GAVI & AMC advocates raise tail price from \$2 to \$3.50, building profit in final price forever.**
  - Violates another principle of original AMC
  - Little discussion of children not saved.
  - MSF & Oxfam oppose.

## Norway takes a Stand:

- Prime Minister ordered team to insist on roll-back to \$7 a dose or withdraw Norway's funds
- GAVI leaders and other donors oppose (why?)
  - But relent.
- Why not \$5? Or \$3.50? Or \$2.00?
  - Greatly increase children saved and affordability.
- Oxfam, MSF join early critics and take stands against AMC design

## GAVI belittled impact of price rollback to \$7

- Said 30% price decrease will not increase # children saved (because GAVI will use other donations to pay for any difference)
- GAVI reserves used also to pay difference btwn \$3.50 and country co-pays, forever.
- Thus AMC is taking over GAVI as \$1.3 bn taken fr core funding for other, cheaper vaccine programs, to subsidize overpriced AMC
  - Do general donors know their money going to profits?

## The Pneumo, Pseudo-AMC:

- **GAVI, advocates postponed start fr 2011 to 2014 and stretch out 10 years.**
  - Both minimize children saved, maximize avoidable disease, hospitalization, deaths
  - Both the delay and stretch-out maximize donations transferred to extra profits through 10% discount rate.
  - Overall, 2/3<sup>rd</sup> donations go to profits.
  - MSF analysis & mine: \$1.0 of \$1.5bn to profits

## ■ Further Deceptions

- Convey \$3.50 is a “sustainable” price, though many times more than poor can afford (\$0.50-\$1.00)
- GAVI’s own tech experts estimated cost \$1-2 per dose; so a 75-350% mark-up! (Why? Basis?)
- No consideration of reducing cost & complexity of mfg a 10-13 valent vaccine by developing 4-6 valent regional vaccines.
  - Multinationals not interested. Killed WHO initiative for regional pneumo conjugate vaccines in 2007

## ■ Further Deceptions – “Borrowed Glory”

- Take credit for new vaccines being developed, for affluent mkts & high profits
- Take credit for expanded mfg capacity, for affluent mts
- Extensive PR Operation
  - - full-time, talented press corps. Large budget.
  - - translation services in many languages
  - - open, friendly, smooth but don't disclose basis for key decisions

## ■ New Study by Jens Plathe, Norway

- Leaders of 9 companies & organizations developing pneumo vaccines all said the AMC did not influence their work
  - Started before the AMC started.
- Thought AMC design impedes good development
  - Tech requirements do not recognize regional versions
  - Also impede development of whole-protein vaccine.
  - “...the design of the AMC is poorly suited to the funding requirements, R&D agendas and marketing strategies of developing country vaccine manufacturers.”

- **Grossly exaggerate lives saved – 5.4 million**

- (-now raised to 7.0 million)

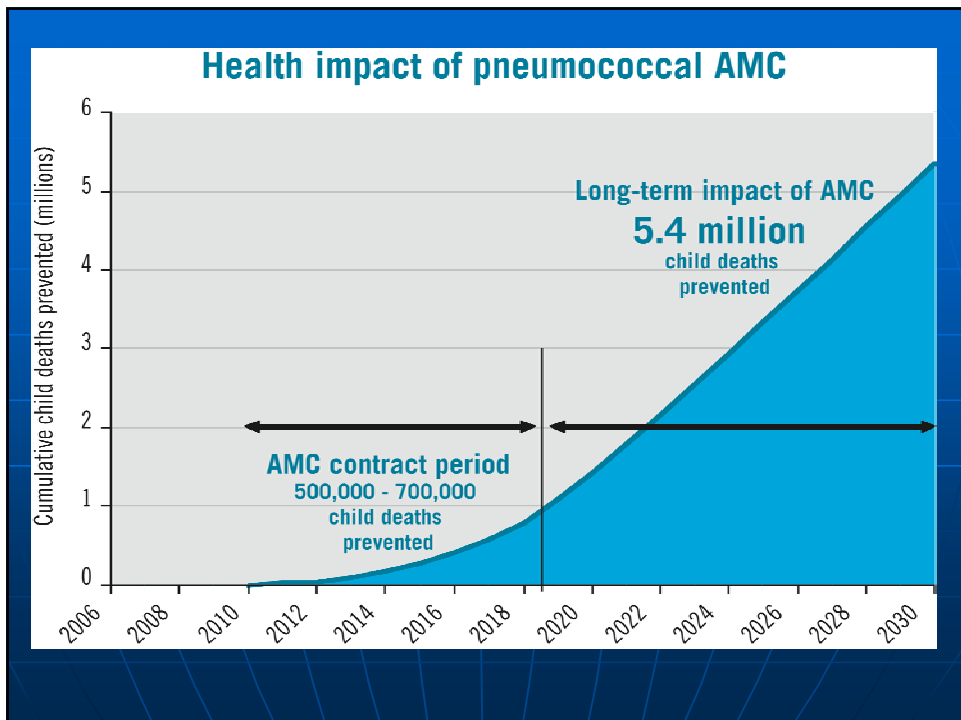
- $\$1.5\text{bn} / \$3.50 = 428 \text{ mm doses} / 3 = 143 \text{ mm children}$ , minus 10% wastage = 128 mm immunized children

- 12.8 million per yr for 10 yrs, average.

- Far fewer after discounting. Perhaps half.

- 1 life saved per 259 immunized = 496,000 lives saved to the end of AMC. (Could be half after discounting) **LESS THAN ONE-TENTH CLAIMED**

- 49,600 saved a yr, at most.



- **The 5.4 million estimate of lives saved:**
  - GAVI assumes no slowdown after money is gone, plus large herd immunity effect
  - Both doubtful. Countries cannot afford more than \$1.00/ dose, so great slowdown.
  - High herd immunity based on affluent, older pop
  - GAVI increased claim to 7 million children saved as it raised the buyout and tail prices!

- **5.4 million or 7.0 million lives saved vs reality**
  - Delayed start and 10-yr rollout minimize lives saved
  - 2010: 800,000 die – zero saved (delayed start)
  - 2011: 800,000 die – zero saved (delayed start)
  - 2012: 800,000 die – zero saved (delayed start)
  - 2013: 800,000 die – zero saved (delayed start)
  - 2014: 800,000 die – 49,600 saved = 750,400 die
  - 2015: 800,000 die – 49,600 saved = 750,400 die
  - 2016: 800,000 die – 49,600 saved = 750,400 die, etc.
  - So only 99,200 lives saved for MGD #4 by 2015.  
2010-2023, 496,000 saved but 10,704,000 die!

- Pneumo AMC is morally offensive. Puts profits before saving children.
- GAVI no longer an honest broker
  - Sacrificing cost-effective programs for the AMC
  - False and misleading claims about the AMC
- Is there a better way?
- Yes. Within AMC frame, why not drop fake buyout price and set price at \$3.50 or lower?
  - Then seek lowest qualified mfg. Serum Institute?
- Or, use political & moral clout to get GSK & Wyeth to offer extra doses at \$2.00?
  - Many more countries can afford to sustain that price

- Have advanced purchase start in 2011 and roll out in 5 yrs, not 10.
- If \$2 a dose, \$1.5 bn = 750,000mm / 3 doses = 250mm children immunized.
  - 2010: 800,000 die – zero saved (delayed start)
  - 2011: 800,000 die – 193,050 saved = 606,950 die
  - 2012: 800,000 die – 193,050 saved = 606,950 die
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  - 2014: 800,000 die – 193,050 saved = 606,950 die
  - 2015: 800,000 die – 193,050 saved = 606,950 die

= 965,250 lives saved by 2015 for MGD #4.  
= sustainable price, without a drain on GAVI

- **A even better way:**
- **Follow strategy of meningitis vaccine project, or PATH with new rota vaccine –**
  - **Budget millions to develop partnership with emerging country producers for 4-6 valent regional vaccines**
  - **Get cost and price down closer to \$1.00 a dose**
  - **Use rest of \$1.5bn to help producers register and market, and help countries to buy and vaccinate.**
    - **Save other GAVI projects from being sacrificed**

- **Conclusions**
- **Goal is to prevent disease, disability, hospitalizations and deaths**
  - **ALL decisions should use this measure**
- **Get price to affordable, sustainable level**
- **End dependency on charity**
- **Increase capacity of lower-income countries**

- **Conclusions**

- **Advance purchase commitments are vital to assure a stable mkt for mfg, countries, campaigns.**

- **But the design shd fit need & circumstances as in Strategy Matrix in HAI Report:**

**Six Different Advanced Purchase Strategies to develop and make vaccines more affordable for low-income countries**

<b>Functions:</b>	<b>Type II Diseases</b>	<b>Type III Diseases</b>
<b>To motivate discovery and procure for delivery</b>	Motivation primarily from highly profitable markets. Much cheaper to fund promising projects directly than through high prices later. Advanced procurement contract a valuable additional motive. Require sharing of IP and know-how in return for large, long contract.	Lack of market incentives. Combine push funding with pull of long-term, advanced procurement. IP not relevant; find neutralizing solutions. Use a combination of prizes.
<b>To adopt for regional use and procure for delivery</b>	If additional regional trials needed, cheaper to fund directly or through milestone payments for successful trials. Best to develop low-cost versions with non-profit, low-cost partners, which protections for innovator companies.	If additional regional trials needed, cheaper to fund directly or through milestone payments for successful trials. Best to develop low-cost versions with non-profit, low-cost partners, which protections for innovator companies.
<b>To procure existing vaccines for delivery</b>	Negotiate very low price as part of social mission commitment. Reliable, long-term contract a valuable incentive for manufacturers and national public health programs.	Negotiate very low price as part of social mission commitment. Reliable, long-term contract a valuable incentive for manufacturers and national public health programs.