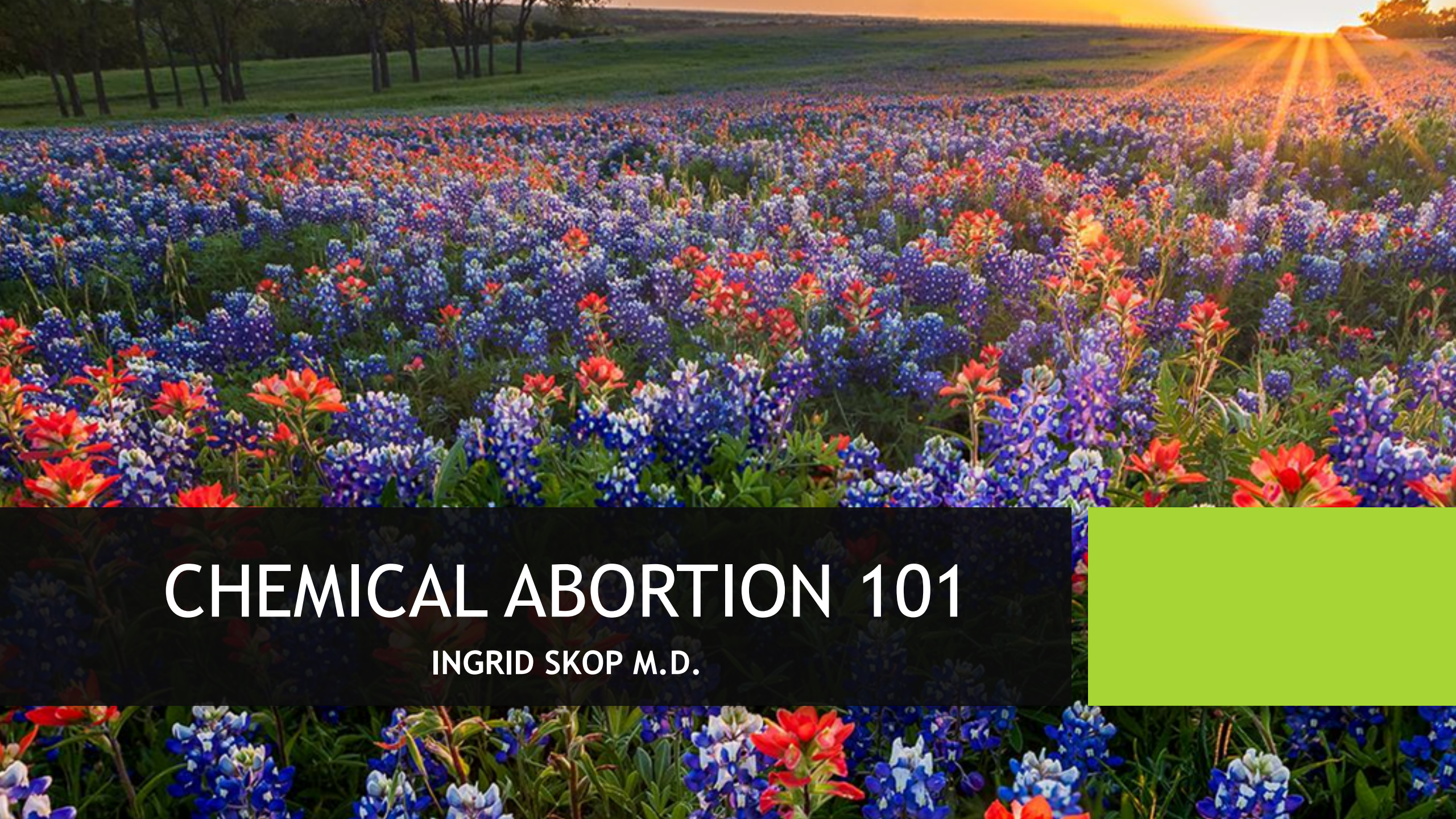


CHEMICAL ABORTION 101

INGRID SKOP M.D.

WHAT WILL YOU LEARN TODAY?

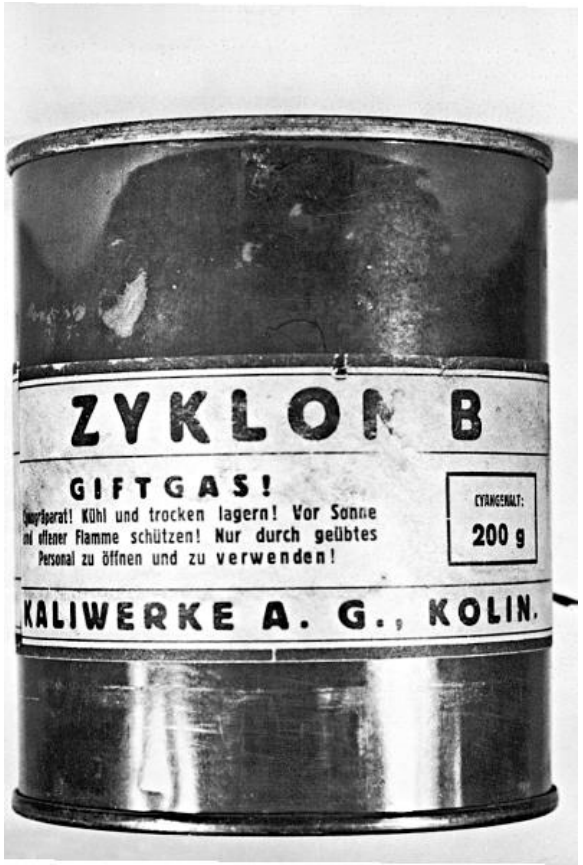
- HOW MEDICAL ABORTION PILLS WORK
- HISTORY OF MEDICAL ABORTION IN U.S.
- REMS RESTRICTIONS ON MIFEPRISTONE
- COMMON EXPERIENCE
- DATA DEFICIENCIES
- ABORTION-INDUSTRY STUDIES
- NON-BIASED STUDIES
- CURRENT & FUTURE ABORTION TRENDS

MEDICAL ABORTION IN U.S.

- Mifepristone (Mifeprex or RU486) taken orally to block progesterone receptors, cutting off hormonal support for the pregnancy, which results in disruption of the implantation site
- Misoprostol (Cytotec) taken sublingually, buccally or vaginally 24-48 hours later to induce contractions to expel the pregnancy tissue

HISTORY OF MIFEPRISTONE IN THE U.S.
(CALHOUN, HARRISON)

- President Bill Clinton wrote the French manufacturer of mifepristone (RU-486) Roussell Uclaf, asking them to file a new drug application with the FDA.
- Roussell Uclaf's parent company, Houest, was formed from the company that created Zyklon B, the cyanide gas used in the Nazi death camps.
- UN Population Council gave manufacturing permission to a company created for this specific purpose, Danco.



ABERRANCES IN FDA APPROVAL PROCESS FOR MIFEPRISTONE

1. **Required two randomized, blinded placebo-controlled trials.** Submitted trials had no placebo groups, and there were concerns about falsification in the French data.
2. **Subpart H: Accelerated Approval Regulations** are intended for serious/life threatening illnesses. The drug so approved must supply meaningful therapeutic benefit over existing therapies.

RISK EVALUATION MITIGATION STRATEGY (REMS)

- SAFETY STRATEGY APPLIED TO MEDICATIONS THAT HAVE A KNOWN OR POTENTIAL SERIOUS RISK ASSOCIATED WITH THEM, DESIGNED TO MINIMIZE COMPLICATIONS
- THIS IS THE ONLY RESTRICTION THAT REGULATES THE DRUG AND PREVENTS UNLIMITED ACCESS

ABERRANCES IN FDA APPROVAL PROCESS FOR MIFEPRISTONE

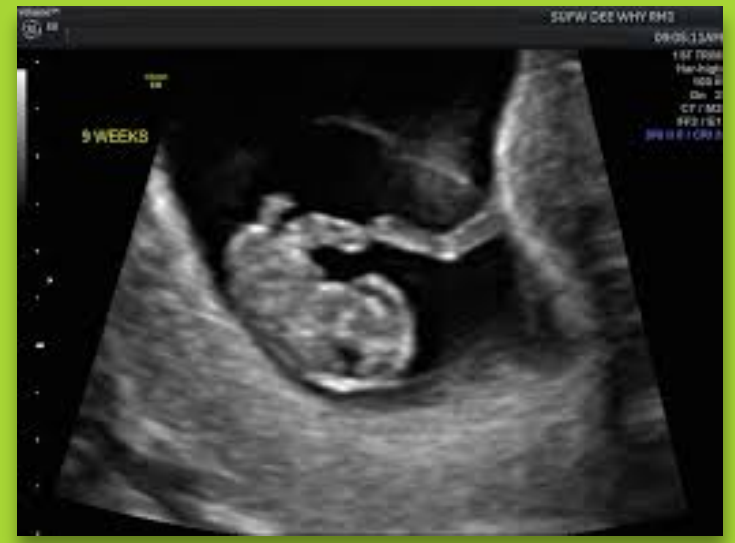
3. FDA based their approval on the combined action of mifepristone and misoprostol together. **Mandated unapproved use of misoprostol despite Searle's objections.**

4. **Required to test a drug in pediatric population,** but this was waived without explanation.

5. Approved regimen **does not mimic clinical trial conditions**- lack of required ultrasound, experienced surgeon dispensing, nearby hospital admitting privileges.

INITIAL FDA APPROVAL OF MIFEPRISTONE 2000

- Approved up to 49 days (7 weeks) gestational age
- Physician provider registered after specific training
- Only dispensed in certain healthcare settings
- Must inform patients of risk of serious side effects
- Mandated complication reporting
- Required fourteen-day follow-up visit

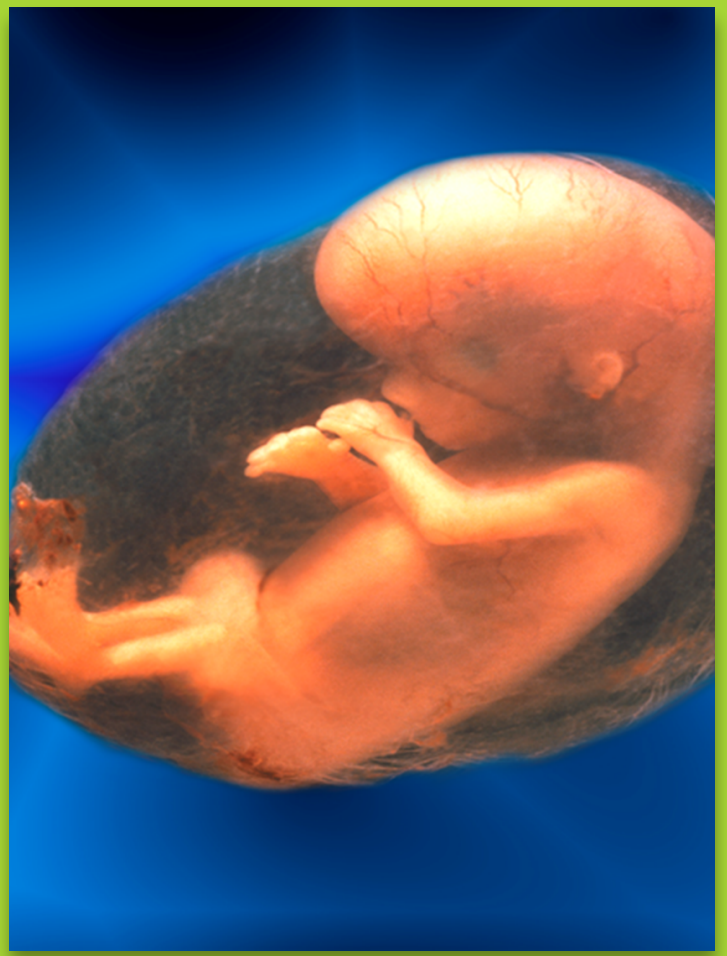


INITIAL FDA APPROVAL OF MIFEPRISTONE 2000

- **Physician providers must be able to:**
  - Accurately determine the gestational age (usually by ultrasound)
  - Determine location of the pregnancy (rule out extrauterine location)
  - Intervene surgically if abortion unsuccessful (or have an agreement with another doctor and facility to provide this care)

SUPPLEMENTAL APPLICATION APPROVAL 2016

- Extended use up to **70 days (10 weeks)** gestational age
  - Far greater failure rates in higher gestational ages
  - 9-10 weeks studied in only 332 women
  - 7% required surgery, 3% failed to kill fetus
- Provider does not need to be a physician
- Modification of dose, timing, and route
- Complication reporting no longer required **unless leads to death**
- Follow-up visit unnecessary



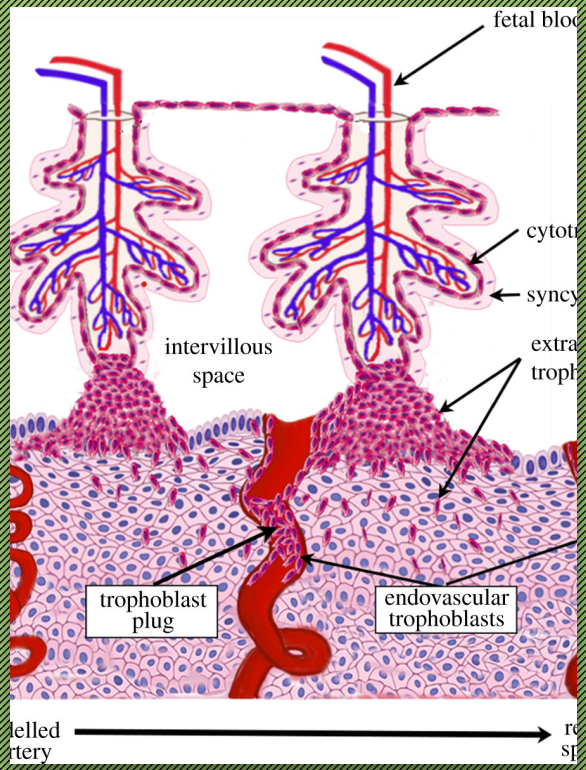
TYPICAL EXPERIENCE OF MIFEPRISTONE/ MISOPROSTOL

- Most women experience the following adverse effects: cramping, heavy bleeding, nausea, weakness, fever, chills, vomiting, headache, diarrhea and dizziness
- Average woman bleeds for 8-16 days
- 8% bleed for more than a month
- **4.5-7.9% require surgical intervention** for hemorrhage or incomplete abortion
- 1% have ongoing pregnancy, 1% require hospitalization
- Teratogenic effects such as limb, facial, cranial and other abnormalities (related to misoprostol) are sometimes seen

“BLACK BOX” WARNING FOR MIFEPRISTONE

- Serious and sometimes fatal infections and bleeding may occur. Watch for:
  - **Atypical Presentation of Infection.** Patients with serious bacterial infections (e.g.,Clostridium sordellii) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion.
  - **Bleeding.** Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.
- Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

HEMORRHAGE AFTER MIFEPRISTONE



- Mifepristone interferes with ability of spiral arterioles to contract.
- Mifepristone has no effect on a pregnancy not implanted in the uterus, thus ruptured ectopic pregnancies can occur.
- Mifepristone is only weakly effective at inducing uterine contractions to expel the pregnancy tissue thus it must be used with misoprostol.

INFECTION AFTER MIFEPRISTONE

- **Direct pharmacologic effects of mifepristone promote infection:**
  - blocks glucocorticoid receptors
  - releases inflammatory cytokines
  - impairs inflammatory response
- **Misoprostol also has immunosuppressive actions,** so when used together, effect is enhanced.
- **Incomplete expulsion** of necrotic (dead) tissue worsens risk.
- **Half of the deaths reported have occurred due to overwhelming sepsis,** many due to Clostridium sordelii, a common, non-pathogenic organism.

MENTAL HEALTH COMPLICATIONS AFTER MIFEPRISTONE

Rat model:

The mifepristone termination group had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety

DEFICIENCIES IN ABORTION DATA COLLECTION: NUMBERS, COMPLICATIONS, AND MORTALITY

- Due to privacy concerns and non-insurance payment for most abortions, there is no accurate central database in the U.S.
- Reporting is voluntary and some states don't report at all. Guttmacher Institute reports about 30% more abortions than CDC.
- Only 28 states mandate complication reporting from abortionists and 12 from other physicians who care for injured women. No enforcement mechanisms or penalties for noncomplicance.

DEFICIENCIES IN ABORTION DATA COLLECTION: NUMBERS, COMPLICATIONS, AND **MORTALITY**

- CDC obtains most abortion-related mortality data from death certificates
- For many reasons **death certificates frequently do not record a preceding abortion**
- Neonatal birth and death certificates are only required after 20 weeks gestation
- No system monitors losses before 20 weeks
- A Finnish record-linkage study found that **94% of abortion-related deaths were not documented on death certificates**

ABORTION:
14 TIMES SAFER THAN CHILDBIRTH?

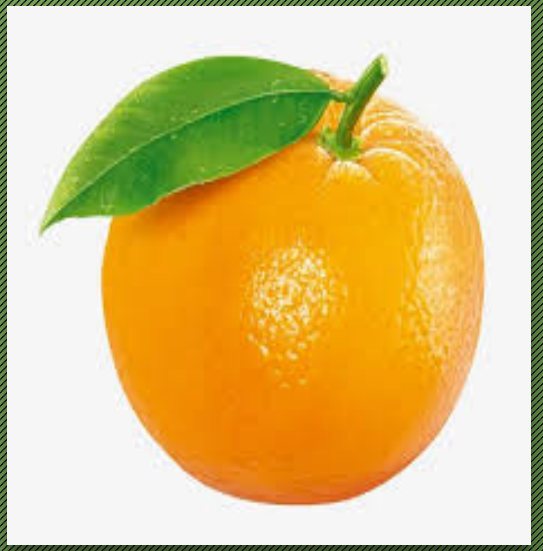
Raymond and Grimes

Abortion mortality rate: deaths/ 100,000 abortions

Maternal mortality ratio: deaths/ 100,000 live births

Of four variables, only live births can be accurately calculated

One cannot use three impossible-to quantify variables to compare two disparate outcomes: it is a false equivalence



2018 National Academies of Sciences, Engineering and Medicine: The Safety and Quality of Abortion Care in the U.S.

- **Serious complications or long term physical or mental health effects are virtually non-existent.**

- Abortion is so safe that the **only deterrent to its safety is legislative restrictions** enacted by the states that may prevent a woman from accessing an abortion immediately, "creating barriers to safe and effective care."

- Abortions can be performed safely in an **office-based setting or by telemedicine without the need for hospital admitting privileges.**

2018 National Academies of Sciences, Engineering and Medicine: The Safety and Quality of Abortion Care in the U.S.

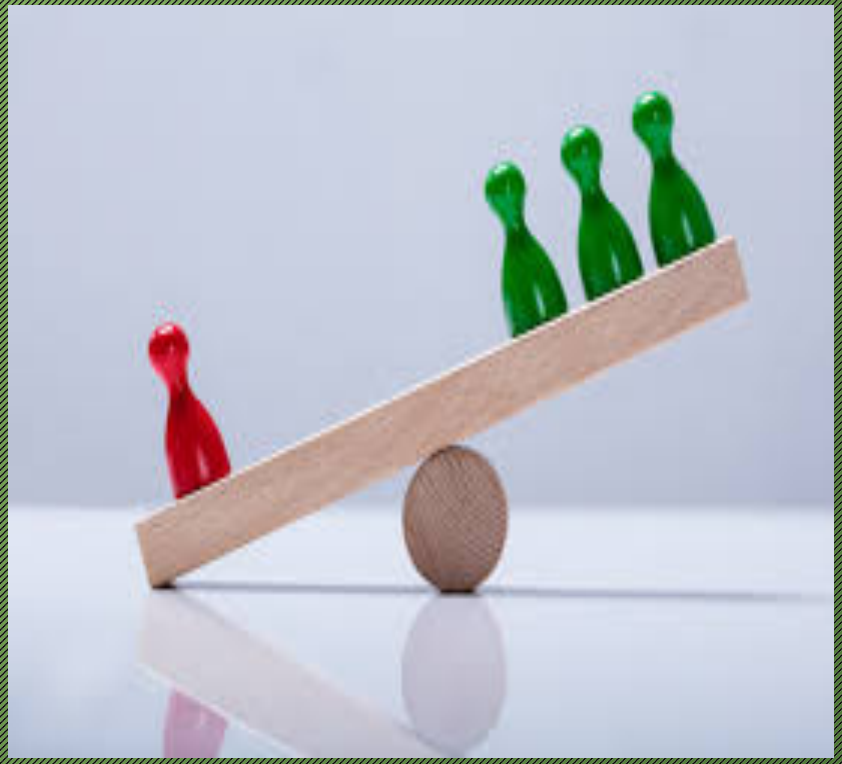
- No special equipment or emergency arrangements are required for medical abortions.
- It does not need to be performed by physicians; it can safely be performed by trained certified nurse midwives, nurse practitioners, and physician assistants.
- **Abortion has no long-term adverse effects**, and it specifically does not increase the risk of preterm delivery, mental health disorders or breast cancer.

NATIONAL ACADEMIES' BIAS?

Commissioned and funded by six outspoken abortion advocacy organizations: Packard Foundation, Grove Foundation, JPB Foundation, Tara Health Foundation, Hewlett Foundation, and Buffett Foundation.

Literature review excluded an extraordinary number of studies for perceived defects. Primarily utilized studies performed by abortion advocate researchers

Thus, in all cases, there were less than five studies on which they based their definitive conclusion of "no long-term impact" (when 75-160 studies were available)



Low complication rates reported from abortion industry studies:

Upadyay, et al (ANSIRH)

ER Visits

54,911 California Medicaid financed abortions

6.4% women had ER visits within 6 weeks

40% visits were “abortion-related”

0.87% were “abortion-related complications”

Ignores the difficulty of ICD search engines to find diagnosis codes specific for “induced termination complications”

When clinic information included, 5.2% medical abortions and 1.3% surgical abortions resulted in complications (four-fold increase)

Low complication rates reported from abortion industry studies:

Cleland and Creinin (Danco)

Significant Adverse Events

Chart review of 233,805 abortions at Planned Parenthood

Significant adverse events: 0.16% hospital admissions, blood transfusion, emergency department evaluation, intravenous antibiotics for infection, and death.

By definition, these serious events would be cared for in hospitals, thus no guarantee that they would be documented in the woman's clinic chart

Low complication rates reported from abortion industry studies:

Ireland and Gatter (Planned Parenthood)

Effectiveness of Medical Compared to Surgical Abortion

30,146 abortions at LA Planned Parenthood.

99.6% successful medical abortions (though 2.1% required surgery and 16% were lost to follow-up)

DID WE ALLOW THE TOBACCO INDUSTRY TO PERFORM THE STUDIES ABOUT SMOKING?

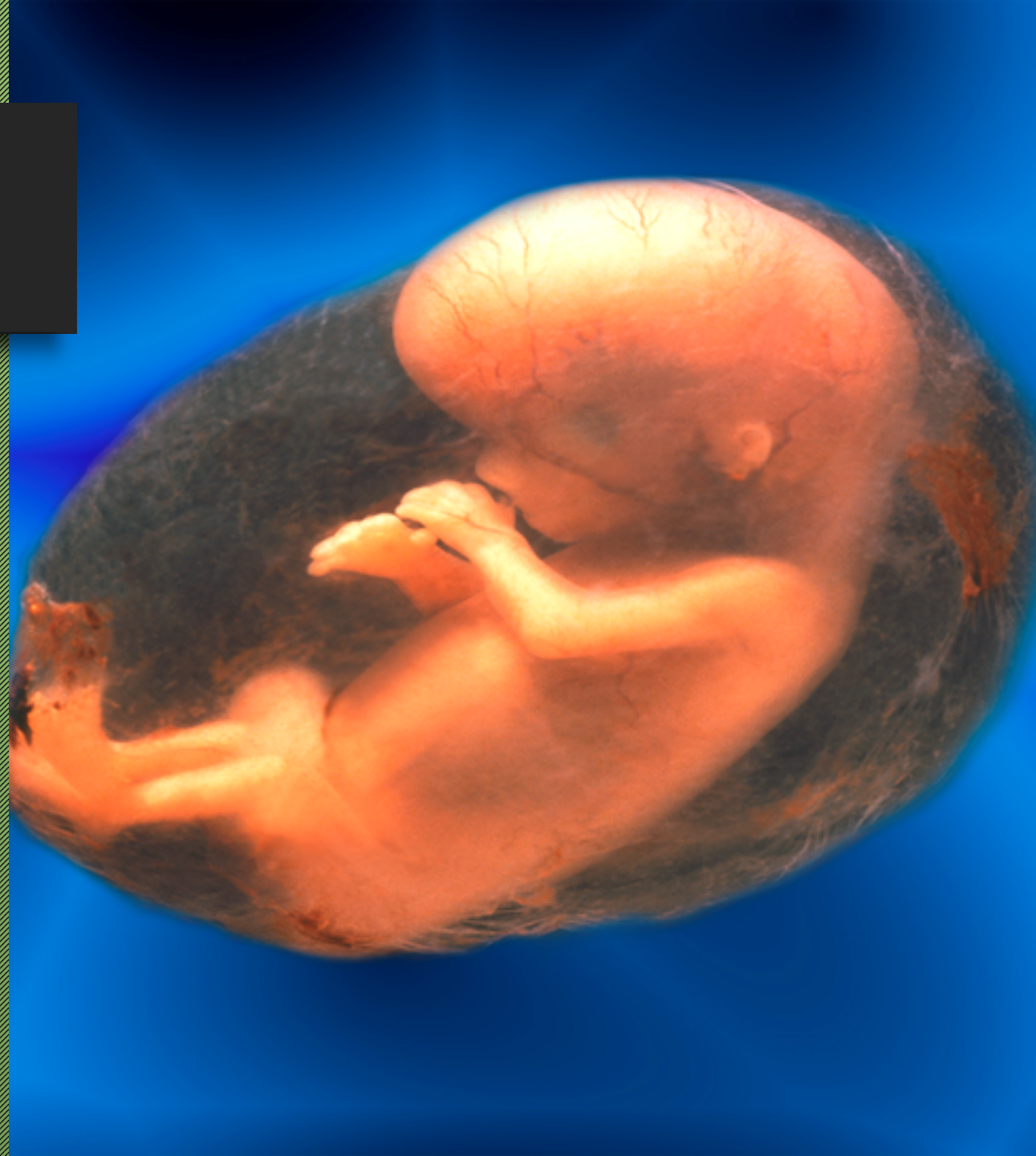
RECORD-LINKAGE STUDY: NIINIMAKI (FINLAND)

- More accurate studies can be obtained where single payer healthcare and meticulous medical record keeping ensure that all pregnancies and all medical events are accurately recorded.
  - 42,619 (22,368 medical and 20,251 surgical) at < 7 weeks gestational age.
  - Overall adverse events fourfold higher in medical vs surgical abortions (20 vs 5.6%)
  - hemorrhage (15.6 vs 2.1)
  - incomplete abortions (6.7 vs 1.6)
  - surgical (re)evacuation (5.9 vs 1.8)

RECORD-LINKAGE STUDY: MENTULA (FINLAND)

Compared first and second trimester medical abortion

- 18,248 women.
- Surgical evacuation:
  - 9.9% first trimester
  - 39% second trimester
- Infections:
  - 2.1% first trimester
  - 4% second trimester



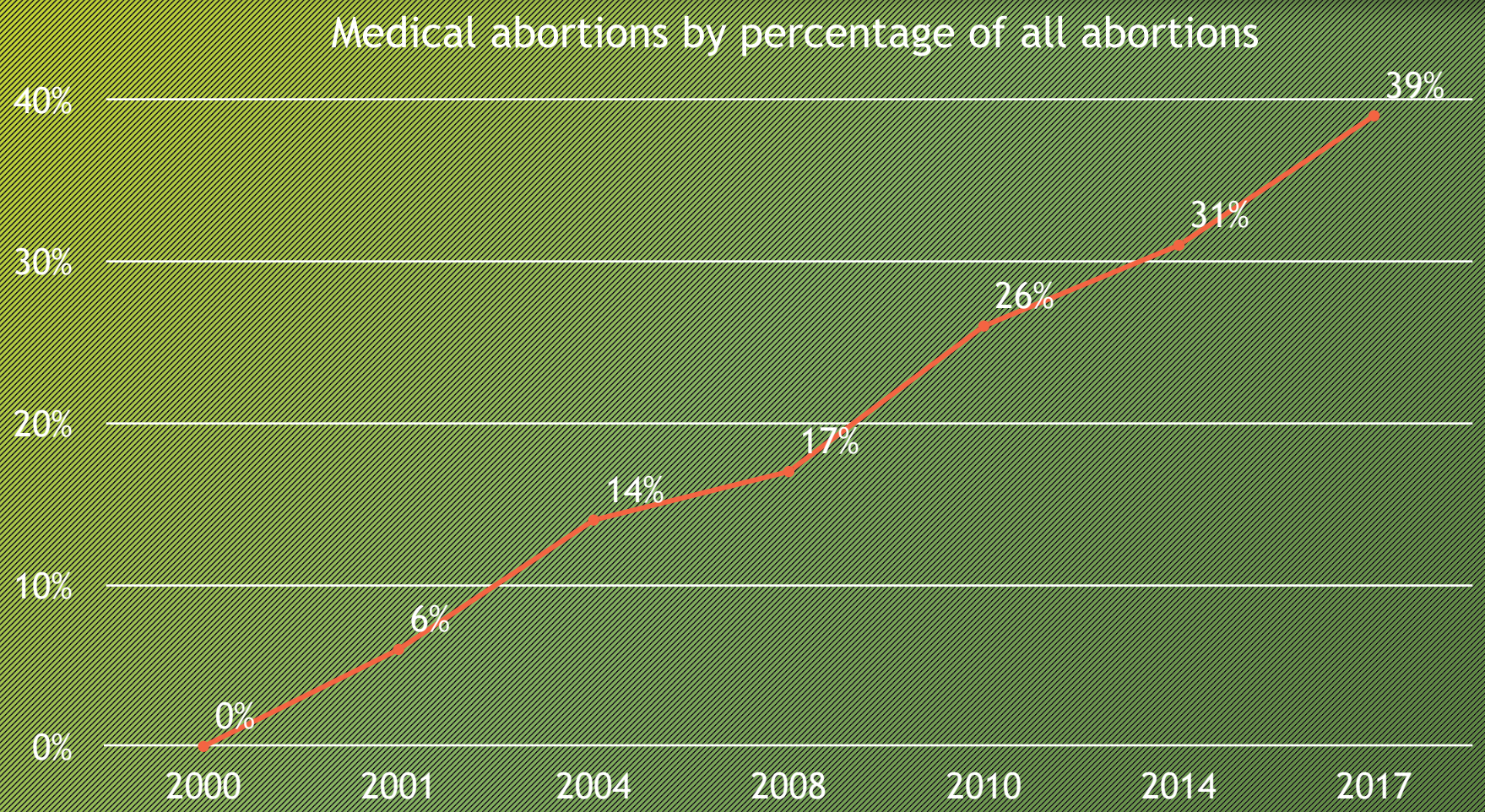
COMPILATIONS OF ALL AVAILABLE MIFEPRISTONE/MISOPROSTOL STUDIES:

- Raymond systematic review:
  - 47,283 women
  - **4.8% treatment failure**
  - 1.1% ongoing pregnancies
- Chen/Creinin (Danco) systematic review:
  - 33,846 women
  - **3.4% failure rate**
  - 0.8% ongoing pregnancies

HOW MANY INJURED WOMEN IN THE U.S.?

- 2017: Approximately 336,000 medical abortions
- If 5% failure rate, 16,800 will require surgery, often in emergent conditions
- Liao study: If medical abortion fails and requires surgical completion, 361% increased risk of extremely preterm birth in a subsequent pregnancy

TRENDS IN MEDICAL ABORTION PROVISION



COMPARISON OF MEDICAL VS SURGICAL ABORTION TECHNIQUES:

MEDICAL ABORTION

- FOR WOMEN:
  - (PRO) DESIRE TO AVOID A SURGERY
  - (PRO) (FALSE) PERCEPTION THAT MEDICAL ABORTION IS SAFER
  - (PRO) MORE "NATURAL AND PRIVATE"
  - (CON) MORE PAIN, BLEEDING
  - (CON) MAY SEE THE CHILD THEY ABORTED
- FOR PROVIDER (PROS):
  - MORE LUCRATIVE: AVERAGE $500
  - EASY TO DUMP COMPLICATIONS ON ER

SURGICAL ABORTION

- FOR WOMEN (PROS):
  - COMPLETED QUICKER
  - FEWER VISITS
  - FEWER COMPLICATIONS
  - ALLOWS TISSUE ASSESSMENT
- FOR PROVIDER (CONS):
  - MORE SKILL REQUIRED
  - FEWER OB/GYNS AVAILABLE
  - HIGHER EQUIPMENT COSTS
  - MUST SEE THE CHILD THEY ABORTED

MEDICAL ABORTION ADVOCACY:

- "Graying" of abortion providers
  - Even "pro-choice" ob/gyns do not want to actively kill one of their patients
  - Only 7-14% of ob/gyns say they will perform an abortion when requested
- Removing REMS will allow more abortions to be performed, by more types of health care providers in more locations
- Forced violation of conscience protections for women's health care providers
  - All ob/gyns will be pressured to prescribe
  - All pharmacists will be pressured to distribute
- Profit: Many outspoken abortion advocates are affiliated with the industry
- For many academic elites, ideologic commitment to eugenic agenda: keep poor and minority women from reproducing

TRENDS IN MEDICAL ABORTION ADVOCACY

- ONCE “SAFE, LEGAL AND RARE”, NOW DEMAND “IMMEDIATE ACCESS AND CONVENIENCE”
- AGGRESSIVE USE OF JUDICIAL SYSTEM TO REMOVE RESTRICTIONS
- CHEERLEADING OF “SELF-MANAGED ABORTION” BY PRO-CHOICE MEDIA
- ADVOCATES WARN THAT WOMEN WILL ACCESS ILLEGAL ABORTIONS IF NOT EASILY AVAILABLE, BUT THEN THEY RECOMMEND ILLEGAL USE TO WOMEN WHO ENCOUNTER BARRIERS

Legal maneuvers

- SCOTUS Planned Parenthood vs Casey 1992
  - Undue burden: Legislation that has "the purpose or effect of placing a substantial obstacle in the path of a woman seeking abortion."
- American Civil Liberties Union (Chelius vs Azar) 2017
  - Challenges FDA's REMS requirement
- American College of Obstetricians and Gynecologists (ACOG vs FDA) 2020
- Challenges REMS requirement of in-person medical abortion prescribing
- Federal district court in Maryland issued a nationwide preliminary injunction asserting that the in-person requirement poses an "undue burden" on abortion access because of COVID-19.
- Will SCOTUS weigh in?

AMERICAN COLLEGE OF OB/GYN (ACOG) ABORTION ADVOCACY

- "Premiere professional membership organization for obstetrician/gynecologists"
- Represents 60,000 obstetricians/gynecologists
- **ACOG's leadership are avidly pro-abortion**
- **ACOG has never polled their membership about their views on their abortion advocacy**
- ACOG has never filed an amicus brief in favor of ANY restriction on abortion
- "Unethical not to provide or refer for abortion"

No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond

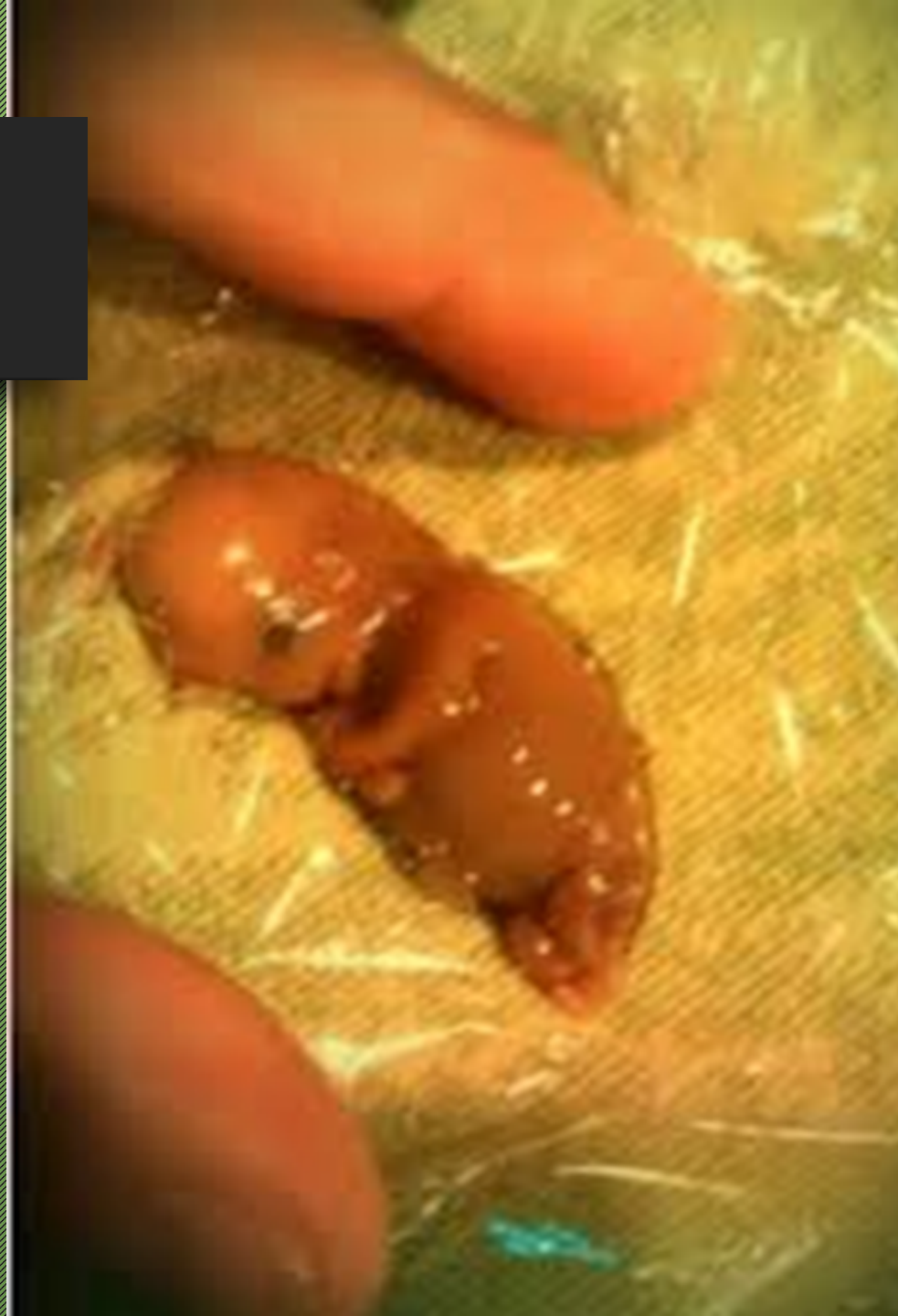
- Some state guidelines designed to decrease demands on medical systems have resulted in limits on elective abortion access.
- Abortion advocates seek to leverage the COVID-19 pandemic to promote chemical abortion without the current safeguards
- Peer reviewed article with pro-abortion authors from:
  - Planned Parenthood Federation of America (PPFA)
  - National Abortion Federation (NAF)
  - Advancing New Standards in Reproductive Health (ANSIRH) of the Bixby Center for Global Reproductive Health, University of California, San Francisco
  - Gynuity Health Projects (telemedicine abortion study ongoing)
  - Danco Laboratories (distributor of mifepristone)

"NO TEST" MEDICAL ABORTION PROTOCOL:

- Patient reports pregnancy < 77 days from LMP
- Patient denies five risk factors for ectopic pregnancy (ignores 8 other risk factors documented by ACOG, and the reality that ½ have no risk factors)
- Patient denies five contraindications to medical abortion (ignores 10 other contraindications documented by ACOG)
- Rh typing and Rhogam administration not required if:
  - Reports Rh positive
  - < 70 days from LMP
  - does not plan future pregnancies
  - patient declines Rhogam
- F/u contact in one week, if no complaints, check UPT in 4 weeks

UNSUPERVISED MEDICAL ABORTION: WHAT COULD GO WRONG?

- Underestimation of gestational age may result in **higher likelihood of failures.**
- Undetected ectopic pregnancies may rupture leading to **life-threatening hemorrhages.**
- Rh negative women not receiving prophylactic Rhogam may experience **isoimmunization in future pregnancies.** 14% untreated affected infants are stillborn and half suffer neonatal death or brain injury.



UNSUPERVISED MEDICAL ABORTION: WHAT COULD GO WRONG?

- Potential for misuse is high when there is no way to verify who is consuming the medication, and whether they are doing so **willingly** (to benefit of sex traffickers, incestuous abusers, coercive boyfriends).
- Medical abortion failure rates are **not negligible (5%)** and will utilize medical resources that need to be conserved during a pandemic.
- Catastrophic complications can occur, and **emergency care may not be readily available** in remote areas.

MISOPROSTOL ONLY

- Abortion advocates sometimes recommend misoprostol alone when barriers encountered in obtaining mifepristone
  - not as tightly regulated as mifepristone (lacks REMS)
  - used for other illnesses, such as peptic ulcer disease
  - available without a prescription in many countries
- Meta-analysis of 12,829 women
  - First trimester, 22% of women required surgical uterine evacuation
  - 6.7% had ongoing viable pregnancies.
  - After the first trimester, 39% of women require surgical completion.

FUTURE GOALS OF ABORTION ADVOCATES: TAXPAYER FUNDING

- Forced taxpayer provision of abortion
- Repeal of the federal Hyde Amendment
- Increasing state Medicaid provision (13 states currently pay for this eugenic action)
- Legislative mandates for university health systems to provide medical abortion to students (California)

- Telemedicine provision
- On-line ordering
- Mail order distribution
- Over the counter pharmacy provision

- 2017 Survey of abortion providers: **1/3 had witnessed complications of self-managed abortion and only ½ felt it was safe**
- **More injured women**

"DO IT YOURSELF" ABORTIONS OR "CHEMICAL COAT-HANGERS"

IS ABORTION THE RIGHT ANSWER?

- **Half** of pregnancies in the U.S. are unintended, yet only **40%** of these women end their pregnancies.
- Easy access to abortion causes this action to be a **knee-jerk response** for many women, which they may later **regret.**
- Many, perhaps most, abortions are chosen due to **lack of partner and social support.**
- **Can't we work harder as a society** to encourage marriage and family, rather than offering women only the **self-destructive option of ending the lives of their unborn children?**

ABORTION PILL RESCUE

- Women do experience regret after taking mifepristone.
- **Progesterone will compete with mifepristone for the progesterone receptors**
- Progesterone is commonly used for many obstetric indications (bleeding, infertility, recurrent pregnancy loss, h/o early delivery) and is considered very safe.
- High dose progesterone supplementation **improves likelihood of fetal survival from 25% to 68%**

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