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THE VOICE
for Women & Families

What's Inside

Can Aspirin Lower Your Risk of Cancer?

Often called a "wonder drug," aspirin reduces aches and pains, fever, and swelling, and lowers the risk of heart attack and stroke. But few of us imagined that it might also lower our chances of developing several types of cancer and help keep cancer from spreading.

Aspirin and many other pain killers reduce inflammation, and inflammation can contribute to the development of certain cancers. Five large studies of daily aspirin use ("baby" aspirin size or higher dose), in more than 17,000 patients, found that people taking aspirin every day were less likely to develop cancer or die from cancer. Compared to people who did not take aspirin, the almost 10,000 patients taking a daily dose of aspirin in the studies reduced their risk of dying from colorectal and prostate cancers. The people taking aspirin who were diagnosed with colorectal, lung, or brain cancer during the studies were also less likely to have their cancer spread (metastasize) to other parts of the body if they took aspirin daily for about 2 years. The risk of cancer spreading was reduced by as much as 40%. Most important, there were fewer total cancer-related deaths among the people taking aspirin every day.

In another analysis of more than 34 studies (more than 69,000 patients), daily aspirin reduced the risk of deaths from cancer and other causes. The people who took aspirin were also less likely to develop colorectal cancer, uterine cancer, lymphoma, and other types of cancer. Earlier studies showed a reduction in cancer risk after taking aspirin daily for at least 5 years, but some of the newer studies suggest that 2 years may help prevent cancer.

Does the Dose Matter?

A standard dose of aspirin (one pill) is typically 325 mg, and a low-dose or "baby" aspirin is 81 mg. Although called baby aspirin, children under 12 should not take aspirin due to the risk of Reye's Syndrome. In a study that compared daily use of very low-dose aspirin (30 mg) to a daily dose of 283 mg, researchers found no significant difference in cancer deaths between the two groups. In six studies of daily low-dose aspirin use (75 to 100 mg), aspirin reduced the risk of cancer by almost 25% after at least 3 years of aspirin therapy. Daily aspirin use appeared to be particularly beneficial in reducing the risk of uterine cancer.

Bottom line: higher aspirin doses, which increase the risk of ulcer and internal bleeding, did not appear to work any better than low doses.

While aspirin may be even more of a wonder drug than we ever imagined, aspirin is NOT for everyone. Aspirin belongs to a group of medications known as "blood thinners." These drugs prevent the body from making potentially harmful clots that can

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Are Some Birth Control Pills Too Risky?

Recent research indicates that Bayer's birth control pills, known as Yaz, Yasmin, Beyaz, and Safyral, have higher risks than other types of oral contraceptives. While all birth control pills contain the hormones estrogen, progestin, or both, manufacturers use different types of each in their products. Bayer's birth control pills and the generic versions contain drospirenone (DRSP), a newer type of progestin not found in many other oral contraceptives.

Growing evidence indicates that DRSP increases the risk of blood clots (deep vein thrombosis) more than other forms of progestin. Blood clots can be painful and can also be fatal if they detach from the vein and travel through the blood stream, blocking blood flow to the lungs or brain.

The Evidence

All birth control pills have a warning that they can cause blood clots. The Food and Drug Administration (FDA) recently reviewed the latest studies to determine whether these risks are higher with pills containing DRSP. Four of the six studies showed that risk of blood clots was 1.5 to 3 times higher in women taking oral contraceptives containing DRSP compared to other types of birth control pills.

Two published studies report there is not an elevated risk with Yaz and generic versions. However, the authors of those two studies had financial and professional ties to the manufacturers that make these pills. There were also differences in the way that these two studies were conducted and analyzed that might explain why their results were more favorable than the studies done by independent researchers.

FDA rarely conducts or funds studies of medical products, but in this case the agency funded an enormous study which reviewed the medical records of 800,000 women using birth control products between 2001 and 2007. Women taking birth control pills containing DRSP were significantly more likely to have blood clots, especially among the women over 35. However, the FDA study also found that when they focused only on women taking birth control pills for the first time, women under 35 taking pills with drospirenone were at a much greater risk of blood clots and heart attacks than women taking pills with other forms of progestin.

Yaz, Yasmin, Beyaz, Safyral: Higher Cost and More Risk

When new medications come on the market, they tend to cost more and be widely advertised, and this often gives the impression that they are better. However, the FDA usually does not require that new drugs show an improvement over older drugs or even require that they be as effective or as safe. Since FDA approval is often based on patients taking a drug for one year or less, the risks may not be obvious.

Bayer's ads for Yaz and its other birth control pills feature attractive, happy young women, and this has resulted in big sales despite the pills' higher price. All birth control pills warn that women who smoke or have a history of blood clots, heart attacks, strokes, or particular cancers should avoid these contraceptive

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A Sudden Loss

Annie Ammons died suddenly in her sleep in November 2009. She was young, healthy, athletic, a physical trainer, and a new lawyer. She ate healthy foods and did not smoke. Annie's death shocked everyone who knew her.

Annie was prescribed Yaz, not for birth control, but for irregular periods. In the 8 months that Annie took Yaz, she rapidly gained weight, noticed that her hair was falling out, and had headaches and insomnia. Her doctors couldn't figure out what was wrong. It was only when she picked up her Yaz prescription refill that Annie noticed that the listed side effects coincided with her own. She immediately called her endocrinologist and was urged to stay on the pills and make an appointment to see her OB/GYN, but Annie died before the appointment took place.

Annie's parents, Dianne and Rick Ammons from Annapolis, MD, gave moving testimony at the FDA Advisory Committee meeting in December 2011 and went with NRC president Dr. Diana Zuckerman to meet with Senator Barbara Mikulski, a strong advocate for women's health, who is also their U.S. senator. "We are very disappointed that the FDA hasn't taken these pills off the market, but we are doing whatever we can so that what happened to Annie will not happen to other young women," Dianne Ammons tells us.

Are Some Birth Control Pills Too Risky?

pills. However, new research raises questions about the risks to healthy, nonsmoking women, as well.

The FDA convened an advisory committee of outside experts to review the studies and then vote on whether "the benefits of the DRSP-containing oral contraceptives for prevention of pregnancy outweigh their risks." Those who voted "no" explained that safer oral contraceptives were available. Almost all of the advisors who voted "yes" indicated that, like all other contraceptives, the DRSP oral contraceptives are safer than pregnancy, which has substantial risks.

The *Wall Street Journal* pointed out that at least four members who voted in favor of keeping DRSP pills on the market had financial ties to Bayer. However, the FDA did not count those financial ties as conflicts of interest because the money was received more than 12 months prior to the meeting.

The vaguely (and we believe inappropriately) worded question about risks and benefits, together with the conflicts of interest of four people who defended DRSP pills, raise very serious questions of bias in the FDA's process.

Coverup?

In addition to the worrisome research findings, internal documents from Bayer suggest that risk information was not provided by the company to the FDA. A report from former FDA Commissioner David Kessler documented how Bayer repeatedly misled the FDA when FDA officials expressed concerns about the risks of Yasmin before and after the drug was approved.

Worth the Risk?

Should birth control pills containing drospirenone remain on the market? There is no evidence that they have significant advantages compared to other contraceptive pills that would outweigh the risks of blood clots or heart attacks. If patients and their doctors understood the latest research, why would anyone choose to take those risks?

In April 2012, the FDA announced that it was adding new information about the increased risk of stroke to the labels of all drospirenone-containing pills. However, the agency did not remove these dangerous pills from the market or even require a "black box" warning indicating that the pills are more dangerous than other birth control pills. This means that the onus is on doctors and patients to be more vigilant about these risks.

Our Annual Cancer Prevention and Treatment 5K in Georgetown: September 23, 2012

We've moved our annual Cancer Prevention and Treatment 5K to the beautiful C&O Canal Trail in Georgetown. The 5K Run/Walk will be on September 23, starting at 10 am.

The C&O trail accommodates a large number of racers, is close to public transportation and large universities, and is in a location where racers, friends, and family can enjoy spending time eating, shopping, or enjoying the riverside park and all that historic Georgetown has to offer. Dogs and strollers are welcome at our 5K, as well as serious racers (they will start first!). This is an event the whole family can enjoy, whether you choose to run, walk, or cheer from the sidelines. Many Georgetown businesses will be sponsoring and providing prizes, so sign up now!

If you can't be there in person, you can be a virtual participant (walking or running in your own home, gym, or community). And, you can donate money in memory of a loved one or to honor a cancer survivor whose name is then printed on all the runners' T-shirts. Form a team in a loved one's name and the team name will be printed on the race T-shirt. Prizes for fundraising teams and racers include gift certificates at Georgetown's best restaurants.

Last year's race winners were Owen Lourie and Anna Bernal and our winning donor teams were Bev's Bosom Buddies and DC 101 DJ Ty Bailey. This year, it could be you!

Visit our race website at www.cancer5k.com to find out more and to register.

Take the politics out of your cancer donation!

Join our Cancer Prevention and Treatment 5K!

Want to Get More Sleep? Don't Pop a Pill

Some say that "sleep is the new sex" because so many of us aren't getting enough. With only six hours of sleep, we can't concentrate as well and our risk of accidents, depression, heart disease, weight gain, and diabetes goes up. And too many hours of exposure to light (for those of us who burn the midnight oil) increases the risk of certain cancers.

So what's a busy, sleep-deprived person to do? Last year we filled 60 million prescriptions for medicines in the hopes of falling asleep faster and staying asleep longer, and that doesn't even count popular over-the-counter pills like Tylenol PM or Sleep-eze. These medicines are not very effective, and a new study shows they can be deadly.

The study by Dr. Daniel Kripke, published in the respected *British Medical Journal (BMJ)* in 2012, looked at the most popular type of sleeping pills, known as hypnotic drugs. These include newer and supposedly safer prescription sleeping pills like Ambien (generic name zolpidem), Restoril (temazepam), Sonata (zaleplon), and Lunesta (eszopiclone), as well as antihistamines containing diphenhydramine (such as Tylenol PM and Benadryl), which can be bought in grocery and drug stores as sleep aids.

The researchers studied 10,529 women and men who were prescribed hypnotic drugs and compared each of them to two very similar patients (same sex, ethnicity, marital status, smoking status, chronic health conditions, alcohol use, and BMI) who were not prescribed hypnotic drugs. All patients were studied for 2.5 years on average, and what they found confirms what other studies have suggested for years: People who take sleeping pills are at much higher risk of dying and developing cancer. The patients who were prescribed sleeping pills were 3 to 5 times more likely to have died during the 2.5 years of the study than were the patients not prescribed sleeping pills. Even people who took as few as 18 pills a year were more than 3.6 times more likely to die.

In addition, people who took more than 18 pills a year had an increased risk of developing cancer. The "heavy users"—132 pills or more prescribed per year—had a 35% greater risk of developing cancers such as lymphoma, lung cancer, colon cancer, and prostate cancer than those prescribed fewer pills. The lead researcher of the study speculates that the pills contribute to depression and somehow affect DNA. Although it was not described in the *BMJ* article, the authors stated elsewhere that people taking the popular antihistamine (diphenhydramine) in most over-the-counter sleep aids also were at increased risk of death.

But I Need More Sleep!

Let's say, in spite of all that, you still want to take a sleeping pill every now and then just to "catch up" on sleep or because you have an important meeting the next day and want to be well-rested. Don't bother. Research conducted by the sleeping pill manufacturers show that these pills don't help you sleep any longer or better than a placebo. Sonata (zaleplon), for example, helped people fall asleep 14 minutes faster during the first week of use than those taking a placebo; this dropped to only 8 minutes faster by the fourth week of use. Even so, both groups slept the exact same amount of time (about 6 hours and 20 minutes a night) and rated their quality of sleep the same.

The real difference between taking a sleeping pill and taking a placebo? People who take sleeping pills are more likely to feel groggy and weak the next day. Sometimes that's from the pill itself, but people taking these medications are known to sleep-walk, "sleep-dial," and even sleep-drive, which certainly reduces the benefits of sleeping.

Your best option is to attack insomnia at its root. See a health care professional about health problems or conditions that may be interfering with your sleep, get regular exercise (preferably 3 hours or more before your bedtime), and cultivate good sleep habits, which include going to bed and getting up each day at more or less the same time.

Leaving a Legacy

Friends and loved ones are helping us honor **Lenora Moody, Marcy Gross, Ros Brannigan, Annie Ammons, and Omega Logan Silva** by naming internships and fellowships in their honor.

Is there someone you would like to honor? Internships and fellowships provide training that can result in a lifetime of good work. Honor a loved one through a donation of cash or stock, a distribution from a retirement plan or life insurance policy, or a will.

For more information, contact Brandel at 202-223-4000 or bfb@center4research.org.

Hormone Therapy: Safe or Not?

Hormone therapy is in the news again. Ten years ago, many experts decided that for most women entering menopause, the risks of hormone therapy outweighed the benefits. But some continued to enthusiastically defend hormones, many of whom had financial ties to the hormone companies. So, who should we believe?

Why the Continued Debate?

Recently, articles have come out questioning research that found hormones risky and emphasizing the benefits of estrogen-only therapy.

The first hormone therapy was estrogen (Premarin), and it was prescribed to cope with "the change of life." When uterine cancer rates started to increase, experts decided estrogen alone was only safe for women who had previously had a hysterectomy and therefore had no uterus where cancer could develop.

Meanwhile, drug companies introduced a hormone treatment that combined estrogen and progestin, which did not cause uterine cancer. By the 1990s, most women were encouraged to start hormone therapy before menopause and take it indefinitely. The goal was to "replace" hormones that decrease with age and thus prevent many of the symptoms of aging, including osteoporosis, memory loss, heart disease, and other symptoms.

However, when NIH's Women's Health Initiative (WHI) study results came out in 2002, they clearly showed that hormone therapy can increase a woman's risk of developing breast cancer and stroke, and possibly heart disease and Alzheimer's. The Million Women Study, conducted on women over the age of 50 in the U.K., confirmed the U.S. findings. As a result, new guidelines told doctors to prescribe hormones to fewer women at "the lowest dose for the shortest time."

The companies that sell hormone therapy quickly responded, offering support to doctors and women's health advocates who were willing to defend hormone therapy despite the research findings. These efforts have continued for the past decade. For example, a 2011 report criticizing the WHI study cited the "possibility" that women who guessed what drug they were taking would be more vigilant about getting mammography, thus leading to higher rates of breast cancer detection. All five authors reported consulting work with hormone therapy manufacturers. This same group of authors also targeted the results of the Million Women Study, saying women with suspicious lumps or suspected breast cancer were more likely to join the study and get regular mammograms.

Estrogen-Only Therapy

Another recent study, funded in part by Wyeth, found that women with hysterectomies who took estrogen-only hormone therapy for about 5 years after menopause had a lower risk of breast cancer than women with hysterectomies who didn't take estrogen. However, women with a family history of breast cancer and women who had one or more breast biopsies in the past due to benign breast conditions were *more* likely to develop breast cancer while taking estrogen than the placebo.

The authors and other researchers believe that estrogen goes from being a cancer-causer to a cancer-reducer **only** if taken after a woman's own estrogen production has stopped. However, by that time, many women will no longer be suffering from menopausal symptoms, so why would they take hormone therapy, which has other risks as well? The authors conclude that women looking to reduce their risk of breast cancer should not take estrogen therapy but rather take tamoxifen or raloxifene, which are hormonal drugs approved to prevent breast cancer.

Any Other Evidence?

Breast cancer rates fell almost 7% in the U.S. during the years after physicians stopped prescribing hormone therapy so often. Were lives saved because fewer women were on hormones? Most experts believe they were, especially because the reduction in breast cancer was among women over 50 with estrogen receptor-positive cancer—the kind that hormone therapy "feeds."

What Are the Alternatives?

Menopausal symptoms can harm a woman's quality of life, but there are ways to reduce those symptoms. For example, vaginal dryness and/or pain with sexual activity can be treated with a lubricant gel or moisturizer, or a vaginal cream with estrogen (which is safer than estrogen pills). Lifestyle changes (e.g., sleep, exercise, and diet) or alternative therapies, such as massage and acupuncture, can help reduce the symptoms of menopause. To treat osteoporosis, cardiovascular disease, and depression, select medications specifically targeted to these conditions, rather than relying on treatment with estrogen.

If you have debilitating menopausal symptoms and you have no family or personal history of cancer, heart disease, or stroke, hormone therapy may still be an option. Choose the lowest dose and take it for the shortest time possible to lower your risk of breast cancer and other diseases.

Can Aspirin Prevent Cancer?

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block blood vessels and cause heart attacks and strokes. For patients taking other blood thinners, aspirin may increase the risk of internal bleeding, which could be life-threatening. Those with severe liver and kidney disease are warned against using aspirin because of the potentially toxic effects on these organs. In addition, asthma patients may be particularly sensitive to aspirin and can experience serious complications.

How Often, For How Long?

What about taking aspirin every other day? In two of the largest studies of aspirin use for the prevention of cardiovascular disease, the Women's Health Study (WHS), involving more than 39,000 women, and the Physician's Health Study (PHS) of more than 22,000 men, the women took 100 mg every other day and the men took 325 mg every other day. Surprisingly, neither study showed a reduction in cancer risk or cancer-related deaths, even after more than 10 years of aspirin therapy.

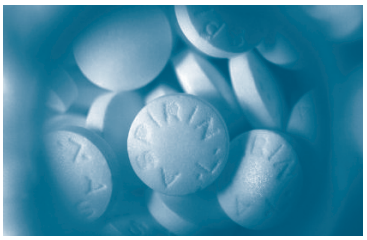
For years, people at high risk for heart attack or stroke have been advised to take a baby aspirin every day. Should this recommendation now include people at high risk for certain cancers? And what about people newly diagnosed with cancer who want to make sure the cancer does not spread? These are still unanswered questions, as is the question of how many years a person needs to take aspirin every day to get the maximum benefit.

Before Starting Aspirin Therapy

Remember that aspirin has risks, even at low doses. You should discuss aspirin therapy first with your doctor and be sure to describe:

- Your medical history and the medicines you are currently using, whether they are prescription or over-the-counter;
- Any allergies or sensitivities you may have to aspirin; and
- Any vitamins or dietary supplements you currently take.

Aspirin should not be taken with certain other over-the-counter pain medications called NSAIDS, such as ibuprofen (Motrin and Advil) and naproxen (Aleve), because they can increase the risk of internal bleeding. That is also true for several herbs and nutritional supplements. Vitamin E, fish oil (omega-3 fatty acids), and what's known as the "four Gs"—garlic, ginger, gingko, and ginseng—can all increase your risk for bleeding when taken with aspirin and other blood thinners.



Quitting smoking, eating a diet rich in fruits and vegetables, and avoiding long bouts of sitting (some people make 10,000 steps a day their goal) are great ways to reduce your chances of developing heart disease and cancer—without any side effects! For people at greatest risk who can't make these behavior changes, aspirin could truly be a lifesaver.

Is Your Medical Device Safe? Ask the Good Wife

Is my artificial hip, knee, or pacemaker safe? NRC for Women & Families has been asking that question for years, and now mainstream media is catching up to us. Articles in *The New York Times*, *The Wall Street Journal*, *The Washington Post*, and *Consumers Report*, and primetime TV shows such as the "The Good Wife" and "Rizzoli & Isles" have all featured stories about unsafe medical devices.

Many people think that medical devices are subject to the same rigorous FDA standards that apply to drugs. That's not true. Drugs must be proven safe and effective in scientific clinical studies, while the vast majority of medical devices—even implantable devices—only have to show that they are similar to a device that's already being sold. Artificial hips and many cardiac devices, for example, do not have to be tested in people before being sold.

One reason for the less-than-rigorous review of medical devices is that the FDA's Device Center is underfunded. The FDA charges user fees to companies that submit a new drug or device for FDA approval to help fund a portion of the FDA budget. The drug industry provides significantly more money through user fees than the device industry does. How big is the difference in the amount of user fees? The largest companies (such as Johnson & Johnson) currently pay device user fees that are only 1% to 12% of the user fee that they pay for a new prescription drug application.

Empowering Teens to End Domestic Violence

Dating violence and sexual assault are all too common among U.S. teens. According to a Centers for Disease Control and Prevention survey, 1 in 10 high school students has experienced dating violence, and 1 in 10 high school girls reported being forced to have sex during the previous year.

The Department of Justice reports that girls aged 16-19 are four times more likely than the general population to be victims of rape, attempted rape, or sexual assault. This is why it's so important to have programs to reduce dating violence and sexual assault among teenagers in the U.S.

Verizon has been a corporate leader in domestic violence for over a decade. Through its philanthropic efforts, the Verizon Foundation is committed to promoting respect and equality, and empowering individuals and families to live safe and healthy lives. **NRC for Women & Families received a grant to evaluate a program that aims to educate and empower teens to end dating and domestic violence**. The program involves collaboration with the Verizon Foundation, the NFL Players Association, and the nonprofit group, A CALL TO MEN—three organizations committed to ending violence against women.

NRC's Public Health Program Director, Dr. Dana Casciotti, attended kick-off events at high schools in Milwaukee, New Orleans, Boston, and Indianapolis. NFL players including Matthew Slater (New England Patriots), Frank Zombo (Green Bay Packers), Zach Strief (New Orleans Saints), and David Caldwell (Indianapolis Colts), spoke to students at these events about overcoming adversity and fostering healthy and respectful relationships. Staff members from A CALL TO MEN urged students to challenge traditional beliefs about manhood and help prevent violence against women.

Following these kick-off events, staff from A CALL TO MEN work with high school teachers to implement a series of classroom lessons called the Coaching Healthy & Respectful Manhood Curriculum.

By evaluating kick-off events and the lessons that comprise the Coaching Healthy & Respectful Manhood Curriculum, NRC is helping the Verizon Foundation and A CALL TO MEN determine which parts of the program are most effective. All the activities are geared to changing attitudes and cultural norms, with the goal of teens interacting with one another with more respect and less violence. "We are very glad to have the chance to work with the Verizon Foundation on this exciting project," says NRC President Diana Zuckerman.

We don't accept funding from drug companies, so we rely on the generosity of individual donors.

We welcome donations to the National Research Center for Women & Families by check or online (www.center4research.org).

You can donate to our Cancer Prevention & Treatment Fund by check, online (www.stopcancerfund.org), or federal employees can designate ***Combined Federal Campaign # 11967.***

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Matthew Slater, New England Patriots

If you want to know why we cheer for this football player, see page 7!

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