Zorginstituut Nederland

Reaching the promised land means taking Jericho

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A LOOK INTO THE FUTURE – HOW TO ENSURE SUSTAINABILITY DISEASES CARE IN 2030

Orphan drug development & pricing essentials

Sanofi buys Ablynx and Bioverativ for € 3.9 bill. and € 11.6 bill.

Takeda buys Shire for € 52 bill.

Conundrum of industry/payer talks

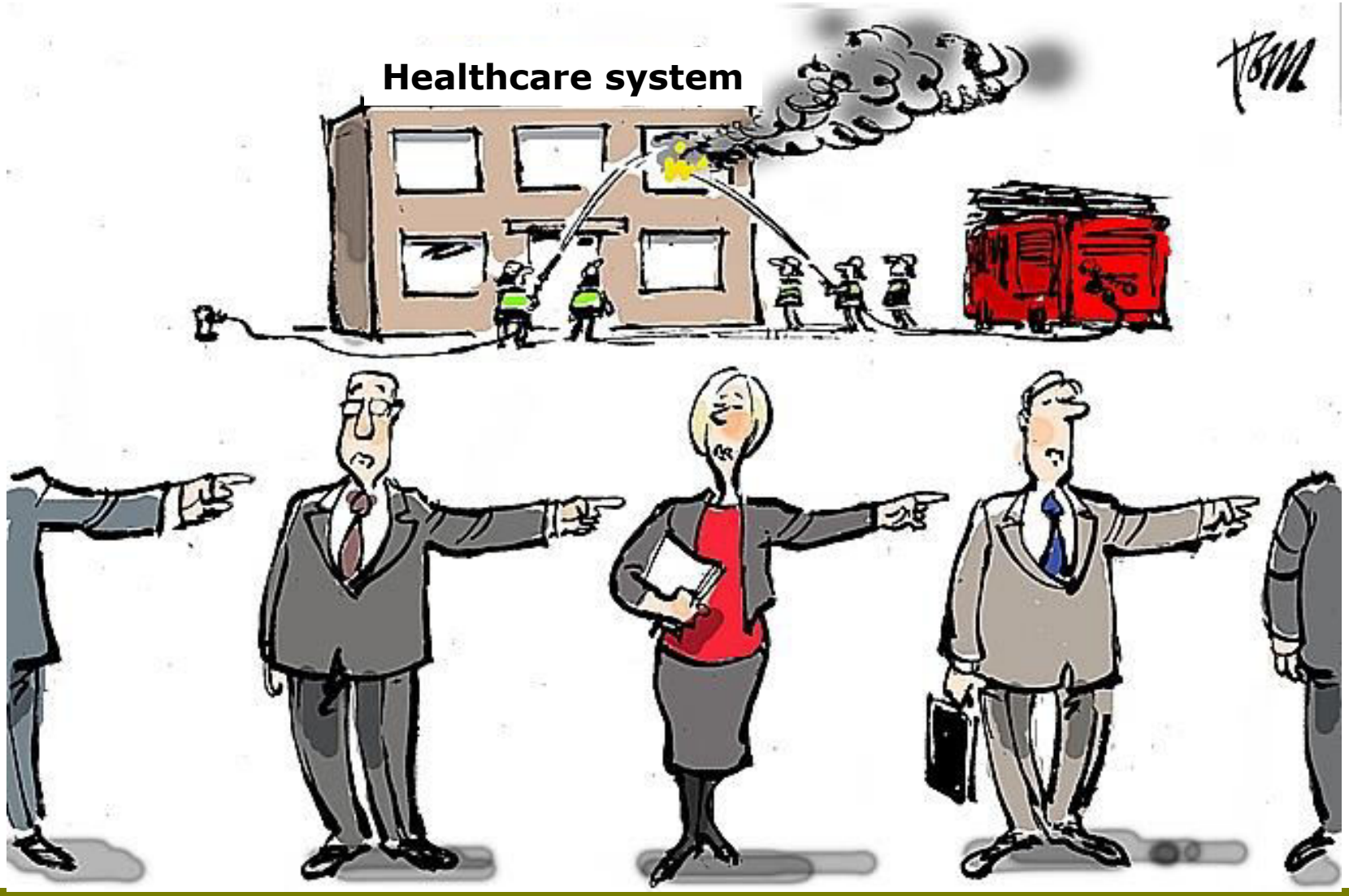
"it is too early to talk about prices"

"Oops, it is too late to talk about prices..

..we are already negotiating with the ministry"


The payer has returned
from the negotiations!!
Pharma industry

"My one strength in negotiating is begging."


Healthcare system

Value means something different to every stakeholder

So value based XXXX is only helpful if

Effects are translated into

Measureable and objectifiable outcomes

That mean something to patients

Nothing is so counterproductive as reacting to an opponent who takes the initiative

EU payers carry a grave responsibility to organise collective measures

To counterbalance industry monopolies

If we fail to do so

Posterity will blame us for letting unsustainability happen

Nothing less than the solidarity of the healthy with the critically ill is at stake

The industry has a price in mind

Reimbursement authorities should have a reimbursement level in mind

And should be the first to state that level

Based on horizon scanning

And displacement principles

Value is not only added value for oprhan patients

But also lost value for other patients

That’s wat we call displacement

2013: Claxton calculates an average intervention costs around 13.000 pounds (~€ 15.000) per QALY

Storm of criticism: UK ceiling 20.000 to 30.000 pounds not adapted

But idea that treatment with very high ICERs cq cost/QALY replace more cost effective forms of healthcare, has stuck.

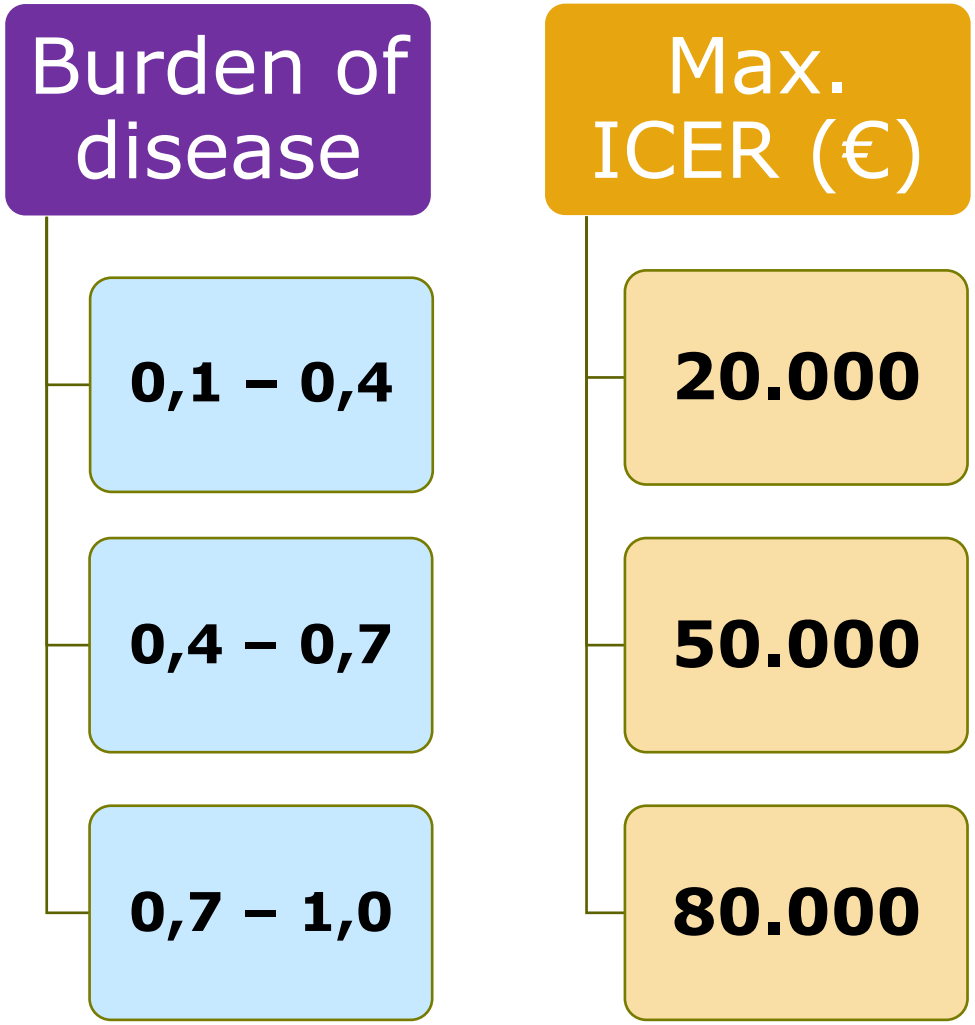
Dimensions of displacement

disease	Rough Annual cost/p (in €)
• Diabetes	• 7.000
• Depression	• 25.000
• MS	• 40.000
• Oncology	• 100.000

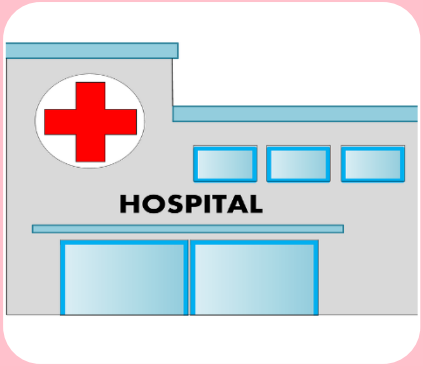
Introduction of reference values instead of limits

in ZIN report on cost-effectiveness

Opinion:limit = 1-3 x GDP (NL € 50.000)



FRAMING of € 30 mill. budget impact

Industry	Hospital	Ministry	Insurers
			
Only € 2 Per insured dutchman per year	Annual salary of 600 nurses	Annual running cost of a small hospital	Annual insurance premium of 20,000 citizens

EURORDIS
RARE DISEASES EUROPE

A structured approach to market access in Europe

Structured voluntary cooperation between healthcare systems in the European Union

1. A new blueprint to cut costs and fast-track R&D
2. Early dialogue and European cooperation on the determination of value
3. A European cooperation framework for fair prices and sustainable healthcare budgets
4. A continuum of evidence generation linked to healthcare budget spending

The structured approach is particularly indicated for low prevalence, highly complex to treat diseases to begin with, where the added value of European collaboration is even more evident.

Need an approach with default reimbursement levels

For poorly proven but promising products

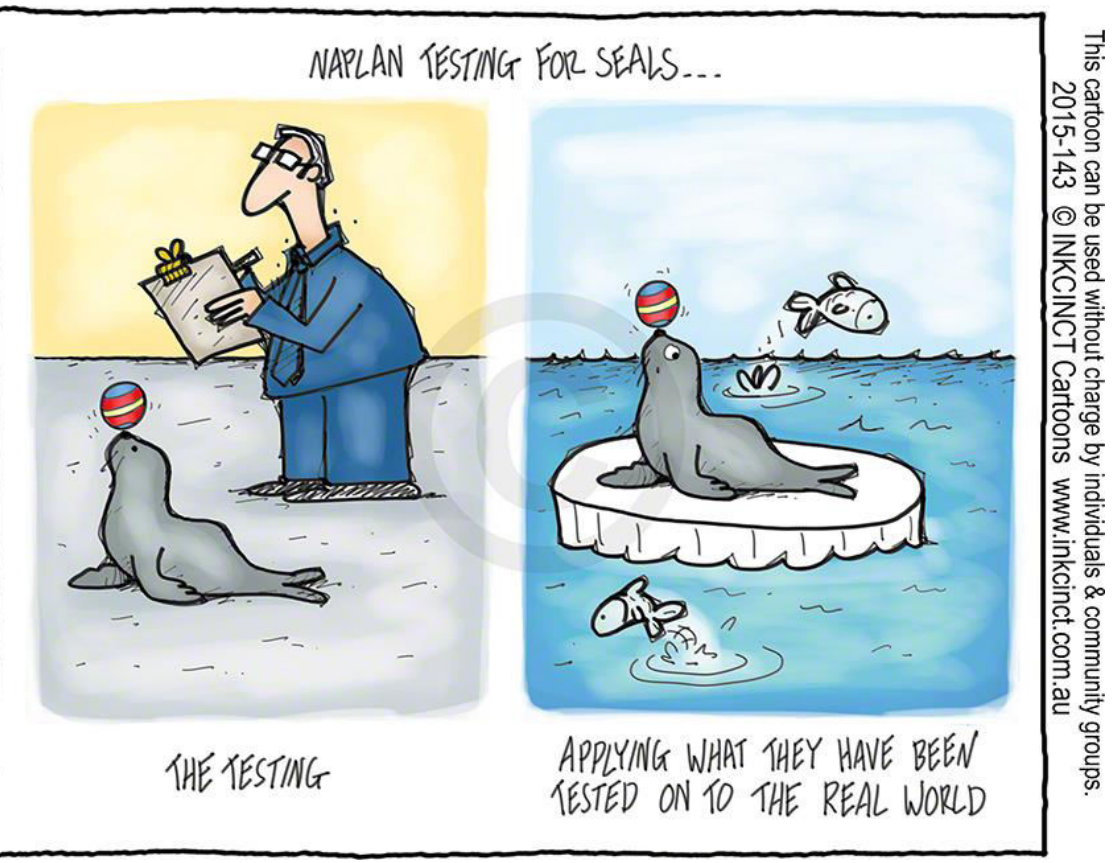
That obviates the necessity for industry to take patient hostages

Everybody can have access to products at registration

At low default reimbursement levels

That may go up provided solid pre-agreed outcomes are achieved

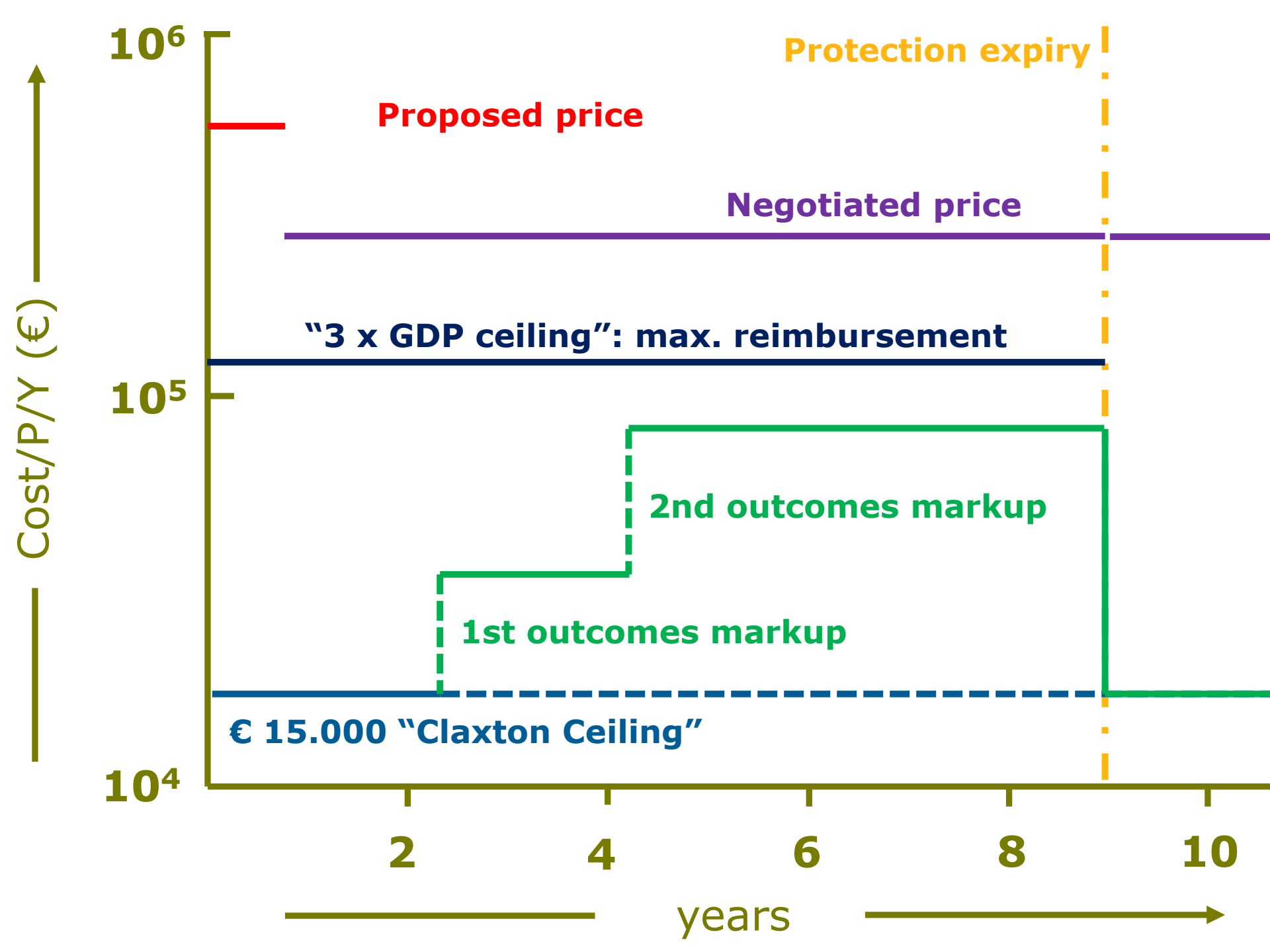
The EMA registers safe quality products that may deliver outcomes over time: hope based products



Conditional registrations

Exceptional circumstances

PRIME products


10^6
10^5
10^4
Cost/P/Y (€)
Protection expiry
Proposed price
Negotiated price
"3 x GDP ceiling": max. reimbursement
2nd outcomes markup
1st outcomes markup
€ 15.000 "Claxton Ceiling"
2
4
6
8
10
years

How can patient organisations help safeguard access?

Give your opinion on pricing in public

Support efforts of payers to create sustainable access

Put pressure on companies: do not only treat them as saviours

Allow access to your data for scientific and reimbursement level purposes

In conclusion

Yes, we can make the unsustainability walls come down

It will require perseverance, hope and faith

But it can be done

And it should be done, in the interest of all stakeholders concerned, but above all in the interest of patients