Newsletter

Prostate Cancer 101, Inc.

http://prostatecancer101.org

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The Prostate Cancer Information and Support Group of the Mid-Hudson

Men's Health Supplements Don't Benefit Prostate Cancer Patients: Study Research suggests these products won't cut risk of disease spread or death

By Alan Mozes

HealthDay Reporter

Oct. 19, 2015 (HealthDay News) -- A new study finds no evidence that men's health supplements help prostate cancer patients.

Although popular, such supplements do not appear to lower the risk for experiencing radiation treatment side effects; the risk that localized cancer will spread; or the risk that prostate cancer patients will die from their disease, researchers found.

The study focused on supplement use among more than 2,200 men newly diagnosed with localized prostate cancer.

"We suspected that these pills were junk. Our study confirmed our suspicion," said study lead author Dr. Nicholas Zaorsky, resident physician in radiation oncology at the Fox Chase Cancer Center in Philadelphia.

Roughly one in two new cancer patients tries some type of dietary supplementation, often without their doctor's knowledge, the study authors say.

For this study, the pills in question were marketed as "men's formula" or "prostate health," often labeled with "clinically proven" or "recommended by urologists" on the bottle, Zaorsky said.

"We're talking about pills that are subject to very limited oversight and have never been studied," Zaorsky said.

The patients in this study were 36 and older, and underwent radiation treatment sometime between 2001 and 2012.

About 10 percent were taking one or more of roughly 50 different men's health supplements either during treatment or in the ensuing four years, Zaorsky said.

Many products bore the wording "clinically proven," or suggested they had anti-cancer benefits, without indicating what had been proven. None of the various brand formulations had been studied in a clinical trial, the study authors said.

More than 90 percent of the supplements contained saw palmetto. This plant extract is often promoted -- without definitive proof -- as a treatment for an enlarged prostate. Some ingredients (sometimes listed as "other" or "trade secret enzyme") remained unidentifiable, the researchers said.

Supplement use was not associated with any negative side effects. But after accounting for lifestyle factors such as exercise, diet and smoking, overall survival was no better for supplement users. And by every other measure, the research team concluded that men's health supplements offered no benefit with respect to prostate cancer outcomes.

Duffy MacKay, senior vice president of scientific and regulatory affairs for the Council for Responsible Nutrition, a trade association for the dietary supplement industry, disagreed with the findings.

MacKay said that most of the main ingredients in men's supplements have demonstrated significant health benefits in clinical trials, though not necessarily prostate cancer trials. Moreover, the study's assertions are the product of 'someone with a conclusion in search of data,' he said. 'I don't know what research databases they're looking at," MacKay said. 'But they are not offering scientific evidence to support their position. And none of these products claim to treat disease. They're not allowed to."

MacKay added that the council encourages responsible supplement messaging, and recommends that patients talk to their doctors about whatever supplements they're using.

Dietary supplements are not subject to the same clinical trial review process that governs conventional drugs in the United States. The 1994 Dietary Supplement Health and Education Act places the burden of safety solely on the shoulders of supplement makers themselves.

Facilities involved in manufacturing dietary supplements must register with the U.S. Food and Drug Administration, but manufacturers and distributors are on the honor system when it comes to the truth of labeling claims.

Dr. Stephen Freedland, director of the Center for Integrated Research in Cancer and Lifestyle at Cedars-Sinai Medical Center in Los Angeles, said he does not recommend supplements to his patients.

'There is a growing number of studies that show they have no benefit, and may actually do harm,' he said. Often, 'patients don't understand the nuances of the claims being made.

'Maybe [some of these claims are] not mislabeling," Freedland added. 'But it's misleading."

The findings were presented Sunday at the annual meeting of the American Society for Radiation Oncology, in San Antonio. Research presented at meetings should be considered preliminary until published in a peer-reviewed medical journal.

More information

There's more on dietary supplement regulations at the U.S. Food and Drug Administration.

Source: Prostate Cancer Foundation http://www.pcf.org/site/c.leJRIROrEpH/b.9318881/k.86B0/Mens_Health_Supplements_Dont_Benefit_Prostate_Cancer_Patients_Study.htm?msource=oct15np&auid=16136513

Our condolences to the family of Richard Kowalski, a member of PCa 101. Thank you for remembering us in Dick's obituary and in the notice to his friends. His memory will continue doing good for others.

Merry Christmas

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Drug candidate kills cancer cells through overstimulation Cell Press

Credit: Lei Wang

A drug candidate that overstimulates proteins crucial for tumor growth shows promise as a new strategy to treat a wide range of cancers. The demands of rapid cell division put a strain on cancer cells, and the approach works by tipping cell stress over the edge. In the August 10 issue of *Cancer Cell*, American researchers show that the drug candidate inhibits tumor growth in a mouse model of breast cancer and efficiently kills a broad range of human cancer cells.

"No prior drug has been previously developed or proposed that actually stimulates an oncogene to promote therapy," says co-senior study author David Lonard of Baylor College of Medicine. "Our prototype drug works in multiple types of cancers and encourages us that this could be a more general addition to the cancer drug arsenal."
Because cancer cells acquire mutations in oncogenes--genes that can transform cells into cancer cells--to support their growth and survival, a great deal of research has focused on identifying oncogenes that could be targeted by cancer drugs. Members of the steroid receptor coactivator (SRC) family of oncogenes are especially promising as therapeutic targets because these proteins sit at the nexus of key signaling pathways that cancer cells use to quickly grow, spread to other tissues, and acquire drug resistance. In a previous study, Lonard and co-senior study author Bert O'Malley of Baylor College of Medicine screened a large number of compounds to identify SRC-inhibiting molecules that kill a wide variety of cancer cells and inhibit tumor growth in animal models.

These compounds are similar to conventional therapies designed to inhibit the activity of key cancer oncogenes. But Lonard and O'Malley had a counterintuitive idea: what if they could disrupt key signaling pathways and kill cancer cells by overstimulating SRCs? After all, cancer cells rely heavily on SRCs to delicately orchestrate a wide range of cellular events, so SRC stimulation might be just as effective as SRC inhibition at disrupting the balance of signaling activity in cancer cells.

To test this idea, they screened hundreds of thousands of compounds to identify a potent SRC activator called MCB-613. This compound killed human breast, prostate, lung, and liver cancer cells, while sparing normal cells. When the researchers administered MCB-613 to 13 mice with breast cancer, the drug candidate almost completely eliminated tumor growth without causing toxicity, whereas tumors continued to grow by about 3-fold over 7 weeks in the control group of 14 mice.

MCB-613 killed cancer cells by causing the accumulation of unfolded proteins in a cell structure called the endoplasmic reticulum (ER). To support their rapid proliferation, cancer cells must synthesize a large number of proteins, putting a strain on the ER to keep up with its heavy workload of properly folding proteins. Overstimulation of SRCs places extra demands on the ER when it is already operating at maximum capacity, causing the accumulation of a large number of unfolded proteins. This triggers a cell stress response that in turn causes the build-up of toxic molecules called reactive oxygen species.

Taken together, the findings suggest that elevating SRC activity beyond the already high levels present in cancer cells further pressures their maximized stress response system and selectively kills them. In future studies, the researchers will continue to explore the mechanisms by which SRCs kill cancer cells and will screen for even better SRC activators. "We are optimistic that these drugs will eventually find their way into the clinic for use in patients," O'Malley says.
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This work was supported by funding from the Susan G. Komen Foundation, the Prostate Cancer Foundation, the Clayton Foundation, the Dunn Foundation, the Department of Defense Breast Cancer Re-

search Program, the Cancer Prevention and Research Institute of Texas, and the National Institutes of Health. Several authors are co-founders and hold stock in Coregon, Inc., which is developing steroid receptor coactivator stimulators for clinical use.

Cancer Cell, Wang et al.: "Characterization of a Steroid Receptor Coactivator Small Molecule Stimulator that Overstimulates Cancer Cells and Leads to Cell Stress and Death"

Cancer Cell, published by Cell Press, is a monthly journal that provides a high-profile forum to promote major advances in cancer research and oncology. The journal covers topics related to molecular and cellular mechanisms of cancer, mechanisms for the sensitivity and the resistance to cancer therapies, development of better cancer therapies, and clinical investigations.

For more information, please visit http://www.cell.com/cancer-cell. To receive media alerts for *Cancer Cell* or other Cell Press journals, contact press@cell.com.

Source: http://www.eurekalert.org/pub_releases/2015-08/cp-dc080415.php

Prostate Cancer Screening, Detection Both Down in U.S., Studies Say. But whether that's good or bad isn't yet clear

By Amy Norton
HealthDay Reporter

Nov. 17, 2015 (HealthDay News) -- Fewer U.S. men are being screened for prostate cancer, and fewer cases of the disease are being diagnosed nationwide, according to two studies published Tuesday.

The big question, researchers said, is whether that trend is bad news or a step in the right direction.

At issue is the prostate-specific antigen, or PSA, test. For years in the United States, men age 50 and older routinely underwent PSA screening to help detect early prostate cancer.

But in 2012, the U.S. Preventive Services Task Force (USPSTF) -- a panel that advises the federal government -- came out against routine PSA screening.

The panel cited evidence that screening might do more harm than good: Prostate cancer is often slow-growing, and may never advance to the point where it threatens a man's life. So men diagnosed with early prostate tumors might needlessly be subjected to surgery, radiation and other treatments that can cause lingering side effects such as impotence and incontinence, the researchers said.

The two new studies, published Nov. 17 in the Journal of the American Medical Association, suggest that the USPSTF recommendations have had an impact.

In one study, researchers with the American Cancer Society (ACS) found that in 2013, 31 percent of U.S. men age 50 and older said they'd had a PSA test in the past year. That was down from 38 percent in 2010, and about 41 percent in 2008 -- the year the USPSTF began advising against routine PSA testing for men ages 75 and up.

At the same time, diagnoses of prostate cancer declined nationwide -- from more than 213,000 men in 2011, to about 180,000 in 2012.

The second study, by researchers from Brigham and Women's Hospital and Dana-Farber Cancer Institute in Boston, and Henry Ford Health System in Detroit, looked only at screening rates and found a similar pattern. The largest decline in PSA screening was among men ages 60 to 64: In 2010, 45 percent underwent screening, versus 35 percent in 2013. Men ages 50 to 54 also saw a big decline, with just 18 percent getting a PSA test in 2013 compared to 23 percent in 2010.

"The decline in incidence and the decline in the proportion of men getting screened likely means that doctors and patients are beginning to understand that it's not known whether prostate

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cancer screening saves lives," said Dr. Otis Brawley, the chief medical officer for the ACS.

On the other hand, Brawley said, it's clear that PSA screening can do harm.
"One of the things we do know," he said, "is that screening is more likely to diagnose the kind of [prostate] cancer that is not a threat to health and does not need treatment."

There have been 11 clinical trials testing the effects of PSA screening, Brawley said, and only two have found benefits for men's lives. "But all 11 show harms associated with screening," he added.

Others, however, were more worried about the trends in the ACS report.

"This study raises a troubling suggestion that we may be missing patients we want to find with screening," said Dr. Richard Greenberg, chief of urologic oncology at Fox Chase Cancer Center, in Philadelphia.

"Specifically, younger men who are currently not getting screened may have cancer 10 years from now that is no longer curable," Greenberg said.

Dr. David Penson, a urologic surgeon at Vanderbilt University, in Nashville, Tenn., also expressed concerns.

"We don't know how this will all play out," said Penson, who wrote an editorial published with the studies. "But I'd be willing to bet that this will be followed by an increase in prostate cancer mortality."

Penson agreed that in years past, PSA screening was probably overused. But the pendulum may be swinging too far in the other direction, he said.
"I would argue that we need to land somewhere in between," he said.

What's needed, according to Penson, is more research to better define which men are higher-risk and could benefit from more -intensive PSA screening. He pointed to one study from Sweden that found that a man's PSA level in his late 40s might help predict his risk of developing prostate cancer later in life.

That raises the possibility that a single PSA measurement at a relatively young age could help doctors figure out when and how often to do further testing, according to Penson.

Another way to address the issue is to further reduce "overtreatment" of prostate cancer. Men diagnosed with small, nonaggressive tumors do not have to be treated right away, Penson pointed out.

"They can opt for active surveillance," he said. "More and more men with low-risk prostate cancer are doing that."

Active surveillance means that a man's cancer is monitored over time, using PSA tests and possibly biopsies of the tumor.

For now, all three experts suggested that men talk with their doctors about the benefits and risks of PSA screening.

"I do hope physicians are talking to their patients and letting the patient decide whether or not to be screened," Brawley said.

For most men that discussion should begin at age 50, according to the American Cancer Society. But men at increased risk should talk to their doctors starting at age 45, Brawley said. That includes black men and those with a brother or father who developed prostate cancer before the age of 65, according to the American Cancer Society.

Source:
http://www.pcf.org/site/c.leJRIROrEpH/b.9351447/k.E2A7/Prostate_Cancer_Screening_Detection_Both_Down_in_US_Studies_Say.htm?msource=NOV15NP&tr=y&auid=16262988

Prostate Cancer Foundation

High-Intensity Ultrasound Device for Prostate Surgery Clears FDA Hurdle

Tony Berberabe, MPH @OncBiz_Wiz
Published Online: Tuesday, October 13, 2015

The FDA has issued a *de novo* clearance for a minimally invasive high-intensity focused ultrasound (HIFU) device called Sonablate 450 for prostate tissue ablation. The device is intended for patients with low- to high-risk prostate cancer with a PSA lower than 10 ng/mL who have progressed on external beam radiation therapy

The FDA's decision marks the first approved device to use HIFU technology in the United States, despite its approval in 49 other countries around the world, according to a statement issued by SonaCare Medical, the company manufacturing Sonablate 450.

"Until now, this technology was not available in the United States," said Herbert Lepor, MD, professor and Martin Spatz Chairman, Department of Urology, New York University School of Medicine, in a statement. "It is anticipated that ablative urological surgeons in the US will quickly master and adapt this technology for their patients. HIFU offers the opportunity for the precise delivery of ablative energy to the prostate. Thus, it can be adapted to whole gland or focal gland ablation."

Sonablate 450 features a fully integrated probe with dual ablation transducers. With the device, ultrasound energy is focused at a specific location in the prostate gland called the focal point, which is heated to nearly 195 degrees Fahrenheit (90 degrees Celsius). The tissue at the focal point is destroyed, but the tissue surrounding the area remains unharmed. Because the technology uses ultrasound energy not radiation to destroy targeted tissue the procedure can be repeated, if necessary.

The minimally invasive procedure can be used to perform prostate ablations that urologists routinely perform on prostate glands up to 40cc without previously performing a TURP (transurethral resection of the prostate) procedure. Tissue analysis is conducted via radio frequency (RF). An RF signal is sent to a targeted ablation site prior to delivery of HIFU and then another signal is sent after delivery of HIFU to the same site. The device calculates the change that

took place and displays it on the screen. Tissue changes are quantified based on a comparison of RF ultrasound pulse-echo signals at each ablation site.

"I believe that we are at a pivotal point in prostate care," said Michael Koch, MD, who was a clinical trial investigator and is chairman of the Department of Urology at Indiana University, said in a statement. "Simultaneous advances in imaging, fusion technologies, and now more focused therapies are going to allow us to precisely diagnose prostate conditions, and ablate these targeted areas rather than perform whole gland prostate surgery, which carries a significant burden on quality of life. HIFU will become the work-horse of subtotal prostate therapy."

The positive decision for Sonablate 450 was preceded by a negative vote from the FDA's Gastroenterology and Urology Devices Panel in October 2014. At this hearing, the panel expressed desires to review further data on the HIFU device. Data reviewed by the FDA and its advisory panel were from the first 100 patients in a 200 patients trial. The mean age of patients in the trial was 69.7 years and the mean pretreatment PSA was 4.9 ng/mL.

In those treated with Sonablate 450 (n = 100), 50% obtained local control of the disease, which was defined as a PSA nadir of 0.5 ng/mL or lower along with a negative biopsy at 12 months (97.06% CI, 0.39-0.61; *P* = .0206). In those with biopsy results at 12 months (n = 78), the local control rate jumped to 64.1% (97.06% CI, 0.52-076; *P* = .0001), which passed the bar for significance, which was set at a local control rate of 40%.

Grade I adverse events (AEs) related to HIFU were seen in 67.2% of participants. Grade 2 AEs were experienced by 81% and grade 3 AEs were seen in 23.3% of patients. The most common all-grade AEs were urinary tract infection (49.1%), incontinence (44.8%), urinary retention (41.4%), and hematuria (40.5%).

The most common grade ≥3 AEs, at 5.2% each, were stricture, which included urethral stricture and bladder neck contracture, and urinary tract infection. Severe incontinence related to the device was experienced by 3.4% of patients.

The combined fistula rate was 6.6% and 3 patients experienced osteomyelitis. After retaining on proper management techniques, the fistula rate dropped to 1.7% and there were no cases of osteomyelitis.

"The FDA's decision on Sonablate is an important step in providing men with prostate conditions access to this less invasive approach," said Neal Kassell, MD, chairman of the Focused Ultrasound Foundation, in a statement. "We hope that focused ultrasound will eventually become a standard of care for treating the prostate."

Larger studies are attempting to validate the efficacy and safety of Sonablate. Additionally, another HIFU device, Ablatherm, which is marketed by EDAP TMS, is undergoing a phase III clinical trial. Patient recruitment and follow-up phases of the study are now completed, according to the company. The pre-market approval file is currently under review by the FDA.

- See more at: http://www.onclive.com/web-exclusives/high-intensity-ultrasound-device-for-prostate-surgery-clears-fda-hurdle#sthash.layNDyAF.dpuf

Landmark Trial Shows Same Drug Effective in Ovarian, Prostate Cancer

Oct. 28, 2015 -- A major new trial, funded in part by the Prostate Cancer Foundation (PCF), has concluded that a pioneering drug—Olaparib—developed to treat women with inherited cancers can also benefit men with certain types of advanced prostate cancer. These exciting results were published today by the study's leaders in the *New England Journal of Medicine*.

"Our trial marks a significant step forward in the treatment of prostate cancer, showing that olaparib is highly effective at treating men with DNA repair defects in their tumors," said trial chief investigator Professor Johann de Bono, Head of Drug Development at the Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust. "It also proves the principle that we can detect prostate cancers with specific targetable mutations using genomic sequencing to deliver more precise cancer care by matching treatment to those men most likely to benefit."

"The potential of this landmark study for the 30% of prostate cancer patients with DNA repair defects in their tumors cannot be overstated," said Jonathan W. Simons, MD, president and CEO of PCF. "We congratulate Dr. de Bono and all of his team on these exciting achievements."

"This clinical trial is significant because it exploits the genetic similarities of prostate, breast and ovarian cancer," said Howard R. Soule, PhD, executive vice president and chief science officer of PCF. "We are excited about this pioneering study because it demonstrates the tremendous crossover and wider applications in the research on these diseases. We are hopeful that the Pharma sponsor of Olaparib will soon launch pivotal clinical trials to confirm these findings and to establish overall safety and efficacy in prostate cancer for this very encouraging therapy."

Olabarib is the world's first medicine approved for the treatment of ovarian cancer patients with mutations of the *BRCA1*and *BRCA2* genes, which play key roles in DNA damage repair. Mutations in these genes have been linked with the development and progression of many tumor types, including prostate cancer.

In the trial, called TOPARP-A, olaparib was found to benefit as many as a third of patients with prostate cancer, including many who did not inherit cancer genes, but whose tumors acquired defects in DNA repair overtime.

Olaparib was determined to be effective in stopping prostate cancer growth, generating lasting falls in prostate specific antigen (PSA) levels, decreases in circulating tumor cell counts in the blood, and radiological responses on CT scans and MRI.

TOPARP-A, is a major milestone in cancer treatment because it is the first to show the benefit of "precision medicine" in prostate cancer. Precision medicine is a new, transformative model of healthcare that utilizes information from tumor DNA to match a patient with the most effective course of treatment.

In addition to the Prostate Cancer Foundation, TOPARP-A received support from the Movember Foundation, Cancer Research UK, Prostate Cancer UK, and Stand Up To Cancer.

For more information, read the press release from the Institute of Cancer Research.

Source: Prostate Cancer Foundation
http://www.pcf.org/site/c.leJRIROrEpH/b.9334061/k.A43D/Landmark_Trial_Shows_Same_Drug_Effective_in_Ovarian_Prostate_Cancer.htm?msource=OCT15NPSP&tr=y&auid=16155864

Relaxed Guidelines on PSA Testing Might Miss Aggressive Tumors: Study Men who could be cured of more advanced prostate disease may be diagnosed late, some researchers say

By Steven Reinberg HealthDay Reporter

Sept. 22, 2015 (HealthDay News) -- Relaxed guidelines on prostate cancer screening may delay diagnosis and treatment of aggressive tumors, a new study suggests.

In 2011, the U.S. Preventive Services Task Force recommended against routine prostate specific antigen (PSA) testing, to curb over-diagnosis and overtreatment of prostate cancer. Since then, PSA screening has dropped by 28 percent, the researchers report.

"On the positive side, there is a lot of prostate cancer that we don't need to know about," said lead researcher Dr. Daniel Barocas, an assistant professor of urologic surgery at Vanderbilt University, in Nashville, Tenn.

These are low-risk cancers that most men will not die of, and the treatment can be more harmful than the cancer, he explained. "To that extent, the guideline had a beneficial effect," Barocas said.
"On the negative side, we seem to be missing intermediate and high-risk cancers in men who would be eligible for treatment," he said. "Those are missed opportunities to identify disease and treat it."

The report will be published in the December issue of the Journal of Urology.

Dr. Kirsten Bibbins-Domingo, vice chair of the U.S. Preventive Services Task Force, said, "When the task force reviewed the evidence on PSA screening for prostate cancer in 2011, what we found is that there is a very small potential benefit and significant potential harms."

Most prostate cancers found by PSA screening are slow-growing and not life-threatening, she explained. "However, there is currently no way to determine which cancers are likely to threaten a man's health and which will not," she said.

Barocas disagreed.
"The policy of screening no one is throwing the baby out with the bathwater," he said.
Some men are at high risk for prostate cancer and should be screened, he said. These include men with a family history of prostate cancer, and black men.
In addition, screening should be combined with treatment. Low-risk cancer need not be treated but watched, while high-risk cancer should be treated, Barocas said. "That's the solution," he said.

Another expert made another point.
Since 2011, when the guideline was published, new techniques, including MRI and ultrasound, have been developed that can diagnose prostate cancer more accurately and distinguish between low- and high-risk cancers. These techniques may need to be taken into account in modifying the guideline, said Dr. Anthony D'Amico, chief of genitourinary radiation oncology at Brigham and Women's Hos-

pital and Dana-Farber Cancer Institute in Boston.
Using the U.S. National Cancer Database, Barocas and colleagues looked at the effect of the new guidelines on the number of new prostate cancer diagnoses between January 2010 and December 2012.

The researchers found that the number of prostate cancer diagnoses dropped more than 12 percent (1,363 cases) in the month after the draft guideline was issued. It continued to drop to an overall decline of 28 percent in the year after the draft guideline was issued.

The diagnoses of low, intermediate and high-risk prostate cancers all decreased significantly, but diagnoses of prostate cancer that had spread beyond the prostate did not change, they found. The decreases were similar for all ages, races, income and insurance.
In the year after the guidelines were published, diagnoses of new low-risk cancers dropped nearly 38 percent and continued to fall more rapidly than diagnoses of more aggressive cancer. This suggests that for low-risk cancer, the guideline had its intended effect, Barocas said.

In addition, prostate cancer diagnoses fell by 23 percent to 29 percent among men over 70 and by 26 percent among men who were not likely to live long enough to benefit from early diagnosis and treatment, the researchers found.

However, researchers also found a drop of 28 percent in diagnoses of intermediate-risk cancer and a 23 percent drop in diagnoses of high-risk cancer one year after the guideline was published.
"These findings are consistent with what we hoped would not happen," D'Amico said.

It is likely that men will develop more advanced prostate cancer before it is diagnosed and be less likely to be cured, he added. "This is a warning that we are not picking up patients who are curable," D'Amico said.

Source: Prostate Cancer Foundation

http://www.pcf.org/site/c.leJRIROrEpH/b.9315429/k.86F1/Relaxed_Guidelines_on_PSA_Testing_Might_Miss_Aggressive_Tumors_Study.htm?msource=OCT15NP&tr=y&auid=16137108

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