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Tragedies in Children Led to Regulations

- 1902: Biologic Control Act
 - Diphtheria antitoxin contaminated with live tetanus
- 1938: Food, Drug, and Cosmetic Act (FDCA)
 - Sulfanilamide elixir in diethylene glycol
- 1962: Amendments to FDCA
 - Thalidomide

Yet...Sick Children Had Not Benefited As Had Adults From Advances in Modern Therapeutics

- **The legislation and rule making in 1938 and 1962 did not ultimately address the needs of children**
- **“The therapeutic orphan” - 1960's**
 - **lack of pediatric studies and labeling persisted despite recognition of the problem, and multiple attempts to correct the situation**

Pediatric Drug Label

Under the “Precautions” Section

- “Not to be use in children, ...”
- “...is not recommended for use in infants and young children, ...”
- “... should not be given to children.”
- “... clinical studies have been insufficient to establish any recommendations for use in infants and children.”

Result



Over

80%

of medicines **were** not studied in children.

Over

90%

of them **have not been** studied in infants.



It Required a Culture Change

- In the general population
- Among Medical Officers in the FDA
- Among physicians and other professionals in the pharmaceutical industry
- Among physicians (including pediatricians) in clinical practice
- Among Academic / University Hospitals and Institutions

The AAP believes it is unethical to deny children appropriate access to existing and new therapeutic agents. **It is the combined responsibility of the pediatric community, pharmaceutical industry, and regulatory agencies to conduct the necessary studies; it is the responsibility of the general public to support the necessary research** in order to assure that all children have access to important medications and receive optimal drug therapy.

AAP, Committee on Drugs; *Pediatrics* **95**:294, 1995.

Legislative Changes in 1997 and 2003

- Best Pharmaceuticals for Children Act
- Pediatric Research Equity Act

100 guinea-pig kids

Shocking new number in HIV tests

By DOUGLAS MONTERO

The Administration for Children's Services allowed more than 100 HIV-positive foster kids to be used as guinea pigs in medical experiments over the past 12 years, The Post has learned.

The preliminary figure — double the earlier number reported — was released by ACS Commissioner William Bell yesterday as his office began a review of its files to determine the extent of the experimentation, said City Councilman Bill DiBlasio.

The Brooklyn Democrat fired off a letter to Bell demanding a full accounting of experiments, including how they were approved, how the kids' natural parents were notified, who gave consent and for how many years the studies were conducted.

"We would like to see the whole picture and we would like to see it quickly," said DiBlasio, the

Shame of the city



■ More than 100 foster kids were used in AIDS-drug experiments.

■ The city says a preliminary review shows none was hurt.

■ A city councilman demanded to know if the kids' parents consented.

The church-run Incarnation Children's Center is at the center of the storm.



chairman of council's General Welfare Committee.

The preliminary review by the ACS has determined that none of the children involved in the experiments was hurt.

AIDS and children's advocates have claimed that some of the kids placed by Manhattan's Incarnation Children's Center, a Catholic-run foster-care agency, were given dangerously

high doses of experimental AIDS drugs. "There is no evidence to suggest that any of these children were harmed as a result of their participation in clinical trials," said MacLean Guthrie, an ACS spokeswoman.

Liam Scheff, a health advocate who investigated the Incarnation experiments and posted his findings on the Internet, was not convinced.

"My main goal is to help

these children because they were being tortured," Scheff said. "The medications they were being given [were] very toxic and not very effective.

"They [Incarnation] were getting away with it because the kids were mostly black, Hispanic and poor."

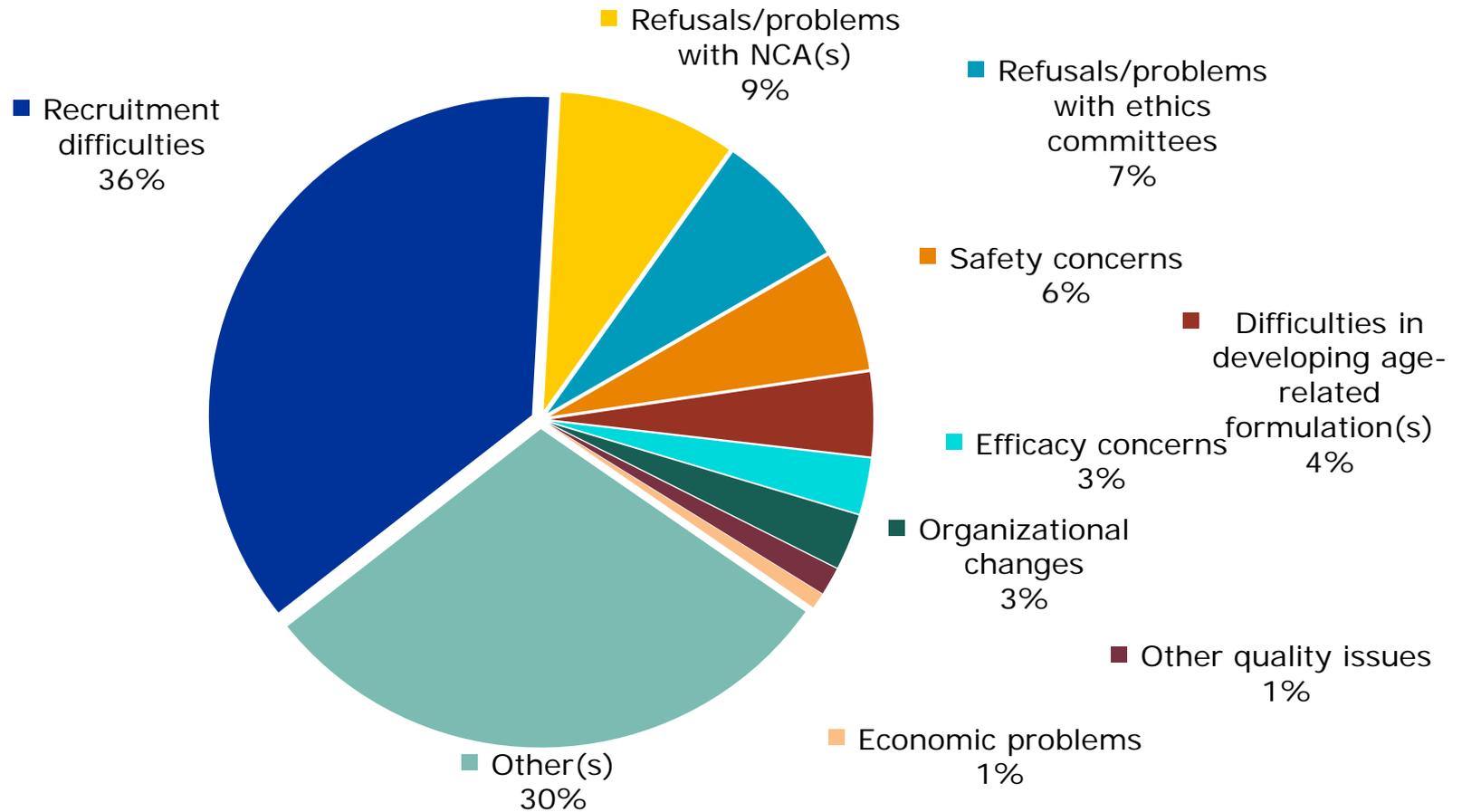
The New York Archdiocese admitted experiments were done, but said they ended in 2002.

Perception in and miscommunication by the lay press

- “FDA considers drugging healthy kids for science”
AP 9/3/04
 - “Is it ethical in the name of science to give a healthy child as young as 9 a controlled substance?”
- “The Body Hunters: As Drug Testing Spreads, Profits and Lives Hang in Balance”
J STEPHENS, Washington Post, December 17, 2000
- “Strong antibiotics to be tested on kids: FDA urges trials despite side effects”
JEFF NESMITH, The Atlanta Journal-Constitution: August 15, 2004

Main Challenges

Reported difficulties in conducted PIP studies



ACTG 076 Story

All Beginnings Are Difficult

When you want
something you've
never had,
you have to do
something you've
never done



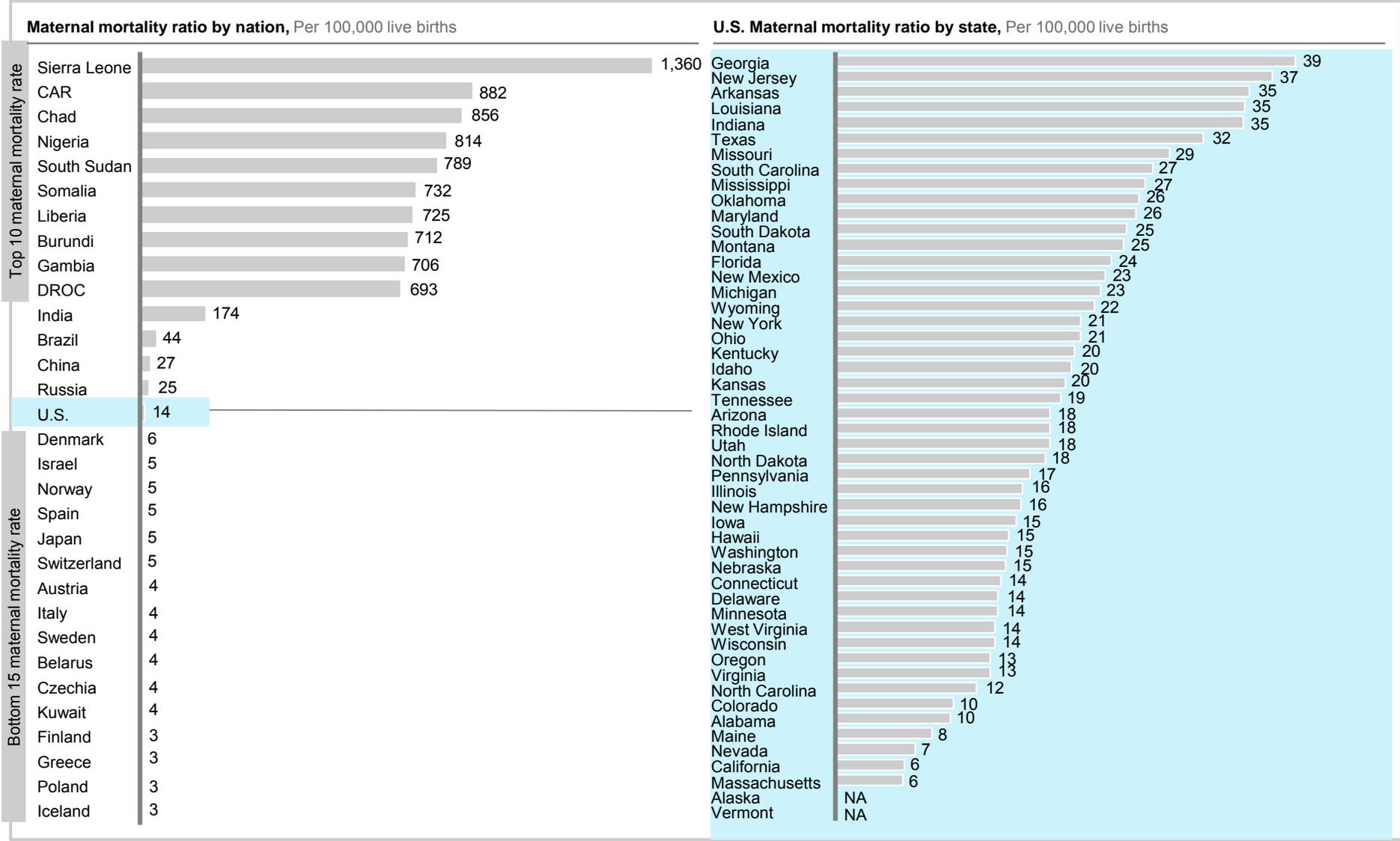
Thank you



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Maternal mortality remains a significant challenge



SOURCE: WHO 2015, America's Health Rankings 2016 Health Report of Women and Children

Maternal mortality has multiple root causes

	Causes of maternal mortality	Key interventions
Family planning	<ul style="list-style-type: none"> ▪ Risky pregnancies (e.g. adolescents) ▪ Complications from unsafe abortion 	<ul style="list-style-type: none"> ▪ Access to contraception ▪ Access to safe abortion services and post-abortion care
Pregnancy	<ul style="list-style-type: none"> ▪ Pre-eclampsia ▪ Other complications driven by indirect causes (e.g. obesity, HTN, cardiovascular disease, diabetes, opioid abuse) 	<ul style="list-style-type: none"> ▪ Detection; administration of magnesium sulfate ▪ Detection; access to pre-natal care
Delivery	<ul style="list-style-type: none"> ▪ Obstructed labor 	<ul style="list-style-type: none"> ▪ Detection; cesarean section or vacuum extraction
Post-delivery	<ul style="list-style-type: none"> ▪ Postpartum hemorrhage ▪ Postpartum depression and suicide ▪ Postpartum infections ▪ Opioid addiction 	<ul style="list-style-type: none"> ▪ Administration of oxytocin ▪ Anti-depressant; mobile support ▪ Proper hygiene

Maternal Health is Ripe for Disruptive Innovation

- Need some significant catalyzing events to shift this healthcare ecosystem
- This Group has much of the power and knowledge to initiate change
- What are the next steps?