Expecting Safety: Preventing Medication and Vaccine Errors During Pregnancy

Taylor Clark, PharmD

Clinical Assistant Professor

Binghamton University

School of Pharmacy and Pharmaceutical Sciences

Disclosures

I nave no conflicts of interest to disclose.

Brand names will be used within the presentation to distinguish between Vaccinations FDA approved for use in pregnancy versus those that are not.

Objectives

- Describe the unique considerations for medication and vaccine use during pregnancy, including maternal and fetal safety.
- Identify common errors related to vaccine administration and medication use in pregnant patients.
- Apply evidence-based strategies to prevent vaccine- and medication-related errors in pregnancy.
- Evaluate patient case scenarios to determine safe and effective pharmacist interventions that optimize outcomes for both mother and baby.

Two Patients, One Plan

Background

Why safety in pregnancy matters

Pharmacologic Changes in Pregnancy

- Physiologic changes begin early in pregnancy and return to baseline around 2 to 12 weeks post-partum

Maternal Characteristic	Change	Time of Change
Plasma Volume	Increases 50%	~ 4 weeks
Serum Albumin	Decreases to 70-80% normal	Second trimester onward
Cardiac Output	Increases 30-50%	Starts at 5 week; 50% of total increase occurring by 8 weeks
Hepatic Clearance	Increased activity in CYP 450 enzymes	Throughout
GFR	Increases 50-80% Decreases Slightly	First trimester Last month
Serum Creatinine	Decreases, then increases	Throughout

Hudson RE, Metz TD, Ward RM, et al. Drug exposure during pregnancy: current understanding and approaches to measure maternal-fetal drug exposure. *Front Pharmacol*. 2023;14:1111601.
Bernstein IM, Ziegler W, Badger GJ. Plasma volume expansion in early pregnancy. Obstet Gynecol. 2001;97:669–672.
Frederiksen MC. Physiologic changes in pregnancy and their effect on drug disposition. Semin Perinatol. 2001;25:120–123.

Medication Recommendations

- Give medications only when clearly indicated
  - Risk to fetus v. benefit to mother
  - Risk of untreated condition v. risk of medication
- Use the lowest effective dose for the shortest effective time
- Prenatal Vitamins: calcium, vitamin D, iodine, iron, folic acid
- Pre-conception planning:
  - Stabilize comorbidities prior to pregnancy if possible
  - Change to alternative medications that are safe for use in pregnancy

Leek JC, Arif H. Pregnancy Medications. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan.
United States Food and Drug Administration. Medicine and pregnancy. Accessed March 12, 2026.
Little BB, Gilstrap LC, Cunningham FG. Medication use during pregnancy. In: Pritchard J, MacDonald P, Gant N (eds). *Part I Concepts in Human Teratology*. 18th ed. Norwalk: Appleton & Lange; 1991

Vaccination Recommendations

- Vaccines lead to antibody production in mom which are passed to the baby for protection after birth
- The CDC and ACOG provide recommendations for which vaccines should be avoided and recommended during pregnancy
- Vaccines to avoid:
  - Live, attenuated vaccines – nasal influenza, varicella, MMR (measles, mumps, and rubella)
  - Human papilloma virus (HPV) vaccine

Vaccine safety during pregnancy [Internet]. American College of Obstetrics and Gynecologists; 2025 [cited 2026 Mar 12].
Guidelines for vaccinating pregnant women [Internet]. Centers for Disease Control and Prevention; 2025 [cited 2026 Mar 12].

Vaccination Recommendations

Recommended Vaccination	Timing
Tdap	Every pregnancy between 27 and 36 weeks
Influenza	Seasonally (early flu season)
RSV (Abrysvo)	32-36 weeks pregnant from September to January
COVID-19*	Any time if not up to date
Hepatitis B	If not already vaccinated
Meningococcal	If not already vaccinated
Pneumococcal*	Risk dependent

* - ACOG recommendation, CDC no recommendation

Vaccine safety during pregnancy [Internet]. American College of Obstetrics and Gynecologists; 2025 [cited 2026 Mar 12].
Guidelines for vaccinating pregnant women [Internet]. Centers for Disease Control and Prevention; 2025 [cited 2026 Mar 12].

Impact of Errors

- Bupivacaine Intravenous Injection
- Thalidomide Tragedy
- Isotretinoin and reproductive age

THALIDOMIDE NIGHTMARE

Truth Reporter

THIS IS BLACK AUGUST. Mothers all over the world will remember it as the end of a nightmare.

THOUSANDS of malformed babies will have been born because of a colossal medical blunder.

New Zealand may not have escaped.

There is one answer to those who say that thalidomide—which wonder-drugged a pill-taking international public into trusting, deep-sleep acceptance—was not readily available in this country.

WRONG!

There was nothing to stop a chemist counter-prescribing this "first-schedule poison." Under the Poisons Act, retail distribution was restricted to chemists.

What happened to chemists—and I suggest there were some of them—who sold it over the counter?

They became "subject to action by the disciplinary committee of the Pharmacy Board."

AND THAT'S ALL.

Thalidomide came to New Zealand in five guises.

It was contained in Valgis, Asmaval, Valgraine, Tensival and Distaval, a Health Department spokesman told me.

Asmaval was for asthma treatment, Valgraine for migraine and Tensival for nervous tension.

The tranquilliser Distaval rode to popularity here on top of a world wave of mass approval. It gave quick sleep, rarely left hangovers, and for would-be suicides it appears it was only expensive.

For expectant mothers it was just the thing.

Now it stands accused of causing foetal malformation.

When the balloon went up overseas nine months ago, the New Zealand distributors—Distillers Co. Biochemicals (NZ) Ltd., Auckland—properly and promptly went into action.

They whisked the five brands of thalidomide-content pills off the market before the Health Department knew of thalidomide's insidious potential.

They sent a letter to all outlets breaking the grim news.

This was December 4, 1961.

Then the Health Department took the lid off the mess.

Beware of leftover thalidomide, it stated.

Destroy remaining samples, said medical authorities.

This was July 27, 1962.

The distributors did all they could as soon as they became even vaguely aware of the thalidomide hazards.

But somehow the health, medical and professional authorities who knew of the likelihood of tragic consequences delayed a proper warning for eight months.

Whist happened in the meantime?

How many sleepless New Zealanders went to medicine cupboards for old-stock solace?

How many chemists kept the odd phial or two for counter trade, rather than send them back for refunds?

Who was the Christchurch chemist who sold an 8/6 thalidomide tranquilliser pack to a visitor AFTER the tablets were withdrawn?

The purchaser of this packet phoned me.

"Are they safe? They work beautifully—send me off in about 10 minutes."

I told him: "Dump the stuff."

The answer might lie in what a Health Department spokesman told me:

"It should be possible to go to every chemist's shop in the country and find a record of every thalidomide disposal since Septem-

Eight months before NZ public was warned . . .

Panic—and frustration

Truth Reporter

PANICKY pregnant women sought reassurance from doctors and chemists after the Health Department warning about thalidomide.

Ironically, on the other hand, women past child-bearing age vainly sought supplies of sedatives containing the drug. They were the most effective sleep-inducers ever, said users.

(See Pat Rockford's comment, Page 21.)

Hope with robot arms

World's legacy of tragedy

THE THALIDOMIDE NIGHTMARE will leave a legacy of tragedy in its wake. The global picture:

LONDON: Three hundred deformed babies are expected to be born during the next few weeks as a result of mothers in England and Wales taking thalidomide during early pregnancy.

WASHINGTON: Hundreds of Americans were given the drug on an experimental basis, according to Dr. Frances Kelsey, the Government scientist who blocked the drug for commercial sale.

LIEGE, Belgium: Susanne Vandeput, 25, is in prison accused of murdering her newly-born armless daughter. She took a tranquilliser drug during pregnancy.

SYDNEY: A baby boy, born without arms because of the effects of the drug thalidomide, has been baptised in a Sydney church. Under the trade name of Distaval, the drug has caused 20 known birth abnormalities in Sydney. Most of the babies have stunted and grossly deformed arms and legs.

NEW YORK: Mrs. Robert Finkbine, 30, wept as she lost her legal battle to abort her "drug baby."

BALTIMORE: Dr. Helen Taussig, John Hopkins University, predicted that babies crippled by thalidomide may reach 7000: "The one-third who are so deformed that they die may be the luckier ones," she said.

ADELAIDE: The drug has caused 12 birth abnormalities.

GERMANY: Doctors expect that by the end of this month, when the last pregnant women who could have taken the drug thalidomide are delivered, births of deformed babies will total 3600 to 6000 in West Germany. About two-thirds of the children will live.

. . . and, believe it or not, this is why

Truth Reporter

THALIDOMIDE was introduced to doctors and hospitals in New Zealand in 1960. Widescale distribution of it as a first-schedule poison started in mid-1961.

IT was withdrawn in December, 1961. Many people consider the Health Department's delayed-action warning—on July 27 this year—was little short of reckless.

I can disclose why it wasn't.

The Director-General of Health has no authority to issue such a warning.

The warning didn't come till someone raised the subject, months later.

This ridiculous situation is currently before Parliament.

Its remedy is one aspect of the proposed amendment to the Food and Drugs Act, which seeks auth-

have power to make statements in the public interest.

SALES "OVER-RATED"

Truth Reporter

THE New Zealand agents will not reveal how many of the deformity-suspect pills were put into circulation in this country.

"There was very, very little sold," a director told me.

Cooper-Roth, Tristan, "The Effects of Thalidomide on Embryonic Development". Embryo Project Encyclopedia (2010-09-12). ISSN: 1940-5030 https://hdl.handle.net/10776/2061
Pile HD, Patel P. Isotretinoin. [Updated 2025 Dec 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan.
Lee, Bee Beng FANZCA, FHKCA; Chen, Phoon Ping FANZCA, FHKCA; Chiu, Albert MBBS. Intravascular Migration of Epidural Catheter During Cesarean Section. Anesthesia & Analgesia 83(6):p 1350, December 1996.

Understanding the Problem

Types and Causes of Errors

Common Vaccine Errors in Pregnancy

- Wrong product
- Wrong timing
- Storage Issues
- Contraindicated Vaccines

Medication Safety Challenges

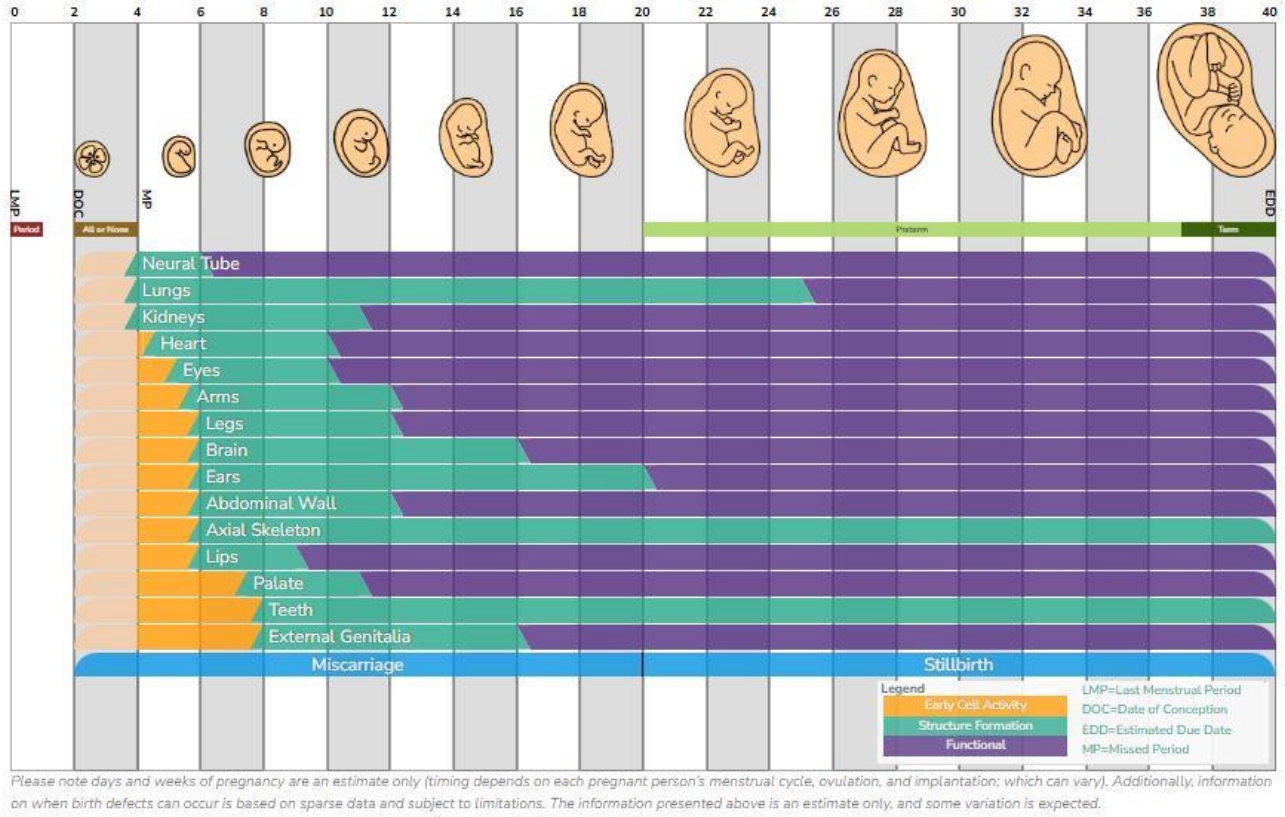
Limited Safety Data

- Pregnant patients frequently excluded from clinical trials
- Reliance on post-marketing surveillance and registries

Clinical Decision Complexity

- Balancing maternal benefit versus fetal risk
- Untreated disease may pose significant harm

Teratogenic Medication Exposure



Chapter 16 Principles of Medication Therapy in Pregnancy and Lactation, Mary Beth O'Connell, Judith A. Smith, Laura M. Borgelt. *Women's Health Across the Lifespan, 3rd Edition;* 2024. [cited 2026 Mar 12].

Critical periods of development [Internet]. The Organization of Teratology Information Specialists; 2025 [cited 2026 Mar 12].

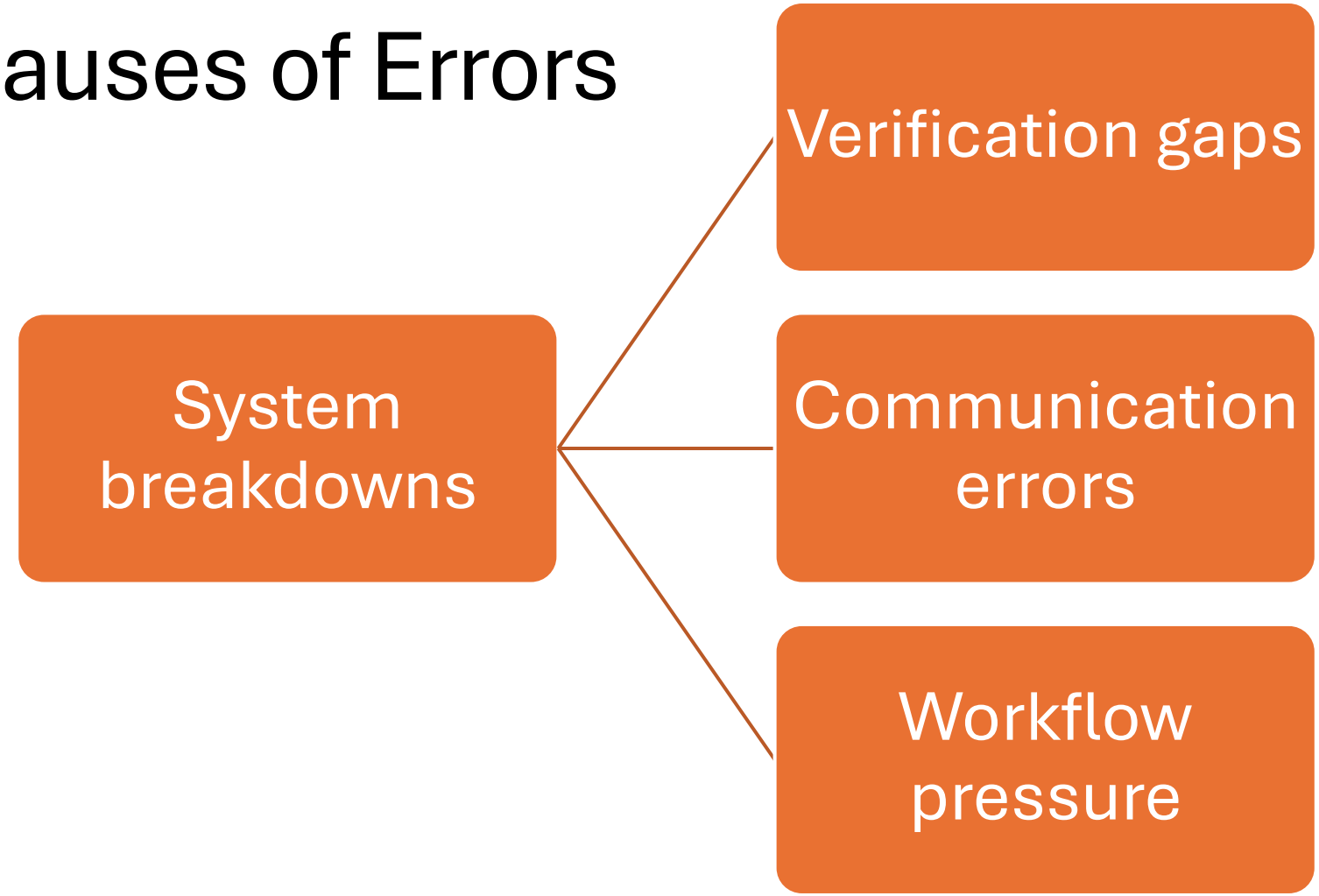
TERIS and Shepard's Catalog of Teratogenic Agents (teratogen information system). Seattle, WA.

Pregnancy and Lactation Labeling Rule (PLLR)

8.1 Pregnancy	• Provides information about dosing in pregnancy and potential risks to the developing fetus • Information on existing pregnancy exposure registries (required) • Summary of risks, clinical considerations, and available data
8.2 Lactation	• Provides information about drugs that should not be used in breastfeeding, known human or animal data regarding active metabolites in milk, and clinical effects on the infant • Sometimes includes PK data such as metabolism and exertion • Notes risk versus benefit of medication use in breastfeeding mothers • Suggests timing of breastfeeding to minimize infant exposure
8.3 Females and Males of Reproductive Potential	• Provides information regarding the effects of medications pertinent to males and female of reproductive potential • Suggestions for pregnancy testing and contraception • Information on infertility wen pertinent to a given drug

Center for Drug Evaluation and Research. Pregnancy and lactation labeling resources [Internet]. FDA; 2014 [cited 2026 Mar 12].

Root Causes of Errors



Vaccine

Volume 81, 10 May 2026, 128570

Pharmacovigilance analysis of vaccination errors during pregnancy using VAERS data

Kenneth L. McCall [a], Jae Hee Park [b], Taylor M. Clark [a], Joshua D. Steinberg [c], Kirsten J. Gallo [b], Lucrecia M. Campisi [b], Sandi S. Khalla [b], Lisa O. Asmar [b], Sarah E. Lynch [a]

McCall KL, Park JH, Clark TM, Steinberg JD, Gallo KJ, Campisi LM, et al. Pharmacovigilance analysis of vaccination errors during pregnancy using Vaers Data. Vaccine. 2026 May;81:128570. doi:10.1016/j.vaccine.2026.128570

What is VAERS?

- Vaccine Adverse Event Reporting System
- Passive surveillance system – relies on reporting
- A single report does not indicate causality or correlation
- Expanded public availability beginning May 2025
  - FDA Adverse Event Monitoring System (AEMS)
    - Drugs and biologics, cosmetics, vaccines

About the vaccine adverse event reporting system (VAERS) [Internet]. Centers for Disease Control and Prevention; 2024 [cited 2026 Mar 12].

Findings from VAERS Analysis

- Most common errors:
  - Wrong product administered
  - Product administered to patient of inappropriate age
  - Extra dose administered
  - Product storage error
  - Inappropriate schedule of product administration
  - Expired product administered

McCall KL, Park JH, Clark TM, Steinberg JD, Gallo KJ, Campisi LM, et al. Pharmacovigilance analysis of vaccination errors during pregnancy using Vaers Data. Vaccine. 2026 May;81:128570. doi:10.1016/j.vaccine.2026.128570

Findings from VAERS Analysis

- Wrong product administered:
  1. RSV
  2. HPV
  3. TDAP
- Examples:
  - Patient is 36 weeks pregnant, administered Arexvy ® instead of Abrysvo ®
  - Administered HPV vaccine when influenza vaccine was ordered on a pregnant patient
  - Wrong vaccine administered in a 32-year-old female patient who received DTaP (Infanrix ®)

McCall KL, Park JH, Clark TM, Steinberg JD, Gallo KJ, Campisi LM, et al. Pharmacovigilance analysis of vaccination errors during pregnancy using Vaers Data. Vaccine. 2026 May;81:128570. doi:10.1016/j.vaccine.2026.128570

Findings from VAERS Analysis

- Extra dose administered
  1. TDAP
  2. RSV
  3. Influenza
- Examples:
  - Tdap administered to a pregnant female twice in one month
  - Patient given a second dose of RSV vaccine during a subsequent pregnancy
  - Extra dose of influenza vaccine was given to an 11-week pregnant patient

Lessons Learned

- Look alike/Sound alike:
  - Stock only RSV vaccines indicated during pregnancy OR conspicuously segregate RSV vaccine inventories
- Extra dose, storage, and scheduling:
  - Automated checks against prior vaccination records to prevent duplicate dosing
  - Separating maternal/adult from pediatric products in the storage area
  - Gestational-age order sets that guide timing windows.

McCall KL, Park JH, Clark TM, Steinberg JD, Gallo KJ, Campisi LM, et al. Pharmacovigilance analysis of vaccination errors during pregnancy using Vaers Data. Vaccine. 2026 May;81:128570. doi:10.1016/j.vaccine.2026.128570

What does ideal practice look like, and how can pharmacists lead that effort?

Best Practices for Prevention

Building a Safety System

Verification

Product Management

Communication

Counseling

Pillar 1: Verification & Clinical Assessment

01

Verify gestational age

02

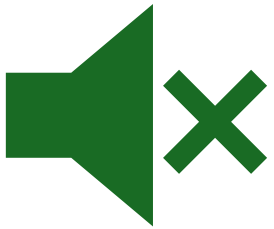
Confirm vaccine/medication appropriateness

03

Use EMR alerts and screening tools

Pillar 2: Product Management and Storage

Proper storage and handling



Prevent look-alike/sound-alike errors

Pillar 3: Communication and Teamwork

Interprofessional collaboration and documentation

Clear communication of pregnancy status and immunization needs

Pillar 4: Patient Counseling & Follow-up

Counsel on safe use, timing of medications, and what to avoid

Reinforce continuity of care across settings

Follow-up closely to assess outcomes and adverse effects

Pregnancy and Medication Safety in the News

FDA NEWS RELEASE

FDA Responds to Evidence of Possible Association Between Autism and Acetaminophen Use During Pregnancy

Agency initiates safety label change and notifies physicians of possible link

For Immediate Release: September 22, 2025

The U.S. Food and Drug Administration today initiated the process for a label change for acetaminophen (Tylenol and similar products) to reflect evidence suggesting that the use of acetaminophen by pregnant women may be associated with an increased risk of neurological conditions such as autism and ADHD in children. The agency also issued a related letter alerting physicians nationwide.

Ahlqvist VH, Sjöqvist H, Dalman C, et al. Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability. *JAMA*. 2024;331(14):1205-1214. doi:10.1001/jama.2024.3172

Liew Z, Kioumourtzoglou MA, Roberts AL, O'Reilly ÉJ, Ascherio A, Weisskopf MG. Use of Negative Control Exposure Analysis to Evaluate Confounding: An Example of Acetaminophen Exposure and Attention-Deficit/Hyperactivity Disorder in Nurses' Health Study II. Am J Epidemiol. 2019;188(4):768-775. doi:10.1093/aje/kwy288

Stergiakouli E, Thapar A, Davey Smith G. Association of Acetaminophen Use During Pregnancy With Behavioral Problems in Childhood: Evidence Against Confounding. JAMA Pediatr. 2016;170(10):964-970. doi:10.1001/jamapediatrics.2016.1775

FDA responds to evidence of possible association between autism and acetaminophen use during pregnancy [Internet]. FDA; 2025 [cited 2026 Mar 12]. Available from: https://www.fda.gov/news-events/press-announcements/fda-responds-evidence-possible-association-between-autism-and-acetaminophen-use-during-pregnancy

MEETING | MIXED

FDA Expert Panel on Selective Serotonin Reuptake Inhibitors (SSRIs) and Pregnancy

JULY 21, 2025

Schneider L. FDA Panel Casts SSRIs During Pregnancy as Risky—Many Experts Disagree. *JAMA*. 2025;334(11):937–939. doi:10.1001/jama.2025.14105
FDA expert panel on selective serotonin reuptake inhibitors (ssris) [Internet]. U.S. Food and Drug Administration; 2025 [cited 2026 Mar 12].

Case Scenarios

Case 1: Wrong Product, Right Intent

Case 2: Medication Confusion in Early Pregnancy

Key Takeaways

- Pharmacists play a key role in leading safety across the continuum

Call to Action

Lead with safety. Protect two patients at once.

Expecting Safety: Preventing Medication and Vaccine Errors During Pregnancy

Taylor Clark, PharmD

Clinical Assistant Professor

Binghamton University

School of Pharmacy and Pharmaceutical Sciences