



**Women's Health Research Institute**  
*Putting Women's Health Research First*

**December 2012**

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Dear Friends,

Many of us take medications as part of our daily routine to insure maximum health and well being. Despite those long lists of side effects reported in TV ads, we feel relatively secure that the drugs and chemicals we ingest into our bodies are safe.

This e-newsletter explores some of the more common safety concerns about medications that we, as consumers, should know. Unfortunately there is a lot of misinformation out in cyberspace and we hope the information provided will be helpful.

We have also included some pictures from our recent Fifth Anniversary celebration. It was a wonderful day that launched a promising future for the Institute!

On behalf of everyone at the Women's Health Research Institute, we wish you a happy and safe holiday season

Sincerely,

The Institute Staff

## **Using Medicines Wisely**

### **Historical Perspective**

In the late 1950's, German scientists developed the drug thalidomide to alleviate the morning sickness, headaches, and insomnia associated with many pregnancies. The drug was quickly adopted in Europe and hundreds of women

pregnancies. The drug was quickly adopted in Europe and hundreds of women found relief. The drug had not yet been used in the United States and probably would have except for the questions raised by Dr. Frances Kelsey, a new physician hire at the Federal Drug Administration (FDA). Dr. Kelsey believed that the European research behind the drug was inadequate and did not prove that it was safe for fetuses. Her instinct was proven correct when, in 1961, thousands of mothers across the globe, gave birth to babies with missing arms and legs.

Because the drug was never approved in the U.S., only 50 of the harmed babies were born in this country. Dr. Kelsey was given the President's Award for Distinguished Federal Civilian Service in 1962 for her courage and persistence in fighting for effective drug regulation and improvement at the FDA. (1)

We now move forward to 2012 and the recent outbreak of fungal meningitis traced to a contaminated steroid made by a compounding pharmacy in Massachusetts and the questions it raises about drug safety. As of November 26, 2012, the number of meningitis cases reached 510, with 36 deaths, according to the Center for Disease Control (CDC). (2)

This recent outbreak focuses on a different and less regulated category of drug manufacturing: compounding. This is concerning to us at the Institute because many women have turned to compounded hormone replacement therapy to relieve menopausal symptoms.

### **What are Compounded Drugs?**

According to the FDA, pharmaceutical compounding is an age-old practice in which pharmacists combine, mix, or alter ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription and tailored to a patient's special needs that may not be commercially available. Here are some examples:

- babies who need extremely small dosages or delivery methods
- children who need flavors to tolerate the drug
- people with allergies to inactive ingredients (e.g., color, peanut oil) used in drug manufacturing
- elderly who need a drug in liquid form
- menopausal women who want customized hormones (see hormone section below)

The quality of a finished compounded drug product can be affected by numerous factors including the quality of the active pharmaceutical ingredient used and the compounding practices of the pharmacy in which the product is created. Direct health risks include unsafe products as a result of poor compounding practices or super-potent or contaminated products. Indirect health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

Compounded drugs are not FDA approved which means that safety and efficacy have not been proven using rigorous research studies. Any regulations or standards that do exist for compounded medications are at the state level or recommended by the [United States Pharmacopeia](#). In some cases, compounders may lack sufficient controls (training, equipment, testing facilities) to ensure

may lack consistent controls (training, equipment, testing, facilities) to ensure product quality control especially for complicated drugs like extended-release medications. When compounders engage in high-volume manufacturing and distribution, the risk of patient harm increases (such as the manufacturer involved in the meningitis outbreak.). The emergence over the past decade of firms with pharmacy licenses making and distributing unapproved new drugs in a way that's clearly outside the bounds of traditional pharmacy regulations is of great concern to the FDA. Unlike commercial drug manufacturers, pharmacies are not required to report adverse events associated with compounded drugs. Also, there is no requirement to include package inserts with compounded products. (3)

To learn about the FDA drug approval process used for prescription and over-the-counter medications, click [here](#).

### **Compounded, Bioidentical, and 'Natural' Hormones**

Despite a history of controversy, hormone therapy is still considered the most effective treatment for the symptoms of menopause (night sweats, hot flashes, vaginal dryness, etc). Many women assume "natural" is better but what does that really mean? Any product whose principal ingredient has an animal, plant, or mineral source is technically natural. It doesn't matter if it is in the form of a pill, liquid or cream, available over-the-counter or by prescription or made by a pharmaceutical company. For example, a soy plant may be ground into a powder and sold as a supplement to ease menopause symptoms and would not require FDA approved safety studies. These types of natural products, which may contain active ingredients that impact the body, may actually do harm. On the other hand, the soy plant is also used to create estrogen through an extraction process and used in the FDA-approved drug Estrace and considered safe. Both of these products come from a natural product!

"Natural" is often confused with the term 'bioidentical', which is used to describe hormones that are identical or nearly identical to the molecular structure of the hormones produced naturally in your body and are metabolized exactly like the ones your body produces. Technically, the body cannot distinguish bioidentical hormones from the ones your ovaries produce. This means if you have blood test (e.g., for estradiol) it would measure all your estradiol whether it comes from your ovaries or from a pill. Bioidentical hormones are generally derived from soy and yams but the product needs to be chemically altered to become a therapeutic agent for humans. For example, synthetic estradiol, taken orally, splits when absorbed in the GI tract and delivers bioidentical estradiol to the blood stream.

This discussion becomes even more complicated when bioidenticals are created through the process of compounding. These are hormone formulas prescribed by a physician after an assessment of individual patient hormone levels. Unfortunately, the salivary testing methods generally used to test and regulate hormone levels are unreliable because your hormone levels fluctuate throughout the day. So some physicians "estimate" and adjust your hormone levels based on symptoms. These compounded products are not regulated in the same way as manufactured hormones are and dosages could be irregular. Different lots of the same compound "prescription" could also vary with compounding due to reasons cited earlier. (4)

Bioidentical hormones are available in many government-approved brand-name

Bioidentical hormones are available in many government approved brand name prescription drugs. Estrogen exists in three forums: estradiol (E2), estrone (E1), and estriol (E3), but only estradiol is currently available as a brand name bioidentical. [Click here to view a list of FDA approved drugs for menopause.](#)

### **Are Generic vs. Brand Name Drugs the Same?**

Generic drugs are copies of their brand-name counterparts and have the same dosage, intended use, action, side effects, route of administration, risks, and safety. People question their effectiveness because they are often much cheaper than the brand name versions. One of the reasons they are cheaper is that the research, development and start-up costs are assumed by the original manufacturer who holds the patent that gives the developer exclusive rights to the drug until the patent expires. Once the patent expires, other manufacturers can produce the generic version. The FDA requires the same manufacturing standards for generics as it does for the original product.

Generic versions of a drug may have different colors, flavors, or combinations of inactive ingredients than the original. U.S. Trademark laws do not allow generics to look exactly the same as the brand-preparation but the medicinal effects must be the same.

### **Do Drugs Work the Same in Men and Women?**

Though most drugs over the years were studied mainly in men, researchers now recognize that the response to medications and therapeutics differs in men and women. We know women wake faster from certain anesthetics, recover more slowly and have more side effects such as headaches and nausea. We are learning that hormone changes during the menstrual cycle can influence the rate that drugs are absorbed and metabolized and may require different dosages at different times of the month. Yet far too many drug approval studies have not looked at sex differences and drugs are universally prescribed to both men and women. A 2005 study of 300 new drug applications between 1995 and 2000 found that even those drugs that showed a substantial difference in how they were absorbed, metabolized and excreted by men and women had no sex-specific dosage recommendations on the labels. (5). Could this be the reason that 1.5 more women than men report an adverse drug reaction? Women's health organizations like our Institute continue to advocate that the FDA mandate that all drug approval studies include sex-specific reactions to medications. (6)

### **Chemicals and Cosmetics**

Americans use about 10 personal care products a day resulting in exposure to more than 100 unique chemicals. Many of these chemicals are absorbed by the body and have been linked to cancer, birth defects, and chronic health conditions. While most of us assume cosmetics are well-regulated, they are not. The federal law that governs the \$50 billion beauty industry has not been updated since 1938. There is a bill pending in the U.S. Congress sponsored by Illinois Representative Jan Schakowsky and others that has been assigned to various committees over several years but has not been enacted. Hopefully, the new Congress will begin to take a serious look at this legislation in 2013. (7)

- (1) Franklin C. *Chicago Tribune Perspective*, Nov 14, 2012.
- (2) *Medpage Today*. Nov 26, 2012.
- (3) <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm>
- (4) [Compounded Menopausal Hormone Therapy Q & A](#)
- (5) Anderson, GD. *J.Womens Health(Larchmont)*. (2005)
- (6) Kim A, Tingen D, Woodruff TK. *Nature*. June 2010.
- (7) [www.SafeCosmetics.org](http://www.SafeCosmetics.org)

## HEALTH TIP Online Pharmacies

Ninety seven percent of online pharmacies don't follow U.S. pharmacy laws. If you buy from one of these online pharmacies, you run a high risk of receiving counterfeit or substandard drugs. You also put your personal and financial information at risk.

Beware of an online pharmacy that shows these signs of being fake:

- Allows you to buy drugs without a prescription from your doctor.
- Offers deep discounts or cheap prices that seem too good to be true.

- Sends spam or unsolicited email offering cheap drugs.
- Is located outside of the United States.
- Is not licensed in the United States.

Look for these signs of a safe online pharmacy:

- Always requires a doctor's prescription.
- Provides a physical address and telephone number in the United States.
- Offers a pharmacist to answer your questions.
- Has a license with your state board of pharmacy. Check to see if it does.

Source: [Food and Drug Administration's BeSafeRx campaign.](#)



## INSTITUTE HAPPENINGS

Nearly 300 faculty, staff, clinicians and supporters attended our expanded Monthly Women's Health Research Forum to celebrate the Institute's Fifth Anniversary. As people entered the room they were met with a wall of slides citing past accomplishments and our new "look" which can be viewed [HERE](#).

Founder and Director Teresa Woodruff, PhD welcomed the audience and highlighted past successes and talked about the future and our new theme: turning possibility into reality!

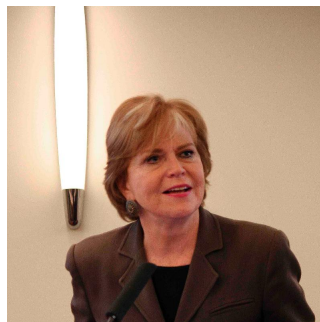
Dr. Woodruff introduced our new "Voice for Women Award" established to recognize individuals who are unafraid of controversy and are effective in

communicating the gaps that still exist between women and men. Chicago reporter Carol Marin was selected to be the first recipient of this award for her balanced and in-depth reporting on issues of concern to women. Carol Marin is the political editor of Chicago NBC affiliate WMAQ-TV, a political columnist for the Chicago Sun-Times and serves as a contributor on Chicago Tonight on the local PBS affiliate, WTTW-TV.

In her comments, Ms. Marin reflected on the outrageous political rhetoric that was witnessed in this last campaign, comparing it to the quiet "radical, prophetic and leading voices" courageously demonstrated by Catholic nuns, who have been pioneers over the past century in women's health searching for equality and justice.

Before starting the keynote address Dr. Katherine L. Wisner, Asher Professor of Psychiatry at Feinberg School of Medicine, introduced colleague Dr. Kara Driscoll who sang a celebratory wish to the Institute--an emotional version of Somewhere over the Rainbow in keeping with our call to dream big! Dr. Wisner's lecture recounted some of the struggles that clinicians have faced in advancing depressive disorders research and care in women and how it was often the women themselves who were a voice for change.

A mountain of cupcakes donated by Mariano's Fresh Market greeted the attendees on their way out!





## UPCOMING EVENTS

**[Tuesday, December 4, 2012, Alzheimer's and Aging: Our Fragile Minds](#)**

**[Tuesday, December 18, 2012, Women's Health Research Monthly Forum: Women and HIV/AIDS](#)**

**[Forward email](#)**



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