

Considerations Regarding Informed Consent of Parents of the Preterm Child

New Perspectives in the Management of
Neonatal Respiratory Distress Syndrome
PAS Satellite Symposium

May 4, 2014

Vancouver, British Columbia

Jonathan Fanaroff, MD, JD
Associate Professor of Pediatrics
CWRU School of Medicine
Director
Rainbow Center for Pediatric Ethics
Rainbow Babies & Children's Hospital
Cleveland, Ohio



Disclosure Statement

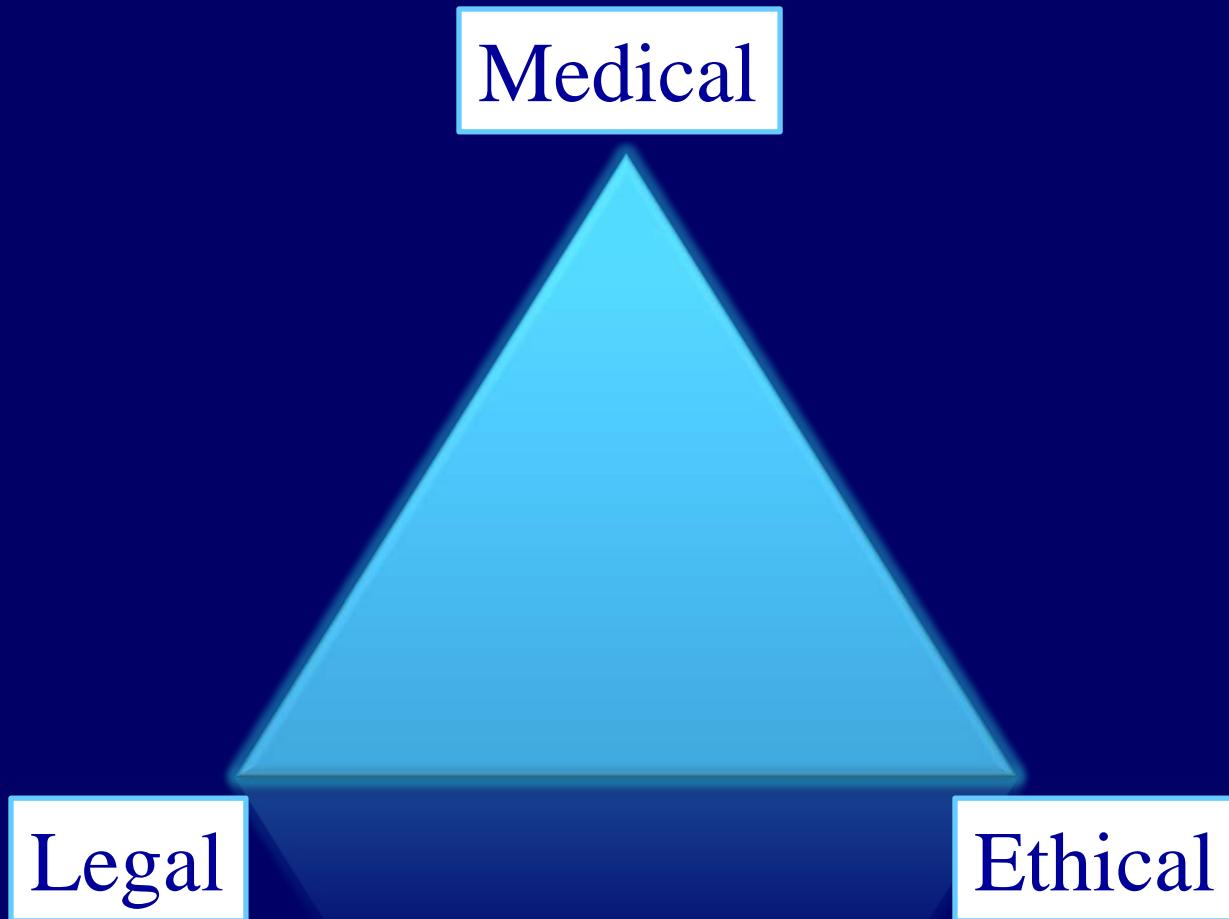
Dr. Fanaroff has disclosed the following financial relationships. Any real or apparent conflicts of interest related to the content of this presentation have been resolved.

- Advisory Board – Discovery Laboratories, Inc.
- Advisory Board – AbbVie, Inc.

Objectives

- Describe the philosophical/historical principles of the informed consent doctrine
- Explain the informed consent process as it relates to neonatal patients
- Discuss how informed consent principles apply with respect to RDS treatment in newborns

Balancing Considerations







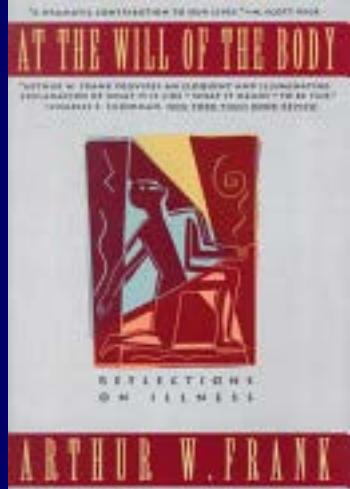


Norman
Rockwell

"The only way I could get my surgeon, a seasoned professional, to talk to me about the details of and alternatives to the operation he was planning...was to refuse to sign the consent form. We then had a long conversation. His knowledge and experience helped me, but this help came only after I had hit him with the only two-by-four a patient has."

Arthur W. Frank,

At the Will of the Body: Reflections on Illness



A portrait painting of Sir William Blackstone, an English jurist, historian, and judge. He is depicted from the waist up, wearing a black robe over a white collar and a red velvet robe. He has long, powdered grey hair and is holding a book in his left hand.

Autonomy

"Every man's person
being sacred and no
other having a right
to meddle with it, in
any the slightest
manner."

Sir William
Blackstone

Autonomy

“Over himself,
over his own body
and mind, the
individual is
sovereign.”



Photo by David Nicholls

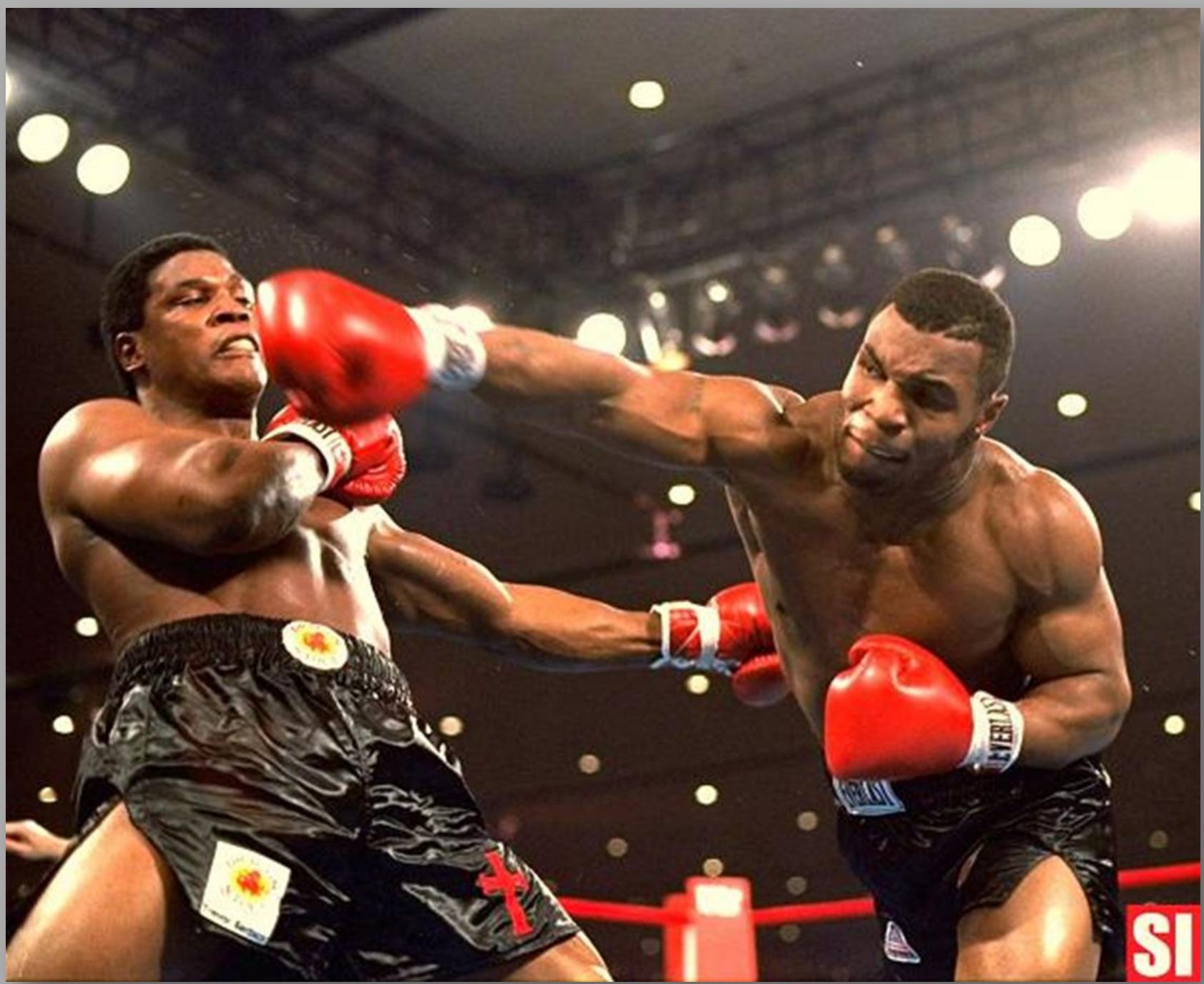


Photo by Jeff Kubina

Schloendorff v. Society of NY Hospital (1914)

- Plaintiff Mary Schloendorff
- Admitted to New York Hospital
- Consented to being examined under anesthesia to determine if a uterine fibroid was malignant
- Withheld consent for tumor removal
- Physician examined the tumor, found it malignant, and removed it anyways
- Ms. Schloendorff gets upset and sues

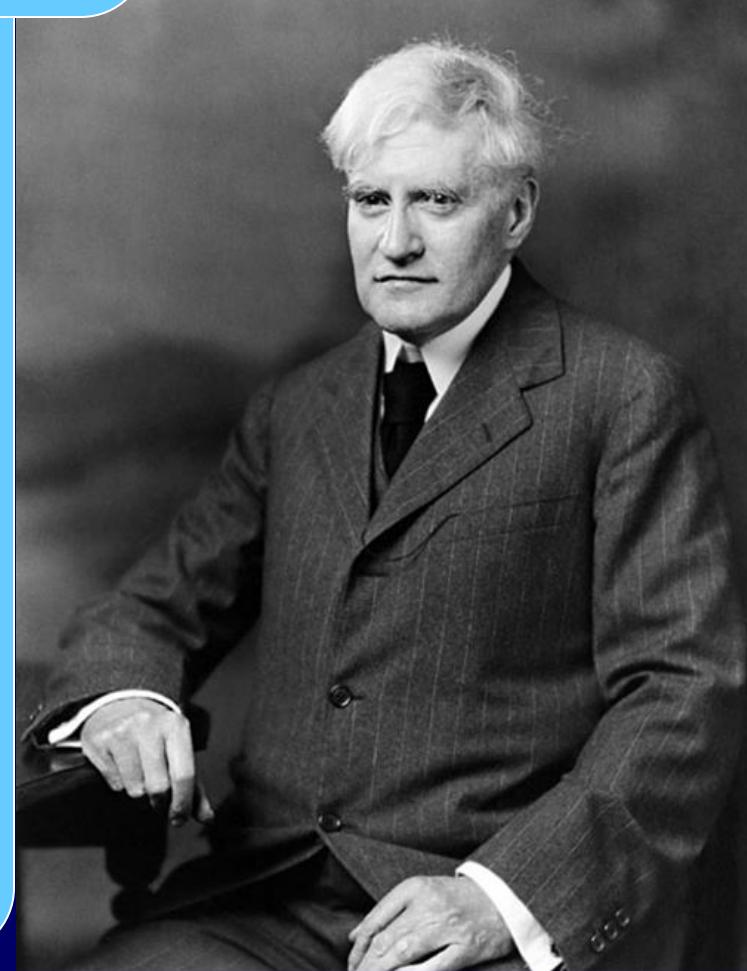




Schloendorff v. Society of NY Hospital

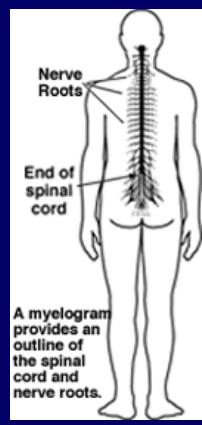
“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.”

Justice Cardozo



Canterbury v. Spence (1972)

- Plaintiff Canterbury – 19 y.o. FBI clerk in D.C.
- Severe pain between his shoulder blades
- Myelogram shows a “filling defect” in the region of the fourth thoracic vertebra
- Neurosurgeon Dr. Spence recommends a laminectomy for a suspected ruptured disk



Canterbury v. Spence (1972)

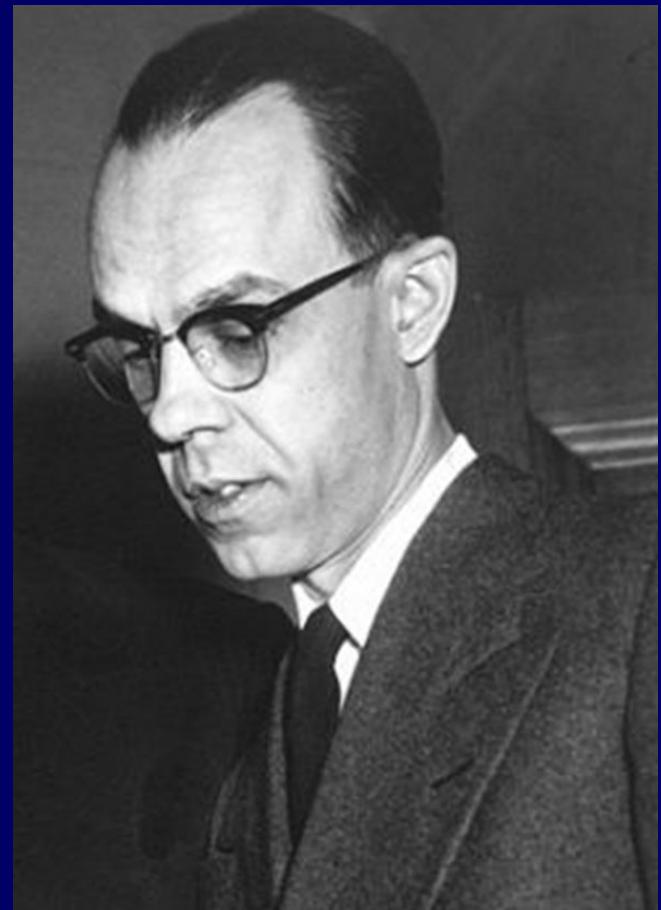
- Canterbury does not raise any objection to the proposed operation nor does he probe into its' exact nature
- When asked by Canterbury's mother over the phone if the operation was serious, Dr. Spence states "not anymore than any other operation."
- Operation is performed on February 11

Canterbury v. Spence (1972)

- Canterbury's mom arrives in Washington that day, but after the operation was over, and signed a consent form at the hospital
- After the surgery Canterbury is worse off
 - Crutches to walk
 - Bowel and bladder incontinence
 - Unable to work
- Canterbury sues for failure to inform him before the operation of the risks involved

"A physician is under a duty to treat his patient skillfully but proficiency in diagnosis and therapy is not the full measure of his responsibility. The cases demonstrate that the physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it."

Judge Spottswood William Robinson III



Canterbury v. Spence



- The patient owns the right to determine what is to be done with his or her body
- Yet “the average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision.”

Legal Requirements Factors to Be Disclosed Informed Consent



Diagnosis

- First describe the diagnosis, including the medical steps preceding diagnosis

Benefits

- Second describe the proposed treatment
- What you want to do
- Why you want to do it
- What are the odds of success?
- How will the patient benefit if successful?

Risks and Outcomes

- What happens if you are not successful?
- What complications may occur?
- Key factor in informed consent ethics & law
- Patient claims – “I didn’t know because they didn’t tell me, and if they did tell me I never would have consented to the procedure.”

What risks should be disclosed?

- Common risks
- Severe risks - the greater the severity, the more likely the risk should be disclosed, even if the incidence of the materialized risk is small
- “Always” material
 - Death, brain damage
 - Quadriplegia, paraplegia
 - Loss of organ function
 - Disfiguring scars

Alternatives

- Nature, benefits, and risks of “feasible” alternatives
- Nature, benefits, and risks of doing nothing – “Informed Refusal”



Consent in Emergencies

- Unable to communicate because of an injury, accident, illness, or unconscious
- Suffering from what reasonably appears to be a life-threatening injury or illness
- Consent is “implied”





Newborns

- Patient **autonomy** is central to modern medical ethics
- Newborns obviously do not have competency to make decisions
- In the absence of a competent patient, **surrogates** are sought
- For newborns, the natural surrogates are **parents**

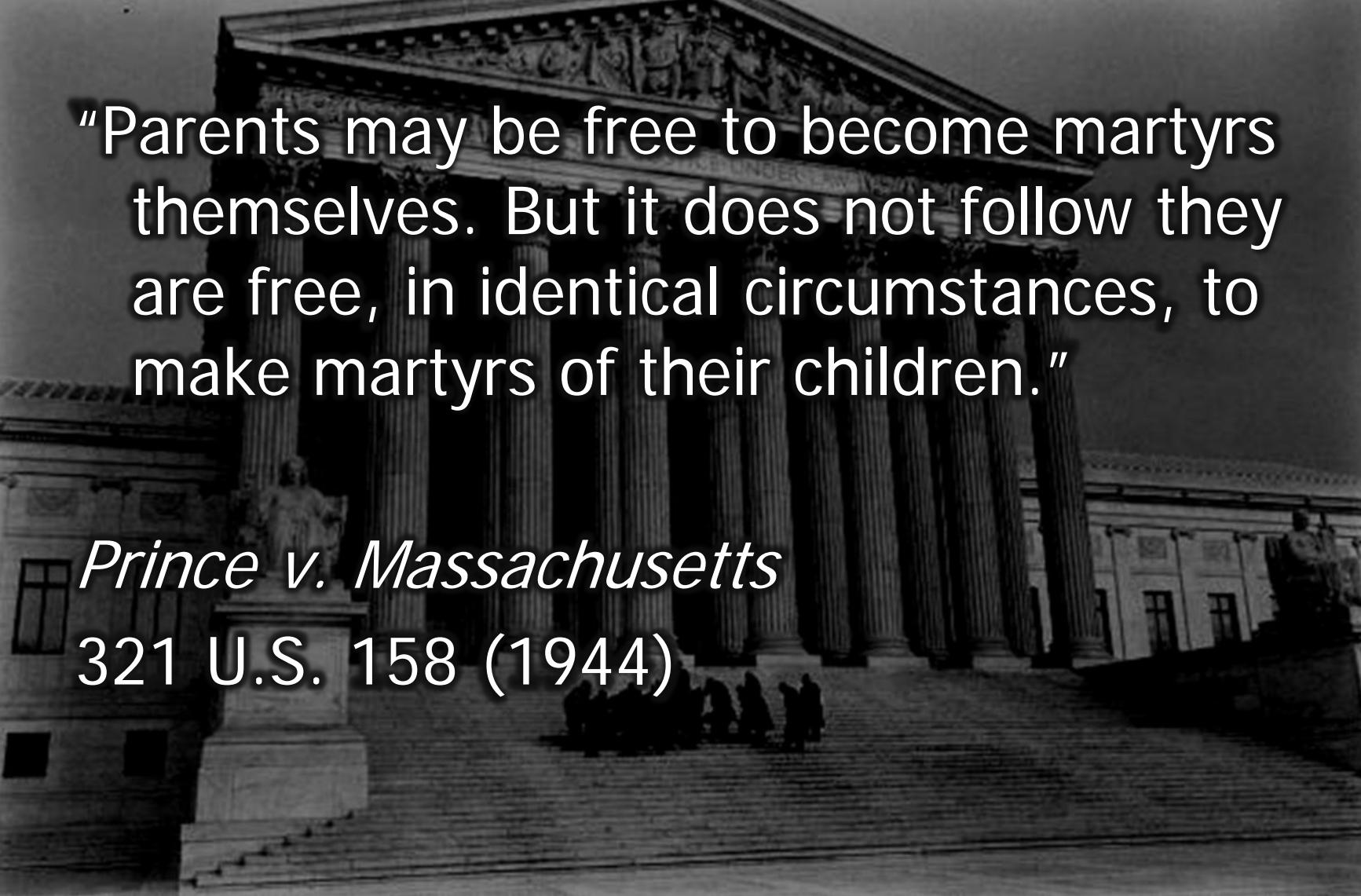


“[There is a] presumption, strong but rebuttable, that parents are the appropriate decision-makers for their infants.”

The President's Commission for the Study of Ethical Problems in Medicine (1982)

Surrogates

- Speak for the incompetent patient
- Not an unlimited right
- Much different from someone making a decision for themselves
- Especially in children



"Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children."

Prince v. Massachusetts

321 U.S. 158 (1944)

AMA Code of Medical Ethics - 2.215

- The primary consideration for decisions regarding life-sustaining treatment for seriously ill newborns should be what is best for the newborn.



AMA Code of Medical Ethics -

2.215

- Factors that should be weighed are as follows:
 - The chance that the therapy will succeed
 - The risks involved with treatment and non-treatment
 - The degree to which the therapy, if successful, will extend life
 - The pain and discomfort associated with the therapy
 - The anticipated quality-of-life for the newborn with and without treatment

Informed Refusal in Pediatrics

- A competent parent can make an informed refusal of care when no life threat or potential for serious impairment exists
- Resources during a conflict
 - Social work → ? medical neglect referral
 - Pediatric ethics consultation/committee
 - Hospital legal counsel/possible courts





Soll R, Blanco F. Natural surfactant extract versus synthetic surfactant for neonatal respiratory distress syndrome. Cochrane Database of Systematic Reviews 2001; Issue 2. Art. No.: CD000144.

Plain Language Summary:

The review of trials compared natural with synthetic surfactant extracts and found a decrease in the risk of pneumothorax and death in babies receiving natural surfactant extracts.

Authors' Conclusions:

Natural surfactant extracts would seem to be the more desirable choice when compared to currently available synthetic surfactants.

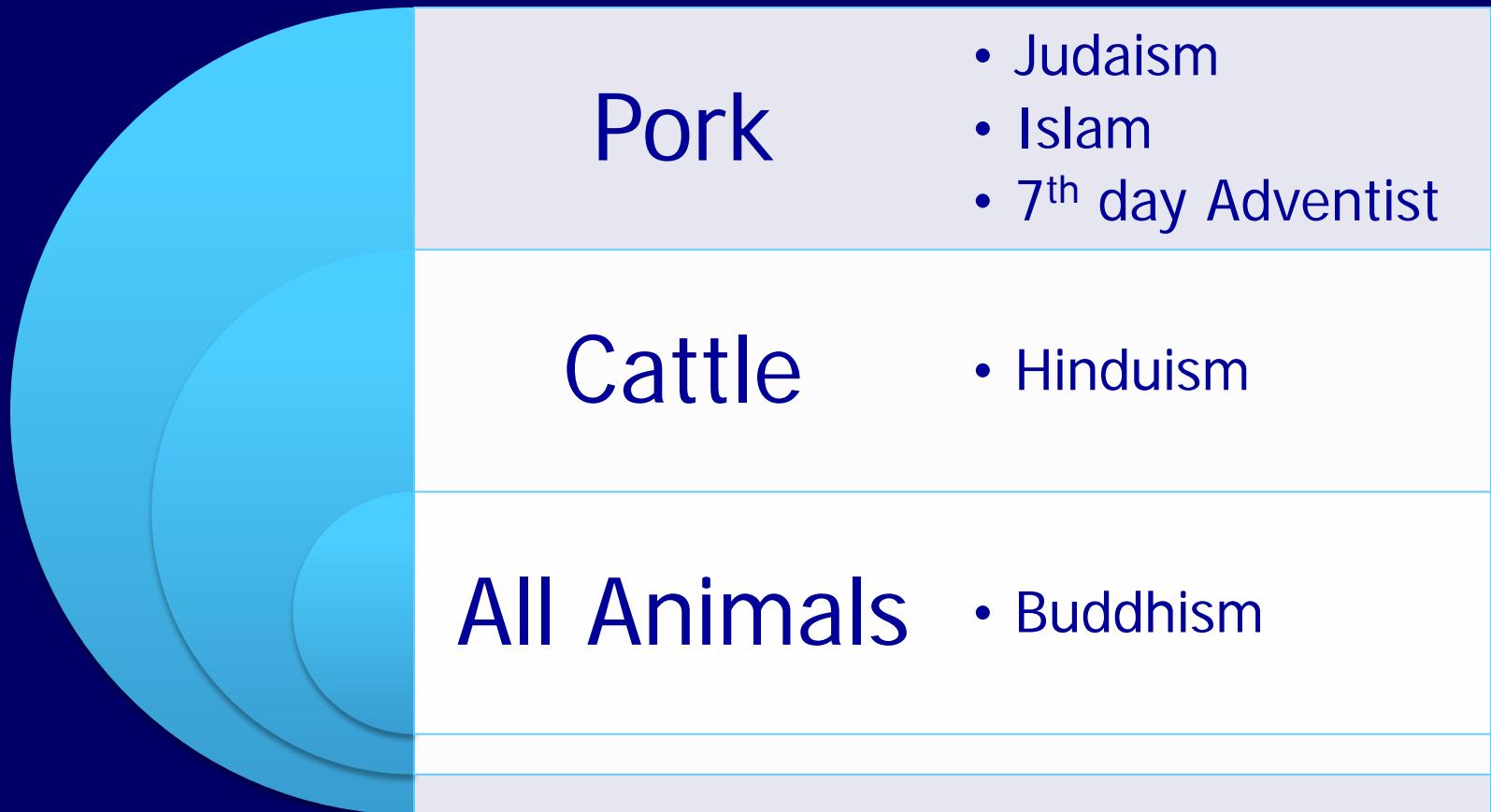
Do neonatologists and parents share the same concerns about animal-derived pharmaceutical agents?

S. Sarkar* and S.M. Donn

Division of Neonatal-Perinatal Medicine, Department of Pediatrics, C.S. Mott Children's Hospital, University of Michigan Health System, Ann Arbor, MI, USA

"[I]t is not often appreciated that sources of pharmaceutical agents may be an important issue for those who may have personal, cultural, or religious objections to products of animal origin."

Religious Considerations



Animal Origins of Surfactant: A Survey of Neonatologists' Perceptions and Practices Regarding Parent Information Sharing

Sean M. Bailey, New York University School of Medicine

Karen D. Hendricks-Muñoz, New York University School of Medicine

Pradeep V. Mally, New York University School of Medicine

- 1002 neonatologists responded
- 47% response rate
- Almost all were using animal-derived surfactant
- 67.5% had access to only one type of surfactant

Animal Origins of Surfactant Survey

- 75% always discussed the plan for the use of surfactant in conversations with parents during a NICU consult
- 71% never discussed the animal origins of the surfactants they use
- 59% did not personally feel that this information should be discussed

Animal Origins of Surfactant Survey

- When neonatologists do discuss the animal origins of surfactant:
 - 23% have conversations “more often than not” prior to the first dose
 - 10% always talk about it prior to the first dose

Animal Origins of Surfactant Survey

- Even with access to different types of surfactant, almost half (48%) of surveyed neonatologists stated that they would not take parental religious preferences into account when choosing a surfactant
- 19% would consider parental concerns
- 33% might consider parental concerns

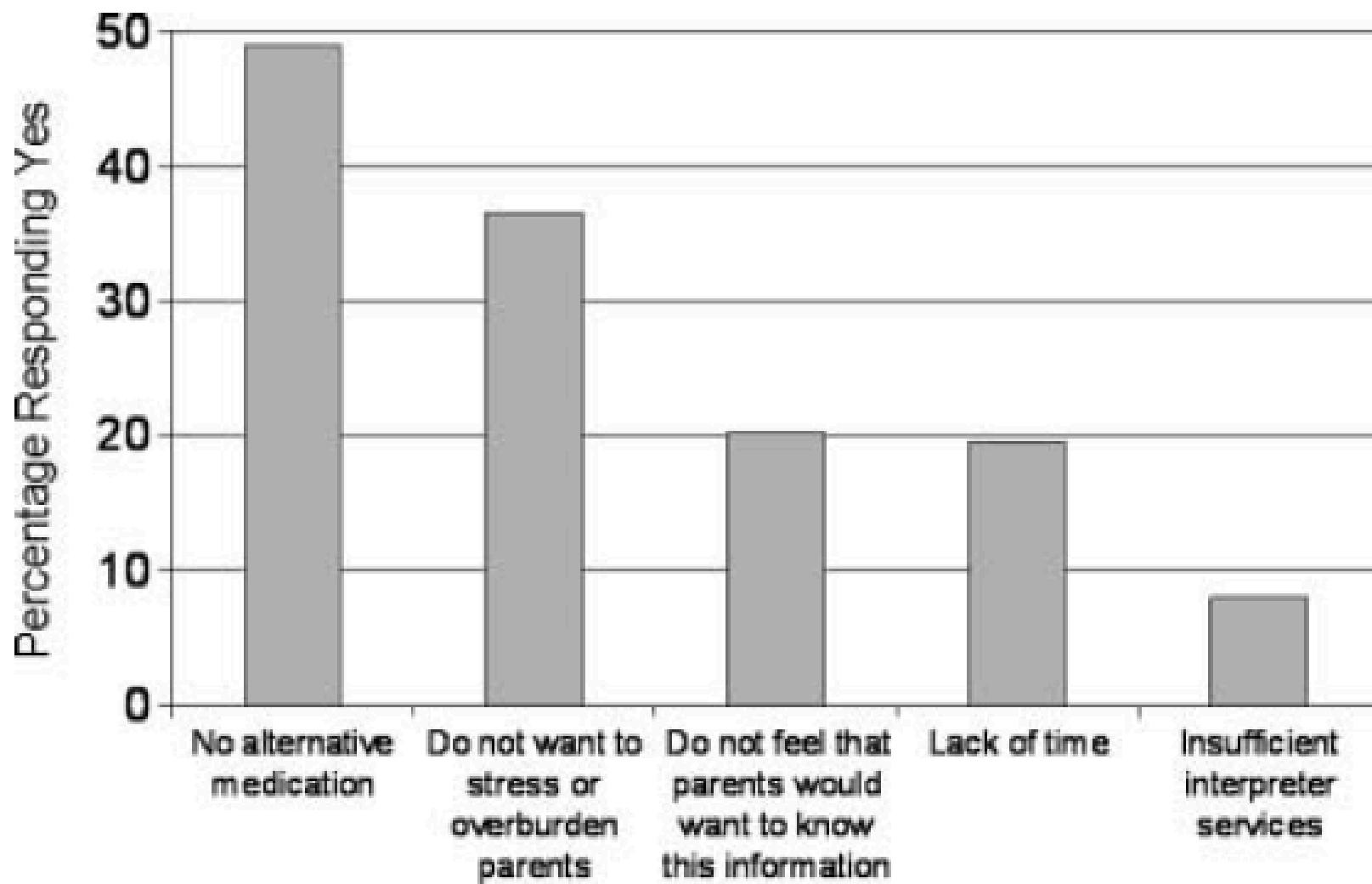


Figure 2. Barriers reported by neonatologists that interfere with sharing information about the animal origins of exogenous surfactants ($n = 833$).

Non-Religious Considerations



Vegans

Animal
Rights

Disease
Transmission

Summary of Survey Findings

- Neonatologists often discuss surfactant use with parents
- Neonatologists rarely discuss the animal origins of surfactant with parents
- Neonatologists vary widely with respect to how much consideration they would give to parental preferences

Is this Consistent With Family-Centered Care?



Religion is Important to Many People



Animal Implants - Religious Considerations



Judaism

- Porcine products acceptable only when no other efficacious alternatives

Muslim

- Porcine implants acceptable only in dire situations after all other options exhausted

Hindu

- Would not accept bovine surgical implants

People of the Same Religion May Vary in their Interpretations



You Will Never Know Unless You Ask Them

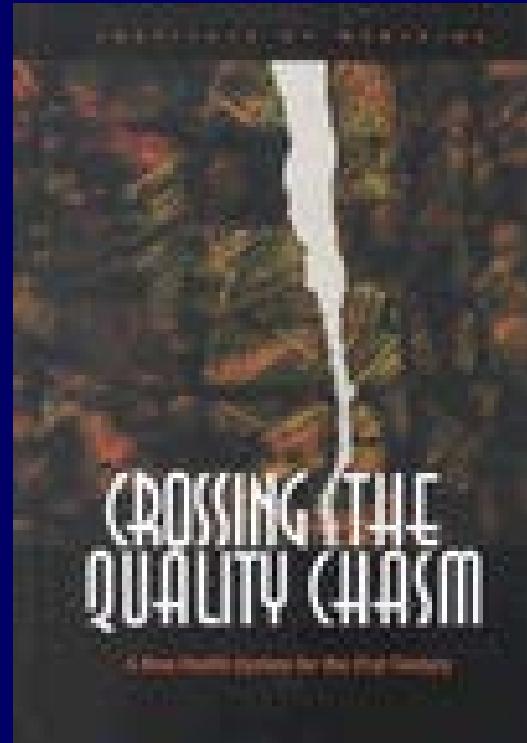


Parent Responses

N=150	Yes	No	Indifferent
Concerns about exposure to animal products	27%	50%	23%
Preference for humanized or synthetic product	54%	16%	30%
Agreement regarding need to make parents aware of a product's animal derivation	67%	20%	13%

IOM Aims for a 21st Century Health System

- Safe
- Timely
- Effective
- Efficient
- Equitable
- Patient-Centered



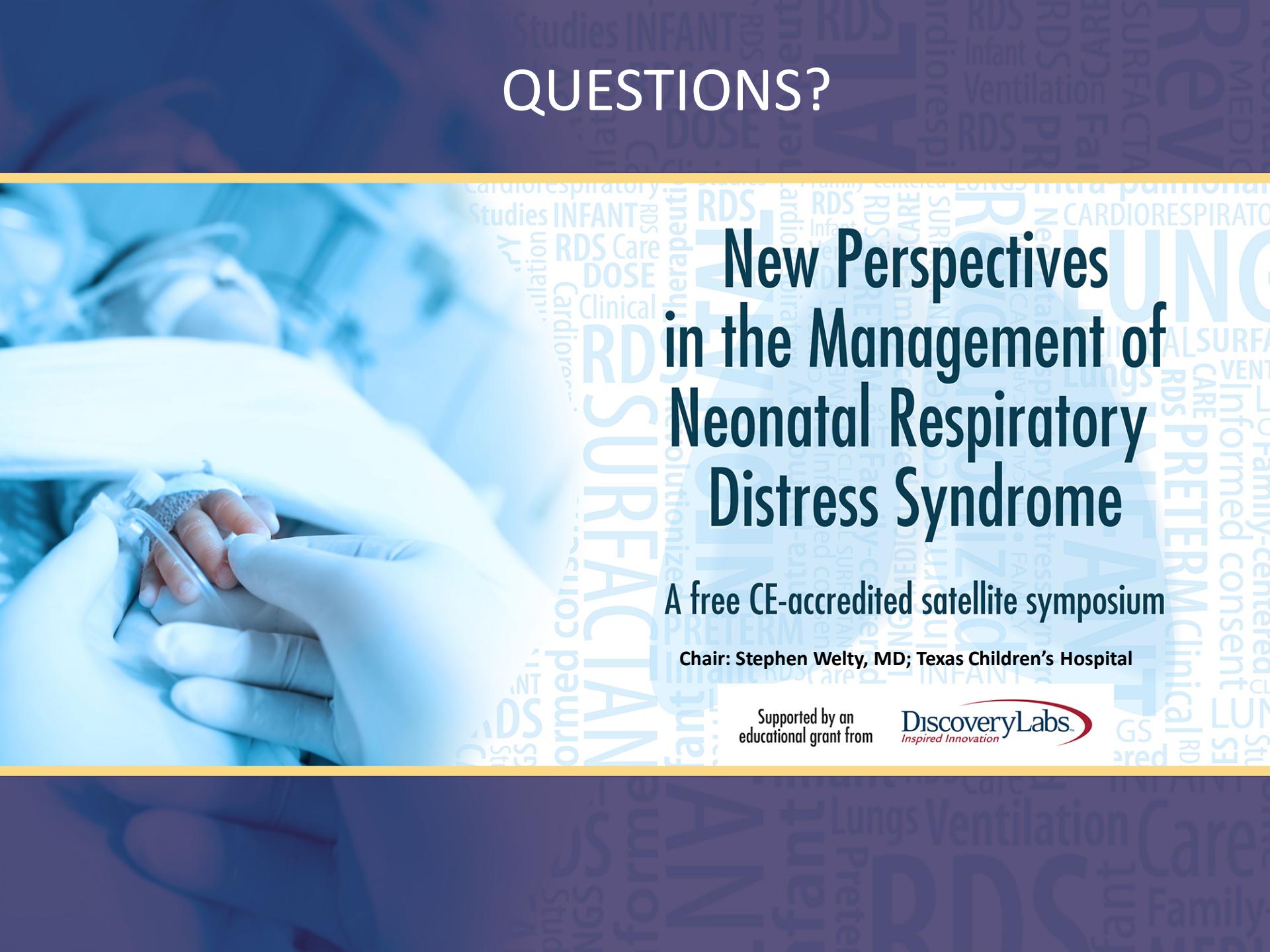
"The AAP wishes to underscore its recognition of the important role of religion in the personal, spiritual, and social lives of many individuals and cautions physicians and other health care professionals to avoid unnecessary polarization when conflict over religious practices arises. Pediatricians should seek to make collaborative decisions with families whenever possible and should take great care when considering seeking authority to override parental preferences."



Policy Statement: Religious Objections to Medical Care. *Pediatrics*. 1997;99(2):279–281.
Reaffirmed May 2009.

Issues for Discussion

- Should parents be informed about the surfactant type being given to their infant?
- Should parents be informed of the animal from which the surfactant is derived?
- Should institutions carry more than one type of surfactant?
- Should parental choice play a role in the type of surfactant given to their infant?



QUESTIONS?

New Perspectives in the Management of Neonatal Respiratory Distress Syndrome

A free CE-accredited satellite symposium

Chair: Stephen Welty, MD; Texas Children's Hospital

Supported by an
educational grant from





New Perspectives in the Management of Neonatal Respiratory Distress Syndrome

A free CE-accredited satellite symposium

Chair: Stephen
Hospitale

Texas Children's
Hospital

Supported by an
educational grant from

DiscoveryLabs
Inspired Innovation