

National Center for Health Research

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The Cancer Prevention and Treatment Fund

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Which Sunscreens Offer the Best Protection?

We all need 15 minutes of sunshine every day to benefit from vitamin D. Otherwise, staying out of the sun is important to prevent skin cancer. But, let's face it, the sun feels good! In addition to avoiding sun exposure in the hours around noon, especially during the summer, sunscreen can also help protect you and yours from some of the damaging effects of the sun.

But what kind of sunscreen is best? Spray or lotion? SPF 15 or SPF 70? Waterproof or moisturizing? It seems like new rules come out every year.

And it is important to know that the Food and Drug Administration (FDA) has never required sunscreens to be proven to prevent skin cancer. They are only required to be proven to prevent sunburn, and since sunburn increases the chances of later skin cancer, sunscreens are assumed to prevent skin cancer. But some sunscreens contain chemicals that can be dangerous when used frequently.

Skin Cancer

Spending too much time in the sun puts you at risk for skin cancer, and so does sunburn. There are three types of skin cancer: basal cell, squamous cell, and melanoma. Basal cell cancers, the most common, are slow growing and are the easiest to treat. Squamous cell cancers detected at an early stage are curable and cause minimal damage. Melanoma is the least common but most dangerous kind of skin cancer. If not caught early, it can spread throughout the body and become fatal.

Most melanomas result from sun exposure, especially for people with fair skin. Sunscreen only lasts about 2 hours, so putting it on first thing in the morning will not last all day. Research shows that applying sunscreen every day reduces aging of the skin by 24%.

Protecting children from sunburns is especially important. Getting sunburns during childhood increases the risk of cancer later in life. Get your



kids into the routine of applying sunscreen every morning (after they brush their teeth) before going to school or to camp, no matter how cloudy it is outside. But remember, they will need to add more if they are in the sun more than two hours later.

Which SPF to Use?

Sun protection factor (SPF) choices range from SPF 8 all the way up to SPF 100+. According to the FDA, SPF 15 protects against sunburns, but they do not prevent damage that can cause skin cancer. On the other hand, very high SPF 30 protects against 97% of UV rays, SPF 50 protects against 98%, and SPF 100 protects against 99%. Sunscreens with the highest SPF cost more and provide little additional protection, and they also encourage people to stay out in the sun longer and reapply less frequently. For effective sun protection, look for an SPF between 15 and 50.

In addition, make sure to choose "broad-spectrum" sunscreen, which guards against both UVB and UVA rays. While only 10% of UV radiation from the sun is UVB, this type of radiation is the primary cause of sunburns, wrinkling, and skin cancer. UVA rays penetrate deep into the skin to cause premature aging, and with enough exposure can also damage DNA to cause cancer.

You may be surprised to learn

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WE'RE IN THE HEADLINES!

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Trump's FDA Nominee Spurs Concerns About Drug Approvals, Off-Label Promotion

Bloomberg BNA
March 14, 2017

Trump Vows to Ease Rules for Drug Makers, but Again Zeros In on Prices

The New York Times
January 31, 2017

Don't Give Kids Cough Syrup Or Pain Meds That Contain Codeine, FDA Says

NPR
April 20, 2017

Cancer drugs may remain approved despite lack of benefit

Reuters
December 1, 2016

Right to Try National Law Would Exploit False Hope

Diana Zuckerman, Chicago Tribune and 20 other newspapers across the country
March 19, 2017

FDA Agrees With WHO, Links Breast Implants To Rare Cancer. How Worried Should Women Be?

Forbes
March 22, 2017

Right to Try? Or Right to be Exploited Before You Die?

Diana Zuckerman, Our Bodies Ourselves
April 17, 2017

In the U.S., cancer drugs are often approved based on preliminary studies showing the tumor shrinks. But the drugs usually stay on the market even if later studies show they don't help patients live longer or better, according to our study published in **JAMA Internal Medicine**. In **New Republic**, **Reuters Health**, **Kaiser Health News**, **Barrons**, and **Stat News**, NCHR's president explained how shocked we were to find that "these drugs don't save lives and don't improve quality of lives." Patients deserve the most effective drugs, but instead too many are spending their life savings on drugs that don't work and make their remaining months miserable. NCHR president Dr. Diana Zuckerman explained to **The New York Times** that when drugs are hastily approved, patients end up with expensive treatments that don't work as well as older drugs.

The FDA now agrees with us and the World Health Organization (WHO) that breast implants can cause a rare type of cancer called anaplastic large cell lymphoma (ALCL). According to WHO, breast implant-associated ALCL is usually diagnosed about 10 years after breast implant surgery. We told **Forbes** that this has been under-reported and misdiagnosed for years. Dr. Zuckerman's blog in **Our Bodies Ourselves** discusses why it took so long to warn women.

FDA will now require that cough, cold, or pain medications with codeine or another narcotic, tramadol, have a label warning against use for children under 12 and women who are breastfeeding. These drugs may also be dangerous for kids ages 12-18. NCHR and other experts testified about this in 2015 at an FDA meeting. Dr. Zuckerman told **NPR** that "The science is clear, so why did it take almost 18 months since the FDA's public meeting on the exact same issue? FDA needs to do more to warn patients about the known risks of medical products as soon as data are available."

"Right to Try" laws that allow patients to have easier access to experimental drugs promise more than they can deliver. Patients already have a "right to try" experimental treatments through a program where the Food and Drug Administration (FDA) provides safeguards and ensures that desperate patients aren't exploited by greedy doctors or companies. Dr. Zuckerman's explanation of a proposed federal Right to Try Act was featured in the **Chicago Tribune** and 20 other newspapers across the country, and also on the **Our Bodies Ourselves** blog. Learn more on page 6.

The nomination of new FDA Commissioner Scott Gottlieb has raised concerns because he has "extensive financial ties to the industries he'd be in charge of regulating and has shown more interest in reducing regulations rather than enforcing them," Dr. Diana Zuckerman told **Bloomberg BNA**. She told **Stat News** that it isn't possible to recuse these conflicts of interest because his ties to pharmaceutical industry executives are so much a part of who Gottlieb is as a person.

A new medical law was signed in December 2016, the **21st Century Cures Act**. It will make it easier for companies to get faster FDA approval for their products, but what happens if those treatments don't actually work? Drugs that seem "promising" in early studies often prove to be unsafe or ineffective when studied more carefully, Dr. Zuckerman told **Fierce Biotech**, **The Hill**, and **Kaiser Health News**.

"We are flooding the market with medical products that don't work very well... and it's contributing billions of dollars to the cost of Medicare, billions of dollars to the cost of health insurance, and thousands of dollars per patient," Dr. Zuckerman explained to **NPR**, **WBUR**, **Wall Street Journal**, **CBS News**, and **New Republic**.



Antipsychotics & Young Kids: How Safe are They?

This year, the FDA approved Latuda for the treatment of schizophrenia in children ages 13 to 17. The drug was already approved to treat schizophrenia and bipolar depression in adults. Is Latuda actually **proven** to be safe and effective for adolescents?

Like many experts, we are not convinced. We are asking a basic question: Where did the researchers find children ages 13 to 15 with schizophrenia? Schizophrenia isn't usually diagnosed until at least age 16, when symptoms such as hallucinations and delusions usually begin. The FDA did not explain why they approved Latuda for schizophrenia for children as young as 13 and 14 or even 15.

FDA approval is based on the FDA's review of studies that are paid for by the company that makes the product. Sometimes company scientists design and/or conduct the study, and other times they pay academic researchers or physicians to design and conduct the study. For Latuda, FDA approval in children ages 13 to 17 was based on one 6-week study of 326 adolescents from 17 countries. Adolescents either received Latuda or a placebo (sugar pill). No information has been made public about how many of those children were only 13 or 14 or who diagnosed them as schizophrenic.

Drugs like Latuda, which act on the brain, should be very carefully studied, since children's brains are still developing. And since children have a different metabolism and immature organs and tissues, they can react very differently to drugs than adults do. Side effects can be different for kids, and may not be apparent until puberty or adulthood. The impact on the developing brain could affect mental health, behavior, or cognitive development.

...there is currently very little scientific data about exactly how these drugs affect the brain or behavior of either children or adults.

There are three traditional antipsychotic drugs that are approved for schizophrenia in children. In addition, there are 6 newer "atypical antipsychotic" schizophrenia drugs, such as Abilify, Seroquel, Zyprexa, Risperdal, and now Latuda that are approved for teenagers, and Invega is approved for children 12 years and older. Unfortunately, there is very little scientific data about exactly how these drugs affect the brain or behavior of either children or adults.

Are these drugs overused?

Once an antipsychotic drug is approved for adults, the FDA doesn't seem to scrutinize it as carefully for kids. Doesn't a 6-week study seem too short for a treatment for schizophrenia, which is often a life-long disease? And yet, once a drug like Latuda is



The FDA did not explain why they approved Latuda for schizophrenia for children as young as 13 and 14 or even 15.

approved for young teens with schizophrenia, they tend to be widely used for depression, anxiety, or behavior problems in children. They are also used for ADHD or autism, even though the drugs have serious risks (such as substantial weight gain and diabetes), and little benefit for either. Risperdal is the drug most commonly used for ADHD and for irritability in children with autism, even though one of the side effects is non-reversible breast development in boys.

The use of antipsychotic drugs in children, adolescents, and young adults has risen over the past 20 years, especially among children in low income families and those in foster care. Although FDA-approved for teens with schizophrenia and bipolar disorder, most of these prescriptions for children are for "off-label use" – in other words, not for the condition that the drug is approved for.

Latuda is widely advertised on TV, and those ads make it seem wonderful. The ads for Latuda's use for children are not yet on the air, but we expect that they will encourage parents to "ask their pediatrician" if the drug is right for their children. Unfortunately, most pediatricians will not be aware of how limited the scientific evidence is.

Adolescence is a difficult time for children and for adults. Many parents welcome medications hoping it will help. Medical professionals and the FDA need to do a better job of studying and explaining that drugs that affect the developing brain may have serious, permanent risks. NCHR is currently studying this issue with Dr. Rick Ostrander from the Johns Hopkins University School of Medicine, to get a better understanding of the risks and benefits. ♦

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Making Our Voices Heard

As a think tank, we frequently share our views with the Food and Drug Administration (FDA), other health agencies, and policymakers. What do these comments have to do with you? How does our work affect **your** daily life? You'll be surprised how relevant our work is to your health, as you can see from these examples.

Hangovers

Wouldn't it be great if a pill could cure your hangover? But what if that pill contained acetaminophen or aspirin – two things you shouldn't take with alcohol in your system?

We testified at an FDA Advisory Meeting that any medications containing aspirin or acetaminophen (Tylenol) shouldn't be sold for hangovers because the risks outweigh the benefits. These risks can be serious, including liver damage and stomach bleeding. All products with acetaminophen or aspirin should have warnings that they're risky to use for hangovers because it is not a good idea to take them before, during, or within a few hours of consuming alcohol.

Chemicals

The new Frank H. Lautenberg Chemical Safety for the 21st Century Act requires that chemicals be evaluated for their risks **before** they go on the market, instead of waiting until after people are harmed. We strongly support the Environmental Protection Agency's efforts to implement this law by testing new chemicals as well as those already on the market. Chemicals at your home or at your work should be proven safe! But will the Trump Administration's opposition to EPA regulation undermine the law?

Cosmetics

We submitted comments to the FDA letting them know that we shouldn't have any lead in our cosmetics unless it is scientifically proven to be safe. This seems like a no brainer, but many cosmetics currently contain lead, so be sure to read the labels.

Breast Cancer

Many women take tamoxifen, raloxifene, or other drugs to try to prevent breast cancer, but experts are questioning the benefits. We supported the U.S. Preventative Task Force's efforts to review and update their recommendations for breast cancer prevention strategies based on evolving research about the benefits and risks.

We also supported their decision to update their recommendations for research needed to study the risks and benefits of screening, counseling, and treatment for women with BRCA1 or BRCA2 genes. These gene mutations make it more likely that women and men will develop certain cancers, but the estimates of those risks are changing and recommendations for patients should evolve with it.

Opioids

The opioid epidemic is raging, and companies are trying to prove their opioids are safer to use. One opioid, called **Opana ER**, was redesigned to try to help prevent abuse, but many addicted patients learned how to crush and inject it. NCHR's Dr. Megan Polanin testified at an FDA Advisory Meeting, explaining that labeling this opioid as "abuse-deterrent" would mislead doctors and patients. The FDA Advisory Committee agreed with us.

Dr. Polanin also testified about a different opioid, called **RoxyBond**, which also claims to be "abuse-deterrent." We urged the FDA to require that the company do research to prove that the drug really does deter abuse in real life, not just that it is difficult to abuse in lab tests. However the FDA did not follow our advice.

We urge the FDA to do more to make sure that the new opioid drugs coming on the market do not add to the epidemic.

Cold Medicine

Codeine can be dangerous. FDA now requires that cough, cold, or pain medications with **codeine** or another narcotic, **tramadol**, should have a label warning against use for children under 12 and women who are breastfeeding. These drugs may also be dangerous for kids ages 12-18.

We testified in 2015 that FDA needed to require this warning label. The FDA finally agreed, announcing the change in April 2017.

It's unfortunate that it has taken so long to add this warning, but now you know not to use codeine medications to treat pain or cough in children under 12.

And remember: some adults also have a bad reaction to codeine. Do you or your kids really need codeine for a cold that will go away by itself?



Do you read the labels on the medications you take? Do you check the risks online? It's time to test your knowledge! Can you link the products below with the risks that come with them?

Products

- 1 **Birth Control Pills made with drosperinone**, such as Yaz, Yasmin, Beyaz, Safyral
- 2 Cipro, Levaquin, and other **quinolone antibiotics**
- 3 **Statins** such as Lipitor, Zocor, Crestor and Vytorin
- 4 **Type 2 diabetes** drugs: Onglyza, Kombiglyze, Nesina, Kazano, Oseni (and their generic forms)
- 5 **E-cigarettes**
- 6 **Heartburn Medications:** Prilosec, Nexium, Prevacid, Kapidex, Aciphex, Protonix
- 7 **Brisdelle** (for menopausal hot flashes)

Risks

- A. Irregular heart rate, tendon ruptures, changes in blood sugar levels, nerve damage, insomnia, seizures, anxiety, paranoia, nervousness or agitation
- B. Increased risk of **heart failure**
- C. Contain “detectable levels of known carcinogens and **toxic chemicals** to which users could be exposed.”
- D. Muscle pain, memory loss, forgetfulness, confusion, and high blood sugar levels that can result in Type 2 **diabetes**
- E. Potentially **fatal blood clots**
- F. **Suicidal** thoughts and behavior, akathisia (an out-of-control feeling of restlessness and high anxiety)
- G. Increased risk of developing serious **kidney disease**

Answer Key: 1:E 2:A, 3:D, 4:B, 5:C, 6:G, 7:F

Leaving a Legacy

As we hear about federal employees being forced to leave public service, we think about Joy Simonson. From 1975 to 1982, Ms. Simonson was the Executive Director of the National Advisory Council on Women's Educational Programs, a Presidentially appointed body which advises Congress and federal officials on educational equity for women and girls. After Ronald Reagan became president, the newly appointed members of the Council removed Ms. Simonson from her position as Executive Director because of her support for the Equal Rights Amendment. Her firing became a cause celebre and a rallying cry for the Women's Movement.

From 1982 to 1990, Ms. Simonson worked as a Congressional investigator, working on issues such as child labor, occupational safety and health issues, and delays in processing age discrimination cases. At her retirement, she was the oldest House staff member. She passed away in 2007, and we named an internship in her memory.

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 us at info@center4research.org.



The Joy Simonson internship honored our Foremother and supporter



Right to Try? Or Right to be Exploited Before You Die?

Diana Zuckerman, PhD

My friend Gwen went from being a healthy woman living a happy life to being diagnosed with a fatal cancer in a very short period of time. The doctors tried one toxic chemotherapy after another.

All were approved by the FDA, which means they had been proven to have some benefits for some patients. But none of them worked for Gwen, and she became a shadow of her former self, living her last months on earth in a limbo of a life, hoping one of these treatments would do some good.

Under current law, all patients in the U.S. have the right to try experimental drugs that have at least some evidence of safety and effectiveness. However, some people want to lower the standard to include treatments with no evidence that they work at all. Would this help patients like Gwen?

The **Goldwater Institute**, a conservative think tank that promotes “Right to Try” legislation, suggests that the government is to blame when patients die. In their fantasy world, experimental drugs that haven’t been proven to work for **any** patients will save the lives of thousands of desperately ill patients, if only the U.S. government would mind their own business and get out of the way.

Think about it. If patients can’t be saved by drugs that are proven to work, what’s the chances that an unproven experimental treatment will save them?

Many people don’t understand how the current system works and believe that “the government” unfairly keeps new drugs out of reach. As a result, Goldwater lobbyists have convinced more than 30 states to pass “Right to Try” laws. But there is no evidence of how many patients have benefited from these laws compared to how many have been harmed.

Now the Goldwater Institute is trying to convince Congress to pass a federal Right to Try law that is much, much more dangerous than the state laws. Here’s what they and their supporters are saying. Let’s set the record straight.

They say that the proposed federal law would merely give patients in all 50 states the rights that patients have in states with state Right to Try laws. NOT TRUE.

Under the state laws, companies can’t charge more for the investigational treatments than their “actual cost” to the manufacturer, because federal law prevents it. However, they are lobbying for a national Right to Try Act that allows companies to decide what they will charge for their experimental drugs. That means desperate patients and their frantic loved ones can be exploited by scam artists and greedy companies selling unproven treatments.

They say that “promising new treatments” take more than a decade to be approved by FDA. NOT TRUE.

Effective treatments may take a decade to develop, but that is not the fault of the FDA. The average drug is approved about a year after its pivotal studies are submitted to the FDA and at least as fast as in Europe.





They claim that the law would greatly increase the number of patients gaining access to promising experimental drugs. They complain that FDA is not allowing most patients to have access to experimental drugs through their Expanded Access program. NOT TRUE.

IS THE FEDERAL RIGHT TO TRY ACT HARMFUL FOR PATIENTS?

All terminally ill patients **already have a right to try** promising experimental drugs under FDA’s **Expanded Access Program**. This access is usually free.

This bill would give patients more access to other experimental treatments but **without the safeguards they have today**.

The proposed federal Right to Try Act would...

-  Make it easier for unethical companies or doctors to exploit desperate patients.
-  Allow companies to charge as much as they want for experimental drugs that may not work and could be fatal.
-  Prevent patients and family members from suing if the treatment harms or even kills them.
-  Prevent doctors and scientists from evaluating the benefit or harm of drugs given to Right to Try Patients.

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The FDA is approving 99% of the applications submitted to them by doctors whose patients want to participate in the program. Only 1,300 patients gained access to experimental drugs in 2015 because most doctors aren’t requesting it or because the companies that make those drugs may not have enough available, or they may believe that the specific patient requesting the drug is more likely to be harmed than helped by the drug.

They even give an inaccurate example. The Goldwater Institute has stated that “most” of the 78 patients treated by an “oncologist” under the Texas Right to Try law “are doing very well.” NOT TRUE.

The doctor they are referring to, Ebrahim Delpassand, is a radiologist, not an oncologist, and he has not said “most are doing very well.” He testified before the Senate that the treatment “has helped many” of the patients. He has refused to answer questions from skeptical reporters about exactly **how many** were helped **or hurt** by the treatments.

They say “something is wrong” because “fewer than one-tenth of 1 percent of terminal patients can take advantage of the FDA’s compassionate use exception.” NOT TRUE.

Experimental drugs are not proven to work or to be safe. Patients can die sooner and in agony from experimental drugs, especially those that have only gone through tiny, preliminary studies of a few healthy volunteers or patients (as the proposed national law would allow).

Only about 15% of the drugs that complete those types of preliminary studies are eventually proven to be safe or effective. The other 85% are either not safe, not effective, or both. **That is a very important reason why most patients (and their doctors) do not seek experimental treatments even when they know they can.**

Our patient protections are working. Major pharmaceutical companies are not lobbying for this legislation, but those who oppose FDA safeguards are. If you want to prevent the exploitation of desperate patients, contact your Senators and Congress and let them know you oppose a “Right to Try” federal law. ♦

Continued from Page 1

that the FDA does not require companies to test the ingredients in sunscreens to prove that they are safe and effective. Many of the active ingredients in sunscreens have been used for so long that they are generally **believed** to be safe and effective, but that is different from being **proven** to actually be safe and effective. For several years, the FDA has been working on a plan to start testing sunscreen ingredients for safety and effectiveness.

Consumer Reports rated the effectiveness of sunscreens but not their safety. This is the list of the top sunscreen lotions and sticks from their 2016 report. However, all of them are made with endocrine disrupting chemicals. The sunscreens that are made with the safer ingredients (zinc oxide and titanium dioxide) scored very poorly in the Consumer Reports report.

Lotions

1. La Roche-Posay Anthelios 60 Melt-in Sunscreen Milk (note that this is much more expensive than other sunscreens listed)
2. Pure Sun Defense Disney Frozen SPF 50
3. Coppertone Water Babies SPF 50
4. Equate (Walmart) Ultra Protection SPF 50
5. Ocean Potion Protect & Nourish SPF 30
6. Aveeno Protect + Hydrate SPF 30

Sticks

1. Coppertone kids stick SPF 55
2. Up & Up (Target) kids stick SPF 55

Lotion or Spray? Waterproof or Water-Resistant?

Avoid powder makeup and instead use liquid makeup products that contain SPF. Loose powders contain zinc and titanium that can be carcinogenic if inhaled. For this reason, the FDA no longer allows the manufacturing of powder make-up with SPF, but some of these products are still on the market.

In addition, be sure to avoid sunscreen sprays, especially for kids. Sprays make it easy to inhale the chemicals that are found in the sunscreens. This can pose a safety issue, especially for small children who tend to squirm a lot while sunscreen is put on them. The FDA has also expressed concern about sprays but has not yet limited their use. Sunscreen lotion provides better protection against burns that cause skin cancer and aging, without the risk of inhaling dangerous chemicals. If a spray sunscreen is the only available option, first spray it in your hands before applying it to children. Do the same before applying it to the face of adults.

Waterproof sunscreens are no longer for sale. The FDA issued new guidelines that sunscreens can only be labeled as “water resistant” and must say whether they protect for 40 or 80 minutes while sweating or swimming. So be sure to reapply your water resistant sunscreen right after getting out of the water.

Which Ingredients to Avoid?

Americans are using sunscreens more frequently and on a

longer-term basis than ever before. In the last few years, scientists have pointed out that we don’t know if sunscreens alone reduce the chances of developing skin cancer. The FDA has proposed new research to make sure that sunscreens do not contain ingredients that can be harmful and that sunscreens are actually effective, especially for infants, children, and pregnant women. However, the sunscreen products currently for sale haven’t been required to pass those tests.

Meanwhile, try to stay away from sunscreens with vitamin A or oxybenzone. Vitamin A is found in about 25% of sunscreens because manufacturers claim that it prevents skin aging. However, the National Institutes of Health (NIH) has shown that the combination of sunlight and vitamin A on the skin can increase your risk of cancer. The Environmental Working Group (EWG) recommends avoiding oxybenzone, which can potentially cause allergic reactions and interfere with hormones.

The Bottom Line


So what should you do to prevent sunburns, aging, and skin cancer? After getting your 15 minutes of sun, apply a generous amount of SPF 15 – 50 sunscreen lotion, wear a hat and sunglasses, and generally try to stay in the shade. Reapply your sunscreen after extended sun exposure, sweating, and swimming. Always check the expiration date on sunscreens before you buy and use them, and stay away from tanning beds and sun lamps. If you are fair-skinned or have a family history of skin cancer, be extra careful. ♦

CHOOSING YOUR SUNSCREEN

Wearing sunscreen is an essential part of protecting yourself from burns and skin cancer. Here's what you should look for when choosing your sunscreen:

- SPF 15-50**
 - Protects against burns, cancer, and aging
 - Higher SPF is not necessarily better
- BROAD SPECTRUM**
 - Protects against both UVA and UVB rays
- LOTION**
 - Protects better than sprays or powders
- NO VITAMIN A OR OXYBENZONE**
 - Vitamin A can cause cancer
 - Oxybenzone can cause allergic reactions

Remember to reapply every two hours or after getting out of the water for the best protection!

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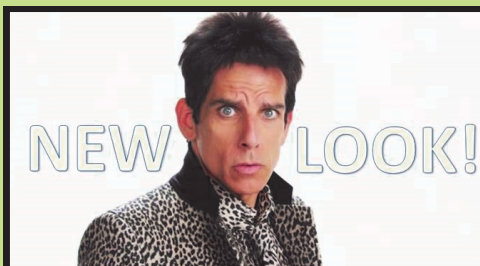
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