



ALMA MATER STUDIORUM  
UNIVERSITÀ DI BOLOGNA

# International Law and Health: Health care rationing. Theory & case studies

André den Exter

# outline

Understanding Health Care Rationing

Rationing and Human Rights

Age-based rationing: Ethics & Law

Conclusion

Case studies



# Novartis ROCHE now has the the most expensive drug ever after getting US approval

Swiss pharmaceutical company Novartis on Friday announced it had received US regulatory approval for a gene therapy that treats a rare childhood disorder and has a price tag of \$2.1 million, making it the most expensive drug in history., 25 May 2019

Libmeldy: €3 million (\$3-3.5 million) 9 July 2021

**England's drug price watchdog rejects Orchard's groundbreaking gene therapy after first round of talks**

## Evrysdi (risdiplam)

t risdiplam zijn € 4 tot 7 miljoen per SMA-  
ijs veel te hoog is om in aanmerking te  
: komt onder andere door onzekerheden over  
dat er al 2 andere geneesmiddelen voor SMA-  
et Zorginstituut de minister van VWS om  
als de prijs fors daalt in de onderhandelingen

**4-7  
miljoen  
p.p.**



# A legal perspective

Is Rationing evil ?



# Understanding health care rationing

Defining Health Care Rationing

Who decides?

What criteria?



# Rationing and Human Rights

- Human Rights
- Legitimacy
- Liability



# Moral considerations

Are all health needs equal

Prioritizing health needs

Should age matter

Should personal responsibility matter

QUALYfying disabilities



# Fair rationing

Has to be explicit, transparent, rationally justifiable, and based on democratic deliberation





# The Controversy: Age-based Rationing

Excluding elderly patients from *specific* life-extending treatment options for cost constraints

Age level as a threshold: “fair-innings” argument

Discriminatory by nature or justified for specific reasons?

*CESCR General Comment no. 20 Non-discrimination (E/C12/GC/20)*



# Age-based rationing and Precision Medicine

- Primary goal is to provide the right drug at the right dose at the right time for the right reason.
- In the case of targeted cancer therapies, there are at least 150 such drugs that have been approved by the FDA in the USA for patients with metastatic cancer; same in the EU.
- These drugs almost all have a cost of \$100,000 or much more for a course of therapy or for a year, with CAR-T cell immunotherapy having a front-end cost of \$475,000.
- Problem: Most of the time these drugs provide some benefit (somewhat marginal) for about 30% of patients who have a relevant molecular target for one of these drugs at a very high cost. “Some benefit” might mean extra months of life, maybe an extra year of life.

Source: Len Fleck 2022



# Weaknesses

Arbitrariness

“Too close to call” cases



# The Judiciary and Healthcare Rationing: Friend or Foe?

Health care as a human right

Method: substance & procedure



# Challenging decisions about resource allocation in UK

General rule: courts will not interfere with the decision about how money is allocated unless that decision is frankly irrational

*Swindon NHS Primary Care Trust* (Herceptin litigation)



# ECrHR and Healthcare Rationing

*Sentges v. the Netherlands, July 8, 2003, App. No. 27677/02 : “ fair balance” test*

*Nitecki v. Poland, March 21, 2002, App. No. 65653/01, §1,*  
*“it cannot be excluded that the acts of omissions of the authorities in the field of healthcare policy may in certain circumstances engage their responsibility under Article 2.”*

*Panaitescu v Romania, ECtHR no 30909/06*



# Conclusions

Rationing unavoidable and necessary

Rationing and human rights

Rationing litigation: Judiciary respects the *politics* of rationing

Exceptions, imposing the reasons for rationing decisions

Role of the courts: triggering that debate and holding health rights justiciable

Need for public debate on fair rationing: democratic deliberation (L. Fleck) (plea for explicit rationing)

Incorporating HTA in rationing debate



# Case studies







Dramatic corona situation – Salzburg hospitals are preparing for triage.

## Dramatic corona situation - Salzburg hospitals are preparing for triage.

BY THOMAS CLEAR ON NOVEMBER 17, 2021

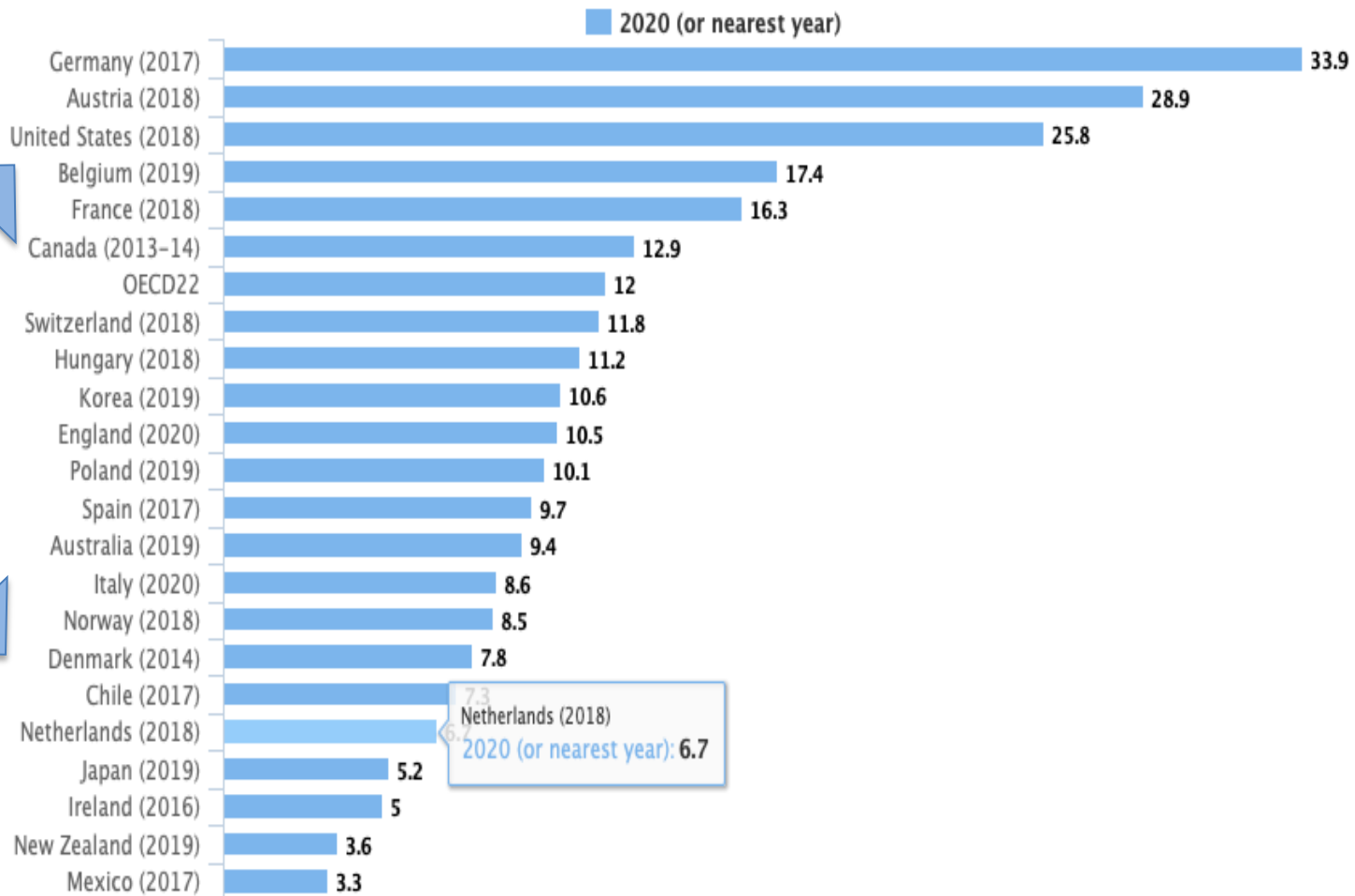
### Dramatic corona situation – Salzburg hospitals are preparing for triage.

Completely overloaded hospitals: Triage teams are being introduced in the Austrian city of Salzburg to decide who is to be helped. (Source:

# 'Code black' ICU triage



# Data :critical care beds compared (OECD)



# Self-regulation: Covid-19 Guidelines Health Professionals

Covid-19 triage guideline ICU admission phase 3 C, 16 June 2020 ('Code Black')

Developed by Medical Doctors Assoc. icw other health groups (HC Inspectorate, Hospitals, Patients Groups, etc.)

Absolute scarcity, medical selection criteria insufficient; highest level escalation model

Aim: to organise and allocate health care:  
guarantee continuity of care



# 'Code Black'

Only applicable ICU care

Both COVID-19 and other ICU patients

'first come, first serve' not appropriate and justified

Priority to patients with short term admission (expected) (Clinical Frailty Scale)

Priority to health professionals (exposure COVID-19)

Selection based on age categories (0-20; 20-40; 40-60; 60-80; 80+): 'fair innings' argument

Irrelevant: social status, disability, ethnicity, nationality, sexe; own fault

Lottery as last resort option



Authorised by the MoH, on request

Triage as part of the standard of 'good care', as defined by national law



# Justification

Ethics: 'Fair innings' argument

Law: understanding the non-discrimination concept (GC no 20, CESCR)

- 'Any distinction excluding patients is prohibited.... but differentiation can be permissible'
- Reasonable, objective & proportionality aim – and effect of measure
- Last resort measure
- Decision-making process: 'democratic deliberation'
- Mechanisms for legal redress

Least onerous, but necessary option



# Discussion

Response MoH: unwillingness to ration

What if max ICU beds has been reached?

Doctors' response?

Legal status Code Black; consequences?





# Reference



EUROPEAN JOURNAL OF HEALTH LAW 27 (2020) 495-498

European Journal  
of  
Health Law

[brill.com/ejhl](http://brill.com/ejhl)

## View. The Dutch Critical Care Triage Guideline on Covid-19: Not Necessarily Discriminatory

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### Abstract

Recently, the Dutch Medical Doctors Association (Federatie Medisch Specialisten en de Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst) drafted the 'Covid-19 triage guideline ICU admission' that has age cut-offs that deprioritise or



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## Role play “Rejuvimab”

John suffers from a rare and fatal form of leukaemia. He is expected to die before Christmas. Until recently no treatment was available to treat this illness. However, a new drug called "Rejuvimab" has recently been licensed for patients suffering this disease. The drug cannot cure the condition. For some, it may prolong their lives by up to four months. For other patients, however, it may cause side-effects that may actually shorten their lives. Because the illness is rare, the price of the drug is high; it is estimated to cost 200,000 Euro per QALY.

John wants to be treated with "Rejuvimab". His daughter is getting married in January and he would love to live long enough to "give her away". He is willing to take the risk that it might not work. John's doctor says that the treatment is suitable for Johan and has agreed to administer the drug and supervise the care.

However, John's health insurer/SNS has noted the "opportunity costs" of "Rejuvimab". The insurer has a finite health care budget and is concerned that the drug has limited clinical effectiveness. It is concerned about single, high-cost treatments because, in common with other health insurers, it is being urged by government to spend more on preventing cardiovascular disease and stroke where use of "statins" can save more lives in future years.

### Question

Since the health insurer/SNS denies John access to “rejuvimab”, Johan challenges that decision at the national court. What would be the outcome of such a Court ruling, and based on what principles/rights?

Parties involved: John (x representatives); Health insurer/SNS (x representatives); Court (x representatives); Note. Each party will argue why the claim should be accepted/denied

