



# THE VOICE for Women & Families

## Susan Wood Speaks Up

**D**r. Susan Wood resigned her position as Director of the FDA's Office for Women's Health because the FDA decision not to allow over-the-counter sale of Emergency Contraception (Plan B) "clearly disregarded the scientific and medical evidence and harmed women's health." In a conversation with NRC's president, Dr. Diana Zuckerman, Dr. Wood explains why the FDA's recent decisions have implications for women and their families that are much broader than just this one product.

**Dr. Diana Zuckerman:** Thanks for agreeing to this interview. We have enjoyed working with you for years and we were sorry to see you leave the FDA, but we support your courageous action.

I know that the FDA decision about Plan B wasn't the only outcome that you disagreed with over your years at the FDA. Why did you quit after the Plan B decision?

**Dr. Susan Wood:** The critical distinction was that the decision about Plan B was taken entirely out of the hands of the scientists at FDA. They didn't even know what the answer was going to be until shortly before it was announced.

**DZ:** The company, Barr Pharmaceuticals, asked to sell Plan B without a prescription to women 17 and older. Why did the FDA refuse?

**SW:** The FDA did not have a scientific argument. The stated con-

cern was that there wasn't enough evidence about whether young teens could understand the label if Plan B were sold over-the-counter. But we've never asked that question of any other over-the-counter product.

**DZ:** That's certainly true. What are the implications for the FDA—not just for Plan B?

**SW:** It puts the credibility of the FDA at risk. For individual health and public health we depend on the FDA to assure the safety and efficacy of the products they regulate. The information on the label is used by doctors and patients to make



health care decisions. The scientific standard set by the FDA is considered the gold standard around the world.

I recently lived in the UK, working with their government, and it was clear that the FDA reputation and credibility was valued by other

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### National Research Center for Women & Families

*We are dedicated to improving the health and safety of women, children, and families by using research to develop more effective programs and policies.*

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## What is Plan B?

When Dr. Susan Wood stepped down from the FDA last August to protest the FDA's decision regarding Plan B, her resignation shone a spotlight on these little pills and left many asking the question: what exactly is Plan B and how does it work?

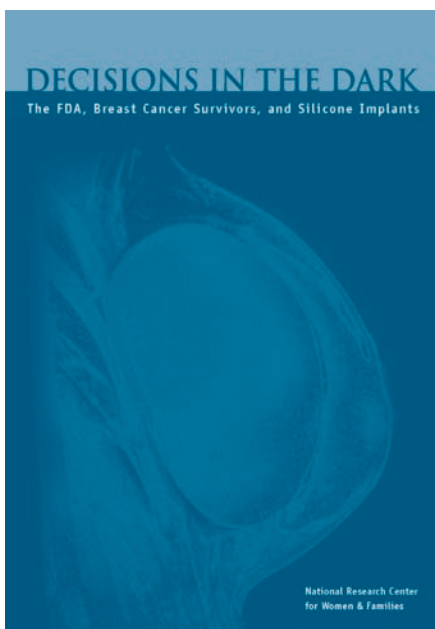


Also known as the “morning after pill,” Plan B is designed to prevent pregnancy—not to terminate it. Emergency contraceptive pills (ECPs), such as Plan B, are not effective once a woman is pregnant, which scientifically is defined as the point at which the egg attaches to the womb (implantation). Regular birth control pills and intrauterine devices (IUDs) can also be used as forms of emergency contraception (EC), but ECPs are the most popular. Plan B is two levonorgestrel pills that are taken orally following unprotected sex or contraceptive failure (such as a condom break). Levonorgestrel is a synthetic hormone that has been used in birth control pills for over 35 years. Essentially, ECPs are birth control pills in more concentrated doses.

Plan B may work in a few different ways. It may delay the release of an egg from the ovary (ovulation), hinder the union of sperm and egg (fertilization), or prevent implantation. It works better the earlier it is taken.

Plan B reduces the risk of pregnancy by 89% when used within the first 72 hours and by 95% when used within the first 24 hours. Medical experts are still uncertain about exactly at what point in the conception process Plan B functions. However, what is certain is that Plan B is only a preventative medicine and should not be confused with RU-486 (the “abortion pill”).

Half of all unplanned pregnancies end in abortion and close to half of all pregnancies in the U.S. are



*The NRC issued the report “Decisions in the Dark: The FDA, Breast Cancer Survivors, and Silicone Implants” to highlight the lack of safety data for breast cancer survivors who are considering reconstruction with silicone implants.*

*The report was released at a National Press Club event with NRC President Diana Zuckerman; Susan Wood; Bettye Green, RN, of African American Women in Touch; Pamela Bridgewater, a Professor of Law at American University and former board member of Our Bodies Ourselves; and breast cancer survivors.*

*For a copy of the report, go to [www.center4research.org/pdf/ImplantReport2006.pdf](http://www.center4research.org/pdf/ImplantReport2006.pdf) or call (202) 223-4000*

unplanned. EC methods have the potential to minimize these numbers. A study conducted by the Alan Guttmacher Institute found that increased EC use accounted for up to 43% of the total decline in abortion rates between 1994 and 2000. The study also found that about 51,000 U.S. abortions were prevented by EC use in 2000. With such success, it is hard to explain why the opposition to EC is so strong. ■

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**Susan Wood**, *continued from page 1*

industrialized nations. This decision puts all of that at risk.

**“I felt it was important to be there to be the voice for women's health.”**

The European Union doesn't look at company safety data the way the FDA does. They don't have the resources.

**DZ:** How is the FDA process supposed to work?

**SW:** FDA reviewers recommend whether a medical product should be approved or not. An advisory panel makes recommendations, but the FDA reviewers don't always agree with the advisory panels. If there is a debate over safety or efficacy among FDA reviewers, their recommendation for or against approval may be modified as it goes up the hierarchy. With Plan B, there was no debate among FDA scientists. Everyone agreed it should be made available without a prescription—until the review reached the highest levels of the agency. The FDA Commissioner decided to overturn the recommendation.

The professional staff was cut out entirely from the decision-making process and therefore could play no further role. This was unacceptable for me as the head of women's health, since I was supposed to be the champion for women's health inside the agency.

Plan B prevents pregnancy by pre-

venting the egg from being implanted. It does not cause abor-

tion. This product has such great potential to help reduce unintended pregnancy and the need for abortion. It can help women who are vic-

tims of rape, who need emergency contraception as soon as possible.

**DZ:** Do you have any concerns about how the science is being ignored for other products?

**SW:** The debates on breast implants, drugs and devices for coronary heart disease, painkillers, anti-depressants, and hormone ther-



*From left to right: NRC President Diana Zuckerman; Cindy Pearson, Executive Director of The National Women's Health Network; and Susan Wood, former Director of the FDA's Office for Women's Health, discuss women's health policy issues at a briefing on Capitol Hill in March. Staff representing 38 Congressional offices attended.*

apy for menopause are just a few of the products where the FDA Office for Women's Health pushed to ensure rigorous analysis and use of good scientific data. Sometimes we

were not successful, but I felt it was important to be there to be the voice for women's health.

**DZ:** What could make the FDA better?

**SW:** The agency needs to base its decisions on science. We need an FDA Commissioner who will demonstrate independence and a commitment to science. There may need to be changes in the current laws to ensure the independence of the agency.

The reviewers inside the agency are committed to public health. However, the environment that they work in, with tight timelines and limited resources, has the potential to shift the balance toward less rigorous review. It makes it difficult to monitor adverse events and industry actions, such as misleading advertising to consumers.

The American people need to be able to count on all the health agencies. They look to agencies like the FDA, Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) as places that offer hope and possibilities to improve their health and reduce suffering. People should demand from their government that we make health policy decisions based on science and in the best interest of public health. We should not let these valued safeguards be dismantled.

Advocates and policy research organizations like the National Research Center for Women & Families are critically important as advocates for the mission of the FDA and other health agencies and, when necessary, as critics to ensure continued progress in women's health. When I worked inside government, organizations like yours helped alert us to important issues and concerns and helped press the FDA to move forward in the right direction. ■

## Teens and Tanning Salons

Artificial tanning is a \$5 billion a year industry with an estimated 30 million people visiting tanning salons each year. A lot of this money is coming from the pockets of the 1.5 million teenagers who use indoor tanning facilities as a way to maintain the "ideal tan" year round.

While advertisements might convince you that indoor tanning is safer than natural sunlight, research shows that may not be true. There are two types of ultraviolet (UV) rays that are emitted, not just from the sun, but from tanning beds and sun lamps as well. These forms of radiation are known as ultraviolet A (UVA) and ultraviolet B (UVB) rays. It has long been believed that UVA rays, or "tanning rays," are not as dangerous as UVB rays in terms of causing skin cancer. This belief is based on the fact that sunburns, which are more likely to be a result of UVB than UVA rays, are the main cause of skin cancer and less likely to result from use of tanning beds. Recent research, however, reveals that even moderate exposure to UVA rays can be hazardous to your health, making tanning beds potentially just as lethal as the sun.

A safe tan may be like a safe cigarette—wishful thinking rather than reality. Whether from a natural or artificial source, exposure to UV

**A safe tan may be like a safe cigarette—  
wishful thinking rather than reality.**

rays seems to be the chief cause of malignant melanoma—the most severe kind of skin cancer. There is no easy cure for this disease and it is frequently fatal if not detected early. Teens tend to be at an even greater risk of skin cancer as a result of continued tanning than adults are. Despite the consequences, however,

many teenagers continue to flock to tanning salons in a quest to look bronzed and beautiful.

**Twenty-eight states have restrictions on  
the use of tanning services by teens.**

Why are tanning salons such a hot trend with teenagers? Teen idols often are tan, which encourages girls to incorporate tanning into their daily lives. For some teens, tanning prior to a major social event, such as a prom, homecoming, or even a middle school graduation, has become a "necessity." Others believe that a "base tan" is important before traveling to a sun-drenched island, a theory that experts claim is untrue. Whatever the reasons, the increase in teen tanning has caused alarm and more regulations are being imposed.

In the United States, 28 states now have restrictions on the use of tanning services by teens and four of those states—Texas, Illinois, California, and Wisconsin—prohibit it entirely for any child under the ages of 13, 14, 14, and 16, respectively. California has just strengthened its law, which previously stated that anyone younger than 18 years old required parental consent; now anyone under 14 must be accompanied by a parent and present a doctor's note. New Hampshire tanners under

the age of 18 also must have the consent of their parents and those under 14 need a doctor's note.

The goal of these laws is to deter teenagers from visiting tanning salons and encourage parents to talk to their teenagers about the risks of skin cancer. Requiring parents to

accompany teens communicates to parents that this behavior is risky; and since many teenagers don't

want their parents going with them and many parents don't have the time to go, it should reduce teen tanning significantly. And, while it might be too late to change the attitudes and behaviors of this generation of teenagers, those coming up behind them might live life under a different motto: it's hip to be fair. ■

### Remembering and Honoring Loved Ones

Showing people how much you care is one of the gifts of life. Sometimes, though, finding the right gift or memorial is difficult. For this reason, we offer a program of Tribute Giving. A gift to our charitable center will help us to continue providing information and educational programs and services free of charge to women and families.

We are sometimes designated as the organization to contribute to in lieu of flowers. Other times, a relative chooses to fund an internship program, named after a loved one, to help us with our research. So next time you are racking your brain for a way to honor someone, please think of a tax-deductible donation to us and help us to continue to do the work that makes such a difference in people's lives.

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## Safety in Numbers Keeping Safe Medications Safe

How is it that one of the safest medications on the market is also a leading cause of acute liver failure?

Acetaminophen, an over-the-counter painkiller best known as Tylenol®, is—when used correctly—one of the



safest painkillers on the market. However, accidental poisonings from the pain reliever seem to be rising; acetaminophen poisoning can

lead to acute liver failure and death, or require a liver transplant.

The medication's safety and usefulness seems to be a double-edged sword. Acetaminophen is in many different medications, from cold relievers to prescription painkillers. People may mix medications without realizing that acetaminophen is in both. For example, if you take Sinutab® for a stuffy nose and Tylenol for a fever, you've taken a double dose of acetaminophen.

Dosage—from all sources—should not exceed 4,000 milligrams a day for most adults. With pills ranging in dosage from 160mg to 500mg, and acetaminophen found in many other drugs, it's crucial to read the labels and talk to your doctor if you're taking other medications. With a little attention, you can keep using this safe medication safely. ■

## Taking medication

- Read the label every time you take medication. Never take more than the prescribed dose, and pay close attention to the list of active ingredients.
- Don't buy combination products unless you really need them. For example, it is better to have separate cold medications for each symptom: one for coughs, one for stuffy nose, one for pain, etc. That way you won't mistakenly take medication you don't really need or want.
- Make sure your doctor knows all the medications and dietary supplements that you are taking. Talk to your doctor about what over-the-counter medications and supplements are safe for you to take with your prescription medications.
- Never take old medication or prescriptions written for other people.
- Never mix medications and alcohol.
- If it's the only spring cleaning you do, clean out your medicine cabinet. Safely dispose of anything past its expiration date, any prescriptions that you didn't finish, and any medications that you don't need.
- Keep other medications in a cool, dry place, out of the light, and in their original containers with the instructions.
- Keep medications out of sight and reach of children.

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## Produce Problems

In a fast paced world, isn't pre-washed and pre-cut produce an easy way to eat healthfully?

Unfortunately, in addition to all the vitamins, fiber, and nutrients in pre-washed fruits and vegetables, there may be something extra in our salads: bacteria. In fact, fruits and vegetables are now responsible for more large scale outbreaks of food-borne illnesses than meat, poultry and dairy, according to data from the CDC.

### The problem

There were more than 500 produce-related outbreaks of bacterial illness in the U.S. from 1990-2003, infecting 28,315 people. There were 19 outbreaks of *E. coli* bacteria in the past decade; the most recent was in November 2005 when 250,000 bags of Dole pre-cut salads were recalled in Minnesota after consumers were infected with *E.coli*. FDA responded with a letter of concern to the California leafy greens industry.

### How it happens

*E. coli* contamination in produce is typically caused by fecal matter that has come into contact with produce at the farm level, through water, manure or wind, or at the processing level, through poor hygiene conditions. Contamination can

occur at any level of production, and food safety experts explain that risk of food-borne illness increases with the greater number of steps between farm and table. So, convenient pre-cut salads and salad bars are more likely to have *E coli* than the non-packaged ingredients that you buy in the supermarket. With



thriving sales of pre-washed salads, \$12.5 billion in 2004, contamination is a serious concern.

A recent survey estimates that more than 65 million Americans become sick each year from food prepared at home. One solution is for consumers to take basic precautions at home. The same survey also reports that 6% of consumers seldom or never wash fresh produce, more than 35% don't wash melons, and half don't wash their hands before preparing fresh produce.

### A solution

The FDA has increased efforts to prevent illnesses from *E. coli* contamination. They now require that all suppliers register with the FDA so that food processors can be quickly located in the event of contamination. They have also issued recommendations for modernizing Good Manufacturing Practice (GMP) to reduce the risk of food-

borne illnesses. GMPs are mandatory for companies that process produce, but are still voluntary for packers. The FDA has proposed guidelines to expand beyond food processors, also covering those who harvest, store, and distribute raw produce. ■

## What you can do

You can reduce the chance of food-borne illnesses at home with a few simple steps. And, there is an added benefit to washing your produce—reducing exposure to pesticides:

- Wash your hands before preparing or eating any food.
- Keep food-preparation areas clean.
- Rinse all fresh fruits and vegetables in running tap water, even if you don't eat the skins (like melons).
- It is safer to buy lettuce and cabbage by the head, rather than pre-cut, and throw out the outside layers of leaves. Despite packaging labels stating that washing pre-cut produce isn't necessary, it can only help to give it an extra wash.
- Eat, cook, or refrigerate cut produce. Don't let it sit out at room temperature.
- You can also make your own pre-cut fruits and vegetables by chopping them ahead of time and refrigerating them.

Keep eating fruits and vegetables! With normal precautions, the risk of illness from contaminated produce is low compared to the many benefits of eating more produce.

### Vegetables to Wash with Extra Care

- Tomatoes
- Melons (especially cantaloupe)
- Lettuce (be sure to remove the outer leaves)
- Sprouts
- Green onions

These fruits and vegetables have been identified by health experts to be particularly likely to harbor bacteria.

## Tom Beall

For nearly 20 years, our board member Tom Beall has helped focus the national gaze on the next big health issue. In the early 1980s, he was working to educate people about HIV and AIDS. In recent years, he has been looking at heart disease prevention.

"I really do think that my colleagues and I have, over 20 years, helped to frame a national response to enormously important issues," he says. "We're touching real people."



Tom was on a straight trajectory from the beginning. "I was deeply influenced by the spirit of social programs—helping the old, the sick, the underserved," he says. "My focus from the get-go was health."

Tom has spent most of his career at Ogilvy Public Relations Worldwide, an award-winning international communications firm that designs and implements communication campaigns.

Ogilvy recently established a Social Marketing Practice, which Tom heads. Social Marketing uses communications to help people make informed decisions about health, safety, and other personal and social issues. It takes an audience-centered point of view to solve public health problems. After outlining the problem and the people they need to

reach to solve it, Social Marketing experts look into where these people get their information; what encourages their actions; and who they trust. Then they deliver a communications campaign that addresses people's concerns and gives people information they trust and can use. These campaigns, therefore, generate real change.

Tom and his Ogilvy colleagues are instrumental in the successful "Heart Truth" campaign ([www.hearttruth.gov](http://www.hearttruth.gov)) for the National Heart, Lung, and Blood Institute, which seeks to raise women's awareness of heart disease. Ogilvy developed and launched the "Red Dress" as the issue's national symbol. The campaign has reached millions of people through the media, materials, events, and partnerships with numerous non-profit groups and businesses nationwide. In less than two years, there was a 21% increase in women who know that heart disease is women's leading cause of death.

Tom believes that this work will become even more important in the years to come. "For better or worse, I believe there will be a growing importance attached to people managing their personal health. Health care and insurance costs are increasing, which means there is a need to do a better job taking control of our health. Responsibilities are shifting back to the individual."

Of his work on the board of the NRC for Women & Families, he says, "Diana inspires me—her zeal, her passion, her drive. It's infectious. If not for her, I probably wouldn't have found the time to be on the board."

Tom holds a master's degree in health services administration and a bachelor's degree in psychology, both from George Washington University. ■

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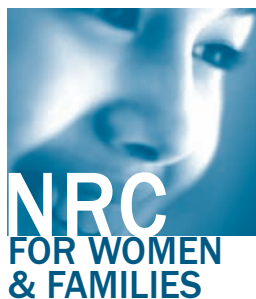
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