

Quinacrine: Tests Find Genetic Damage

Coinciding with the announcement by Family Health International (FHI) that its recent *in vitro* toxicology tests link quinacrine to genetic damage, proponents of this new form of chemical sterilization used the Fourth World Conference on Women NGO Forum to introduce this method.

Quinacrine sterilization is a permanent, non-surgical form of female sterilization in which seven pellets of quinacrine are inserted into a woman's uterus in two doses, one month apart, causing blockage of the fallopian tubes. The method, which is inexpensive and does not require hospitalization, has been used on 100,000 women in 15 countries to date. Its failure rate is between 3 and 5 pregnancies per 100 women after five years. Use of quinacrine for sterilization has not been approved by any major drug regulatory agency and the World Health Organization does not recommend its clinical use until additional toxicology studies are completed.

According to the Sept. 1995 issue of *Network*, "FHI-sponsored short-term tests on genetic toxicity . . . confirmed that quinacrine can cause genetic damage in the *in vitro* (test-tube) systems used." FHI launched this toxicology study in 1994. Previous FHI-sponsored toxicology studies were conducted more than 10 years ago, when U.S. government requirements for evaluating toxicity were significantly different. The article also notes that FHI lacks funding to continue the 8-year, US\$8 million studies.

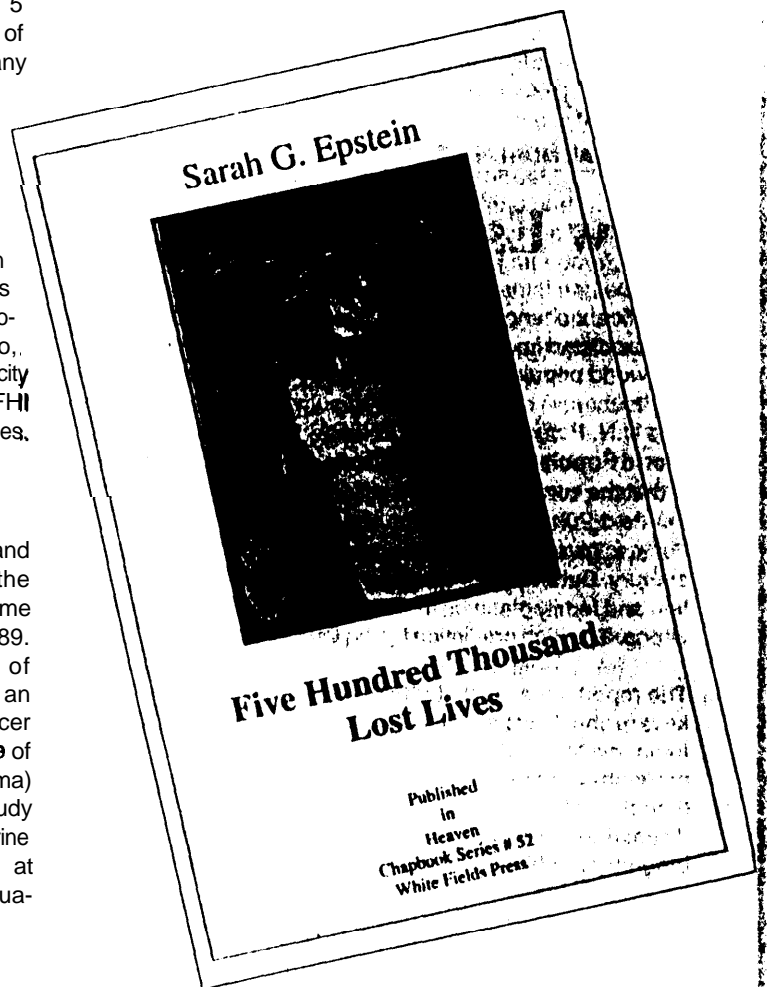
Retrospective Studies Continue

FHI will continue with retrospective studies in Chile and Vietnam. The Chilean study was prompted by the appearance of a cluster of cancer cases among some 1,500 women given quinacrine between 1977 and 1989. Initial findings published in the August 1995 issue of **Fertility and Sterility** confirmed the occurrence of an unusual cluster but found no evidence of excess cancer risk associated with quinacrine. However, occurrence of one provocative observation (a uterine leiomyosarcoma) merits continued surveillance. In Vietnam, the FHI study will follow-up more than 2,000 quinacrine users. Quinacrine sterilizations were suspended in Vietnam in 1993 at WHO's suggestion, pending further toxicological evaluations.

Quinacrine in Beijing

Meanwhile, quinacrine proponents took their efforts to China during the 4th World Conference on Women. At the NGO Forum at Huairou, a new 22-minute training video on

Quinacrine Sterilization (QS) was premiered by the U.S.-based institute for Development Training (IDT) with accompanying manual and information brochures for service providers and potential clients. The presentation took place in a workshop held by quinacrine advocate Dr. Elton Kessel and included presentation of data from a clinical study in India. In an exchange of views at the close of the session, quinacrine opponents questioned presenters on safety and ethical issues.

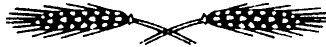


In **Five Hundred Thousand Lost Lives**, family planning expert Sarah Epstein questions the "Western perspective and pressure" that led Vietnam to cancel its quinacrine program.

The **48-page** IDT training manual addresses the issue of safety by noting the possibility of long-term risk but weighing this against savings in maternal mortality, stating that the "only one rational **crit**erion to judge the use of a new treatment... is the risk-benefit analysis." **Accompanying** brochures answer the question "How safe is QS?" in this way: "QS is still a new method. It has been shown QS is safer in terms of complications than surgical **sterilization**, especially in parts of the world where hospitals/clinics

are poorly equipped." Under disadvantages, it notes the following: "QS is still a new method. There may be risks which are not yet known."

While in China, quinacrine proponents met with family planning officials. Sterilization is the most prevalent method of birth control in China. Chinese researchers are currently conducting their own investigations with quinacrine compounds.



In Chile, QS Studies Continue

In Chile, the **birthplace** of quinacrine sterilization, it's "business as usual" for this controversial form of chemical sterilization after a short-lived public outcry and temporary suspension.

Scrutiny by local women's health activists last year stopped the Chilean Health Ministry from entering expanded trials and brought about first-ever talks between feminists and quinacrine researchers.

Quinacrine sterilization has been part of the national research landscape since the early **1970s**, when it was first developed by Chilean scientist Dr. Jaime Zipper. Some 1,500 women have undergone quinacrine sterilization to date in Zipper-supervised trials conducted in three public hospitals.

But it wasn't until Health Ministry plans to participate in expanded **trials** came to light last year that quinacrine use erupted into public controversy.

The uproar began when women's health activists received copies of a Sept. 1994 memo from the U.S.-based Center for Research on Population and Security, stating that the Chilean Health Ministry was replacing surgical sterilization with quinacrine in the nation's two most populous regions. CRPS presented this possibility as a policy, saying that Chile's support of quinacrine — and its courage in the face of the World Health Organization's "ridiculous" position against clinical use— was a landmark event that would pave the way for quinacrine sterilization throughout the region. The bombastic assertions turned out to be false. But probing by activists determined that the Chilean Health Ministry was, in fact, studying plans to join the Zipper team in providing quinacrine sterilization to up to 1,000 women in central and southern Chile.

Chile's Contradictory Context

The ironies of quinacrine development in Chile are considerable. Female sterilization is highly restricted (medical reasons only, over age 30, four living children, spousal authorization) under a 1975 decree by the pro-natalist Pinochet regime. Vasectomy in public health services is virtually unheard of. **Abortion** for whatever reason (including to save the mother's life) is strictly illegal.

Nonetheless, demand for female sterilization is high, with public health services performing up to 15,000 surgical sterilizations a year. Unmet need is high, too, due to exclusionary restrictions, complicated **paperwork** for allowable cases and the limited number of public hospital beds available for elective surgery.

While governed by the same restrictions as surgical sterilization, the out-patient quinacrine procedure provides Chilean women who cannot afford private medical care with a fast **track** to sterilization that eliminates the long wait for a public hospital bed. Women who come to the public health services voluntarily seeking sterilization and agree to be treated with quinacrine are informed that it is definitive and irreversible, that it has a 3 percent failure rate and that alternative methods exist to prevent pregnancy. Nowhere is it stated that the Chilean health services classify the treatment as "investigational," as opposed to routine.

With women's health activists sounding the alarm over quinacrine safety and the specter of experimentation on poor women, the Chilean Health Ministry withdrew its support of quinacrine research and called, in December 1994, for suspension of its use. More than a ban, however, this proved to be a short hiatus in which the three public hospitals conducting trials were asked to review

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their internal ethical procedures. (In Chile's **decentralized** public health care system, research decisions **are made by** the Ethical Committee of each hospital.)

In response, the **Sótero del Rio** Hospital — Dr. Zipper's research base and home to the country's largest maternity ward — stopped quinacrine sterilizations for three months. It has since reinstated its program, however, and is conducting a privately-financed trial with up to 700 women. (As of mid-year, quinacrine programs in two other hospitals were still under internal review.)

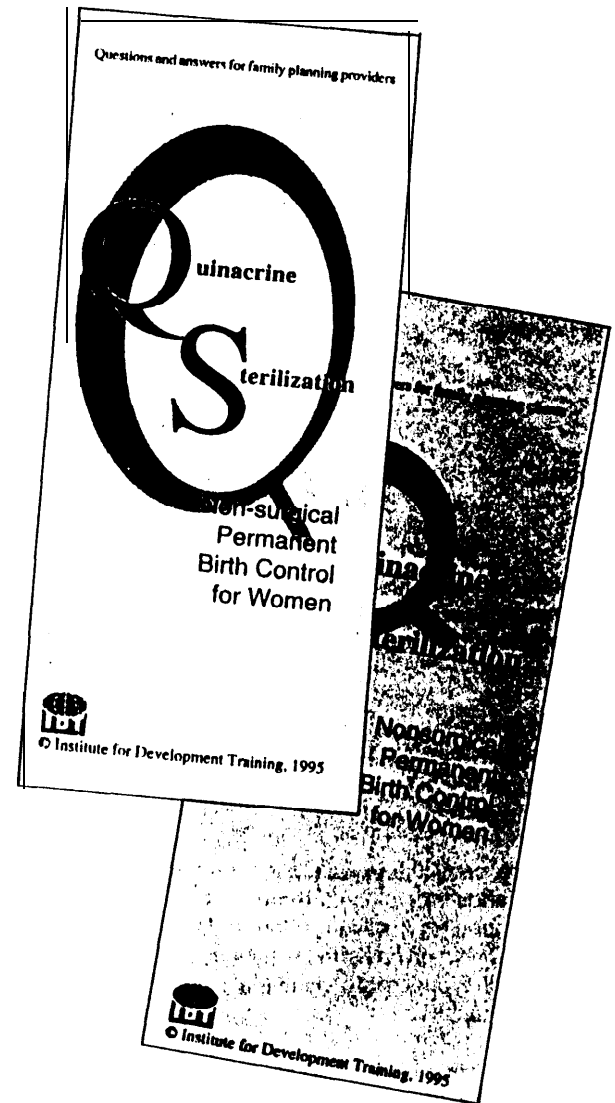
Despite its decision to distance itself from trials, Health Ministry officials continue to view quinacrine as a promising option to satisfy the unmet need for voluntary sterilization.

Zipperites meet Feminists

Leading public scrutiny of quinacrine use in Chile is the Santiago-based *Foro Abierto de Salud y Derechos Reproductivos* (Open Forum for Reproductive Health and Rights.) The *Foro* has expressed three basic concerns: 1) unresolved issues of safety, including the need to delay clinical use until toxicology trials are satisfactorily completed; 2) the need for improved informed consent procedures; and 3) the need for greater transparency of information and improved access to hospital ethical committees.

In June 1995, the *Foro* met with Dr. Zipper and his team, including experts from various medical specialties. Citing the backlog of women requesting sterilization and the danger of unwanted pregnancy while awaiting for surgery, the Zipper team defended its decision to resume quinacrine use while awaiting new toxicology reports. They acknowledged the weakness of existing informed consent protocols and broached the possibility of holding additional meetings with the *Foro* to discuss this issue, possibly with representatives from the Ministry of Health.

The Pan American Health Organization's Latin American and Caribbean Regional Program on **Bio-Ethics** has also expressed reservations about unresolved issues of quinacrine safety and informed consent to national health authorities. However, the Program views its role as educational, not activist, in monitoring ethical issues concerning reproductive rights in Chile.



From: "Progress Report: **Quinacrine** Pellet Method for Nonsurgical Female Sterilization", Center for Research on **Population** and Security (USA), Sept. 30, 1994; "**FHI's Role in** Search for Nonsurgical Sterilization," Network, May 1994; "**FHI Quinacrine** Studies" Network (USA), Sept. 1995. institute for Development Training Module 1, "**Quinacrine Sterilization**," Sept. 1995; *Journal of Reproductive Medicine* (China) Vol. 3, No. 1, Dec. 1994; *Five Hundred Thousand Lost Lives*, Sarah Epstein, Chapbook Series #52 (USA), 1995.