



CPR's THE VOICE for Women & Families


ARE MEDICAL PRODUCTS TESTED ON 'WHITES ONLY'?

By Diana Zuckerman, Ph.D., President, CPR for Women & Families

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The National Center for Policy Research (CPR) for Women & Families uses research-based information to promote the health and well-being of women, children and families.

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Everyone knows that medical products are supposed to be safe and effective in order to be sold in the U.S. Unfortunately, our Center's examination of medical product safeguards has found that the very laws that are designed to protect consumers have lots of loopholes – and many people are unaware of just how hazardous those loopholes can be.

For example, it's usually good to be colorblind, but not when safety studies are being conducted. The Food and Drug Administration (FDA) does not require that safety studies include African Americans, Asian Americans, or any specific racial or ethnic group – even when there is very good reason to believe that a product might be less safe for some groups than others.

The lack of racial minorities in safety testing recently came to our attention when we attended the FDA's February

the Plexiglas. Because Plexiglas is a foreign body, the body will produce its own collagen to surround each bead, 'plumping up' lines in the face.

While the long-term efficacy of Artefill is unknown, the study that Artes Medical conducted for the FDA is clearly troubling. The one-year study included only 115 women and men, a size too small to pick up on rare but serious side effects. In addition, the study included only one Asian American – and no African Americans.

Why are we concerned about Artefill? Although there are certainly more important medical products, Artefill is a prime example of a product that should be tested carefully on African Americans and Asian Americans. The study found a 16% adverse reaction rate during the first year, which included bumps and scarring,

The FDA doesn't take into account racial and ethnic differences when testing a product, although research has confirmed that some products may pose greater risks to different groups.

2003 review of Artefill (also called Artecoll), a permanent cosmetic treatment for facial scars and wrinkles. Artes Medical is seeking approval to sell the product in the U.S., and it's been hyped as the 'next Botox.'

Artefill is a mixture of collagen from cows and Plexiglas beads. It hardly sounds like a beauty product, but Artes Medical claims that the trick to Artefill is

complications that are likely to be more common among African and Asian Americans than Whites, since both racial groups tend to scar more noticeably. African Americans are also more susceptible to autoimmune diseases.

Despite the lack of safety information for racial minorities, the FDA committee voted to recommend approval. While the committee recommended that the FDA

BREAST IMPLANT SAFETY QUESTIONED

It's been more than a decade since breast implant horror stories first surfaced. Many people think that the dangers of breast implants are yesterday's news. Little do they know that the surgeries — and problems — are more common than ever.

Last year alone, more than 236,000 women received implants to increase their breast size, and 40,000 received implants after a mastectomy. The number of women and teenage girls who underwent breast augmentation surgery more than doubled between 1997 and 2002. At the same time, the

The scientists described the growing research evidence of problems caused by breast implants and the shortcomings of research claiming to prove that implants are safe.

number of women getting their implants removed is also higher than ever — more than 60,000 last year.

Clearly, business is booming for plastic surgeons and implant manufacturers — but are implants a safe bet? Is there reason to be concerned that increasing numbers of women with implants will be diagnosed with serious illnesses in the years to come?

To answer that question, scientists gathered in Washington, DC in May 2003 at the first scientific meeting in the last decade featuring independent research on breast implants. At the conference, sponsored by the National Organization for Women (NOW), scientists described the growing body of evidence revealing problems caused by breast implants and the shortcomings of the research claiming that implants are safe.

The FDA's Dr. S. Lori Brown described her study of women with silicone gel implants, which found that most women had at least one broken implant after 11 years. One in five had at least one implant

that was leaking liquid silicone from the implant. Dr. Terrance O'Hanlon, from the National Institute of Environmental Health Sciences, described pathology reports that found silicone in the tissue surrounding breast implants, and also described an "immunological link" between silicone from women's implants and their autoimmune diseases.

Dr. William Katzin of Case Western Reserve School of Medicine reported finding silicone oil, gel, and pieces of the implant's shell in the lymph nodes of women who had silicone breast

implants. Dr. Ernest Lykissa, formerly of Baylor College of Medicine, and Dr. Michael Harbut, of Wayne State University, explained that the tiny amounts of platinum from the implant shell were highly toxic and could account for some of the illness among women with implants.

"It's very worrisome that the studies showing silicone in women's lymph nodes haven't been publicized," says Dr. Diana Zuckerman, CPR's President. "Studies conducted by NIH and FDA scientists indicate potentially fatal health risks, yet the FDA does not seem to be considering their findings as they review the safety of breast implants."

"The results of the studies were consistent with the mail we receive from implant patients," explains Liz Nagelin-Anderson, a Public Policy Fellow at CPR. "So many of the women who contact us have fibromyalgia-type pain. Every week we hear from women with leaking implants who don't have the money to have their implants removed. I hope that this research can be used to address an issue that has harmed the health of so many women."

What's Known — and Not Known — About Breast Implants

Research presented at the recent scientific conference indicates serious problems. The FDA has reported an increased risk of fibromyalgia and other serious autoimmune diseases among women with leaking silicone implants. The National Cancer Institute reported an increase in deaths from brain and lung cancers and suicide compared to other plastic surgery patients, and a recent Swedish study found an increased risk for lung cancer and suicide for women with implants compared to other women their age.

Why are these new study results so different from other studies of breast implants? Dr. Diana Zuckerman, CPR's President, explained at the conference that there are serious shortcomings in the research that was summarized by the Institute of Medicine and other reports several years ago.

These shortcomings include:

- **Studies that have too few women with implants to study rare diseases.** For example, the study by Dr. Sara Strom compared women with rheumatological diseases with women without diseases, and only one woman with implants was in the study.
- **The women in the studies didn't have implants long enough to develop a disease.** For example, a study by Dr. Mark Schusterman included women who had breast implants for less than 2 years. Most autoimmune diseases take much longer than just 2 years to develop and be diagnosed.
- **Studies did not include a medical exam of the women with implants.** Most of the studies relied on medical records, some on hospitalization records, and a few on self-reported illness. The most objective, reliable measure would be by a physician who was unaware of whether the woman had implants or not.
- **Studies only evaluated a few, classically diagnosed diseases, not the kinds of symptoms that are most widely reported by women with implants, such as pain, memory loss, and fatigue.**

For more information: www.breastimplantinfo.org

DO VIOLENT SONGS INFLUENCE KIDS?

Although Eminem and other rappers have attracted a great deal of attention for violent song lyrics, little is known about the impact of their music. In contrast, there are hundreds of studies showing that violence in movies and TV can make kids and young adults think and behave more violently, and a growing number of studies show similar problems resulting from violent computer games and videogames.

Are violent songs as influential as these other media? Favorite songs may be listened to hundreds of times and can have a strong emotional impact. On the other hand, there is no visual impact, and some kids may not even listen to the lyrics.

Research has shown that kids who enjoy or listen to heavy metal and rap music tend to be more hostile, have negative attitudes toward women, have lower academic performance, exhibit behavior problems in school, and are more at risk for drug use and arrests. However, those studies couldn't tell us if kids with these problems chose to listen

to violent songs or if the song lyrics actually influenced the kids.

In April 2003, several published studies of Midwestern college students by psychologist Dr. Craig Anderson and his colleagues at Iowa State University attempted to answer that question. They found that exposing students to violent lyrics increased the students' feelings of hostility and apparently increased the chances of responding to ambiguous situations as if they were hostile. This study was important because the kids did not choose the songs: they were asked to listen to them as part of the studies. However, the studies didn't examine how long-term the impact was, or whether repeated exposure would make the listener even more hostile. Violent **behavior** was not evaluated.

The bottom line: kids are influenced by what they see and hear. That can be good for parents and teachers who are trying to influence kids in positive ways, but can cause problems in a culture where kids are exposed to so many violent programs, games, and music.

How You Can Make A Difference

Many of our readers have asked us how they can help make sure we continue our work. Here are three of the many ways you can help:

This one is easy: If you have a cellular phone that you aren't using, you can drop it off at our office OR contact us at info@center4policy.org. If you email us, we will send you a free, postage-paid box to ship your phone to WirelessFundraiser.com. They will recycle the phone and send us a donation for each phone donated. It's easy-- and free!

This one is almost as easy: If you have a car or other vehicle that you would like to donate, that is another great way to help CPR. Just contact us at info@center4policy.org.

This one is more serious: Many of us would like to leave a lasting legacy to contribute to causes that we care about. Please let us know if you would like to make a gift to CPR in your will, and we will be glad to help you, so you may continue to help women and families.

Thanks to all of you for your support. We couldn't do it all without you! Please contact Nikki at (202) 223-4000 if you would like more information about helping to support CPR.

Are Medical Products Safe for 'Whites Only'?

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require additional research to determine long-term safety, they did not require safety data for African Americans or Asian Americans – even when I asked at an FDA public meeting how the FDA could possibly approve a medical product that was tested on "Whites only." Meanwhile, the FDA issued *A Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials*. These guidelines for all FDA studies merely encourage manufacturers to identify the race and ethnicity of men and women participating in clinical trials. The FDA has no plans to *require* that racial or ethnic groups be studied to find out if the product is safe for them.

In an effort to remedy the situation, CPR joined with the National Medical Association, expressing our concerns to FDA Commissioner Dr. Mark McClellan. Our letter, cosigned by Dr. L. Natalie Carroll, President of the National Medical Association, stated that the FDA, like the National Institutes of Health, should be required to make sure that medical treatments are safe and effective for all Americans.

Our concerns also sent us to Capitol Hill, where CPR Advisory Board member Dr. Shari Miles and I met with Congresswoman Donna Christian-Christianson, chair of the Congressional Black Caucus Health Braintrust. As a physician, Dr. Christianson clearly understands how dangerous it can be to approve drugs, vaccines, and medical devices based on their safety and effectiveness for Whites only. Representative Christianson also wrote to the FDA Commissioner, and her letter was cosigned by 26 members of the Congressional Black Caucus.

'Whites only' studies are not acceptable in any day and age – and certainly not now. That's why CPR is working with Congress, the FDA, and other organizations interested in improving medical care to change these policies.

MEDICARE MAKEOVER

Hold on to your hats, because the Bush Administration is trying to reform the two largest government health care programs. Don't let your eyes glaze over, because the results could affect you, your friends, and your family.

The program currently being debated is Medicare, which provides health care for retired and disabled adults. The Bush Administration has pledged to add a prescription drug benefit to the health care plan, and lawmakers on the Hill have been burning the midnight oil in an effort to find an affordable way to do that.

Every U.S. citizen who earns a salary helps pay for Medicare — to the tune of 2.9% per paycheck (half paid by the employee and half by the employer). In return, Medicare has saved lives by making medical care affordable for elderly and disabled adults, 56% of whom are women.

Medicare was created in 1965 because private companies did not offer affordable health insurance to older people. Medicare is a two-part system. Part A, hospital insurance, covers inpatient, hospice, and some home care. Part B, medical insurance, covers outpatient services, such as doctor's visits. The program's greatest shortcoming is that it doesn't cover the cost of prescription drugs unless they are taken while in the hospital. With the cost of pharmaceuticals skyrocketing, many seniors must choose between paying for food and paying for medications. But with a huge deficit, and baby boomers soon to become Medicare patients, how can Congress find the money to expand Medicare?

The House and Senate each passed a "Prescription Drug bill" in June 2003 that would change Medicare in many

ways — not just by adding coverage for prescription drugs. The House and Senate bills differ substantially, and now Congress faces a formidable challenge to reach a compromise that can pass. What will the compromise look like? It's not too late to make sure that your Senators and Representatives know what you think the bill should include.

There is good news and bad news in both the House and Senate bills. Some people would benefit more than others, but here are some highlights:

■ **The good news is that both the House and Senate versions of the bill would help most people on Medicare who have very high prescription drug costs.** However, coverage is not free and only makes sense for those who know their prescription drug costs will be

There is good news and bad news in both the House and Senate Medicare bills.

high. To buy prescription drug coverage, each person would have to pay a monthly fee, a deductible, and co-payments. They would have to pay approximately \$775 under the House bill or \$1115 under the Senate bill before this plan would save them any money on their prescriptions.

■ **The bad news is that both bills rely on private insurance companies to provide prescription drug coverage, instead of Medicare.** Remember that Medicare was started because insurance companies did not sell affordable policies to seniors. Under both House and Senate bills, insurance companies would decide the monthly charge for the prescription drug benefit. So, it is not clear whether private insurance companies will want to offer prescription drug benefits to seniors, and if they do, whether they will make it

affordable for most people. Congress estimates an average cost of \$420 per year just to buy the insurance, but nobody knows what the real cost will be.

■ **Benefits differ substantially in the House and Senate bills.** For example, the House bill would require beneficiaries to pay 20% of the cost of each drug, compared to 50% for the Senate bill. These co-payments would be for the first several thousand dollars of drug expenses, and then 90% of the costs would be covered in the Senate bill and 100% would be covered in the House bill.

■ **Both bills would increase the cost of traditional Medicare,** but the House bill would do it sooner. Both dramatically increase the deductible for outpatient treatment, the House starting immediately and the Senate in 2006.

■ **The House bill does not guarantee that a drug benefit would be available in every community,** unlike the Senate bill.

■ **And what about Medicaid?** Medicaid is the health program available for low-income individuals and families, such as those on welfare or disabled children. The Bush Administration hopes to reform Medicaid this fall, after signing a new Medicare law. Stay-tuned: We'll tell you all about it in the next issue of *The Voice for Women & Families*.

For more information about how to make your voice heard in these policy decisions, please go to www.center4policy.org/difference.html for information on how to contact your Congressional representatives.

ART CAPLAN: CPR BOARD MEMBER TALKS ABOUT ETHICS, SCIENCE, AND PUBLIC POLICY



Dr. Arthur Caplan

Making scientific research more accessible and more influential in policy-making is a mission of CPR for Women & Families, and of CPR's board member, Arthur Caplan, Ph.D., one of the world's leading experts in the field of bioethics. Dr. Caplan is currently the Director of the Center for Bioethics at the University of Pennsylvania, as well as the Emmanuel and Robert Hart Professor of Bioethics and Chair of the Department of Medical Ethics.

There is little armchair science in this doctor's office. Dr. Caplan works to improve public policy by promoting decision-making based on scientific knowledge. Notes Dr. Caplan, "While people might think that a bioethicist simply philosophizes about ethical issues, that's not the case. I'm actively involved in creating a stronger link

"I believe that the public should be made aware of bioethics issues, and given the opportunity to decide what to do about them." -- Dr. Art Caplan

between biological research and public policy. That is why I am glad to be on the board of CPR. They work hard to make sure that policy decisions rest on a strong empirical basis."

Dr. Caplan has a broad range of interests, bringing his expertise and energy to many hotly debated topics. Not only did he chair the committee advising the

United Nations on the issue of human cloning, Dr. Caplan also served as chairman for the advisory committee on blood safety and availability to the U.S. Department of Health and Human Services. In addition, Dr. Caplan participated in a special advisory committee on genetics and gene therapy for the International Olympic Committee, the organization overseeing the Olympic Games. Currently, he has been studying policies for the recruitment of organ donors, the ethical implications of conducting research in third world countries, and — as he says wryly — "less controversial issues, like stem cell research and human cloning."

As an internationally respected scientific leader, Dr. Caplan brings bioethics issues into popular discourse, authoring books for the general public, writing a regular column for msnbc.com, and working frequently with the news media. "I believe that the public should be made aware of bioethics issues and given the opportunity to decide what to do about them. I like to encourage public debate on these topics."

Dr. Caplan notes that women and families aren't as well-represented or strongly positioned in policy debates as they should be. While there is a great

deal of research on families, it seems to rarely enter into policy discussions — often because the science is not translated into easy-to-use language. "CPR is committed to doing something about the gap between what science says women and families need and the policies that are currently in place. I strongly support that goal."

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OBESITY AND KIDS' LIVES



Photo by Liz Nagelin-Anderson

Cookies, candy and other fattening temptations are everywhere.

At the same time that millions of Americans are obsessed with their diets, obesity has become a serious public health problem. Unfortunately, the scales aren't off the charts for grownups only; our kids are getting heavier, too.

Obesity among kids between the ages of 6 and 19 has tripled since the 1960's. Today, 30% of kids in America are overweight. Of that 30%, half of the children are very overweight – for example, a 10-year-old who is only four and a half feet tall, but weighs more than 100 pounds.

Obese children are at increased risk of hypertension, diabetes, sleep disturbances, liver disease, and early puberty. CPR is not only interested in the consequences of obesity for children's health, but its emotional repercussions too. This concern is shared by one of our new Research Network members, Dr. Jeffrey Schwimmer, Assistant Professor of Pediatrics at the University of California, San Diego.

Dr. Schwimmer conducted a recent study based on samples of children ages 5 through 18 in southern California. The study confirmed that obese children have a much lower quality of life than their healthy classmates – they are more likely to have impaired agility, emotional well-being, peer relationships,

and school functioning. Obese children also missed three more days of school each month, on average, than healthy children.

In fact, Dr. Schwimmer found that obese children have a quality of life equivalent to children who have cancer and are undergoing chemotherapy. This finding is especially disturbing, since children with cancer tend to have the lowest health-related quality of life compared to other children, even those with other chronic diseases.

"What our data suggest," he says, "is that when children reach a certain degree of obesity, the condition becomes the focal point of their lives. It affects the way they interact with the world and the way the world interacts with them."

Obesity is a controversial issue. Although the health risks of obesity are

"When children reach a certain degree of obesity, the condition becomes the focal point of their lives." -- Dr. Jeffrey Schwimmer

worrisome, some experts are concerned that focusing on obesity will contribute to eating disorders and an increased societal emphasis on the thin body ideal. In addition, there is prejudice against people who are overweight, with many believing that obesity is a sign of laziness or a lack of willpower. "This makes it difficult to treat obesity as a societal – rather than an individual – problem," Dr. Schwimmer points out. "If we refocus our discussion on the consequences that obesity has for individuals' health and happiness, we will be better able to come up with a clear strategy to address this problem."

Health and happiness aren't the only concerns; childhood obesity is also expensive. Dr. Schwimmer notes that recent estimates place the costs of obesity

in the U.S. at \$117 billion per year – and these estimates are based only on adult obesity. "At least one-third of obese adults were obese in childhood," explains Dr. Schwimmer. The figure is closer to one-half for severely obese adults. So in the long-term, obese children and adolescents are in large part driving the health care costs of obesity in the nation. "The rates of obesity have tripled in 25 years. What does that suggest for the future?" Dr. Schwimmer asks.

CPR for Women & Families is examining potential policy solutions, ranging from policies to promote healthier eating habits, increase exercise, decrease junk food in schools, and improve access to treatment. For example, most insurance companies do not cover the treatment or prevention of obesity itself, although they pick up the

costs of its complications, like diabetes, liver problems, and joint trouble. "Our country could help these children through public policies that prevent obesity, by helping kids develop better exercise and eating habits, and by making obesity treatments more available and affordable," comments Dr. Jennifer Brooks, CPR's Senior Policy Research Associate.

"Many kids can be and are effectively treated for obesity. We still have a lot to learn, though, and we need greater coverage and availability of treatment programs," concludes Dr. Schwimmer.

MEET OUR NEW CAMPUS PARTNERS

"We are so impressed by our affiliates. I am very proud to share the latest news from our campus partners at Mills College and Kent State University."

-- Diana Zuckerman, President, CPR



Dr. Margo Okazawa-Rey, Director, WLI

The Women's Leadership Institute (WLI) at Mills College in Oakland, California is a "think and do tank," says Dr. Margo Okazawa-Rey, WLI's Director. "Through a multicultural, interdisciplinary emphasis on scholarship and activism, WLI aims to strengthen women's capacity to influence their communities, our nation, and the world." Some of the highlights of WLI's programs are:

- **The Visiting Scholars** program provides a stimulating environment for younger scholars to increase their progress in the academic world, with an emphasis on supporting women of color. WLI offers research stipends to scholars so they may conduct research. In addition, unpaid placements are available for advocacy and arts projects. After their year at Mills College, scholars will have accomplishments that boost their chances for tenure and promotion.

- **New Generation of Campus Leaders** is designed to prepare students to become future leaders in their communities. The program sponsors workshops, film series, and campus events for students linked to the theme, *Women Redefining Security*. The program also enables students to play hands-on

leadership roles by planning Institute events. Visiting Scholars hold regular office hours to talk to students, and invite them to attend professional engagements and networking events.

- **Transformative Community Leadership** is provided by a multiracial, intergenerational group of women community activists. They develop practical models for conceptualizing, creating and maintaining effective grassroots organizations. In collaboration with community advocates and leaders, WLI conducts workshops, creates syllabi, and produces study materials. In addition, WLI facilitates discussion-and-strategy sessions for women activists and leaders.

"Our programs offer many opportunities for women. WLI helps students prepare for leadership, supports scholars in their academic pursuits, and collaborates with grassroots organizations so they may better serve their communities," notes Dr. Okazawa-Rey.



Aleksandra Bednarowska, Director, WRC

The Women's Resource Center (WRC) at Kent State University serves the day-to-day needs of women and supports women participating in campus and community leadership roles.

"We founded our Center because we believed there was a need for a space in which women could work on improving the visibility of women and focus on the needs and accomplishments of women

at the University and in the local community," explains Aleksandra Bednarowska, the Center's Director.

- **In an effort to support women in the professional sector**, WRC organizes luncheons, silent auctions, book-signings and dinners, so women may come together to network, share information, and offer professional support. WRC has also created and supported a women's scholarship fund in an effort to increase women's higher education opportunities.

- **WRC founded a domestic and dating violence program**, which offers support networks, workshops, and training for women on campus and in the community. For her work on violence prevention, Ms. Bednarowska received The Fruit of Her Hands Award from the Black Church and Domestic Violence Institute in Atlanta.

- **The Center's health program promotes breast cancer education, treatment, and prevention.** The Center also offers regular mammogram screenings. The Cleveland portion of "Race for the Cure," a national breast cancer fundraiser, is organized by the staff of the Center and Kent State University. Women and men from WRC, Kent State, and the community at large participate as a team in the race. Currently, CPR hopes to partner with WRC, working together through CPR's public education project *Breast Cancer Patients Have Options*.

"I am very proud of what we have accomplished since our founding in 1996. We have been able to offer a multitude of services to help improve the lives of women. We look forward to growing our services to continue to meet the needs of women in our community," concluded Ms. Bednarowska.

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AND MORE!

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