



## Commentary

## Policy Implications of a New National Institutes of Health Agenda for Women's Health Research, 2010–2020

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Article history: Received 20 July 2010; Received in revised form 6 January 2011; Accepted 7 January 2011

### Introduction

September 27, 2010, marked the 20th anniversary of the establishment of the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH). The responsibilities of the ORWH include advising the NIH director on matters relating to research on women's health; strengthening research related to diseases, disorders, and conditions that affect women; ensuring that NIH research adequately addresses women's health; ensuring that women are appropriately represented in research supported by NIH; enhancing recruitment, retention, reentry, and advancement of women in biomedical careers; and directly supporting research on women's health issues in partnership with the institutes and centers (NIH, 2009).

Indeed, the 1990s marked a proliferation of focused efforts to marshal research resources aimed at informing and refining our understanding of sex and gender issues across the spectrum of health—from basic science to clinical research to health services and health policy research. In addition to the NIH, several U.S. government agencies established offices and agencies to support these efforts (Mazure, Arons, & Vitale, 2001), most notably:

- The Department of Health and Human Services (DHHS) Office on Women's Health;
- The Food and Drug Administration (FDA) Office of Women's Health;
- The Centers for Disease Control and Prevention Office of Women's Health;

- The Health Resources and Services Administration (HRSA) Office of Women's Health; and
- The Agency for Healthcare Research and Quality Office of Priority Populations, which includes women.

As a part of the health care reform legislation that was signed into law in 2010, these offices joined the NIH ORWH with new statutory authority establishing these offices in law (the NIH office was codified in 1993), and ensuring that they all report directly to the agency leadership.

Other government agencies also have included gender- and women-specific research efforts, notably the Maternal and Child Health Bureau in the DHHS HRSA and the DHHS Office of Population Affairs, as well as other agencies such as the Department of Defense, the Department of Homeland Security, and the Department of Veterans Affairs.

In 1999, after an extensive national collaborative effort that convened scientists, researchers, advocates, and many other stakeholders with interests in women's health, the ORWH released its landmark report, "Agenda for Research on Women's Health for the 21st Century: A Report of the Task Force on the NIH Women's Health Research Agenda for the 21st Century" (DHHS, 1999). Ten years later, in 2009, ORWH embarked on a similar effort to update the 1999 report by launching a series of scientific workshops and public hearings to revise the NIH research agenda in women's health for the next decade. The results of this collaborative approach "Moving into the Future with New Dimension and Strategies: A Vision for 2020 for Women's Health Research" were released in late 2010 (ORWH, 2010).

Clearly, women's health research is at a turning point with the launch of new NIH strategies for the second decade of the 21st century. In this paper, we address selected issues in women's health research identified at a recent workshop convened by the Jacobs Institute of Women's Health with support from the NIH ORWH. We discuss some key policy implications related to basic science research, cross-disciplinary research, and health professional education and training.

The views expressed in this paper are solely those of the authors and do not represent the official views or positions of the NIH, ORWH, or any other federal agency.

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## The Research Endeavor Synergy

Awareness of potential sex/gender differences in health research permeates the entire synergistic process of the research endeavor. At its most basic level, we envision this endeavor as composed of four interrelated dimensions (Figure 1) that are grounded in interdisciplinary approaches and training of researchers throughout their careers.

This research synergy includes how sex/gender issues are specified in study design and data collection for proposed research projects (whether investigator-initiated or created by funding bodies' requests for proposals). Requirements to collect data by sex are only the start of the process. There need to be similar assurances that researchers analyze and present these data in meaningful ways, even when no apparent sex/gender differences exist. Indeed, null findings can be important findings nonetheless, and it is important to know this. The International Committee of Medical Journal Editors (ICMJE, undated) underscores the need for publishing these null or negative findings in its policy on "Obligation to Publish Negative Findings":

Editors should consider seriously for publication any carefully done study of an important question, relevant to their readers, whether the results for the primary or any additional outcome are statistically significant. Failure to submit or publish findings because of lack of statistical significance is an important cause of publication bias. (ICMJE, undated)

Study protocols, designs, and analysis plans should reflect an intentional awareness of the importance of this issue, from basic bench science to clinical research to health services and health policy research. In fact, the NIH's current policy on the inclusion of women and minorities in clinical research states:

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic

group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants. . . . Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice. (NIH, 2001)

Since 1997, the NIH has monitored compliance with its inclusion policy by publishing annual reports that summarize the numbers of men, women, and minorities included in the research it funds. These comprehensive reports have documented that, since the establishment of the inclusion policy, the number of women relative to men included in clinical research has been steadily increasing (ORWH, 2008). Furthermore, having information about both sex and race/ethnicity improves our ability to study what researchers have termed the "intersectionality paradigm" to inform measurement of the consequences of multiple intersecting inequalities on people occupying different social strata (Kanzanjian & Hankivsky, 2008). One pertinent example is research that studies the intersectional effects of sex, race, and ethnicity on receipt of preventive services for cardiovascular disease. The authors of a 2007 study found that women were less likely to receive these services as compared with men, and that among women, there are racial/ethnic differences that mirror what was observed in the entire sample of men and women (Bird et al., 2007).

Finally, research endeavors are influenced by (and can influence) what gets published and by whom. Although dissemination pathways are complex, consider for example two venues: 1) interim and final reports required by funders and 2) manuscripts published in the peer-reviewed literature. In both cases, the inclusion of sex/gender issues can be required by both funding agencies and journal editors as a condition of successful project completion and/or publication.

## Gender Differences in Basic Science

Inclusion of women in clinical studies, at least in NIH-funded or U.S.-based clinical research, has been largely successful, although women are still underrepresented in early phase clinical studies and in some therapeutic areas for FDA-regulated products (Gochfeld, 2010; Pinnow, Sharma, Parekh, Gevorkian, & Uhl, 2009; Yang et al., 2009). However, sex difference studies at the basic cellular and animal levels have not yet become the norm for biomedical research (Zucker & Beery, 2010). The Institute of Medicine's 2001 report, "Exploring the Biological Contributions to Human Health—Does Sex Matter?" found that research on biological sex differences was a maturing science and needed to overcome barriers that range from continuing confusion about terminology (e.g., "sex" versus "gender"), lack of dedicated resources, and the lack of reporting of the sex of origin of cell and tissue culture material in the literature (IOM, 2001). Yet nearly 10 years have passed with limited change.

Recent advances in molecular and cellular biology have found that the sex of particular stem cells can result in different effects on the medical conditions under study. For example, a study published in 2007 about transplantation of muscle-derived stem cells in mice revealed that female stem cells regenerated skeletal muscle more efficiently than male stem cells (Deasy et al., 2007). The authors noted that their findings provide a compelling

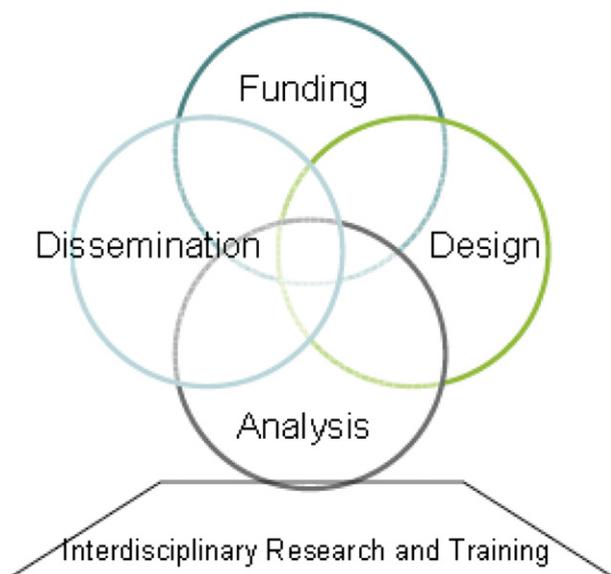


Figure 1. The synergy of research endeavors.

rationale for researchers to report cell sex and to consider the implications of research when only one stem cell sex is used. Further research findings in the physiology of hypertension (Sandberg & Ji, 2008; Ji et al., 2010) demonstrate the need for research beyond questions of hormonal differences and reproductive biology.

The policy questions and strategies that flow from this research include determining which institutions and policy makers can have effects on the research priorities of the scientific community, as well as which approaches will have measurable impacts.

#### *The Role of the NIH*

It is critical that policy changes addressing the importance of studying sex differences at the basic science level be developed and implemented. Sex differences research at the basic science level has been identified as the first goal for the NIH in the new Vision for 2020. Translation of this into funding and implementation will be critical next steps. There is a central role for leadership in changing perceptions and priorities of both the institutes as well as of investigators. Given that the development of “personalized medicine” has been identified as a research priority, it is important to recognize that understanding potential sex differences is the first step in understanding variability in populations. Funding needs to be targeted toward research that can provide new data. The scientific community needs to be engaged by the NIH by convening workshops focused on the basic science of sex differences across the range of health conditions or priority areas.

#### *The Role of Congress*

Congress has played a significant part in the expansion of women's health research through oversight and funding directives for NIH, as well as through statutory requirements. However, Members of Congress too have typically focused on clinical research. Yet it falls to congress to set the overall funding levels for NIH each year for both clinical and basic science. Those members of congress interested in increasing research on women's health should consider making basic science research in sex differences a priority, either through funding directives or through statutory changes.

#### *The Role of Peer-Reviewed Journals Is Profound*

Policy changes across many journals, particularly the leading basic science journals need to be put in place to ensure that data on sex of cell lines, animal models, and so on, are presented in datasets and journal articles submitted for publication. Currently some clinical journals, such as the *Journal of the National Cancer Institute*, call for submission of data on inclusion of women and of analysis of findings, but this policy is not found for basic science journals. Journal editors rightfully retain independence of funding agencies and entities, but should take the lead on ensuring the quality of data submitted and that results reflect examination of potential sex differences (whether positive or negative results). “Best practices” for journals should be developed regarding requirements for analysis, publication of negative results, which can have real value in understanding sex differences, and requirements that authors discuss limitations when only one sex is studied.

## **Women's Health and “Team Science”**

Cross-disciplinary science, ranging from multidisciplinary teams working in parallel on related research, to interdisciplinary research that crosses disciplines to develop new approaches, to transdisciplinary research that has the potential to develop long-term integrated research approaches, has developed side by side with research on women's health over the last two decades. Indeed, some of the funding mechanisms developed by NIH ORWH such as the Building Interdisciplinary Research Careers in Women's Health program, and the Specialized Centers of Interdisciplinary Research on Sex and Gender Factors affecting Women's Health, as well as the National Centers of Excellence in Women's Health funded by the DHHS Office on Women's Health, have established a number of interdisciplinary research groups across the country (Mazure et al., 2000). These mechanisms, along with the broader NIH focus on cross-disciplinary research identified in the NIH “Roadmap” (NIH, 2008) and with the recent development of NIH and FDA collaborative efforts on Regulatory Science (FDA, 2010), are supporting innovative research strategies that have great promise. There are even key aspects of team science that are now being studied as a field all its own—the science of team science (Stokols, Hall, Taylor, & Moser, 2008). Evaluating success through specific measures is important to ensure that the strategies of interdisciplinary research are in fact productive. Indicators of successful research and training include measuring scientific advances, development of new methods and approaches, translations of research into health practice as well as into important new health policies, and ultimately seeing improved health outcomes.

#### *Cross-Disciplinary Research Challenges and Opportunities*

Focusing efforts on women's health research, linking across fields to bring basic science research methods together with clinical, translational, and policy research have thus far been fruitful (Brittle & Bird, 2007; Greenberger & Becker, 2009) and should be continued. Linkages with health services research, often funded by other sources, including the Agency for Health Care Quality and Research, need to be expanded and integrated. In addition, the evaluation and measurement of impact components need to be strengthened to a comparable level of rigor as applied to other research. Cross-disciplinary research also faces administrative challenges within academic institutions where publication and grant support is traditionally assigned within one department or school and therefore can inhibit collaboration across disciplines. The Building Interdisciplinary Research Careers in Women's Health program has a core component of mentoring and development of independent research capability, and is a model for career development for junior faculty in an interdisciplinary setting that is a priority across many NIH training programs.

#### *The NIH and Cross-Disciplinary Research*

The NIH policies for multiple principal investigators begin to address this potential conflict with the nature of interdisciplinary research, but further actions to support innovative projects that cross traditional boundaries within universities and medical centers need to be undertaken. A goal of the Vision for 2020 identifies multidisciplinary research and collaborative partnerships as critical to women's health research. Moving toward new

research models may require new orientation and education for reviewer and study sections at the NIH as well as with faculty organizations within academic research institutions. Successful models for promotion and tenure for more senior scientists in the context of team science need to be identified and disseminated widely.

### **The Health Care Workforce and Translation of Women's Health Research**

The recognition that women's health encompasses more than reproductive health and is in fact intrinsically interdisciplinary has led to calls to reduce fragmentation in health care delivery to women. Traditionally, various modalities of care have been offered by obstetricians/gynecologists (OB/GYNs), internal medicine, family medicine, and general medicine practitioners, although there is increasing recognition of a need to provide more comprehensive care that includes all aspects of a woman's health across her lifespan. Despite these calls to reduce fragmentation, many practitioners remain underinformed about critical aspects of women's health, such as the fact that cardiovascular disease is the leading cause of death among women in the United States (Centers for Disease Control and Prevention [CDC], 2006). To bring about practice changes, training of medical and allied health professionals needs to incorporate relevant and up-to-date scientific findings on sex and gender differences and women's health—especially those that inform health care provision—into curricula used to train and update knowledge for the health care workforce (Correa-de-Araujo, 2004).

The undergraduate medical curriculum remains one of the chief ways that health care providers receive training in women's health. However, practical training for medical students and faculty development women's health are still not consistently represented in medical school curricula. In 1994 and 1995, the Association of American Medical Colleges, the ORWH, and other federal agencies surveyed the curricula of medical schools to determine women's health content. Seventeen percent of respondent schools indicated that they had a "core curriculum" in women's health, although these curricula were limited to a single course or seminar focusing on such topics as domestic violence or the didactic component of an existing clerkship or clinical elective. One fourth of the schools offered a clinical rotation in women's health that was separate from a rotation in obstetrics/gynecology (HRSA, 1996). A review of published surveys that tracked women's health curriculum activities in U.S. medical schools between 1994 and 2001 concluded that progress has been slow at best (Henrich, 2004). A 2006 study found that fewer than 9 schools out of 95 who entered courses into Association of American Medical Colleges' Curriculum Management and Information Tool from November 2003 to February 2004 met the authors' criteria for an interdisciplinary women's health curriculum (Henrich & Viscoli, 2006).

Henrich and Viscoli (2006) suggested that the slow integration of gender-specific information into curricula can be attributed to a variety of reasons, including lack of awareness of data on gender differences, the lesser value placed on this information by some faculty members, and difficulties schools face in adding new information to an already overloaded curricula. The integration of new knowledge into medical school curricula is indeed a difficult process, involving the development of a core women's health faculty, development and assessment of specific competencies, interdisciplinary team teaching that crosses traditional disciplinary boundaries, standardized patients who demonstrate

complex women's health issues, and comprehensive and current reference resources.

### *The Role of the NIH and Related Offices of Women's Health in Partnership with Clinical Education Systems*

Agencies and offices with roles in provider education should expand partnerships with organizations that approve medical school curricula and specialty medical organizations to strengthen and broaden the women's health science/research basis of curricula for graduate medical training. Continuing Medical Education in particular provides an important opportunity to incorporate clinically relevant gender information into the periodic updates required of all practicing physicians. For example, the DHHS Office on Women's Health provides online professional education materials and Continuing Medical Education credits on the topic of women and cardiovascular disease via its HeartTruth campaign, conducted in collaboration with the NIH and the American Heart Association (available: <http://www.womenshealth.gov/hearttruth/>). These materials are currently being updated with a special focus on ways that OB/GYNs (who are the providers many women most often see) and other reproductive health clinicians can effectively integrate screening for common risk factors for heart disease among women, as well as effective management of these risk factors.

In addition, there is an opportunity to reach out to new audiences and try new strategies. Medical specialty board examinations can directly affect what is studied and learned, and may be a tool to expand knowledge of the next generation of health professionals. Efforts should be broadened to improve women's health and basic sex differences educational curricula for trainees and continuing education for practitioners for all members of today's new interdisciplinary health care teams, for example, nurses, nurse practitioners, physician assistants, dentists, health psychologists, dietitians, and physical therapists.

In conclusion, the launch of a new strategy by the NIH ORWH can serve as a catalyst for promulgating a heightened awareness of the importance of sex and gender differences throughout the health research community. Biomedical research is not done purely for its own sake; it has implications for health outcomes. It is ultimately connected to the education and training of health care professionals and to the quality of care that we receive. It is funded largely through tax dollars based on priorities set by elected officials and through peer review by the scientific community. Beyond calling for increases in overall funding for research, the research community needs to examine the policies underlying the NIH's research portfolio and prioritize the opportunities that exist in research on sex differences, women's health, and cross-disciplinary research, and ensuring the communication of research findings to current and future health professionals. The research community also needs to improve the connections between the biomedical research funded by the NIH with health services and comparative effectiveness research that incorporates questions on the impact of both sex and gender.

Although the IOM identified the study of sex differences as a maturing science in 2001, not as much progress in basic science has been made as we would have expected. Incremental progress has been made in specific areas, but this approach needs to be adopted for many diverse research questions. This should not be seen as a mandate, but rather as an exciting and productive avenue of research that can lead to elegant experiments and novel findings that will contribute to overall health outcomes improvement for the entire population.

New mechanisms for innovative research through interdisciplinary teamwork have opened new horizons, but institutions have not yet adapted to really stimulate this type of research. Women's health research has been shown to be a productive model for this type of research, and the output of existing projects should be rigorously evaluated so that effective methods can be disseminated and replicated. With good evaluation, the next level of cross-disciplinary research—working across institutions drawing on research teams and expertise across the country—can flourish.

The health policy community in the United States is currently focused on the implementation of national health insurance reform. Its impact on women's health presents significant questions. With increased access to coverage, will health professionals have the capacity and skills to provide quality care? With expanded research on comparative effectiveness, will knowledge about sex and gender differences with clinical relevance be translated into practice? As new health delivery systems and financing arrangements are developed in response to national health reform and its focus on quality and prevention, this new knowledge about women's health must be gained through rigorous research, and it needs to be mainstreamed throughout health professional curricula, Continuing Medical Education, and other training.

Opportunities abound for the scientific community, health professionals, key federal research agencies such as the NIH and its sister agencies the FDA, AHRQ, HRSA, and CDC, for policy makers in congress, and for women's health research advocates to move the women's health research agenda (and its downstream effects) to the next level to improve health care for everyone. The challenge is to inspire current and future leadership at every level to identify priorities in women's health research, and to move these forward in visionary and thoughtful ways.

## References

- Bird, C. E., Fremont, A. M., Bierman, A. S., Wickstrom, S., Shah, M., Rector, T., et al. (2007). Does quality of care for cardiovascular disease and diabetes differ by gender for enrollees in managed care plans? *Women's Health Issues*, 17(3), 131–138.
- Brittle, C., & Bird, C. E. (2007). "Literature Review on Effective Sex- and Gender-Based Systems/Models of Care." Produced for the Office on Women's Health within the U.S. Department of Health and Human Services by Uncommon Insights, LLC. Available: <http://www.womenshealth.gov>. Accessed June 23, 2010.
- Centers for Disease Control and Prevention (CDC). (2006). Leading causes of death in females United States, 2006. Available: <http://www.cdc.gov/women/lcod/>. Accessed July 7, 2010.
- Correa-de-Araujo, R. (2004). A wake-up call to advance women's health. *Women's Health Issues*, 14, 31–34.
- Deasy, B. M., Lu, A., Tebbets, J. C., Feduska, J. M., Shugar, R. C., Pollett, J. B., et al. (2007). A role for cell sex in stem cell-mediated skeletal muscle regeneration: Female cells have higher muscle regeneration efficiency. *Journal of Cell Biology*, 177, 73–86.
- Food and Drug Administration (FDA). (2010, February 24). NIH and FDA announce collaborative initiative to fast-track innovations to the public. FDA–NIH News Release. Available: <http://www.fda.gov/>. Accessed June 23, 2010.
- Gochfeld, M. (2010). Sex-gender research sensitivity and healthcare disparities. *Journal of Women's Health*, 19, 189–194.
- Greenberger, P., & Becker, J. (2009, May 1). Society for Women's Health and the Women's Health Coalition written testimony before the House Appropriations Subcommittee on Labor, Health and Human Services, Education and Other Related Agencies. Available: <http://www.womenshealthresearch.org>. Accessed June 23, 2010.
- Henrich, J. B. (2004). Women's health education initiatives: why have they stalled? *Academic Medicine*, 79, 283–288.
- Henrich, J. B., & Viscoli, C. (2006). What do medical schools teach about women's health and gender differences? *Academic Medicine*, 81, 476–482.
- Health Resources and Services Administration (HRSA). (1996). *Women's health in the medical school curriculum. Report of a survey & recommendations (HRSA-A-OEA-96-1)*. Washington DC: U.S. DHHS, HRSA, and NIH.
- Institute of Medicine (IOM). (2001). Exploring the biological contributions to human health: Does sex matter? Washington, DC: The National Academies Press. Available: <http://www.nap.edu/>. Accessed June 23, 2010.
- International Committee of Medical Journal Editors (ICMJE). (Undated). Uniform requirements for manuscripts submitted to biomedical journals: Publishing and editorial issues related to publication in biomedical journals: Obligation to publish negative studies. Available: <http://www.icmje.org>. Accessed June 11, 2010.
- Ji, H., Zheng, W., Wu, X., Liu, J., Ecelbarger, C. M., Watkins, R., Arnold, A. P., et al. (2010). Sex chromosome effects unmasked in angiotensin II-induced hypertension. *Hypertension*, 55, 1275–1282.
- Kanzanjian, A., & Hankivsky, O. (2008). Reflections on the future of women's health research in a comparative context: Why more than sex and gender matters. *Women's Health Issues*, 18, 343–346.
- Mazure, C. M., Arons, A., & Vitale, A. (2001). Examining structured representation and designated fiscal support for women's health in the U.S. Department of Health and Human Resources. *Journal of Women's Health & Gender-Based Medicine*, 10, 849–860.
- Mazure, C. M., Espeland, M., Douglas, P., Champion, V., & Killien, M. (2000). Multidisciplinary women's health research: The National Centers of Excellence in Women's Health. *Journal of Women's Health & Gender-Based Medicine*, 9, 717–724.
- National Institutes of Health (NIH). (2001). NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research—Amended, October, 2001. Available: <http://grants.nih.gov>. Accessed June 10, 2010.
- National Institutes of Health (NIH). (2008). Overview of the NIH roadmap. Available: <http://nihroadmap.nih.gov/overview.asp>. Accessed June 23, 2010.
- National Institutes of Health (NIH). (2009). Report of the Advisory Committee on Research on Women's Health, fiscal years 2007–2008." Available: <http://orwh.od.nih.gov>. Accessed June 7, 2010.
- Office of Research on Women's Health (ORWH), NIH (2008). Comprehensive reports, 1997–2008. Available: <http://orwh.od.nih.gov>. Accessed June 10, 2010.
- Office of Research on Women's Health (ORWH). (2010). Moving into the future with new dimensions and strategies: A vision for 202 for women's health research. Available: <http://orwh.od.nih.gov>. Accessed Nov 15, 2010
- Pinnow, E., Sharma, P., Parekh, A., Gevorkian, N., & Uhl, K. (2009). Increasing participation of women in early phase clinical trials approved by the FDA. *Women's Health Issues*, 19, 89–93.
- Sandberg, K., & Ji, H. (2008). Why can't a woman be more like a man? Is the angiotensin type 2 receptor to blame or to thank? *Hypertension*, 52, 615–617.
- Stokols, D., Hall, K. L., Taylor, B. K., & Moser, R. P. (2008). The science of team science: Overview of the field and introduction to the supplement. *American Journal of Preventive Medicine*, 35(Suppl. 2), S77–S89.
- U.S. Department of Health and Human Services (DHHS), Public Health Service, National Institutes of Health. (1999). Agenda for Research on Women's Health for the 21st Century. A report of the Task Force on the NIH Women's Health Research Agenda for the 21st Century, volume 1 (NIH Publication No. 99-4385, 1999). Executive summary. Bethesda, MD. Available: <http://orwh.od.nih.gov/>. Accessed June 7, 2010.
- Yang, Y., Carlin, A. S., Faustino, P. J., Motta, M. I., Hamad, M. L., He, R., et al. (2009). Participation of women in clinical trials for new drugs approved by the Food and Drug Administration in 2000–2002. *Journal of Women's Health*, 18, 303–310.
- Zucker, I., & Beery, A. (2010). Males still dominate animal studies. *Nature*, 465, 690.

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