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Women’s Health Research at Yale generates research findings that transform the scientific community’s understanding of women’s health, answer important questions, and advance knowledge to improve well-being for all.

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2014 Pilot Project Grants Target Endometrial Cancer, Infectious Disease Prevention/Contraception, Endocrine Dysfunction

Jumpstarting highly inventive research with major clinical implications, Women’s Health Research at Yale is supporting studies on some of today’s most vital women’s health areas. This year’s Pilot Project Program “seed” grants, augmented by an inaugural Pioneer Award for research on the verge of a significant breakthrough, will allow Yale researchers to:

➢ create a revolutionary treatment model for uterine serous cancer — the most lethal endometrial cancer — that will usher in optimal, “individualized” intervention to improve survival and outcomes.

➢ design and create the first dual-purpose intravaginal ring for prevention of HIV and other sexually transmitted infections, and unwanted pregnancy.

➢ continue closing the gap in advancing stem cell therapy promising a cure for hypoparathyroidism, an endocrine disorder resulting from inactive hormone function of the parathyroid glands and primarily affecting women.

WHRY’s Pilot Project Program funds studies on women’s health and gender-specific medicine that demonstrate new approaches to major challenges in women’s health, and describe a clear path to implementation for clinical or public health benefit.

The reach and productivity of the Pilot Project Program have been dramatically increased this year with the inaugural Wendy U. and Thomas C. Naratil Pioneer Award. This new annual award was made possible by an endowment gift last year from Yale College ’83 couple Wendy and Tom Naratil. The award is for an investigation that is either highly inventive or close to a major breakthrough in advancing women’s health — where funding is needed to reach its aims.

(Continued on page 4)

Foundation Gifts Extend Long-Term WHRY Partnerships ... see page 3

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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.

In Partnership with You

*Women’s Health Research at Yale* generates new research findings, trains the next generation of investigators, and shares valuable health information with the community.

All to improve your health and healthcare.

To Every Donor – Thank you!

See Donor Recognition on pages 6–7
WHRY Longtime Foundation Partners Renew Support

Four foundations that are among Women’s Health Research at Yale’s most important, dedicated partners in advancing gender-specific medicine have once again provided major gifts.

These generous grants were awarded to our Center by the Mary W. Harriman Foundation, The Seymour L. Lustman Memorial Fund, The Seedlings Foundation and the Werth Family Foundation.

Importantly, at a time of reduced federal funding for health research, the support from longtime partners of Women’s Health Research at Yale will be used to fund our Center’s strategic initiatives: initiating highly inventive research on women’s health and gender differences, training the next generation of health researchers, and sharing our findings with the community.

“We are truly thankful to have each of these foundations as partners for so many years,” said Dr. Carolyn M. Mazure, Director of Women’s Health Research at Yale. “Their commitments and generosity have been and will continue to be essential to our shared success in studying women and gender differences, and translating our scientific findings into health-improving and lifesaving practice for all.”

The Mary W. Harriman Foundation has been a partner of Women’s Health Research at Yale for 15 years, since 1999, the first year after our Center’s founding.

The Seymour L. Lustman Memorial Fund has been one of our essential partners for 12 years — since 2002. This fund was established in memory of Dr. Lustman, who was Professor of Psychiatry on the faculty of the Yale Child Study Center for more than 20 years. In addition to being a gifted clinician, Dr. Lustman was a dedicated researcher who believed in rigorous scientific investigation as the basis for good clinical care.

The Seedlings Foundation has been a vital partner for 13 years, since 2001 — when it provided support for our Center’s overall operations and our Pilot Project Program.

The Werth Family Foundation has been a key partner for eight years, since 2006, when it helped sponsor a benefit concert for Women’s Health Research at Yale that featured Judy Collins.

“Renewing and reinforcing our longstanding partnership with Women’s Health Research at Yale allows the Werth Family Foundation to ensure that, together, we will continue to initiate scientific discoveries that yield important health improvements for our communities,” said Suzanne K. Werth, Werth Family Foundation Board Member.

The renewed support from these partners will help expand our Center’s broader missions by helping to fund our overall operation, allowing our Director discretion to use funding as needed for innovative projects as opportunities arise.

Susan Lustman Katz, J.D., Chair of the Lustman Fund, said recent reductions in federal funding for health research helped strengthen the Fund’s resolve to continue its commitment to WHRY.

“We began supporting Women’s Health Research at Yale because we felt it was a revolutionary research center that reflected our core commitment to medical research. We have kept supporting the Center because it has been so enormously successful, and the focus on gender differences and gender-specific medicine is still absolutely critical,” Katz said.

“Our grants to fund WHRY’s operations reflect both our long relationship with the Center and our trust in the way the funding is marshaled,” she said. “We want to not only sustain Women’s Health Research at Yale but ensure that the Center’s impact grows.”
2014 Pilot Project Grants Target Pressing Health Conditions

“Our Pilot Project Program and Naratil Pioneer award study the kind of original, creative projects that have tremendous potential for quickly translating findings into significantly improved treatment and prevention options, some of which will be 'personalized' for each patient,” said Dr. Carolyn M. Mazure, Norma Weinberg Spungen and Joan Lebson Bildner Professor of Psychiatry and Psychology, and Director of Women’s Health Research at Yale.

The 2014 Pilot Project Program Awardees

Diane S. Krause, M.D., Ph.D., Professor of Laboratory Medicine, of Cell Biology, and of Pathology.

Continuing the Development of Stem Cells for Therapy in Hypoparathyroidism

Thyroid cancer occurs three times more often in women than men. Treatment often includes the removal of the thyroid gland, and a common, unavoidable complication of surgery in eliminating malignancies is removal of the nearby parathyroid glands, which are critical for calcium balance in the body. Hypoparathyroidism, which results from defects in the parathyroid glands or their removal during surgery to remove a cancerous thyroid, is a devastating condition that primarily affects women. Because patients lack the ability to regulate calcium levels in their blood, they are at risk for irregular heartbeat, debilitating muscle cramps, seizures and other serious conditions. Treatment typically involves taking oral calcium but this can prove very challenging over a long period. Dr. Krause’s team previously was funded through a WHRY pilot grant to begin development of stem cells that can be transformed into parathyroid cells. This project is to continue the inducement of stem cells to develop into parathyroid cells that would secrete parathyroid hormone to maintain normal calcium balance. Cellular replacement could promise a cure.

W. Mark Saltzman, Ph.D., Goizueta Foundation Professor of Chemical and Biomedical Engineering, and Chair of Biomedical Engineering.

Creating a Dual-Purpose Method to Prevent Sexually-Transmitted Infections and Pregnancy

No adequate methods to protect women from the transmission of Human Immunodeficiency Virus (HIV) and other sexually transmitted infections exist. Dr. Saltzman will design a new intravaginal ring (IVR) for the simultaneous prevention of sexually transmitted infections and unwanted pregnancy, using materials and methods known to be safe and expected to be acceptable to women. Saltzman brings an extensive biomedical engineering background in developing drug delivery systems using materials such as safe, ultra-tiny nanoparticles and non-toxic polymers. Specifically, he will develop an IVR that will slowly release contraceptive agents embedded within the ring and will

About the Investigator —

Dr. Diane S. Krause earned her M.D. and Ph.D. degrees from the University of Pennsylvania, and performed her post-doctoral studies at Johns Hopkins University. She is Associate Director of the Yale Stem Cell Center. A key focus of her research is to define the mechanisms that regulate the self-renewal and differentiation of stem cells, so that findings can be translated into improved therapies for a variety of health conditions.
also slowly release nanoparticles loaded with drugs to provide sustained protection against sexually transmitted infections.

Such sustained-release formulations have proven difficult or impossible to achieve with other IVR designs. Dr. Saltzman will overcome this challenge through the use of two independent mechanisms for releasing the different preventive agents, and using specially-designed nanoparticles that will safely penetrate tissue and slowly release drugs locally. This new dual prevention method will have the potential to significantly reduce the 7,000 new HIV transmissions that occur in women worldwide each day, while simultaneously providing a safe, effective method of contraception.

Dr. Bothwell will tackle this challenge by developing a radically innovative mouse model of uterine serous cancer, which more closely simulates a patient’s experience than existing models, by integrating the patient’s immune system and tumor pathology. This model will allow treatments to be tailored and optimized for individual patients. Specifically, Dr. Bothwell will test, for the first time, how drugs or drug combinations interact simultaneously with immune response, tumor response and genetic factors. Because uterine serous cancer spreads quickly, the evaluation of therapies must be completed as rapidly as possible to benefit patients. This experimental model will allow evaluation much faster than would be possible in human clinical trials, thus providing tremendous clinical benefit.

The Inaugural Wendy U. and Thomas C. Naratil Pioneer Awardee

Alfred L.M. Bothwell, Ph.D., Professor of Immunobiology.

“Personalized Medicine” for the Most Lethal Endometrial Cancer

Endometrial cancer is the most common gynecological cancer in the U.S., with approximately 50,000 new cases and more than 8,000 deaths annually. Uterine serous cancer, a particularly aggressive form, accounts for 10 percent of endometrial cancer cases, but is responsible for nearly 40 percent of endometrial cancer deaths. Thus, new, more effective treatment strategies are desperately needed.

Dr. Alfred L. M. Bothwell earned his Ph.D. from Yale. He is Director of Graduate Studies for the Immunobiology Graduate Program.

His research focuses on understanding the development and function of regulatory T cells (key immune system cells) and characterizing cellular mechanisms that affect autoimmunity, inflammation and transplantation. He is involved in developing effective treatments for various types of cancer, diabetes and other health conditions.

The Women’s Health Research at Yale Pilot Project Program is supported in part by the Maximilian E. and Marion O. Hoffman Foundation, the Seymour L. Lustman Memorial Fund, The Seedlings Foundation, The Werth Family Foundation, and anonymous donors.

The Wendy U. and Thomas C. Naratil Pioneer Award, supported by an endowment gift from a Yale College ’83 couple, expands the Pilot Project Program by funding investigations that are highly inventive or close to a major breakthrough in advancing women’s health.
Recognizing Our Friends (July 1, 2013 – June 30, 2014)

Women’s Health Research at Yale is pleased to acknowledge the many important gifts from our Society of Friends. Members of the Society of Friends support the vital mission of our program and provide much needed resources to ensure that research in women’s health continues. Each and every gift is valued by Women’s Health Research at Yale.

Thank you for your continued support.

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We Can Change the National Research Landscape — Now!

Carolyn M. Mazure, Ph.D.

It often seems that the daily demands of our busy lives prevent us from taking stock of the moment. Yet, this is one of those moments in the 16-year history of Women’s Health Research at Yale that warrants reflection on the outstanding support we have received to study women’s health, and the privilege that we have enjoyed in illuminating our knowledge of gender-sensitive health outcomes. As importantly, this also is the moment that affords us the opportunity to encourage further change in the national research landscape.

The support that we receive means everything to us. In the past year alone, we have received new endowment gifts that have expanded our Pilot Project Program’s research portfolio to include a new Pioneer Award, and funded an endowed professorship — securing the permanent leadership for our Center. Moreover, generous, sustained support has come from foundations and individuals who contributed greatly to the success of our just-ended annual appeal. These sources of support have grown our research efforts, and our outreach in communicating the practical health benefits derived from our work.

On the national stage, we have advocated for inclusion of women and the study of gender differences in all clinical research. Similarly, we have supported the study of female animals and cell sex-typing in laboratory research as this work provides the basic biological foundation for all health research. Now, the National Institutes of Health has finally taken the first key step in implementing the inclusion of females in all funded research. This is a momentous change. In addition, the U.S. Food and Drug Administration recently acknowledged the essential importance of studying gender differences in health and disease, and is drafting a plan to increase the representation of women and minorities, and improve data collection, analysis and communication about gender differences in clinical trials of FDA-regulated medical products.

A bipartisan group of women who are U.S. Senators and House members, including honorary WHRY advisory Council member Congresswoman Rosa DeLauro, is pressing the FDA to ensure that clinical trials for drugs and medical devices account for differences between women and men. “We hope that, 20 years from now, we can look back and say that the FDA’s plan was a significant milestone in women’s health — not a missed opportunity,” the lawmakers said in a letter to the FDA.

This is our chance to ensure that everyone knows about and understands the importance of these potential changes. Our advisory Council has stepped up its role both in guiding and securing the financial foundation of our Center and in its commitment to further developing our national voice. Join us in getting the word out that, with these changes, we will finally have data on medications, medical devices and treatments to guide the best care for women and men.

WHRY’s French Connection

Former WHRY Postdoctoral Fellow Pioneers Gender-Sensitive Research in France

The investigation of gender differences is generally not part of the scientific tradition for health research in Europe. But a researcher who was mentored by our Director as a WHRY Postdoctoral Fellow from 2004 to 2007, Dr. Mathilde Husky, is starting to change that. In collaboration with Dr. Mazure and WHRY, she is beginning to pioneer the study of gender differences in mental health in her home country of France.

“I see tremendous opportunity to do this,” she said in a recent interview during a return visit in June.
We Cannot Improve Women’s Health Without You

Thank you to all of our donors who gave generously during our 2014 Annual Appeal. With your vital support, we will remain a national leader in initiating research to advance gender-specific medicine, sharing our findings with the community, and training new generations of health researchers focused on gender differences in health and disease.

In this newsletter, we announce our 2014 Pilot Project Program awards and the inaugural Naratil Pioneer Award. These “seed” grants are allowing our newly-funded scientists to devise ingenious ways to overcome crucial challenges in women’s health.

As you can see, your support is critical to our success. When you make a gift to Women’s Health Research at Yale, you directly influence our ability to commence and sustain the highest caliber medical research on gender-sensitive disease prevention and treatment – for the betterment of all.

Thank you!

Patti Russo, Chair
Philanthropy Committee

After earning her Ph.D. at the University of Bordeaux, she came to Yale as a WHRY Postdoctoral Fellow and trained under Dr. Mazure’s guidance, honing her research skills as an investigator in the areas of mood disorders including depression and co-occurring addictive behaviors including smoking.

Now a tenured Professor of Clinical Psychology at the University of Paris Descartes, Dr. Husky’s research focuses on understanding the cognitive processes involved in the onset of depression and identifying risk factors for depression and suicide. To improve her understanding of how daily life activities relate to mental health disorders, she uses real-time ambulatory monitoring (with wristband devices and other tools.)

She recently won a prestigious research career development award from the French University Institute. This is allowing her to begin analyzing nationally representative sets of health data for information on gender differences.

During her visit to WHRY, she met with Dr. Mazure to plan continued transatlantic collaborative research including a third scientist, Dr. Joel Swendsen, Professor of Clinical Psychology at the University of Bordeaux. He taught Husky as a graduate student, sent her to Dr. Mazure as a post-doctoral fellow, and has co-authored studies with our Director and Husky.

“Together, we’re launching investigations of gender differences in France and the French population that have not been done before,” Dr. Mazure said.
Investigator News...

Dr. Lynn Cooley Appointed Dean of Graduate School of Arts and Sciences

Lynn Cooley, Ph.D., the C.N.H. Long Professor of Genetics, of Cell Biology, and of Molecular, Cellular and Developmental Biology, has been named Dean of Yale’s Graduate School of Arts and Sciences.

Cooley is a member of Women’s Health Research at Yale’s Scientific Review Committee, which reviews the proposals that Yale researchers submit to our Center for Pilot Project Program awards. She has served as Director of Yale’s Combined Program in the Biological & Biomedical Sciences since 2001.

Her research focuses on the development of female gametes, or eggs, in Drosophila (fruit flies), especially on two key aspects of initial egg development: the role of intercellular bridges called ring canals in developing egg chambers, and the regulation of egg cell growth.

Cellular mechanisms controlling egg cell development in Drosophila are directly relevant to female fertility in humans.

Dr. Cooley earned her B.A. from Connecticut College and her Ph.D., from the University of Texas. She serves on the board of the Genetics Society of America, has been recognized with a Pew Scholar Award, is a member of the Connecticut Academy of Science and Engineering, and is a fellow of the American Association for the Advancement of Science.

Yale University President Peter Salovey announced Dr. Cooley’s appointment May 21. ■

Annual Grand Rounds Lecture

Translating Substance Abuse Research Into Community-Based Treatments

Dr. Maxine Stitzer, Professor of Behavioral Biology at Johns Hopkins University School of Medicine, devoted much of her career to bridging the gap between research and treatment practices involving addictions.

As Principal Investigator at one of 13 regional centers of the National Drug Abuse Clinical Trials Network, she has focused on improving the effectiveness of both pharmacological and behavioral substance abuse treatments by demonstrating what actually works in community treatment centers.

As Director of the Women’s Behavioral Health Research Division in Yale’s Department of Psychiatry, Dr. Mazure invited Stitzer to be the annual Grand Rounds visiting lecturer in May. Stitzer highlighted the design features and findings from research conducted within the Clinical Trials Network since established by the National Institute on Drug Abuse in 1999.

“The whole idea was to translate findings into clinical practice,” she said in an interview. “This is done through rigorous multi-site investigations of treatment practices in real-world settings.”

The Clinical Trials Network consists of partnerships between academic research centers and community treatment programs. Research grants are awarded based on scientific merit, innovation, clinical relevance and potential to sustain and duplicate newly developed interventions in the community treatment setting.

Since the CTN began, more than 50 studies have been completed in three major areas, including medications (especially buprenorphine, used in opioid addiction treatment), specialized behavior therapies, and HIV testing and risk reduction. ■
Press Notes...

**NIH Policy Affirms WHRY Practices**

There is no other way to put this. The May 14 announcement that preclinical research funded by the National Institutes of Health will require that both sexes be represented in animal models and cell lines was long overdue.

It has been more than two decades since federal law began requiring gender balancing in human clinical trials funded by the NIH. Although there has been progress in this area, improvement is still needed.

In the laboratory, the widely accepted practices of excluding female animal models and not paying attention to the sex of cells did not make for good science — and had to be changed.

From Women’s Health Research at Yale’s vantage, the sea change in policy affirmed the research practices and policies implemented and advocated by our Director since founding WHRY in 1998. Our research has explored gender differences in numerous areas, including cardiovascular disease, mood disorders, addictive behaviors, infectious diseases, trauma, and workplace injuries.

Media outlets gave widespread coverage to the NIH policy shift. This attention added to the momentum in focusing on gender differences that began to build earlier this year, after CBS “60 Minutes” aired a segment on how the same medications can affect women and men differently, and U.S. Food and Drug Administration officials said they wanted public input on how to ensure further progress in the collection, analysis and communication of data on gender differences discovered in clinical trials.

“The NIH plan to change the longstanding, inadequate representation of females in animal models and laboratory research with cell lines is essential to gaining an understanding of gender differences in human health and disease,” our Director said in a statement responding to the NIH announcement. Dr. Mazure’s response was published by the online health news service CT Health I-Team and its newspaper partners around the state.

Hooray for sound science and journalism.

**Community Event**

**Dr. Mazure on Public Radio**

Our Director spoke during Faith Middleton’s “Great Ideas” radio show on July 15 about the momentous policy change the National Institutes of Health announced earlier this year.

The new policy will require agency-funded scientists to use female as well as male animal models and cell lines in basic research — opening many new paths to understand gender differences that will guide clinical studies.

Our Center has implemented and advocated these practices since inception. Now the world’s largest funder of health research is finally embracing this change, Dr. Mazure explained. “That’s really a very exciting and big new idea,” she told Middleton and her WNPR (CT Public Radio) listeners.

Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) – Our junior faculty training program graduated four Scholars (L–R) Elise DeVito, Tomoko Udo Schaller, WHRY Dir. Carolyn Mazure, Azure Thompson, Megan Smith
THE DANGERS OF EATING TOO MUCH SUGAR

Most Americans consume more added sugar than recommended for a healthy diet.

YOU can reduce your risk by following some simple tips.

Heart Health Q&A
Providing useful information on the latest cardiovascular health news.

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