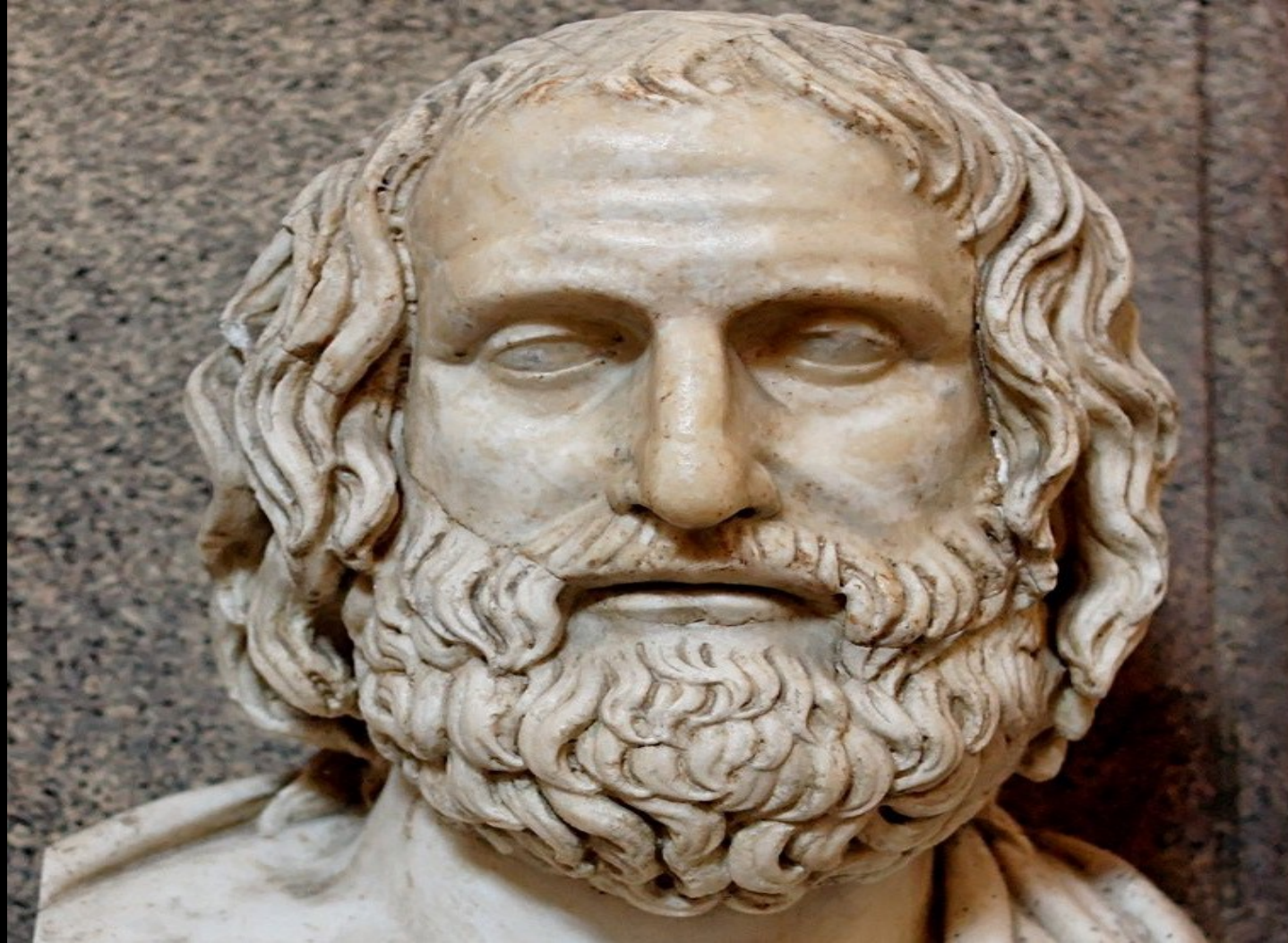


# Vaccine Safety and Efficacy The Legal Situation in India

Jacob M. Puliyeel MD  
[Puliyeel@gmail.com](mailto:Puliyeel@gmail.com)

Protagoras of Abdera (c. 490 - c.420 BCE)

Man is the Measure of All Things



# Delhi Bank Van Robbery

## September 28, 1973

- Sunil Batra killed the driver and guard of the cash-van of the Union Bank.
- Lodged in jail pending the disposal of the appeal of his death sentence

# Prison Rules and Cruelty

Courts in those days had little power to interfere with how prisons were run, or its rules and regulation

- *Platek vs. Aderhold*, 73 F.2d 173 (5th Cir. 1934)
  - *Johnson vs. Avery*, 393 U.S. 493(1969)

August, 1979

Sunil Batra - letter to a Judge of the Supreme Court of India,

Alleged torture by jail warden on another prisoner

Prem Chand, the victim, sustained serious anal injury  
because of inhuman torture

<https://indiankanoon.org/doc/778810>

# Locus Standi

The court will allow litigation only from parties that have been harmed directly or Indirectly in the case

# Letter Treated as Writ Petition

Sunil Batra had no **Locus Standi**

His letter was converted into a writ petition

Court issued notice to the State

Appointed amicus curiae

authorised them to visit the prison.

# Sunil Batra V/s Delhi Administration

<https://indiankanoon.org/doc/778810/>

- Extensive Prison Reforms
- Arguably the first Public Interest Litigation



# Indian Court Removes Locus Standi Requirements

Vigilant citizens can, through the court, get the government to take action on matters of

- human rights of the marginalized
- consumer welfare
- Environment

**Locus Standi not needed**

The court fees are minimal

- PIL in India

Legal precedent: Cite Internationally

Aside: Sunil Batra

Death sentence commuted life sentence

He studied law while in jail

After his release he is a respected PIL lawyer fighting mostly for prisoners

# Examples of Vaccine PIL

- Writ to restrain government from introducing expensive vaccines with low utility in the country without local epidemiological evidence
- Plea: formulate rule-based rational vaccine policy

Dr K B Sexana and others Vs Union of India and others

Writ Petition (Civil) No. 13698 of 2009

# Pentavalent deaths evidence

- Brighton classification changed

[http://www.rho.org/files/rb3/AEFI\\_Causality\\_Assessment\\_WHO\\_2005.pdf](http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf)

- Certain

- Probable

- Possible

- Unlikely

- Unrelated

- Unclassifiable

Deleted probable and possible from the classification

Sexana et al BMJ 2010;341 c4001 Page 218

Review: WHO Revised AEFI classification

<https://doi.org/10.12688/f1000research.13694.2>

**Only known reactions qualify as as Consistent with Causal Association.**

**New reactions noticed in post marketing surveillance will not qualify**

**All these are to be classified as 'Not an [AEFI]' according to CIOMS/WHO**

[https://www.who.int/vaccine\\_safety/initiative/tools/CIOMS\\_report\\_WG\\_vaccine.pdf](https://www.who.int/vaccine_safety/initiative/tools/CIOMS_report_WG_vaccine.pdf)

# WHO New Classification only for the poor?

- Rebecca E Chandler: WHO AEFI classification is for poorer countries.
- These reactions are not recorded in any database for pharmacovigilance.

<https://www.bmj.com/content/365/bmj.l2268/rr-8>



# Are EU Countries Safe from WHO AEFI?

Paolo Bellavite points out this system is used in Italy to deny AEFI compensation

<https://f1000research.com/articles/9-170>

PIL: Rota virus vaccine trial data

Intussusception data from Vellore

- Case No. W.P.(C) No. 289/2016

# Measles Rubella Campaign 2018/19

WHO want to introduce Measles Rubella vaccine in India

Rubella spreads easily in childhood.

Natural immunity before adolescence

# Congenital Rubella

- Cataract
- Congenital Heart Disease
- Mental Retardation

Natural infection in childhood  
induced immunity

- No case of congenital rubella in Delhi
  - Right to information Delhi 1314 of 2019

- WHO recommends vaccine to reduce nonexistent congenital rubella
- To be given to 5.5 million children in the age group of nine months to fifteen years , regardless of previous vaccination status or history of Measles /Rubella like illness
- Without obtaining any consent from parent

# Delhi High Court

## Writ Petition by Children and Parents

- 1. [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=5921&yr=2019](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=5921&yr=2019)
- 2. [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=13258&yr=2019](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=13258&yr=2019)
- 3. [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=23136&yr=2019](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=23136&yr=2019)

# Vaccination Only After Informed Consent

## Delhi High Court

- Vaccination only after informed consent from parents.
- Parents must be informed about all the benefits and adverse effects of the vaccine



## Government Stand on Informed Consent

Should the side effects and contraindications be publicised, it would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided.

# Enlightened Vaccination Law in India

- No mandatory vaccination
- Informed parental consent before vaccination
- No penalty for refusal to vaccinate

Then came the Corona Pandemic

# The Epidemic Diseases Act, 1897

Law for plague epidemic broke out in the 1890s

Legal immunity to a person acting under its provisions.

- Forcible segregation of affected persons
- Demolition of affected areas
- Banning of public gatherings

Last Invoked in 2009 for so called swine flu epidemic

# The Madras Public Health Act, 1938:

- The Act was enacted for making vaccination compulsory.
- Sweeping powers to government authorities but applicable only in places where there is a high risk of an epidemic spreading and jeopardising public health

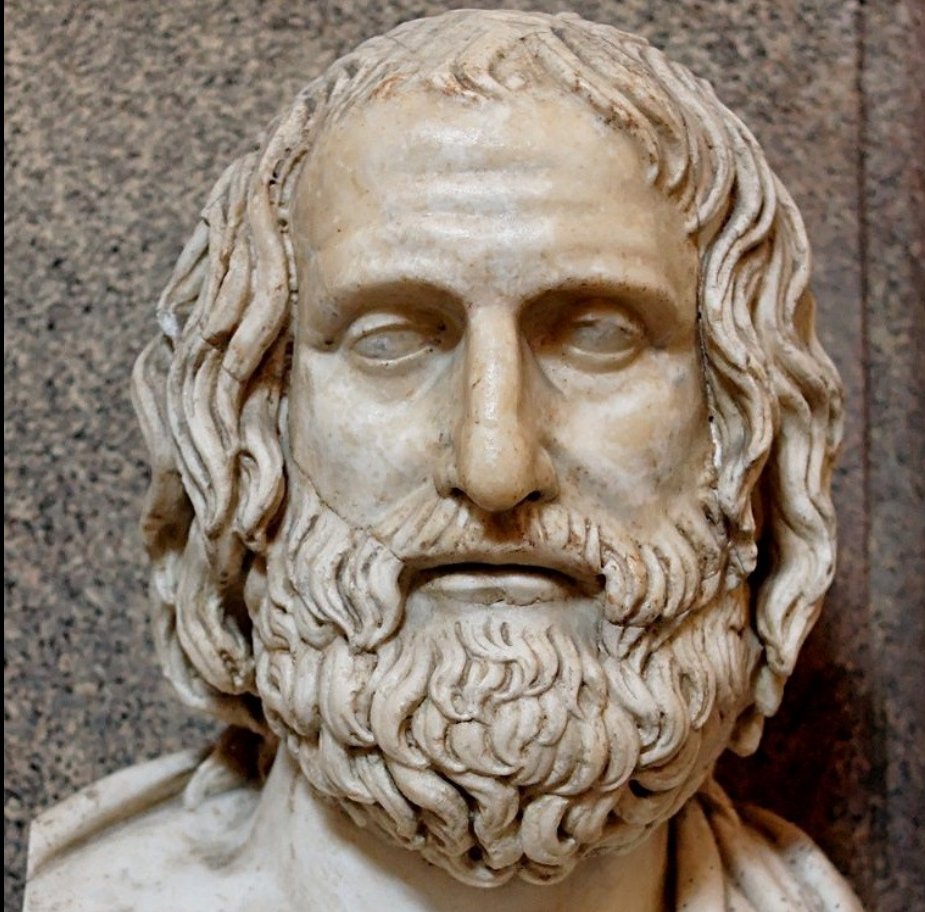
- On the one side we have hope
  - PIL
  - Need for informed consent
- 
- On the other side we see the sweeping power of Epidemic laws and the Public Health Acts

The way of the world

Roots

Alex Haley

# Protagoras paradox: Both sides feel they will win



Some judges may be taken in by the arguments of the other side

When we take the case to the next court of appeal, we must remember, if it is in the public interest, it is in the interest of everyone and that includes the our opponents and the judges.