WHRY “Seed” Funding Program Has Bountiful Results

The researchers funded through our Pilot Project Program routinely use the results of their Women’s Health Research at Yale studies to obtain larger grants from sources such as the National Institutes of Health (NIH). These external grants are channeled directly into the researchers’ laboratories and clinical research settings, allowing them to continue the work begun through our pilot funding.

To update you on our success rate, nearly half of our funded investigators have obtained external funding – more than double the success rate for NIH applications.

A recent example of this success is our 2010 pilot study of the use of nanoparticles to strategically target and destroy ovarian cancer cells. Drs. Alessandro Santin, Professor of Obstetrics, Gynecology and Reproductive Sciences, and W. Mark Saltzman, Professor of Bioengineering, are specially formulating these ultra tiny particles in a new way to treat ovarian cancer, which has the highest mortality rate among gynecological cancers.

This team demonstrated that their nanoparticles could strategically target cancer cells with greater accuracy and tumor-killing power than existing therapies. Preliminary results in hand, the investigators applied for and received an NIH grant of more than $1.3 million to move forward with next steps toward translating their approach into a treatment.

These are but two of the dozens of Yale scientists who have generated feasibility data through our “seed” funding program, allowing them to gain external grants to continue their research on women’s health. Since inception, our program has awarded more than $4.2 million in pilot grants and our researchers have obtained nearly $47 million in new external grants for further research – a testament to the strength of our research findings.

“By carefully selecting research projects that are highly relevant to important areas of women’s health and leveraging those investments,” said Program Director Carolyn M. Mazure, Ph.D., “we expand the power of your support.”
JOIN THE SOCIETY OF FRIENDS
Consider a donation to Women’s Health Research at Yale in celebration of the birth of a child, a birthday, or to honor that special someone in your life.

Our Society of Friends ensures the future of Women’s Health Research at Yale. Gifts are welcome at all levels.

To make an online gift visit www.yalewhr.org or mail your gift to Women’s Health Research at Yale
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Women’s Health Research at Yale was founded in 1998 with initial funding from The Patrick and Catherine Weldon Donaghue Medical Research Foundation.
Joint Pain Causes Some Post-menopausal Women With Breast Cancer to Stop Taking AIs

Next Step: Could Exercise Help These Women Tolerate the Medications?

A recent consensus panel of oncologists recommended that all post-menopausal women with early-stage, hormone-receptor positive breast cancer – approximately two-thirds of all women diagnosed with breast cancer – receive medications called aromatase inhibitors, or AIs, as part of their therapy to prevent tumor recurrence.

As aromatase inhibitors have become the standard of care in preventing recurrence of breast cancer in post-menopausal women, they have replaced tamoxifen, which had been the mainstay therapy for many years.

Breast cancer tumors that are estrogen-receptor-positive need estrogen to grow. Both tamoxifen and aromatase inhibitors are hormone therapies, designed to prevent estrogen from stimulating the growth of breast cancer cells. But they work differently.

Tamoxifen chemically resembles estrogen, so the medication tricks the breast cancer cells into accepting it instead of estrogen, effectively blocking out the estrogen. Unlike estrogen, tamoxifen does not stimulate the growth of breast cancer cells and is often called an anti-estrogen drug.

Aromatase inhibitors work by stopping production of estrogen in post-menopausal women.

Before menopause, estrogen is produced by the ovaries. After menopause, the ovaries no longer produce estrogen and it is instead made in the adrenal glands, the liver and fatty tissues in the breasts. Specifically, cells in these three areas produce a substance called androstenedione, which is converted into estrogen by an enzyme – aromatase – produced in fat and muscle tissue.

AIs prevent androstenedione from being converted into estrogen by blocking aromatase.

These medications cannot stop the ovaries of premenopausal women from producing estrogen but they can halt estrogen production from other tissues. This is why they are recommended only for women who have reached menopause.

Aromatase inhibitors are the preferred therapy for post-menopausal women primarily because they work better than tamoxifen in preventing the recurrence of tumors. Moreover, AIs do not have risks of certain serious potential side effects from tamoxifen, including cancers of the uterus and blood clots.

However, there has been concern that AIs have their own negative side effects, notably joint pain and stiffness that can sometimes cause patients to stop their medications before they complete the recommended course of therapy, which is usually five years. When patients stop taking the AIs, they do not get the full benefit of therapy to prevent recurrence of tumors.

Dr. Cary Gross, Associate Professor of Internal Medicine at Yale School of Medicine, used a Women’s Health Research at Yale Pilot Project Program grant to study the relationship between aromatase inhibitor therapy for breast cancer and the risks of joint pain, frailty and reduced mobility. Importantly, this clinical study was designed to measure whether the women adhered to their therapy regimen or whether some women stopped taking their medications as a result of joint pain and decreased physical functions.
Gross and his colleagues, including oncologists Drs. Gina Chung and Andrea Silber, enrolled women who were patients at Yale-New Haven Hospital and the Hospital of St. Raphael in New Haven. These post-menopausal women from the community were beginning their adjuvant therapy (treatment in addition to surgery and/or radiation to kill cancer cells) with AIs to prevent recurrence of breast cancer.

Gross found in the recently completed study that approximately half of the women stopped taking their aromatase inhibitors 12 to 18 months into their therapy because of joint pain.

He said this study was the first to explicitly map the affected joints (fingers, toes, ankles, knees, etc.) and chart degrees of functional ability (going up and down stairs, walking, bending to the floor) associated with the reported pain attributed to taking the medications.

The results showed that one of the most prominent complaints from the women in the study and a common cause of stopping the medication was pain in the hands. In addition, while there was not a dramatic decline in mobility because of decreased function of the legs, about 40 percent of the women in the study experienced a subtle decline in their balance, walking and leg strength, Gross said. This decline of mobility, he explained, was measured using a widely accepted, standardized approach to assess lower extremity function and mobility. However, he noted, the change represents a decline compared to this group of patients’ own baseline mobility scores, not a comparison against a control group of similar women who were not taking AIs.

Researchers cannot yet answer the key questions of how or why aromatase inhibitors cause the unwanted side effect of joint pain. Some scientists have proposed that the lack of estrogen – the desired condition of the beneficial therapy to combat the recurrence of breast cancer – may lead to increased sensitivity to pain. In addition, estrogen has a complex relationship with the immune system, Gross said, as estrogen deficiency has been associated with inflammation. Higher levels of inflammatory molecules could be involved in the mechanism that links AIs to joint pain. “No one knows as of yet why AIs cause joint pain,” he said.

His pilot study results, nevertheless, are beginning to form the basis for a model for predicting whether post-menopausal women can tolerate AIs or will stop taking them, Gross said.

“The best medicine in the world for a particular condition is not going to do you any good if you’re not taking it,” he said. “The end goal of this line of research is to identify patients who are at highest risk of stopping their medication or being unable to tolerate it, and then developing interventions that can address those modifiable risk factors,” he said.

One immediate benefit of Gross’s pilot study has been to use it as a model for several collaborations with other scientists on larger studies of the tolerability of medications for breast cancer and other cancers.

In one of these collaborations, Gross is working with investigators in California on a study of 500 older women with breast cancer to identify factors associated with the tolerability of chemotherapy. The study, which was recently funded by the National Institutes of Health, is using physical assessment measures directly guided by the design of Gross’ Women’s Health Research at Yale-funded pilot study on aromatase inhibitors.

In another collaborative study, here at Yale, Gross is working with Dr. Melinda L. Irwin, Associate Professor of Epidemiology in the School of Public Health, on a randomized trial of post-menopausal women taking aromatase inhibitors to prevent recurrence of breast cancer. Led by Dr. Irwin, this National Cancer Institute-funded study will determine whether exercise can help prevent or alleviate some of the joint pain that occurs as a side
Q & A: Breast Cancer, Aromatase Inhibitors and Joint Pain—with Dr. Cary Gross

Q: Aromatase inhibitors have replaced tamoxifen as the preferred therapy for preventing recurrence of breast cancer in post-menopausal women. However, AIs apparently can cause joint pain that prompts some women to stop their therapy early. When you investigated this in your Women’s Health Research at Yale-funded study, what did you find?

A: We found that almost half of the women who started their AI medications at the beginning of the study were still taking them on a daily basis one year later. Of the women who stopped taking their AIs, joint pains were the most commonly cited reason. We found that the hand joints were the most common site of pain, while large joints (shoulders, hips, knees) were affected less frequently.

Q: Did some of the women feel joint pain and simply tolerate the medications to gain the benefits?

A: Yes. Pain did not uniformly lead to discontinuing the AIs. Some women with pain stopped their AIs, and some continued. A critical area of research is to determine what strategies can help women minimize the side effects of AIs, so that women who are experiencing side effects can manage them safely and effectively.

Q: Are your findings informing further research, and providing practical benefit?

A: This study has practical benefits for both patients and healthcare providers. The American Society of Clinical Oncology recommends treatment with an AI in the care of postmenopausal women with breast cancer. However, it appears that many women are not able to complete the full course of treatment, which is recommended to be at least five years. By alerting clinicians and patients to the challenges in adhering to this medication, our results can help guide discussions about side effects and decisions about continuing the AI medications.

Q: What are the next steps in your research in this area?

A: The study design, results, and conceptual model have been incorporated into new grant proposals, including a study now funded by the National Institutes of Health to investigate factors associated with toxicity and side effects among women with breast cancer undergoing chemotherapy. The overarching study question is similar to that posed in our AI study — can we identify factors associated with tolerability and completion of breast cancer therapy? We are poised to begin enrolling patients this fall, and the goal is to identify modifiable factors that can affect chemotherapy toxicity.

The most exciting part of his evolving research, Gross said, is being able to provide information to patients that can help them make the most informed decisions about effective treatments for their particular situations, in this case older women with breast cancer.

“There’s one practical benefit which can actually be taken to the bedside immediately, and that is the knowledge that many women who are starting these medications are stopping them,” he said. “So it is important for clinicians to counsel their patients about the importance of continuing their medicine, or, if they feel like they are experiencing side effects, to discuss with their clinicians what they are feeling, and think of alternative treatments.”

Knowing that there is a 50-50 chance that post-menopausal women taking AIs to prevent recurrence of breast cancer will stop taking their medications after a year is important knowledge for clinicians to have and use immediately, Gross said.
Health care coverage is an issue for all but a few in our country. However, by almost any measure, women today are faring worse than men when it comes to having health insurance.

Similarly, women generally have been paying higher health care costs than men for many years, and this trend appears to be continuing or worsening since the major economic downturn began in 2008, according to Dr. Susan Busch, Associate Professor of Health Policy in the Yale School of Public Health.

Against this economic backdrop, Busch was reading national news reports and listening anecdotally to personal stories in the past few years that women were receiving unexpected bills for so-called “out-of-network” health care expenses more often than men. If this was so, she wondered, why? And if it was indeed happening, could this account at least in part for the higher health care costs paid by women?

In many insurance plans, most health care expenses are more generously covered if a patient uses a provider that is part of the insurer’s network. However, services rendered by providers outside an insurer’s network are covered at greater out-of-pocket expense for the patient.

Trained as a health economist, Busch strongly suspected that one of the reasons that women paid both higher health care costs overall and more out-of-pocket expenses than men was women’s use of out-of-network health care services.

However, when she looked for reliable information on whether the news reports were true and explanations for why women purportedly were using out-of-network health care services more than men, she found virtually no nationally representative data.

Dr. Busch, and Dr. Kelly Kyanko, a physician who trained with Busch as a Robert Wood Johnson Clinical Scholar at Yale, had to create their own nationally representative survey of privately insured adults, ages 18 to 64, in order to gain what amounts to the first high-quality, unbiased data about this important health policy topic for women.

“This is clearly an area where we felt that policy could be informed by good research, given how much we spend on health care and health insurance,” Busch said. “Not enough was being done to look at it.”

Busch and Kyanko applied for and obtained a Women’s Health Research at Yale Pilot Project Program grant in 2010 to conduct a timely, year-long investigation of women’s use of out-of-network health care services. In a collaboration with our program, The Robert Wood Johnson Clinical Scholars Program helped fund this investigation.

Specifically, the investigators set out to determine which individuals are most likely to use out-of-network health care services and, if women were using out-of-network care, whether women were doing this intentionally or unintentionally.

This survey of patients and their healthcare utilization was conducted earlier this year, relying on data from more than 700 participants who completed the assessment.
Preliminary results suggest the rate of out-of-network use is approximately 60 percent higher for women compared to men.

**Why the Higher Rate for Women?**

To be sure, some women deliberately choose to use out-of-network health care providers. In some cases, the women are following the advice of family or friends to use a particular provider, or they continue to use a provider when that provider no longer is within their insurer’s network.

Busch, who has done extensive research on mental health care financing and accessibility, said that people using mental health care services often use out-of-network counselors or therapists either because their insurance does not cover such services, or they are comfortable with a particular provider – regardless of the network status. In the mental health area, Busch said, women are much more likely than men to use an out-of-network provider.

However, in some cases in other areas of health, women receive unexpected charges from out-of-network providers – even when the women use emergency rooms or hospital facilities that are part of their insurer’s provider network. Examples of these unexpected charges include billing by anesthesiologists who provide epidural anesthesia for women in childbirth, and neonatologists who provide pediatric intensive care.

“This adds clear data to what I see as a major consumer-advocacy issue,” said Kyanko, who has since gone on to become an Instructor in the Division of General Internal Medicine at New York University School of Medicine.

Most people who need medical services know to ask if a provider is within their insurer network, Busch said. However, in some cases, Kyanko added, patients might assume the physicians attending them are part of their network, or the patients might be so immersed in dealing with their medical problems that they simply “don’t think of asking each doctor who comes to their bedside.”

To follow up on their pilot study results, the researchers will conduct in-depth telephone interviews with patients who have had experiences with the use of out-of-network health care services, exploring financial or other personal consequences. This qualitative follow-up study will investigate questions that could not be answered from the quantitative

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**Health Care: Terms & Definitions**

**In-network health care providers:** Physicians and other providers contracted by private health insurance plans to create a network of preferred providers.

**Out-of-network health care providers:** These physicians and others do not participate in the patient’s insurance plan network, though the patients sometimes receive care from these providers even if the patients are in their insurer’s preferred hospital/emergency room.

**Out-of-pocket health care expenses:** Costs which patients must pay on their own for medical services, medical supplies, office visits to health care providers, and prescription drugs. These expenses often include health insurance deductibles and co-payments, both of which have increased steadily over time.

**Balance billing:** A practice in which health care providers seek to recoup from patients the charges that an insurer does not pay.

**Patient Protection and Affordable Care Act:** Federal health care and insurance law enacted by Congress and signed into law in March 2010 by President Obama. An estimated 15 million women would gain health insurance coverage when the law takes effect over the next several years.

**New Emergency Care Provision:** Under rules already in effect in the new law, health insurance plans cannot charge members higher co-payments or cost-sharing expenses for emergency care, regardless of whether the care was provided in or out-of-network. However, this new rule does not prevent an out-of-network health care provider from balance billing for emergency care.
survey that was conducted, Busch said.

“We will be looking to obtain more detail for the reasons patients use out-of-network health care, intentionally or unintentionally,” she said. “We want to get more of a flavor for why it happens.”

One hypothesis of this study, buttressed by the news reports that first interested Busch, is that a significant share of unexpected charges for out-of-network care involves medical emergencies. Busch and Kyanko expect to determine whether this is true.

Although overall solutions to the problems of out-of-network costs will have to come from federal and state legislation, and the medical and insurance industries, there are some things that consumers can do for themselves, Busch said. First, “Try always to ask if a provider is in-network or out-of-network,” she said. “Second, if a patient receives an unexpected bill for out-of-network charges, try to negotiate with the provider and try to get the insurer to cover the charge or reduce it.”

Some help for solving this problem is on the way in a little known provision of the Patient Protection and Affordable Care Act, enacted by Congress and signed into law last year by President Obama, Busch noted. This provision of the law requires insurers to cover emergency care services regardless of whether the care was provided by an in-network or out-of-network physician. The effect is that patients who receive emergency care in or out of their insurer’s network will not have to pay higher co-payments or cost-sharing expenses to their insurers.

This provision, however, does not prevent an out-of-network health care provider from billing an emergency care patient the difference between what the insurer covers and whatever the health care provider might charge – so called “balance billing.” Some states prohibit this practice.

Physician groups say balance billing is necessary to make up for underpayment by insurers, while insurers say that charges billed by out-of-network providers often are unreasonably high and that they should not be required to pay them.

This emergency care provision took effect in September 2010, but it applies only to new health insurance plans, not previously existing ones.

Busch said that policy solutions in the Affordable Care Act may not go far enough to protect women consumers from unexpected out-of-network costs. Transparency is needed, she said, so that patients can easily determine if a provider is in network or out of network, and what costs to expect.

Overall, the new federal health care law represents a major step forward for women’s health. New federal rules issued under the Affordable Care Act by the U.S. Department of Health & Human Services will ensure that women, for the first time, have access to a range of preventive health services without having to pay insurance co-payments or deductibles. The types of services covered by the rules include well-woman visits, contraception methods approved by the U.S. Food and Drug Administration, breastfeeding support and domestic violence screening and counseling. These rules will require new health insurance plans beginning August 1, 2012 to cover these services without out-of-pocket charges.

In addition, the new federal law will go a long way toward helping women gain insurance coverage and access to health care once it is fully implemented over the next several years, Busch said. An estimated 15 million women would gain insurance coverage through expansion of Medicaid and the offering of health insurance plans through state health insurance exchanges to be established under the new law.

Our Pilot Project Program is supported in part by The Maximilian E. & Marion O. Hoffman Foundation.
Join Us to Reach Ever Higher

We need your help now more than ever. Women’s Health Research at Yale has matured to the point where we are setting our sights on ensuring our role as the nation’s foremost center for uncovering new medical information on women’s health and sharing this essential, practical information with women across the country.

To accomplish this, we are taking the immediate step of setting an even more ambitious goal for our 2011 Annual Appeal than we set last year, and at the same time planning for long-term growth by seeking sustained commitments that span a number of years.

Federal funding for health research, let alone research focused on women’s health, remains under pressure, and the economy is still fragile. Yet if we are to grow to become THE central hub for biomedical research on women’s health and THE main source of the latest information on gender-specific medicine, our support must grow dramatically now - and keep growing.

As you know, our program was established in 1998 to begin to fill a knowledge gap on women’s health that resulted from the historic omission of women from clinical research studies. We have made tremendous progress, but we still have so much more to do! Social justice for women will remain elusive as long as gender inequality exists in the area of health research.

We need you to help now and become a partner with us in the march toward better health for women.

Thank you!

Ways to Give: Planned Giving...

One way to ensure our program flourishes on sound financial footing and continues to improve health for generations of mothers, daughters, sisters, and friends is through Planned Giving.

A Charitable Remainder Trust is One Option

How it works: As the donor, you transfer cash or assets to the trust (1). The trust pays a percentage of the value of the principal over your lifetime or a term of years to you or beneficiaries you name (2). When the trust terminates, the remainder passes to WHRY (3).

For information on any aspect of making gifts, please call, email, or write to Ramona Gregg.

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*Reminder to Yale College Alumni: Your Class Gifts Can be Designated to Women’s Health Research at Yale

Women’s Health Research at Yale is a program within Yale University School of Medicine. Yale University is a 501(c)(3) non-profit organization.
**Council News...**

**A Much Deserved “Thank You” to Kitty Friedman**

The Council and staff of Women’s Health Research at Yale wish to thank Kitty Friedman, J.D., for her incredibly effective leadership as Council Chair during the past four years. Kitty skillfully guided the Council through a period of steady growth for our program. A founding supporter of our endowment, Kitty will remain on the Council and we will continue to benefit from her wisdom.

**Carol Ross Takes the Helm as Council Chair**

Carol Ross, a founding supporter of our endowment and a Council member since 2009, stepped in as our new Council Chair in September. Carol has served on the boards of numerous non-profit civic organizations, including The Community Fund for Women & Girls, which last year awarded its single-largest and first-ever multi-year grant to our program. She has also served on the boards of arts and music organizations such as the Connecticut Arts Alliance. Carol, a fellow of Yale’s Calhoun College, taught Latin in secondary schools for more than 30 years and retired as an instructor in Latin poetry and rhetoric at Choate Rosemary Hall.

**Lynne Schpero Returns**

Lynne Schpero, a founding supporter of our endowment, rejoined the Council earlier this year with a renewed commitment to helping us ensure a strong financial foundation. Lynne, who joined the Council in 2006, has returned after a leave of a little more than a year. She continues to serve on the Council’s Philanthropy & Communications Committee.

**Press Notes...**

**For Women, There’s A Lot to Like In New Federal Health Care Law**

The federal health care legislation enacted by Congress and signed into law by President Obama last year is arguably the most controversial new law to come out of Washington since President Franklin Delano Roosevelt managed to muscle through the Social Security Act of 1935.

Today, women have a greater chance of exhausting their savings in retirement and must rely more heavily on Social Security than men. One factor in this disparity – leaving aside the pay gap for now – is that women pay more than men for health care. (See related article on page 6.)

Just like the Social Security law, the Patient Protection and Affordable Care Act benefits women in ways that anyone who counts themselves an advocate for women’s health simply cannot ignore. For example, new health insurance plans beginning next August will be required to cover preventive health services (as recommended by the independent Institute of Medicine) that specifically help keep women healthy – without charging an insurance co-payment or deductible. Such services include well-woman visits, mammograms, domestic violence screening, and contraception.

When the new health care law is fully implemented over the next several years, an estimated 15 million women now without health insurance will gain coverage.

But just like the Social Security law, the federal health care law is being challenged all the way to the U.S. Supreme Court. And the outcome will again matter – especially for women.
Community Events...

Our Director in Huffington Post: Women’s Health Struggle Continues...

...Dr. Mazure wrote a fact-filled opinion piece on the nation’s need to pay special attention to the need for health insurance and health care for women – who are less likely to be able to afford health care compared to men – as debate over the Patient Protection and Affordable Care Act moves forward. Her piece, published in August on the Huffington Post webpage Huff Post Women, began by honoring the life and work of Bernardine Healy (who died a week earlier), the first and only woman to be named Director of the National Institutes of Health. Her passing, wrote Dr. Mazure, is a reminder of the struggle to call attention to women’s health, as well as “a call to action – because these battles are not over.”

Research on Women’s Health...

...In a Grand Rounds talk to members of the Therapeutic Radiology department this September, Dr. Mazure explained how research on women’s health has only just begun to embrace gender differences as key variables. Considering and including such differences in study design, however, has illuminated the need for gender-specific prevention and treatment strategies in a variety of diseases, including cancer. She noted that current and former members of the Therapeutic Radiology faculty (including Drs. Bruce Haffty, Sara Rockwell and Joann Sweasy) conducted pivotal studies with pilot funding from Women’s Health Research at Yale.

Chicago Congress Envisions Equality...

...Vision 2020, a national project to foster gender equality in America by 2020 (the 100th anniversary of women getting the right to vote), held its second annual national congress over three days in October. Delegates from around the country gathered in Chicago to plan strategies for how to meet five main goals: achieving pay equity, increasing the number of women in senior leadership positions, educating employers about enabling men and women to fairly share family responsibilities, educating girls and boys to respect differences and act on the belief that the country is at its best when leadership is shared and opportunities are open to all, and mobilizing women to vote. Dr. Mazure attended as a Visionary Delegate, one of 13 women chosen from around the country to advise the state delegates and connect them with resources and organizations that can help move their various states toward gender equality. Dr. Mazure is working with Connecticut delegates as they plan a statewide Vision 2020 conference for next year. ■

To read more news, please visit our website at: www.yalewhr.org

WHRY on giveGreater.org

Women’s Health Research at Yale now is among the non-profit organizations which community members can choose to support through The Community Foundation for Greater New Haven’s giveGreater.org online giving site.

Workshops...

Scientists Need a “Policy Voice” in Current Funding Climate...

...Sara Rosenbaum, J.D., a nationally recognized health policy expert, told researchers with Yale’s Interdisciplinary Research Consortium on Stress, Self-control and Addiction that, in the current climate in Washington, direct governmental support of science research to improve health is “facing the potential of real cuts.” Introduced by Dr. Mazure at the presentation in September, Rosenbaum implored the scientists to help shape policy by telling stories about the importance of their work and findings through the media. This is a “matter of survival,” said Rosenbaum, who is Chair of Health Policy at George Washington University School of Public Health and Health Services. ■

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Our “Community” section now features information to help you understand and reduce your risks for Cardiovascular Disease.

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