

# Patient Empowerment



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PATIENT

# IMA's Four Pillars

Combating Chronic Disease

Patient Empowerment

Transparency in Medicine

Building a Healthy Culture

Mommas  
will be  
Mommas



# Dr. Kim Biss Background

- Educational
  - BA Biology, Mount Holyoke College, 1989
  - MD, Tufts U. School of Medicine, 1993
  - Surgical Internship, Emory School of Medicine, '93-'94
  - OBGYN Residency, Bayfront Medical Center, St. Petersburg, FL, graduated 1998
- Professional
  - Private Practice, Bay Gynecological Associates, '98-'06
  - Fellow of ACOG and ABOG Diplomate
  - WomensCareFL, New Beginnings OBGYN, '07-present
  - Medical Leadership '06-'23 Orlando Health, Bayfront Hospital (formerly Bayfront Medical Center), last role Chief of Staff from '20-'23
  - Testified for Rep. Marjorie Taylor Greene and other members of Congress 11/2023
  - Senior IMA Fellow OBGYN May 2024
- *I am speaking to you on my own behalf; I do not represent my employer nor the hospital of which I am on staff in good standing.*

December 2007

## Ethical Decision Making in Obstetrics and Gynecology\*

As previously noted, one of the most important elements of informed consent is the patient's capacity to understand the nature of her condition and the benefits and risks of the treatment that is recommended as well as those of the alternative treatments (30). A patient's capacity to understand depends on her maturity, state of consciousness, mental acuity, education, cultural background, native language, the opportunity and willingness to ask questions, and the way in which the information is presented. Diminished capacity to understand is not necessarily the same as legal incompetence. Psychiatric consultation may be helpful in establishing a patient's capacity, or ability to comprehend relevant information. Critical to the process of informing the patient is the physician's integrity in choosing the information that is given to the patient and respectfulness in presenting it in a comprehensible way. The point is not merely to disclose information but to ensure patient comprehension of relevant information. Voluntariness—the patient's freedom to choose among alternatives—is also an important element of informed consent, which should be free from coercion, pressure, or undue influence (31).

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Category:

Subject: Statement Regarding Misinformation and Disinformation and Medical Professionalism

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The American Board of Obstetrics and Gynecology (ABOG) issued a statement regarding Dissemination of COVID-19 Misinformation on September 27, 2021. The following statement reiterates and expands ABOG's position.

Patients rely on physicians to practice medicine based on fact-based scientific data. ABOG standards and policies for certification and maintenance of certification have clear expectations about medical professionalism and professional standing that physicians agree to as part of the certification process. Intentionally providing misinformation and disinformation that may harm patients or public health does not meet these agreed-upon standards and may be grounds for adverse action on an OB GYN's certification status.

Free speech is a right in our country, and medical providers may practice according to their conscience and religious, moral, and ethical values. Diplomates are not required to provide services that conflict with these values. Facts, science, and evidence-based medicine are critically important guides to OB GYN clinical practice. The dissemination of misinformation and disinformation not only involves COVID-19, but is a threat to the access to and the ability to provide legal and safe evidence-based comprehensive reproductive health care, including contraception and abortion. Opinions publicized by OB GYNs about COVID-19, reproductive health care, and abortion should reflect the specialty's commitment to scientific and clinical excellence and to the needs of our patients.

Misinformation and disinformation about contraception and abortion can create false narratives about essential safe practices in the specialty. In addition, false or misleading information from board-certified medical professionals can also be used to advocate for legislation, regulations, criminal code, and health policy. ABOG considers the dissemination of misinformation and disinformation that may threaten the health of the patients who place their trust in its diplomates to be a violation of medical professionalism.

ABOG will review reports of dissemination of misinformation and disinformation about COVID-19, reproductive health care, contraception, abortion, and other OB GYN practices that may harm the patients we serve or public health. Eligibility to gain or maintain ABOG certification may be lost if ABOG determines that diplomates do not meet the standards that they have agreed to meet and that the public deserves and expects.

# TIME LINE For Use of mRNA Injections in Pregnant Women

- **12/11/2020** EUA granted based on Pfizer trial BNT162b2 results
- TRIAL -- Published NEJM **12/31/2020**
  - 43448 Participants randomized to mRNA or placebo
    - 18198 mRNA arm – 8 C19 infection – Risk = **0.04%**
    - 18325 placebo arm – 162 C19 infection – Risk **0.88%**
    - “95% efficacy” was **RRR**
    - **ARR** was **0.84% (0.88-0.04)**; not reported as FDA requires
      - Reduction in **MINOR** symptoms was **0.84%**
      - **SEVERE** symptoms reduced by **0.037%** (never defined in the trial)
    - 119 people needed to be vaccinated to prevent a sore throat in 1 person
    - 2711 people needed to be vaccinated to prevent one severe case
- All participants in placebo arm were supposed to be followed for two years
  - Due to ethical reasons **all** provided with the vaccine
  - “This report does not address the prevention of Covid-19 in other populations, such as younger adolescents, children, and *pregnant* women.” **PREGNANT WOMEN NOT ENROLLED IN TRIALS**”
- Whistleblower stated many in the mRNA arm developed symptoms of C19 but were not tested for it
- Six months after the trial more participants died in the mRNA arm
- Peer reviewed re-analysis of the trial data showed that one was more likely to suffer a severe AE if vaccinated than to be hospitalized for C19

# TIME LINE For Use of mRNA Injections in Pregnant Women

- **12/31/2020** ACOG guidance: defer to ACIP's (Advisory Committee on Immunization Practices) guidelines ([link to ACIP](#)) -- First Responders in group 1
- **2/28/2021** Post marketing data (FOIA required to access) ([post marketing link](#))
  - 12/1/2020 – 2/28/2021
    - 126,212,580 doses with 42,086 AEs and **1223 deaths**
    - 270 pregnancy cases (238 cases with no outcome provided)
    - 26/32 miscarried = **81%**
    - If the remaining 238 had not miscarried = 9.6% miscarriage rate (normal 5-6%)
- **4/16/2021** CDC Director Rochelle Walensky MD MPH and Eric Rubin PhD ([NEJM audio link](#))
  - “Safe and effective in pregnant women”
- **4/2021** ACOG received 11 million dollars to market injections (FOIA'ed information)
- **6/2021** – NEJM Shimabukuro article VSAFE cohort 827 women
  - Safe, miscarriage rates 13% “normal” – actual **> 82%** (denominator should be 127)
- **7/30/2021** Official SMFM/ACOG statement (same today)
  - Vaccinate all women “thinking of getting pregnant, pregnant, or breast feeding.”
- **8/2021** Comirnaty (Pfizer) (First to receive FDA approval) package insert states:
  - “[a]vailable data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy”

## Should I get a COVID-19 vaccine?

Yes, you should get a COVID-19 vaccine. The American College of Obstetricians and Gynecologists (ACOG) strongly recommends vaccination if you are pregnant, breastfeeding, or planning to get pregnant. The vaccines are effective at preventing infection, severe illness, and death from COVID-19, including from new variants.

Getting a vaccine during pregnancy could also help your newborn. When you get vaccinated, the antibodies made by your body may be passed to your fetus. These antibodies may help protect your baby from the virus after birth.