

Editorial Comment

Dr. Vivian W. Pinn's Decade at the Office of Research on Women's Health: Reaping a Rich Harvest

Writing the first editorial for *Gender Medicine*, the official journal of the Partnership for Gender-Specific Medicine at Columbia University, prompted me to ask Dr. Vivian W. Pinn, the first director of the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH), to share what she's accomplished in the past 10 years. I wanted to know what she found most difficult during her tenure and which goals, as yet, were unrealized. Her commentary targets the obstacles encountered and accomplishments achieved in advocating women's health research and, in some respects, is different from anything I've ever known her to discuss.

Combating the notion that studying women is a waste of money and resources isn't an easy task, even today. In her commentary, Dr. Pinn reviews some of the arguments raised in opposition to the founding of the ORWH. To my mind, one of the most ridiculous was the assertion that "we'd get around to studying women in the normal course of events anyway." Nothing could have been less likely. After World War II—which taught women they could make decisions, earn significant salaries, and do things that had previously been the exclusive province of men—it took four more decades of work to get government-supported legislated attention for women's unique health needs. It took leaders like Bernadine Healy and Lila Wallis to begin a meaningful, comprehensive, relevant movement within academic medicine to study women. Those early efforts met with formidable opposition. To assess the obstacles to the direct study of women's health other than reproductive biology, we consulted the 1993 critique of the Women's Health Initiative (WHI) offered by the Institute of Medicine (IOM).¹ Following are excerpts from that report:

- "The committee feels that the WHI had inadequate peer review from within NIH or from outside scientists." *Implication:* The proposal itself had serious flaws because it had escaped the usual rigorous scientific review allotted to NIH-supported research.
- "The US House of Representatives' Appropriations Committee...was concerned that the rapid escalation in cost estimates might be a signal of poor planning and...directed NIH to contract with the IOM to complete a review of the design and estimated costs of the WHI by February 1, 1993. NIH first formally approached IOM in February 1993 to discuss the Appropriations Committee-requested project. [The IOM staff began work] on April 23, 1993, well after the due date of the study requested by Congress. Whether the delay was due to a slow-moving bureaucracy or to other causes is unknown...As a result, however, the committee was faced with the task of critiquing a study in progress." *Implication:* The review of the WHI proposal was unacceptably delayed, possibly deliberately.
- "Colleagues, advocacy organizations, executive and legislative branch representatives all approached the committee with reasons why the WHI should proceed and why canceling it would unleash disasters. If it is canceled, some argued, no one would ever trust the government again; it would prove that the government does not really care about women's health; it would so greatly disappoint the community which has gathered around this project that it will be impossible to ever galvanize them again; it would be seen as an unwelcome political blow to those in Congress who have pressed for more women's health research." *Implication:* Essentially, the WHI was planned and going forward primarily for political reasons, rather than scientific merit.
- "While recruitment of study participants has already begun, serious questions remain about the design, timetable, and likely results of this \$625 million public investment." *Implication:* The study was so flawed and so without scientific merit that it would be a significant waste of public money.

Obviously, one of Dr. Pinn's most serious challenges was to prove that interest in women's health was not simply politically motivated. Only if the scientific basis was compelling would research on women be considered a necessary step in improving human health. In no small part due to her leadership and programs, that has proved to be right. We now diagnose and treat osteoporosis more frequently and effectively in men. We frame questions we never would have contemplated before discerning the differences in the male/female experience of the same diseases, eg, why does diabetes mellitus increase women's risk for coronary artery disease 4- to 6-fold whereas it only doubles that for men?² For the benefit of both sexes, can we unlock the secrets of women's relative longevity despite their disadvantaged positions in societies that offer better educational, nutritional, and vocational opportunities to men?

Ten years after Dr. Pinn took the helm of the ORWH, she can rightfully claim she has formed a network of alliances that deserve special praise for their diversity and inclusiveness. She has worked actively to support women in biomedical careers and help facilitate reentry into research (one of ORWH's congressional mandates when the Office received legislative authority in 1993) for those returning to the workforce. Her consistent emphasis on the importance of interdisciplinary research in solving the complex issues of women's health has been one of the most valuable and original contributions of her leadership. In short, she has played a vital, trailblazing role in helping investigators, practitioners, and patients understand how sex and gender define health and how the pathophysiology of disease impacts human life.

Nowhere is our progress better outlined than in the two contrasting IOM views about the value of studying the impact of sex and gender on health. In 1994, an expert committee, looking at whether or not both sexes should be included in research projects, wrote: "In an era of concern about the nation's resources, and about expenditures on health in particular, it is argued that a study-by-study application of this requirement makes for both questionable policy and questionable science. When no subgroup differences are anticipated, requiring scientists to enroll sufficient numbers to ensure the statistical power to detect unsuspected differences would produce little additional information at a greatly increased cost."² How did the committee determine that looking for sex/gender differences "would produce little additional information?" Recent studies have shown that we should never assume that any phenomenon is identical for both men and women without testing that assumption. A change in viewpoint is evident, seven years later, when in 2001 IOM published *Exploring the Biological Contributions to Human Health. Does Sex Matter?* expressing a much more enthusiastic, proactive approach. The contents of this second report³ are remarkable in that they show how far we've come since women were first considered appropriate, and indeed necessary, subjects of research:

- "Every cell has a sex."
- "Sex begins in the womb...It is important to study sex differences at all stages of the life cycle, relying on animal models of disease and including sex as a variable in basic and clinical research design."
- "Sex affects health: males and females have different patterns of illness and different life spans...understanding the basis of these sex-based differences is important to developing new approaches to prevention, diagnosis, and treatment."

In short, says the expert committee, sex does matter—to a degree and in ways we are only beginning to uncover.

The ORWH is exceeding our most ambitious hopes. If its productivity, relevance, and leadership continue, gender-specific research and the gender-specific treatment of all patients will be a common standard for every subspecialty in medicine. Dr. Pinn can look back on the past 10 years with pride as she considers the abundant, unimagined richness gleaned from the study of sex and gender.

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