
Women
Deserve Free
Contraception
Non-surgical permanent
contraception for women (QS)
should be available everywhere

Women Deserve Free Contraception

Non-surgical permanent contraception for women (QS) should be available everywhere

ISAF Publishing

P.O. Box 7132
Van Nuys, CA 91409
Phone: (202) 656-6421

Published by ISAF Publishing 03/03/2022

ISBN: 9798425699091

Print information available on the last page.

Any people depicted in stock imagery provided by Getty Images are models, and such images are being used for illustrative purposes only.

Certain stock imagery © Getty Images.

This book is printed on acid-free paper.

Because of the dynamic nature of the Internet, any web addresses or links contained in this book may have changed since publication and may no longer be valid. The views expressed in this work are solely those of the author and do not necessarily reflect the views of the publisher, and the publisher hereby disclaims any responsibility for them.

This book is a work of non-fiction. Unless otherwise noted, the author and the publisher make no explicit guarantees as to the accuracy of the information contained in this book and in some cases, names of people and places have been altered to protect their privacy.

Dedication

This book is dedicated to generations of strong women who've added joy to our lives: wives, mothers, sisters, daughters, grandmothers, aunts, granddaughters, great granddaughters, competitors, and friends. We send love and strength to all women of the world on your journey to become equal to men. We wish women were equal to men already and want to accelerate the process.

Acknowledgements

Thank you to the following family, advisors, friends, and colleagues for making editorial suggestions and improvements to the book:

Sarah G. Epstein
Dr. Jack Lippes
Donald Collins, Sr.
Dr. Stephen D. Mumford
Lola Heavey
Declan Heavey
ISAF Board of Directors

Contents

Introduction

This book is a thank you to generations of women who have directly enhanced our lives and to the young women taking over who are in their prime, working, and may be the key to saving humanity's future.

The pioneers in this book spent their lives helping women and by extension many children and families. On March 3, 1873, Congress passed a law, later known as the Comstock Act. The statute defined contraceptives as obscene and illicit, making it a federal offense to disseminate birth control through the mail or across state lines. Dr. Clarence Gamble and Margaret Sanger battled to eliminate Comstock a hundred years ago. Today there are powerful forces in the U.S. that would return us to those dark backward times. We must not allow this to happen.

My wife and I and our siblings were born to loving parents in an enlightened time compared even to the 1920s. Thanks to our parents' sacrifices, we experienced idyllic childhoods compared to most.

But, there's more, as famous investor Warren Buffett said about the "ovarian lottery", a phrase he coined:

> "It's the most important event in which you'll ever participate," Buffett said at Berkshire's annual

> shareholder meeting in 1997. "It's going to determine way more than what school you go to, how hard you work, all kinds of things. You're going to get one ball drawn out of a barrel that probably contains 5.7 billion balls now, and that's you.
>
> Buffett noted that he and his business partner, Charlie Munger, won the lottery by being born white, smart, able-bodied, male, and in America."

By my calculation, I won the "ovarian lottery" with incredible odds, (1 in 1000) compared to others in the world. Born white (1 in 6), to a family in the top quintile of U.S. income (1 in 5), born without a defect in U.S. (1 in 1), expected male income in U.S. (1 in 2), born in the U.S.A. (1 in 16). Sadly, few people had odds as good as mine. My wife had similar odds, but women in the U.S. earn $0.82 for every $1.00 men do, they control only 31% of household assets, and they must pay to protect themselves with birth control. How could this still be true in the 21st century for U.S. women?

The biggest factor above was being born an American with the freedom and opportunities a constitutional federal republic provides. A friend reminded me recently what Thomas Paine said in *Common Sense*, that "the law is king." I'm thankful to those who served and gave the ultimate sacrifice to win and protected our United States for over

245 years. Of course, many in the world don't share our good luck.

After this main advantage, the key takeaway from this simplified calculation is that for women to be equal to men, they must have at least three things, 1) control over their bodies including free contraceptives with education about how to use them, 2) a good education so they qualify for high pay, both of which 3) leads to them obtaining equal capital. That is why I encouraged my daughters to get educated, use birth control, and have control over their own finances in any partnership they were in. In other words, maintain your own personal power and have a separate brokerage account and fill it as though it will be your only capital, your only means of support, when you can no longer work.

My siblings and I owe much of who we are today to our loving mother who, like she said about her mother, "had a strong sense of what was right and wrong, of duty, and that it should always be performed gracefully." She told us obey the golden rule, be honest (*Crime and Punishment* was her favorite book), have fun, and shoot for the stars.

Because of the selfless actions of the women who have helped us, we are grateful and optimistic about women's future, and want to help by proposing doctors combine 60-year-old Lippes Loop IUD technology with a 45-year-old method called non-surgical permanent contraception

for women (QS), both proven technologies into ***A simple idea*** for women to be equal to men (4♀2B=2♂) today.

Contraception is the first best (safest and effective) biological equalizer for women. Some strides have been made in family planning since the advent of the Pill in 1957 and since Dr. Lippes invented his Loop (IUD) in 1962. But not enough. Sadly, on the eve of the Loop's diamond jubilee the U.S. Supreme Court may overturn Roe v Wade which legalized abortion nationwide for 49 years since 1973.

Why don't all couples practice birth control to prevent pregnancy? According to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System (CDC), the provisional number of births for the United States in 2019 was 3,745,540. In that same year, the CDC reported there were 629,898 abortions proving that U.S. family planning is not working **BECAUSE CONTRACEPTIVES AND THE EDUCATION IN THEIR USES ARE STILL NOT UNIVERSALLY AND FREELY (PAID FOR WITH TAX DOLLARS) AVAILABLE IN THE U.S.** This book advocates for a safe, effective, and inexpensive solution.

Don't we all love new ideas that help people? One's legacy, after one's children, might be as ancient Hebrews said Tikkun Olam to "heal the world." Aperion Care, Inc. has a website, that shows the

number of human lives saved per invention with a timeline and references. Imagine if all birth control methods (like QS and the Lippes Loop) were universally available for free. The author estimates the impact of this (QS, Lippes loop, and other contraceptives available for free) added to the table. WHAT IF EVERY CHILD WAS A WANTED CHILD!

Year	Invention	Human Lives Saved (billion)
1875	Toilets	1
1909	Synthetic Fertilizers	1
1913	Blood transfusions	1
1945	Green revolution	1
1955	Vaccines	1
2022	Universal Free birth control	2
1890	Pasteurization	0.25
1928	Antibiotics	0.2
1919	Water chlorination	0.175

(Credit: ISAF)

Thanks to Julia Kahrl, founder of Grandmothers for Reproductive Rights, GRR who posted Tonto Dikeh's saying.

> "One man can impregnate 9 women every day for 9 months. Those are 2430 pregnancies. One woman can only get pregnant once within 9 months, even

> if she beds 9 men every day within 9 months. That's only 1 pregnancy. So clearly, society is placing the birth control responsibilities on the wrong gender. Science is busy making pills, and hormone-altering devices for the wrong person. The culprit is known and on the loose."

Mea culpa, I was not the husband I could have been. My sons and sons-in-law are so much more committed to sharing the workload at home than I was. I'm very proud.

So, this book is also a request to men everywhere to take up this issue (consider having a vasectomy) so the women in your lives (and all women) can become equal to men today.

Thank you,
Don Collins, Jr.
P.O. Box 7132
Van Nuys, CA 91409
donjr@quinacrine.org
(202) 656-6421
March 2022

Chapter 1 A Simple Idea Lets Women Influence their Family's Destiny

(Credit: USDA)

19 November 2021

The U.S. Centers for Disease Control (CDC) reported in 2019, that California women gave birth to 446,479 kids. That's about a 1% increase considering 39+ million people live in CA.

According to the U.S. Department of Health and Human Services' Healthy People 2020 campaign, 51%

of the 6.6 million pregnancies in the United States each year are unintended.

In 2012, the (CDC) also reported that 37.8% of those births from unintended pregnancies were to women who did not want that pregnancy nor any more pregnancies in the future (unwanted as opposed to ill-timed). In California in 2019, there were 86,072 of these births to women who didn't want any more children.

In 2015, U.S. Department of Agriculture reported that a child born in 2015 costs $233,610 to raise to 17 years old, excluding college.

So, in 2019, why did each of 86,072 California families spend almost $14,000 ($1.2 billion total) to raise children they didn't plan on having?

Gaining equality for women is mostly an economic issue. To generate income leading to capital, women must work in the marketplace or become business owners both of which takes time and effort. The most effective way for a woman to control her economic situation is by controlling the way she spends her time and energy. So, limiting the number of children a woman has leads to more free time thus more equality.

Caught in the same situation as described above, my very successful 37 and 39-year-old daughters (both

with careers) and their husbands, don't want to have any more kids. To eliminate the worry of having a child or abortion in the last decade of their fertility, my daughters must undergo surgical tubal ligation which they don't want.

Why isn't there a better alternative for them than the Pill or a long-acting reversible contraceptive (LARC)? They have all the children they need (can afford - given limited resources) but don't want to undergo a surgical procedure.

Likewise, my 33-year-old twin stepdaughters might benefit from a more benign (nonhormonal and nonmetal) LARC like the Loop as they may want to have more children. We're so proud of our six children (Brady bunch) who have excelled beyond our accomplishments and are so much more in the know than we were.

Kristina Wright at mom.com found *23 Moms (who) Share How They Knew They Were Done Having Kids*

> "Deciding to have a baby is a big step in your life. For many of us, it's just a matter of when to start our family, because we've always known we wanted kids. For some of us (me, included), we go years, even decades, thinking we don't want kids until one day … we do. But as big

and monumental as it is to start a family, how do you know when you're done? How do you decide that this baby is the last baby?

For me, I don't know that I ever "knew" I was finished having babies. I told a lot of people I was done after one, but I still couldn't bring myself to get rid of the baby clothes. Good thing, as his baby brother came along before he had even turned 2! We talked about a third, but health issues postponed it and then my age was a factor. Even now, at 49, it's hard to say, "I'm done," even though I know I am—biologically, if not emotionally.

I asked other moms how they knew when they were done having kids. If you're undecided about whether you would like another baby (or two), maybe their answers will help you make up your mind."

"As a young girl, I wanted as many kids as I could afford to take care of—of course, I had no concept of how much they actually cost. I had four with my ex-husband and believed we were done and I have one with my husband now and miscarried another. I wanted more but I couldn't deal with (another miscarriage) again. So we haven't." – Renee

"The youngest got to be too old (in my mind) and I'd gotten too used to sleeping at night." – Fedora

"We couldn't afford daycare for more than one. I can actually remember the day we sat down and examined our finances. We weren't willing to short our son in order to have another, and we'd have to. Vasectomy was then scheduled!" – Jackie

"I saw my husband holding our second daughter, and I knew that everyone who was supposed to be there, was." – Kristine

"Ha! When people kept assuming our youngest was our grandson." – Karen

"I decided at a young age I didn't want anymore after 30, but I was 23 with my last pregnancy and it was such a hard pregnancy. We sat down and looked at our projected income and decided we couldn't afford anymore and my husband had a vasectomy." – Saranna

"I barely survived diapers and the terrible toddler years. Once my son started school, I knew he was it and I wouldn't be having any more." – Audra

"I knew I was done after I found out I was having a second, though hubs would likely say it was after we

found out about the first. After our daughter, I wanted another one. Maybe if we were younger I would have wanted three, but not any more than that." – Tina

"I wanted one. We had twins. Now I am overstocked. (Happily though.)" – Lori

"When my youngest was 2 or so, I wanted another but my marriage and finances were a mess and my pregnancies were all so hard. So my husband got a vasectomy. At this point, it would just be crazy. I'm 45 and my oldest is 24." – Judy

"I really want one more, but circumstances say no. Since I have done foster care and I may again, it is hard to say when I may decide I'm done." – Krista

"When I could not imagine a circumstance—up to and including the death of both of my children—in which I would want another." – Janet

"It sounds really weird, but after our twins were born we joked about being done, but I remember standing in the shower at the hospital and just 'knowing' there was another baby floating out there in the ether. And three years later, when we had our second daughter, I looked into her eyes and knew that was our family and I was done. Besides, I hated being pregnant so much

there was not a force in the universe that could force me into it again!" – Axie

"When I ran out of hands to kid-wrangle." – Kathleen

"I had one and wanted more. I loved being pregnant but couldn't have another. It still hurts, 16 years later." – Ericka

"When my doctor discovered, in the middle of a C-section with my third, that I narrowly missed a catastrophic end to my pregnancy. I had dreamed of having more. " – Leah

"When my youngest was 4, we moved into a new house. I didn't plug up the outlets, I set plants on the floor, I arranged the knickknacks on shelves, and then I thought how I was ready to leave it all that way. I always wanted four kids and I had two. As life went on, I became more and more at peace with that." – Amy

"When, after one miscarriage, then three sons, and then four more miscarriages, we decided we couldn't go through another loss and we were so grateful for our healthy three. We didn't know when we were having that conversation that our fourth boy was in utero, having a laugh." – Lisa

"I never felt done. I decided to take measures to not have anymore because I had three quickly and young (at 23, 27 and 29) and I was feeling overwhelmed. I still regret that decision to this very day. I'd have another in a minute!" – Donna

"When I saw a new baby and thought, 'UGH GROSS. YOU CAN KEEP IT.'" – Delilah

"When I was told that if I got pregnant again I'd likely spend the majority of it in the hospital being monitored and away from my existing babies. That was a big old NOPE." – Chris

"When I had amniocentesis for one while waiting to hear about potential problems with the one that was already here." – Treva

"I didn't want children for a long time. It wasn't in my life plan. When I got married, I made sure my husband understood that I didn't want any. Then one day, the biological clock went off and I felt very differently about it. The hubby and I had a long talk and decided that we would try. After I had her, I didn't want any more. I got the best kid ever and never felt the need to have a second." – Sarah

If you are one of 85 million moms in the U.S. today, are finished having children, don't want surgical tubal

ligation because of the risk, pain and inconvenience, or cost, but do want permanent contraception so you never have to worry about becoming pregnant again, learn about QS on our webite, read this book, share it, and email donjr@quinacrine.org to give us your ideas and tell us what you want and how we can do a better job for you. Please take our survey.

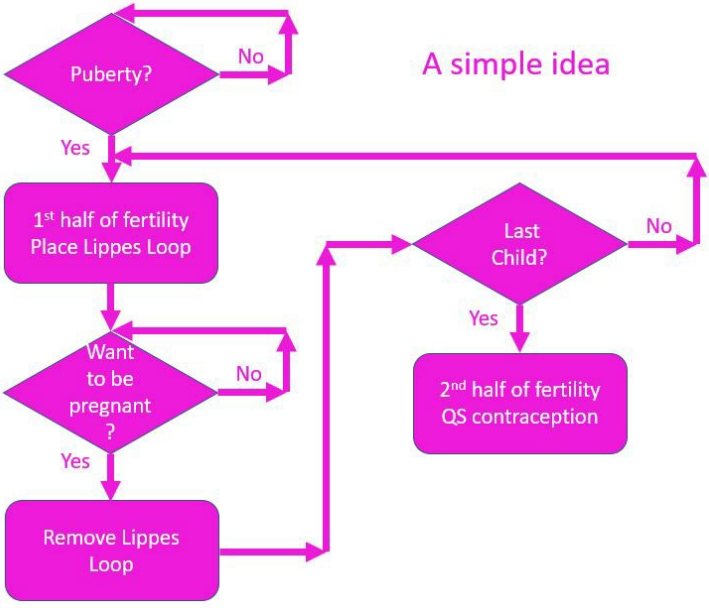
If any of this hits a chord with you, click here to contact your member of Congress or call or email the best advocates for you (women leaders who work for you):

Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111
kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=2♂ today in all of society.

Chapter 2 A Personal Choice made with your Doctor



(Credit: ISAF)

4 December 2021

Your doctor should give you a choice of contraceptives and explain when you need them and how each works.

The American College of Obstetricians and Gynecologists (ACOG), the ultimate experts in U.S. women's reproductive health, offers comprehensive education on birth control here. Often, the first doctor a woman sees

about birth control is her family doctor. They should like ***A simple idea***.

We learn by reading about data of various methods and about the birth control experiences of other women. You can perform your own research, or read about women's experiences by following these five links below:

1) Planned Parenthood Stories: The Benefits of Birth Control

2) Byrdie: 11 Stories of Women and Their Birth Control, Because Talking About It Is Helpful

3) BBC: 'It sucked': Eight women open up about being on the pill

4) Healthline: 4 Things I Wish I'd Known About Birth Control When I Was Younger

5) The CDC says:

> "Women's health and women's reproductive health are high priorities for CDC's Division of Reproductive Health. Our goal is to improve women's health from menarche through menopause. CDC/DRH activities focus primarily on research about the following:

> Contraception (birth control), Depression, Hysterectomy, Female Genital Mutilation/Cutting, Infertility, and Menopause."

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 3 Women Become Equal to Men in the Year 2227

(Credit: Dreamstime.com)

24 June 2019

Thankfully, there are more significant resources being deployed in the women's equality effort than this book. In 2019, Melinda French Gates reported in the evoke.org blog entitled The daunting, damning number that should spur us to action:

> "Based on data from its widely respected Global Gender Gap Index, WEF estimates that it will take the United States another 208 years to reach gender equality. You read that right. At the current pace of

change, gender equality won't arrive in the U.S. until the year 2227. . .

Although women now earn college and graduate degrees at higher rates than men, they remain concentrated in certain majors, and, early in their careers, they are often channeled into less lucrative jobs. Men are 70 percent more likely to be executives than women their same age. . .

On the political front, women are 51 percent of the U.S. population, but hold only 24 percent of seats in Congress. And unlike 59 other countries—including India, Israel, Liberia, Slovakia, Mali, and Malawi—the U.S. has yet to have a female head of state. . .

WEF's projection also reflects the grim reality that the U.S. is the only industrialized nation where maternal mortality rates are actually getting worse. The risks are especially high for African American women, who are three to four times more likely to die during or after delivery than white women. . .

While comprehensive data on U.S. philanthropy is hard to find, there's evidence that gender equality in the U.S. has been chronically underfunded. Preliminary research suggests that for every $1 spent on gender equality by private donors, there

> are $9.27 spent on higher education, and $4.85 spent on the arts. What's more, 90 percent of the money that is going toward women's issues is going toward women's reproductive health specifically. If we want to make gender equality a priority, we need to be spending more—and spreading those resources more broadly."

And, thanks to Melinda French Gates, as we write this, the U.S. House of Representatives has passed the "Build Back Better" (H.R. 5376) act which includes paid family leave.

Checkout these other organizations promoting women.

GENDER EQUALITY AND WOMEN'S EMPOWERMENT

Goal 5: Achieve gender equality and empower all women and girls

Equality Now, A Just World for Women and Girls

FACTS ABOUT WOMEN'S RIGHTS

Awardees Announced for $40 Million Equality Can't Wait Challenge

Regarding equality and your future, someday, you may not be able to earn the high salary you do now because of your health, the competitiveness of the labor market, your age, or something else.

Experts, suggest that you should save 10% of you money and invest it in a stock index fund. Here are the opening DOW and S&P index prices since 1975. The average growth per year for both indexes is roughly 10%. I am not qualified and am not giving investment advice. . . . but;

If you started with an income of $1000 in 1975 and it increased by $1000 per year until reaching $46,000 and you socked 10% of it away in a S&P index fund like SPY, then at the end of your working life you would have over $500,000 in your account as shown in the graph below. Following expert's advice again, and withdrawing 4% per year gives you $20,000 income per year.

(Credit: ISAF)

That's insufficient (a third of what is needed), but with an average social security payment of $1,555 per month or $18,660 per year, you'll take home $38,660 per year before

taxes. Your brokerage account will still grow by approximately 6% per year.

There are many resources out there to determine best practices for retirement. Today, you should calculate how much money you need to retire from your 7am to 7pm job (that is, how much money do you need in your ***Replace Your Salary Account***?) so that you don't have to work for The Man anymore ten years from now.

Shoot for it. You should never stop working (doing something you love) since experts say this is bad for your health. Imagine working on something that you are passionate about, that gets you up in the morning with a smile on your face. You can do that if you have capital. You can *work for free* on issues that really matter to you.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 4 ACA – the Biggest Gain for Women in Decades

(Credit: Dreamstime.com)

23 March 2010

The Affordable Care Act (ACA), enacted by the 111th U. S. Congress, and signed into law by President Barack Obama on March 23, 2010, guaranteed free contraception coverage for all Americans.

In July, 2021, NPR reported, Contraception Is Free To Women, Except When It's Not:

> "Before the Affordable Care Act (ACA) required no-cost birth control coverage, researchers estimate

> that up to 44% of women's out-of-pocket health care spending went toward contraceptives.
>
> Church plans and religious nonprofits, as well as employers and schools that object to contraception, are exempt from the coverage requirements. Plans that were grandfathered under the law are also exempt. Uninsured women don't benefit from the mandate either.
>
> But the federal rules do not require health plans to cover every single contraceptive. After the ACA passed in 2010, the federal Health Resources & Services Administration (HRSA) developed guidelines for women's preventive services.
>
> Those guidelines say women should have access without cost sharing to a list that covers the 18 FDA-approved methods, including oral contraceptives, vaginal rings, cervical caps, IUDs, implantable rods and sterilization. Under federal rules, health plans must cover at least one product in each category."

As shown in the article above, even with the ACA, all U.S. women lack the best freely available contraceptives. More can be done. Which method do you use or want to use for free in the future?

See WebMD 5-year costs of contraceptive methods:

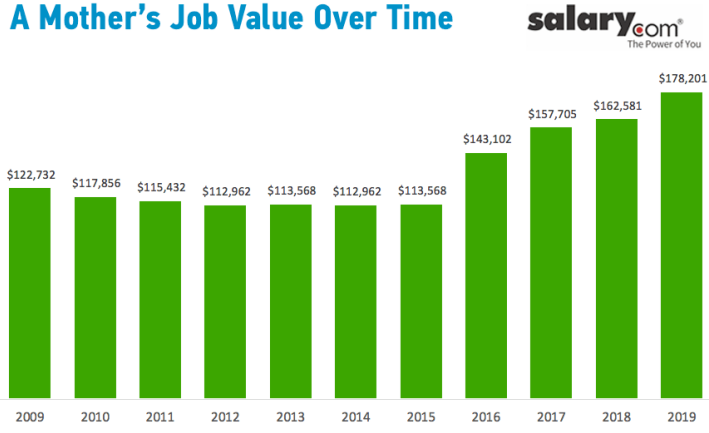
Method	Efficacy	Costs
Tubal Ligation	99%	$2,611
ParaGard IUD	99%	$1,678
Lippes Loop IUD	97%	$318*
QS	96%	$160**
Birth control pills	96%	$2,578
Diaphragms	80%	$2,960
Female condoms	79%	$3,107
3-month injectable	79%	$2,195
Spermicides	74%	$3,002
Cervical caps	60%	$3,831

*Two placements / removals - not currently FDA approved
**Two insertions of non-surgical permanent contraception for women (QS) - not yet FDA approved

The numbers in the 5-year contraceptive costs chart, (average cost to women of $549/year or $46/month – excluding the Lippes Loop and QS) reminds us that every family should track their monthly expenses, so they only spend money on what they want to spend money on. Every six months, try to reduce those expenses by changing suppliers or eliminating a monthly expense. Of course, you should always be trying to increase your income. As many people's income goes up, they tend to spend the increase, and not reduce their expenses. You and your husband are on a team where all the players should be

equal in financial strength. In other words, your husband should pay ½ of these contraceptive costs since he benefits.

Like for income and retirement, there are many expense reduction experts out there to advise you. I'm grateful for Dave Ramsey and his baby steps. As a woman, you must reduce expenses so you can put more into your ***Replace Your Salary Account***. Your husband shouldn't be the only one socking money away for the future. Maybe it's time to sit down with your partner and have the discussion about where the household income goes.



(Credit: Salary.com)

Estimate the value of your time if you stay home and are taking care of your kids. The average hourly wage in the U.S. is $31/hour. According to Salary.com in 2019, if you were an average stay at home parent working 98 hours per

week, and paid for your services, you would be looking at a median annual salary of $178,201 or $35/hour.

Here's to all the women in our lives! Thank you for your love. May we all work 4  2B=  today in all of society.

Chapter 5 Is U.S. Congress in the Loop - Spending on the Right Stuff?

(Credit: Dreamstime.com)

24 September 2021 ($115 million F-35 pictured)

Although, as you read in Chapter 3, most resources to help women are deployed in women's reproductive health, The Guttmacher Institute reports there is no better reward than $7 benefit to society for every $1 government spends on family planning. We should allocate maximum resources toward contraceptives and the education in their use.

In 2009, Lester Brown estimated in his book Plan B 4.0 on page 263 that it would cost $20 billion / year to give all of

humanity (all couples in the world) free "reproductive health and family planning".

According to Govconwire.com on September 24, 2021

> "The House on Thursday voted 316-113 to pass a $777.9 billion defense policy bill . . .
>
> The proposed National Defense Authorization Act for fiscal year 2022 reflects a 5 percent increase, or approximately $37.5 billion, in defense spending over last year's enacted budget and a rise of about $25 billion from the president's proposed budget of $752.9 billion for the Pentagon."

Americans could fulfill Lester Brown's recommendation with 10 days of our military's spending at $2 billion per day. Using The Guttmacher Institute's estimate of a 7 times benefit to society (mostly women and children) for $20 billion per year spent by the U.S. to give all people of the world free family planning leads to $140 billion in benefits to worldwide society. Isn't that a no-brainer?

Why not spend 2.6% of our military budget for 7 times gain in love for America from the rest of the world? Wouldn't that be more effective than participating in police actions to secure natural resources (oil) around the world?

All reproductive service charges for American women and men for their lifetimes should be covered by U.S. tax dollars. This must emphasize first choice - contraceptives including permanent contraception, but also include backup choice - abortions, which should rarely happen.

I'm reminded of a story from a traveler who met a mother in her home (a mud hut) in a country in Central America who had given birth to 26 children, several died, and some who survived but were severely disabled requiring repeated long treks (her husband was on one as they spoke) for medical care. This traveler asked the mother how many children she wanted to have. That mother held up one finger. What if all women could control their own fertility?

You say, how will the U.S. distribute contraceptives through corrupt dictators to their people? World Population Review tells us; "As of 2020, there are 52 nations (out of 262 the CIA recognizes) with a dictator or authoritarian regime ruling the country: Three in Latin America and South America, 27 in Asia and the Middle East, and 22 in Africa." Remember back to the biggest factor (16 times) in my ovarian lottery, being born an American.

What if, there was a United Nations agreement with all countries that allowed their populations to emigrate to the U.S. (and other developed nations) only after all people in those countries received free contraceptives and the

education in their use? This could be a program running in concert with existing food and supply donation programs with every effort to eliminate coercion.

Shouldn't countries follow a best practices guide so their citizens achieve the healthiest, most meaningful, and happiest lives while every county's environment becomes sustainable not just for humans but for all species? Perhaps the United Nations could work toward David Skrbina's plan here similar to what we said here;

> "All this boils down to two essential principles of global sustainability:
>
> 1) Each nation should set aside half of its land area, as wilderness or protected land.
>
> 2) Each nation should adjust its population and consumption to live on the other half."

David Attenborough supports this in *A Life on Our Planet* Seems like a no brainer, but this takes a reset in leadership.

May we talk about our new military branch, the Space Force or NASA costing together about $40 billion per year? The earth is the only home for all creatures. Of course, we must protect it from being hit by asteroids, but we can't travel fast enough to reach the next planet and living in a tube on Mars

is not a reasonable option although our richest man wants too.

Question: Does mankind appreciate the natural world enough to save it?
Answer: Not so far

Question: When nature is gone will we like living in tubes or domes on Mars?
Answer: That's where government and business is headed

Question: Will we be able to reach another goldilocks plant like earth soon?
Answer: Let's figure it out below

Question: How far is the closet star Proxima Centauri from earth in miles?
Answer: 4.3 light years or 25 trillion miles

Question: How many years to travel to Proxima Centauri at 1 million miles per hour?
Answer: 2854 years

Question: What is the fastest mankind has flown so far?
Answer: Apollo 10 moon mission reached a top speed of 24,791 miles per hour

Question: How many years to travel to Proxima Centauri at a top speed of 25,000 miles per hour?
Answer: 114,155 years

Would the $40 billion per year for the Space Force and NASA be better spent helping women and children around the world?

If any of this hits a chord with you, click here to contact your member of Congress or call or email the best advocates for you (women leaders who work for you):

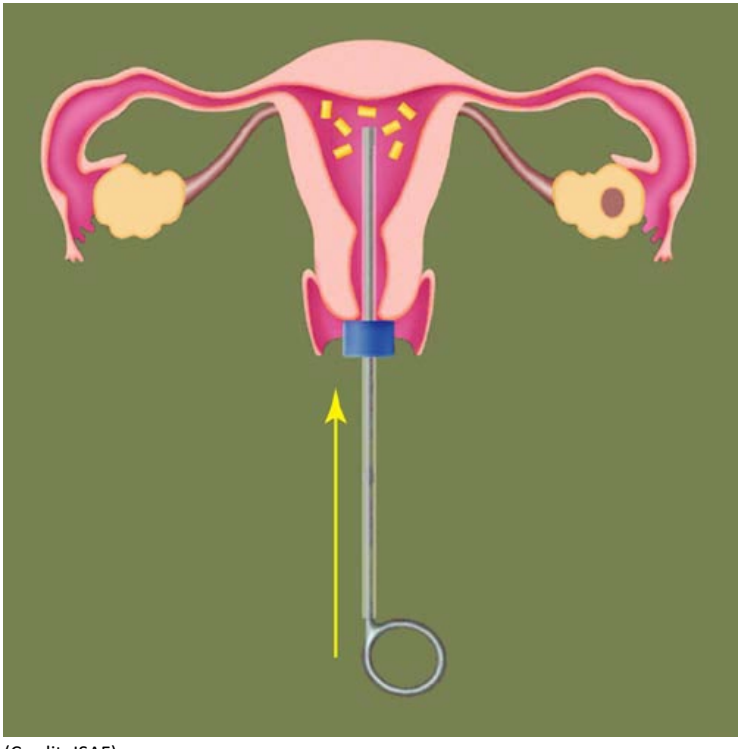
Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111
kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

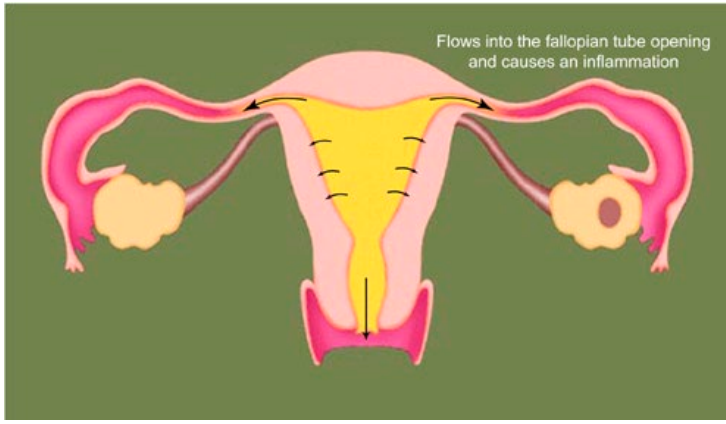
We would love to hear from you too - send an email to donjr@quinacrine.org. Please take our survey.

Here's to all the women in our lives! Thank you for your love. May we all work 4  2B=  today in all of society.

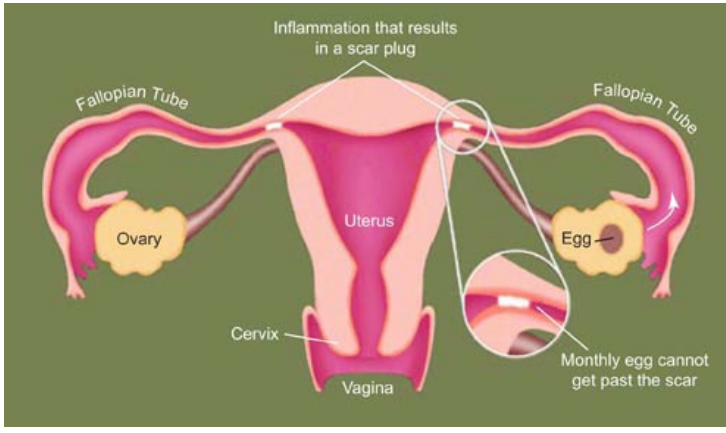
Chapter 6 What Happened to Non-surgical Permanent Contraception for Women (QS)?



(Credit: ISAF)



(Credit: ISAF)



(Credit: ISAF)

Non-surgical permanent contraception for women (QS), previously called quinacrine sterilization in many of the scientific papers in this book is a non-surgical female method, used by 200,000 women in over 50 countries, including the U.S. Since 1976, QS is accomplished by

inserting seven (7) pellets, 36 milligrams each (252 milligrams total) into a woman's uterus in two (2) doses. The first dose is inserted within 6 to 12 days after a woman's menstrual period starts. The second dose is inserted one month later.

ISAF subscribes to all recommendations of the ACOG Committee Opinion number 695 issued April 2017 (Replaces Committee Opinion Number 371, July 2007. Reaffirmed 2020) on Sterilization of Women: Ethical Issues and Considerations listed here:

- "Respect for an individual woman's reproductive autonomy should be the primary concern guiding sterilization provision and policy.
- Coercive or forcible sterilization practices are unethical and should never be performed.
- Obstetrician–gynecologists should provide presterilization counseling that includes a discussion of a woman's reproductive desires and places her wishes at the center of care. Patient counseling should emphasize the permanence of sterilization and include information about reversible alternatives, especially long-acting reversible contraception (LARC) methods, which are as effective as permanent sterilization.

- In appropriate cases, sterilization of a male partner should be discussed during presterilization patient counseling as an option with fewer risks and greater efficacy than female sterilization.
- It is ethically permissible to perform a requested sterilization in nulliparous women and young women who do not wish to have children. A request for sterilization in a young woman without children should not automatically trigger a mental health consultation. Although physicians understandably wish to avoid precipitating sterilization regret in women, they should avoid paternalism as well.
- Obstetrician–gynecologists should consider the role of bias in counseling and care recommendations and avoid actions based on biases about race, ethnicity, socioeconomic status, sexual orientation, and motherhood, which can, despite best intentions, affect interpretation of patients' requests and influence provision of care.
- Only rarely should incarcerated women undergo sterilization, and only after access to LARC methods has been made available and excellent documentation of prior (preincarceration) request for sterilization is available. Special procedural safeguards and

oversight are needed when incarcerated women are sterilized because of the likelihood that the coercive environment of prison impedes true informed consent.

- If individual physicians or institutions will not provide sterilization because of personal religious beliefs or institutional policy, patients must be informed as early as possible and provided with an alternative form of contraception that is acceptable to the patient or be referred elsewhere for care. When difficulties in meeting a postpartum sterilization request are anticipated and sterilization is desired by the patient, transfer of care for the remainder of pregnancy should be offered."

For the reader to gain an appreciation for ISAF in support of past organizations which have done the important work to bring QS to women of the world with no financial gain for themselves, what follows is a Board of Directors report covering the period November 1, 2005, to the end of ISAF fiscal year June 30, 2007, an exciting and productive period for ISAF, written by Dr. Stephen D. Mumford, ISAF CEO.

IND/PHASE III TRIAL APPROVED

Our years-long strategy to submit the most complete Investigational New Drug (IND) application possible, attempting to answer in advance all potential questions

from the FDA, was rewarded in June of 2006. While Oxford Pharmaceuticals compiled the massive document required describing the study, ISAF finalized our list of investigators and secured from each of them the necessary documentation for submission to FDA as a part of our application process. Paring down our list of 78 potential investigators and collecting the necessary documentation to ensure that each investigator would be acceptable to the FDA was a major undertaking. We selected 40 investigators, including 18 from U.S. medical schools and 8 from Planned Parenthood affiliates. Two investigators from Canada, one each from Mexico, Chile and Brazil, and four from India were included. The IND application was submitted on April 8, 2006, and was approved by the FDA on June 8, 2006.

On July 5, 2006, ISAF held a Phase III Clinical Trial planning meeting in Research Triangle Park, NC, to prepare for the trial's implementation. This meeting included all of the U.S.-based administrative QS team members. Plans were drawn for the implementation of the 40-site clinical trial. This included development of the clinical record forms, training of investigators and their clinical research coordinators (CRC), study monitor selection and training, arrangements for shipping of product to study sites, and selection of equipment. Dr. Elizabeth Bianchi, a Planned Parenthood affiliate physician from Spokane, WA, was

chosen to perform the clinical training of the investigators. Four regional training sites were chosen.

The first regional training meeting was held in New York City for northeastern investigators and their CRCs on October 6, 2006. The faculty included Richard Guarino MD, president, Oxford Pharmaceutical Resources; Donald Collins, Sally Epstein, and Stephen Mumford DrPH of ISAF; Jack Lippes MD, chief investigator; Dr. Bianchi, clinical trainer; Gary Mantell PhD, data manager; Mark Bradshaw, PhD, statistician; and Charlene Okoye of LABCORP, the central laboratory. This one-day training program was repeated in West Palm Beach, FL, on October 14, in Chicago on October 28, and in Phoenix on November 3. All of these training programs were well received. Only one trained investigator has withdrawn from the study as of this date. This physician withdrew following her resignation from her academic institution to go into private practice.

On November 15 and 16, 2006, a two-day training program was conducted at ISAF's Research Triangle Park office by Dr. Guarino to train the five monitors for the Phase III trial. Each monitor was assigned a specific group of investigators. The monitor will make nine visits to each clinical site over the course of the trial to ensure that every QS procedure is performed and followed in the manner prescribed by the protocol and according to Good Clinical Practice (GCP) requirements.

On October 19, 2006, a drug shipment planning meeting was held at Eminent Services Corporation (EMC) in Maryland. Eminent will be responsible for accounting for every dose of the drug manufactured for and used in the trial. This meeting was attended by EMC president, Dr. Paul Thadikonda, Dr. Richard Guarino and Gary Mantell from Oxford, and Stephen Mumford from ISAF. The date for the shipment of the inserters to the investigators was set for January 12, 2007.

Planned Parenthood Status for the Phase III Trial

In January of 2006, Planned Parenthood Federation of America (PPFA) reaffirmed its participation in the Phase III trial. The following March, a meeting was held at its New York Headquarters to work out the details, and subsequently the Federation submitted its letter of intent to the FDA. However, at a Planned Parenthood National Medical Committee (NMC) meeting in October 2006, the committee voted to withdraw its approval of affiliate participation in our Phase III trial. Don Collins, Sally Epstein and Stephen Mumford were invited to attend this meeting of the NMC, and were surprised and perplexed to learn of their vote. We are confident the reason for their withdrawal was not scientifically based. In a phone call the following week, Dr. Vanessa Cullins, Vice-President for PPFA Medical Affairs notified me of the NMC decision, and in the same conversation stated that as soon as QS is

approved by the FDA, ISAF should be back in communication with PPFA about making the method available in Planned Parenthood clinics. In December 2006 Cecil Richards, President of PPFA, in a letter to Sally Epstein, stated that QS is not only important to women in developing countries but also to women served in Planned Parenthood clinics in the United States. Thus, we are assured that Planned Parenthood will be back on board as soon as QS is approved by the FDA.

Cost of Finished Product Estimated for the Phase III Trial

Development of the inserter manufacturing process for the Phase III trial positioned ISAF to request an engineering company experienced in preparing such estimates to determine the manufacturing cost of a single-dose, mass-produced, quinacrine-pellet-loaded, packaged and sterilized inserter ready to ship to a clinic. Two inserters or doses are needed for each QS procedure. This firm estimated cost for each finished product or inserter at $0.53. We believe that nearly all of the world's poorest women will be able to afford $1.06 for the two needed inserters.

CLINICAL HOLD

On January 9, 2007, ISAF received a telephone call from the U.S. Food and Drug Administration requesting a conversation regarding our NDA. A conference call between all interested parties – FDA, ISAF and Oxford

Pharmaceuticals – was held on January 10, wherein we were dumbfounded to have the acting director of the FDA Urologic and Reproductive Division, Dr. Scott Monroe, inform us that our trial was being placed on Full Clinical Hold, effective immediately. This decision was based on FDA's receipt of unpublished data from a 2-year rat study of QS undertaken by Family Health International (FHI). FHI had also issued a "Dear Colleagues" letter on December 18, 2006, indicating its withdrawal from further study of QS due to the results of this rat study. FDA cited this Dear Colleagues letter as further substantiation for issuing the Full Clinical Hold.

ISAF's president and FHI founding board member, Don Collins, immediately contacted FHI requesting to see the rat study data. His request was denied, except for issuance of one limited table, accompanied by a short narrative, showing tumors resulting in the study. This limited information, however, was sufficient to reveal that something was scientifically amiss with the data.

Upon examination, it became clear that this FHI rat study is seriously flawed. The study design violates basic established guidelines for scientific investigation. The most fundamental guideline, establishment of the maximum tolerable dose (MTD) before initiating a study, was not performed, resulting in the deaths of one-third of the rats in the two high-dose groups. The FDA agreed that these two

dose groups exceeded the MTD and should be discarded. The middle dose group exhibited 10 different types of cancer. Usually only one or two types of cancer are seen in a 2-year rat study evaluating a drug, suggesting that in this case, the cause of these 10 types of cancer was method-related, not drug-related.

FDA regulations allow for face-to-face appeals when issuing a clinical hold, via a Type A meeting, which we immediately requested at the earliest possible date. An appointment was scheduled for March 6, at FDA headquarters in Silver Spring, Maryland. For this meeting, we contracted toxicologist Evan Siegel, president of Ground Zero Pharmaceuticals in Irvine, California, and former FDA toxicologist, to review and present the limited data for inconsistencies. Dr. Siegel was unable to convince FDA of the study's scientific problems, and FDA maintained that the rat study was sufficiently worrisome to uphold the clinical hold. Instead of being allowed to resume our program, we were directed to gather as much human data as possible to show QS's safety, and we agreed to submit data on 3,000-5,000 QS acceptors. We immediately shifted our resources and energies from the Phase III study to this task, informing participating physicians of the hold and beginning the enormous job of designing an epidemiological survey for overseas data gathering, now in process.

It was of course imperative to continue an investigation into the apparent flaws in FHI's rat study, and to that end a world-class toxicologist, Dr. Gene McConnell, former Director of the U.S. National Toxicology Program, was contracted to review the study. His concerns about the limited data given to us were great enough to present to FHI's CEO, Al Siemens, who agreed that the questions were valid and reasonable. At their meeting in late May, Siemens agreed to submit McConnell's list of issues to FHI staff for consideration. As of the date of this report, we await his response.

FOLLOW-UP PROJECT

Formulation of the FDA-directed epidemiological follow-up survey of QS acceptors began immediately after our Type A meeting. We set an ambitious deadline for ourselves for completion of this project by the end of this calendar year. A historical survey was made of all QS cases performed worldwide to determine where to concentrate data collection. Initially, eight of the most committed QS scientists were contacted, all of whom were eager to participate. It was decided, however, that the survey should be carried out only in Vietnam, China and Chile, as in these countries combined, the health status of roughly 30,000 women could be reported on.

The Degge Group, Ltd., of Arlington, Virginia, expert consultants in clinical drug safety, pharmacovigilance, and

pharmacoepidemiology, was contracted to produce the study materials at an expedited pace. At the time of this report's writing, Drs. Stephen Mumford of ISAF and Richard Guarino of Oxford Pharmaceuticals have just completed training visits in Vietnam, China and Chile, equipped with the study's rigorous set of materials, including protocol, case report forms and training manual.

In order to manage this mammoth project, in addition to her increasing duties as the Phase III trial coordinator and office administrator, Margaret Growe was added to the ISAF payroll as a full-time employee.

EXHIBIT/TRADE SHOWS

Dr. Elton Kessel, Ms. April Mayberry, Dr. Stephen Mumford 2006 (Credit: ISAF)

In 2006 we exhibited at 15 medical meetings, 11 domestic and 4 international, including the ASRM (American Society of Reproductive Medicine) meeting at which a significant

proportion of the attendees are from outside of the United States. Following is a list of the meetings attended. The report of these meetings is attached.

• PPFA [Planned Parenthood Federation of America] Nurse Practitioners, Nurse Midwives & Physician Assistants in Women's Health Care, 30th Annual Post Graduate Seminar

• CREOG & APGO [The Council on Resident Education on Obstetrics & Gynecology and the Association of Professors of Gynecology & Obstetrics] Annual Meeting

• Contraceptive Technology-East Spring 2006

• Contraceptive Technology-West Spring 2006

• PPFA [Planned Parenthood Federation of America]–HCI [Health Care Institute] Conference

• ACNM [American College of Nurse-Midwives] 51st Annual Meeting & Exhibit

• CFHC [California Family Health Council] 25th Annual Reproductive Health Medical Symposium

• ESHRE [European Society of Human Reproduction & Embryology] 21st Annual Meeting

• ARHP [Association of Reproductive Health Professionals]: Reproductive Health 2006

• FECASOG [Federación Centroamericana de Asociaciones y Sociedades de Obstetricia y Ginecología] XXV Congress

• ASRM [American Society for Reproductive Medicine] 62nd Annual Meeting

• FIGO [International Federation of Gynecology & Obstetrics] XVIII World Congress on Gynecology & Obstetrics

SELECTED COUNTRY PROGRESS REPORTS

Peru Project

In 2006, April Mayberry made two trips to Peru – one in July and one in January. The main purpose was to visit Dr. John Apaza of Arrequipa Peru, a QS investigator who works for the MINSA (Ministry of Health) Regional Hospital Honoraio Delgado. Dr. Apaza asked ISAF to come to his city and help him expand his QS study, with the permission of the regional OBGYN chief and the state minister of health. At the time that he contacted ISAF, Dr. Apaza had performed three cases with good results. His idea was to disseminate more information throughout the regional medical community and try to increase the number of QS cases. The July trip was designed as a planning meeting to prepare for this endeavor, and also to meet with other clinicians interested in working with QS or with those who had ordered materials.

In January, April Mayberry returned to Peru to meet further with Dr. Apaza and discuss the QS regional project and possible venues for its implementation. During this time, the FDA clinical hold was announced on our Phase III study. Dr. Apaza expressed that he would have to put his own QS work on hold until there is a decision by the FDA, at which time he would confer with his superiors and make a decision based on the outcome. He also expressed that he still has confidence in QS, but must be cautious for political reasons. In turn, Dr. Apaza was assured that ISAF would assist with any necessary follow-up of his cases or other support he needed. Other meetings were scheduled with potential Peruvian investigators, but due to the clinical hold on the Phase III trial, it was decided to postpone the meetings until the outcome is known.

Mexico Trip Report – August 2006

In August, April Mayberry visited some of our Mexican investigators to discuss their trials, to evaluate them as potential study sites for our phase III FDA study, and to discuss their QS projects. Discussions of the details of each meeting are attached to this report.

April Mayberry traveled again to Mexico in December upon the request of some newer potential QS investigators and also to follow-up some on-going projects. Most of the cities visited are in western Mexico, and because airfare is so expensive, Ms. Mayberry traveled by car, accompanied by

Jose Bautista, who helped navigate the road systems of Mexico and with interpretation if necessary. Eight meetings had been pre-scheduled with clinicians. She had attempted to schedule more but was unable to coordinate them. Reports of these meetings are attached. Follow-up visits were planned to Mexico in the spring or early summer of 2007, but these trips have been delayed as a result of the FDA clinical hold on the Phase III trial. Instead, we will send requests for information on the projects.

INSERTER FABRICATION

During this reporting period, April Mayberry made three trips to fabricate and sterilize QS inserters, twice to Switzerland and once to Mexico. Usually for this task, only one trip to Switzerland is required a year; however, there were so many requests for studies and additional inserters during the ESHRE, FECASOG, and FIGO 2006 meetings, an additional trip was necessary to make more. Local people were employed to help with assembly and other tasks and traveled to other cities to deliver the inserters to the facilities for sterilization. The trips were as follows:

Destination	Mexico	Switzerland	Switzerland
Date	February 06	February 06	August 06
Number Fabricated	746	2442	2266
No. Persons Employed	1	1	1
Sterilization Date	Feb. 9	March 3	Aug. 30

TRAINING MATERIALS/PROJECTS

QS Tradeshow Sign: After years of use, our old exhibit sign was beginning to deteriorate and needed an overhaul. Fortunately, we received a grant from Carolyn Burgess and Ted Hoffman for the redesign and printing of the sign, along with a new frame and carrying case. The new sign is a definite improvement. It is easy to read and eye-catching. Additionally, it is more convenient to ship and carry.

QS Patient Information Poster: Due to recurring requests from investigators for posters to hang in their offices and waiting rooms, a patient information poster was developed. It has a similar format as the medical conference exhibit sign, but it is more simplified and geared toward the concerns of women. The color scheme is also slightly modified to be more feminine and attention-grabbing. It is available in English, Spanish and French. It has been translated into Arabic and Portuguese, and will also soon be translated to Chinese. This poster is already one of the most popular offerings at our exhibit booth and is being used in clinical settings. It has been selected for use in our FDA Phase III QS study.

QS Exhibit Marketing Materials: At trade shows it is common and expected that exhibitors hand out small items, like pens and bags with the company logo and contact information printed on them. These items are helpful in bringing attendees to the exhibits, can be used to contact a

company or an organization, and aid in product recognition. This period, the following items were produced:

• Buttons – Several years ago, an individual donor paid for the production of QS buttons. Since this supply was low, more were produced with the updated QS logo and colors, and the website address was added.

• Emery boards – Designed with the QS logo, the motto "Another Choice for Women", and the QS website address, these fingernail files have been produced in Spanish and English and are probably the most popular item with the conference attendees.

Provider Resource and Training DVD: When we help an investigator initiate a study, we send a complete training and information package. This set contains numerous items, including the training video and manual, patient consent form, educational materials and current published research. During the years of corresponding with QS investigators, we have noticed occasional deviations from the protocol, and that clinicians were asking questions that they should have known had they properly studied the materials sent. In response to this The QS Training & Resource DVD was developed. This DVD contains all materials necessary to initiate and complete a study. It is designed to guide an investigator through the training process and reinforce compliance to protocol. The DVD includes:

- Training video & manual
- Patient video & brochure
- Patient consent form (including different localities)
- Published research
- Information on packaging and sterilization processes
- A self-test
- Contact information

The DVD is to be available in the following languages:

- English
- Spanish
- Chinese
- French (IGJO-abstracts only)
- Portuguese
- Arabic (on this disk the IJGO will only be in English)

We have already produced the prototype in English, and the Spanish is ready for review. The Arabic versions are in development and almost complete. We still need to complete some more items before going forward with the Portuguese and Chinese versions. The goal is to have all of them finished by the end of 2007.

2006 Report on the Translation of QS Education and Training Materials

The goal of this project is to translate all training and patient materials into the following languages: French, Arabic, Chinese and Portuguese. These languages are selected because they cover a wide geographic area. At this time, we have available in English and Spanish an effective informational kit for the QS method, which includes a set of training materials (video and manual), the QS supplemental issue of the IJGO, and a set of patient information (consent form, brochure and CD). While these languages do cover a wide geographic area, there are many regions where QS could be of benefit and appeal in which we do not have training and patient materials available in the primary tongue. We have received repeated requests for materials in other languages, especially French and Arabic.

Before beginning the project, the following items were available in the following languages:

ITEM	*FRENCH*	*ARABIC*	*PORTUGUESE*	*CHINESE*	*Spanish*
Training Video				X	X
Manual				X	X
Consent form			X	X	X
Patient brochure			X	X	X
IJGO			X	X	X
IJGO Abstracts					
Pt. Video			X		X

Items that have been translated since the initiation of the project:

ITEM	*FRENCH*	*ARABIC*	*PORTUGUESE*	*CHINESE*
Training Video	X	X	Transcript only	N/A
Manual	X	X	X	N/A
Consent form	X	X	x	N/A
Patient brochure	X	X	N/A	N/A
IJGO	-	-	N/A	N/A
IJGO Abstracts		-	N/A	N/A
Pt. Video	X	X	N/A	

Items to be completed:

ITEM	*FRENCH*	*PORTUGUESE*	*CHINESE*
Training Video		Transcript done need to do audio video portion	
Manual			
Consent form			
Patient brochure			
IJGO			
IJGO Abstracts	X		
Pt. Video			X

IJGO DISTRIBUTION

On August 24, 2006, our most important information dissemination project for QS was completed, with the distribution of 5,900 copies of the special QS supplement of the International Journal for Gynecologists and Obstetricians in Mexico. This distribution was supported by Pfizer Pharmaceutical, by its instructing of all Pfizer representatives in Mexico to deliver a copy to each of their obstetricians. Pfizer volunteered to undertake this task following a request from Andrea Trujillo, wife of Dr. Valentin Trujillo in Chile. In Latin America 13,500 copies were distributed to Spanish-speaking OB/GYNs. In all of Central America, only in El Salvador, Honduras, Haiti and

Guatemala was this issue of the journal not systematically distributed.

This translation project was remarkably successful, as 5,000 copies were printed in Vietnamese and distributed in that country as well. In China 10,000 copies were distributed in Mandarin. And 15,387 copies of the Portuguese translation were distributed in Brazil. So obstetricians in Latin America, China and Vietnam are prepared for the introduction of this method.

WEBSITE

The QS Website continues to be an important and well-used resource for collaborators, clinicians, scientists, policymakers and the interested public worldwide, with an average of 15,330 'hits' per month. The design strategy has been and continues to be focused on providing access to all scientific papers, up-to-date clinical information, and answers to common questions, in such a way that it can be easily used by people with the lower-speed internet connections found in most of the developing world. Over the years the world minimum standard for internet connectivity has steadily risen, and the site has endeavored to increase its technological basis to meet this rising capacity.

In late 2005 we completed the implementation of a major site redesign reflecting the new logo, graphics and layout. This

also included adding new site search capabilities, editing the Research Index and several other sections of the site, including Frequently Asked Questions and the on-line training manual.

In mid-2006 we began a structural technical overhaul so that new indexing and other technologies could be employed. This included restructuring the Research Index and beginning the development of a video clip library for a clinical tutorial section.

In February 2007 we migrated the site to a new hosting server to take advantage of emerging technology capabilities required for site improvements. The new design with added features scheduled for the end of June 2007 includes:

• Site structured around clinical tutorial

• Introductory training videos in English, Spanish, French, Portuguese, in Arabic

• Access to multilingual reference areas including on-line access to the Spanish, Chinese, Vietnamese, and Portuguese versions of the IJGO abstracts and research papers.

FUND-RAISING [include this category?]

• OTHER TRIPS

AUDIT

In 2006 the decision was made to perform a complete audit of the two ISAF offices. It was thought prudent to have such documentation in readiness once the Phase III trial of QS commenced, so that our operations would be transparent to any party in such a position as to require this type of assurance, i.e., funders. The audit would take place in North Carolina, as it was decided that the merged administrative records would be kept in that location. The Research Triangle Park office's payroll and tax accountants, Blackman & Sloop of Chapel Hill, were the natural CPAs with whom to contract, and we held a planning meeting to lay out a strategy for this task in August of 2006. The audit would cover ISAF's 2006 fiscal year – July 1, 2005-June 30, 2006. Blackman & Sloop assigned Deetra Watson, CPA, to our account in March of 2007.

Ms. Watson's first request was the actual physical transfer of all Washington DC "source documents" for the period FY06 to Margaret Growe in RTP for integration into the computerized accounting system. These documents included all original bank account, credit card, travel, tax, telephone, expense and revenue records, which were received in good order. The substantial task of precise entry and reconciliation of the accounts began immediately. While this mechanical chore was executed, other necessary documents were generated for all relative financial

institutions, donors, organizations and individuals, so that confirmation of all moneys paid, received and owed would go smoothly. Additionally, a comprehensive list of anticipated tasks was made covering all office procedures so that a clear understanding could be had by the auditor of our current operations, and appropriate adjustments could be suggested and implemented to her satisfaction while the detailed financial reports were generated.

In early April, once the financial accounts had been merged, the computer file was submitted to Blackman & Sloop. By April 9, all pending documentation issues had been answered and were also given to Ms. Watson, whereupon she compiled a second list of items for review regarding expense and income allocations. Justification/explanation for each issue was supplied to her expeditiously, and by April 13 these items were completed, i.e. all revenues had been confirmed both in our records and by the donors, and the finances were balanced.

The final phase of the audit involved clarification of the two respective locales' staff responsibilities and office procedures. Additionally, a "management questionnaire" issued by Blackman & Sloop was completed describing the offices' related party transactions, substantive events, risks/uncertainties, commitments/contingencies, and environmental liabilities (none). Ms. Watson expressed her

appreciation for a relatively smooth audit, and the decision was made to make this an annual exercise for ISAF.

As of the writing of this report, we await receipt of the formal audit document, in which we anticipate suggestions for several refinements in office policies and procedures that will elevate the overall quality of our operations. The report will be available to potential funders and other parties deemed relevant immediately upon its release.

SUMMARY OF EXPENSES FOR FY2006

Though the narrative of this report covers the 18-month period of January 1, 2006, through May 31, 2007, the following table summarizes the ISAF expenses for the fiscal year 2006, July 1, 2005-June 30, 2006.

General QS support	$205,678.80
QS exhibiting & travel	$ 72,131.79
Sr. Proj. Coordinator	$ 23,557.33
President salary (45%)	$ 27,000.00
Office Administrator/Program Coord. (RTP)	$ 8,261.56
Office Administrator (DC)	$ 17,170.14
Office expenses (combined offices)	$ 13,218.50
TOTAL	$367,018.12

All these big plans and this effort was in vane as the FDA, for unscientific reasons as provided by FHI, halted the QS Phase III clinical trial and to this date refuses to release its hold.

The ideologically based FDA ban makes it impossible for women to have QS in the United States or in the rest of the world. Our experience was that if a foreign pharmaceutical company with any business that required FDA approval decided to make QS, then that company would be pressured (by the loss of FDA approval for their other lines) to not make QS. This has played out in foreign governments as well, see Appendix 3 slides 5 and 6.

Dr. Gio Gori was the Editor-in-Chief of Regulatory Toxicology and Pharmacology (RTP) in 2010 when FHI published its paper claiming that QS was carcinogenic. In 2015, we read Dr. Gori's Petition, An appeal for the integrity of science and public policy. We decided to ask Dr. Gori to retract FHI's hopelessly flawed paper. In a phone call, he agreed and asked that we undertake a project which he estimated would cost $35,000. In March 2016, after the project was prepared to launch to the 6 toxicologists he had selected, he informed us that he did not want to go any further with this project.

In 2020, we learned that Dr. Aylward had become the Editor-in-Chief of RTP. Dr. Lesa Aylward, courageously supported Dr. Mumford's commentary by identifying as the Handling Editor.

"What happened to quinacrine non-surgical female sterilization?" commentary by Dr. Stephen D. Mumford

published in August 2021 in Regulatory Toxicology and Pharmacology (RTP) is a story about how "the FDA failed to follow The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

> "The FHI 2-year rat study, Cancel et al., does not qualify as a study designed for Regulatory use. It does not conform to that described by the ICH in its S1C(R2) guidance. FHI's claim that quinacrine is a genotoxic carcinogen is unsubstantiated. FHI's flawed CaBio was sent to the FDA. It became the FDA's responsibility to ensure that the ICH guidance was followed. The FDA failed. The outcome is the termination of all clinical research of QS. QS should be an option for the hundreds of millions of women worldwide who want to avoid unwanted pregnancies. Cancel et al.'s study was flawed in the following ways:
>
> 1) Since no appropriate dosing studies were performed, the MTD was exceeded (up to 35x).
>
> 2) The CaBio study had a "dosing phase" and a "observational phase", which does not conform to the ICH standards.
>
> 3) The authors cite the intended outcome of the range finding studies was to "mimic" fibrotic

closure of the uterine horn, but no uterine fibrotic closure were reported in any of the rats in the CaBio study.

4) The drug formulation used in the CaBio (slurry) differed from what is used in women (pellets), and contained a known tissue irritant.

5) Histopathologic examination found that the doses used in the CaBio study caused massive necrosis of the uterus and chronic inflammation.

6) The reported tumors originating from primitive cell types in the high dose groups likely indicated that other factors were influencing tumorigenesis, such as chronic inflammation."

In 2019 ISAF approached Bayer, J&J, and several other pharma companies to partner (we made it clear ISAF had no interest in financial gain) on QS.

The Head of Technology Scouting from Germany at Bayer said, "we have talked to our respective colleagues and they do not see enough benefits for such a development. This is purely based on the judgement of our current portfolio, but not on the technology per se."

And a spokesperson for J&J in New Jersey said, "While we appreciate your proposal, we routinely seek out to align with new partners who offer revolutionary ideas and business solutions that align with our brand equities and business. At this time, we are not actively pursuing new partners. . ."

Their message, QS would compete with these large Pharma companies' current business. If you think QS should be subsidized by the U.S. government, click here to contact your member of Congress or call or email your best advocates (women leaders who work for you):

Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111
kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

We would love to hear from you. Please take our survey.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 7 Best Evidence for QS Safety and Efficacy by Dr. Hieu et al in Vietnam

Dr. Do Trong Hieu 1993 (Credit: ISAF)

There were over 1600 healthcare professionals who promoted QS in their medical practices and we thank you all for your efforts. But, Dr. Do Trong Hieu was a champion of QS while he was affiliated with the Ministry of Health in Vietnam. Following the publishing of his article below in July of 1993 where he said that he planned to perform 6.2 million procedures from 1994 to 1998, WHO HRP sent a letter to Vietnam stating, "WHO experts and FDA officials have said that they would be surprised if

quinacrine did not turn out to be carcinogenic." This statement based on a flawed rat study was essentially a lie aimed at killing QS.

As a result of this, the Vietnam QS program was immediately brought to a halt for reevaluation. See Dr. Hieu's entire presentation in Appendix 3. Vietnam Health Ministry is threatened if they didn't stop QS then they will lose their WHO and UNFPA financial support.

Dr. Hieu et al, ***31781 cases of non-surgical female sterilisation with quinacrine pellets in Vietnam*** As reported by Dr. Hieu:

"The quinacrine method of non-surgical female sterilisation involves transcervical intrauterine insertion of 252 mg quinacrine as pellets during the proliferative phase of the menstrual cycle; the drug causes inflammation and fibrosis of the proximal fallopian tube. We have carried out a field trial of 31,781 cases in twenty-four provinces of Vietnam from Jan 2, 1989, until October, 1992. There were 818 pregnancies after the procedure, of which 80 were carried to term. Some women received only one dose of quinacrine; the majority received two doses with an interval of one month. Cumulative life-table pregnancy rates per 100 women at 1 year (for studies of at least 50 cases followed for 12 months) were 2·63 (SE 0·17) among 9461 women who received two doses and 5·15 (0·48) among 2225 who received only one dose. Failure rates

(pregnancies) were strongly affected by the skill of the doctor or midwife. There were no deaths and only 8 serious complications were reported (0·03%); by contrast, in a similar series of women undergoing surgical sterilisation, 30 deaths and between 540 and 1812 serious complications would be expected. All reported side-effects were minor and of short duration. There were 19 ectopic pregnancies, and the incidence was 0.89 per 1000 woman-years of use. There was one birth defect (anencephaly), in a fetus conceived 2·5 months after quinacrine insertions; however, we believe it is not related to the procedure. An estimated 242 maternal deaths will be averted by these 31 781 sterilisations. This method is safe and acceptably effective for female sterilisation.

The main advantages of this method for a developing country are the possibility of raising contraceptive prevalence among women who want no more children, while providing more effective contraception than temporary methods. We can calculate from the maternal mortality rate in Vietnam of 380 per 100 000 livebirths,' assuming that each sterilisation procedure prevents 2 pregnancies, that each 1000 sterilisations prevent 7.6 maternal deaths-i.e., 242 maternal deaths will be averted by these 31,781 sterilisations. The cost of quinacrine for two insertions is less than US $l. This procedure represents our most cost-effective way of lowering maternal mortality."

Here's to all the women in our lives! Thank you for your love. May we all work 4  2B=  today in all of society.

Chapter 8 Excellent Evidence for QS Safety and Efficacy by Dr. Lu et al in China

Test Site	# Subjects	(ratio)	# of follow ups	(follow up rate)	# of Pregnancies	(failure rate)
Nanming District	975	16.5%	970	99.5%	10	1.0%
Huaxi District	976	16.5%	969	99.3%	17	1.7%
Zunyi County	1334	22.5%	1330	99.7%	18	1.3%
Rongjiang County	898	15.2%	854	95.1%	17	1.9%
Fenggang County	799	13.5%	799	100.0%	19	2.4%
Liping County	728	12.3%	651	89.4%	2	0.3%
Yuqing County	207	3.5%	207	100.0%	5	2.4%
Total	5917	100.0%	5780	97.7%	88	1.5%

Clinical Study of Quinacrine Female Voluntary Non-Surgical Sterilization, International Journal of Reproductive Health/Family Planning, Volume 31, Issue 2, March 2012, p93-96 Table (Credit: ISAF)

30 March 2012

After research was halted in the U.S. by the FDA, Dr. Lu et al, performed a study and published results in a Clinical Study of Quinacrine Female Voluntary Non-Surgical Sterilization, International Journal of Reproductive Health/Family Planning, Volume 31, Issue 2, March 2012, p93-96. As reported by Dr. Lu:

"Objective: To investigate the safety, reliability, and acceptability of large-scale clinical use of non-surgical sterilization (QS) for women with quinacrine.

Methods: From March 2007 to July 2010, 6,000 women who voluntarily received QS were recruited in Guizhou Province, namely: 7 (252 mg) quinacrine pellets were placed in the modified T-copper intrauterine segment. The IUD is placed in the device, and the pellet is placed into the uterus 3 to 7 days after menstruation is clean, or 6 weeks after childbirth and induced abortion. The second dose was completed after 4 weeks. Follow-up was performed at 3, 6, 12, and 24 months after surgery. Results: 5,780 follow-up forms and 88 pregnancy forms were recovered. The longest follow-up time was 1,248 days. The main adverse reactions were yellow vaginal discharge, dizziness, fatigue, irregular menstruation, etc. No serious adverse reactions were found. The effective rate of sterilization is 98.5%, and the drug application status and the number of times of application affect the success rate.

Conclusion: QS is low in cost, easy to operate, non-invasive, painless, less adverse reactions, and more acceptable to voluntary sterilized women and clinicians. Preoperative physical examination to exclude contraindications, 6 weeks postpartum or 3-7 days after menstruation, 2 doses of medication, 2 hours of lying down after surgery, and 3 months of postoperative contraception

are beneficial to improve the success rate of QS. The promotion of QS has a positive effect on improving the acceptance of female sterilization and reducing the cost of family planning surgery."

In 2003, Dr. Lu et al, published a study ***A comparison of quinacrine sterilization (QS) and surgical sterilization (TL) in 600 women in Guizhou Province, China*** As reported by Dr. Lu:

"Objectives: Compare the safety and efficacy of quinacrine sterilization (QS) and surgical sterilization, also known as tubal ligation (TL). Methods: 300 women accepted QS in Guiyang, China during the period from July 1995 to September 1997.

Each patient was scheduled for follow-up at 3, 6, 12 and 24 months. In March 1998, a comparison group of 300 women electing TL during the same time period was systematically chosen. Researchers visited the village of every woman and conducted a structured interview. Each candidate was given a general health and pelvic exam at a clinic in her village. All interviews and exams were completed in August 1998.

Results: Of the 289 QS patients interviewed (a follow-up rate of 96.3%), 265 had had 2 insertions. There were 3 pregnancy failures for a cumulative life table failure rate of 1.2 per 100 women at 24 months. The 299 TL patients (a

follow-up rate of 99.7%) had a similar rate of 0.7. There were no life-threatening side effects or deaths in either group. QS was less disruptive, more easily tolerated, required fewer resources and was viewed more favorably than TL by women and their spouses.

Conclusions: Both methods were found safe and very effective. However, QS was considered to be more acceptable than TL."

Years before Bill Gates and his company TerraPower went to China in 2011 to pursue science that the U.S. government wouldn't endorse, the Governor of Guizhou Province for Outstanding Scientific and Technological Education Talents in China funded a project with Dr. Lu on QS.

Now Mr. Gates is funding about half of TerraPower design in his Natrium 4th generation $4 billion nuclear reactor in Kemmerer, Wyoming. As Reuters reported November 17 2021, "Gates had initially hoped to build an experimental nuclear plant near Beijing with state-owned China National Nuclear Corp. But TerraPower was forced to seek new partners after the administration of Donald Trump restricted nuclear deals with China."

Perhaps a trial of QS in a U.S. state could be initiated similar to a study described in the New Your Times: *Colorado's Effort Against Teenage Pregnancies Is a Startling Success*, By Sabrina Tavernise, July 5, 2015

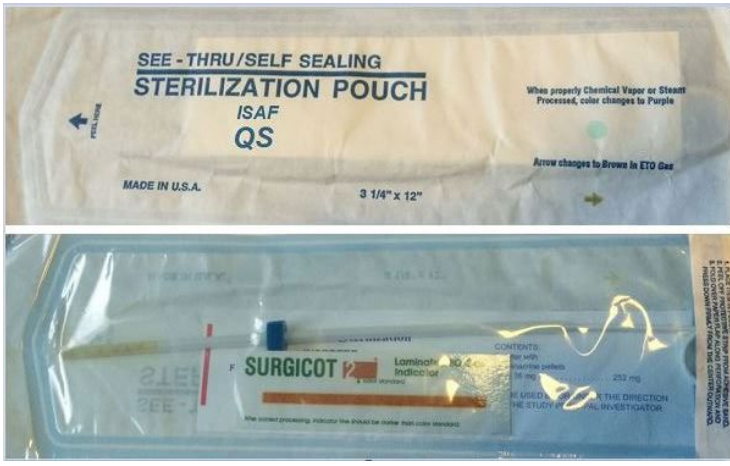
"Colorado's program, funded by a private grant from the Susan Thompson Buffett Foundation, named for the billionaire investor Warren Buffett's late wife, was the real-world version of a research study in St. Louis (also paid for by the foundation, which does not publicly acknowledge its role). The study came to the same conclusion: Women overwhelmingly chose the long-acting methods, and pregnancy and abortion rates plunged.

'The difference in effectiveness is profound,' said Dr. Jeffrey Peipert, a professor of obstetrics and gynecology at Washington University in St. Louis, who ran the study. The failure rate for the pill was about 5 percent, compared with less than 1 percent for implants and IUDs."

Whenever legislative bills at a national level fail, then enterprising individuals take the battle to the states. PBS reported February 15, 2022, "Birth control is now available in North Carolina without a prescription. . " where it was stated that "North Carolina is now one of more than a dozen states to make contraception available over the counter, according to Elizabeth Nash, a state policy expert with the Guttmacher Institute." Hopefully, more state legislatures will act to make contraceptives more available.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 9 FDA is Key - Committee Meeting Following Formal Dispute Appeal



Non-surgical permanent contraception for women (QS) kit (Credit: ISAF)

18 December 2014

The FDA held a meeting in Washington, DC at their headquarters. Colleagues interested in QS attended (see picture below) including Jack Lippes, Gene McConnell who authored McConnell et al., and Joe Haseman who authored Haseman et al., Donald Collins Sr., Stephen Mumford, and two (2) eminent epidemiologists, Judith K Jones (founder of the Degge Group) and Arlene Tave. Jones and Tave presented two epidemiological studies of 21,040 patients in Vietnam.

This analysis was a 16-year retrospective. Jones and Tave found that the incidences of cancer, ectopic pregnancy, and hysterectomy in QS patients was not increased. They further analyzed the incidence of cancer, ectopic pregnancy, and hysterectomy in two (2) other groups of patients. Each group was matched with one of 10,503 QS patients by age and parity. One group consisted of 1333 women who had surgical tubal ligation (STL) and were never exposed to quinacrine. The second group of 9204 women used IUDs for family planning.

The incidence of cancer, ectopic pregnancy, and hysterectomy in these two (2) groups was the same as the incidence in QS patients.

During the meeting, none of the voting executives or advisors of the FDA made any mention of the work of Jones and Tave and their final vote was 29 to 1 against moving forward with a QS Phase III clinical trial. The Wall Street Journal's lead Editorial, "The FDA's Rigged Drug Committees" on January 3, 2017 makes it clear outcomes like ours happen frequently.

Prior to and after December 18, 2014, much correspondence took place between ISAF and the FDA (see below list) always rejecting QS, until we found this on the internet.

March 24, 2021: FDA file, Nomination and Review of Clinical Need for Quinacrine Hydrochloride to be

Included on the 503B Bulk Drug Substances List, p4-5 – here stated "Jones et al. (2017, 2018) completed a retrospective cohort study of a population of Vietnamese women who underwent sterilization or contraception procedures between 1989 and 1996. These patients were interviewed regarding health outcomes approximately 16 years post exposure to compare the quinacrine pellet system (10503 interviews) versus intrauterine devices (9204 interviews) or tubal ligation (1333 interviews) for contraception. A 95% response rate based on the treated population resulted in a total of 21,040 interviews and found no significant excess of long-term risk of reproductive tract cancer, hysterectomy or ectopic pregnancy associated with quinacrine. **These data updates do not provide adequate evidence regarding the safety profile for intrauterine quinacrine, and the potential effectiveness of drugs compounded from quinacrine for female chemical sterilization such that FDA would depart from DBRUP's 2016 findings and recommend adding quinacrine to the section 503B Bulks List for this use."**

How could the FDA conclude that these data updates do not provide conclusive evidence that QS does not increase the incidence of cancer or ectopic pregnancy compared to FDA

approved methods like intrauterine devices and surgical tubal ligation?

December 18, 2014, The ISAF meeting in Washington, DC at FDA headquarters where the FDA committee final vote was 29 to 1 against moving forward with a QS Phase III clinical trial. (Credit: ISAF)

Top Row left to right: Roger Growe, Errol Zieger, Gene McConnell, Joe Haseman, John Pezzulo, Mark Heller, Mike Luster,

Middle Row left to right: Carol Danielson, Margaret Miller Growe, Kristin Davenport, Steve Mumford

Front Row left to right: Valentin Trujillo, Judith Jones, Sarah Epstein, Elizabeth Bianchi, Jack Lippes, Don Collins

What follows is a brief timeline of FDA actions regarding QS and the drug quinacrine and final correspondence with ISAF.

CORRESPONDENCE AND SUBMISSIONS TO/FROM THE FDA REGARDING QS

February 2, 2007: FDA letter to Dr. Richard Guarino, M.D. Director, Clinical Research, Oxford Pharmaceutical Resource, Inc., working on behalf of ISAF – IND 74,802, which allows for the study of quinacrine hydrochloride for the non-surgical sterilization of women, is being placed on FULL CLINICAL HOLD – link here

March 8, 2016: FDA-Briefing-Information-for-the-March-08--2016-Meeting-of-the-Pharmacy-Compounding-Advisory-Committee – link here. Two papers referenced here and here

August 26, 2016: IND 074802, serial No. 0035-Formal Dispute Appeal to the Commissioner, Robert Califf, M.D. – link here

December 9, 2016: Final FDA rejection of QS by Luciana Borio, Acting Scientist – link here

February 2020: University of Maryland, REVIEW OF NOMINATION Quinacrine (UNII code: 81A613ZZ6X) was not nominated for inclusion on the 503B Bulks List. – link here. We received no answer to our letter suggesting they used insufficient search terms to find the articles in this book.

July 1, 2020: 503A updated – link here
503A Category 1 – Bulk Drug Substances Under Evaluation: Quinacrine Hydrochloride (except for intrauterine administration)
503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks: Quinacrine Hydrochloride for intrauterine administration

March 24, 2021: FDA file, Nomination and Review of Clinical Need for Quinacrine Hydrochloride to be Included on the 503B Bulk Drug Substances List, p4-5 – here.

"**A. Non-surgical female sterilization**
The 503A review by (then) DBRUP recommended that quinacrine not be included on the 503A Bulks List, given that quinacrine is known to be genotoxic and cytotoxic. The review cited an October 14, 1998, warning letter issued by FDA requesting that unapproved quinacrine pellets for non-surgical female sterilization be immediately removed from the

market.[8] In addition, the review concluded there was "lack of compelling evidence of efficacy" that (use of quinacrine) is at least comparable to currently available methods of female sterilization, such as surgical procedures. The World Health Organization's 2009 interim statement, recommending that "quinacrine should not be used for non-surgical sterilization of women either in clinical or research settings" has not been updated or removed as of the date of this review.[9]

Quinacrine use for female chemical sterilization was placed by FDA in Category 2 for purposes of FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A in 2016, as having significant safety risks.[10]

FDA conducted a literature review of PubMed to identify articles published between January 1, 2016, and October 8, 2020, that provided updates from 503A review and 2016 Pharmacy Compounding Advisory Committee (PCAC) about quinacrine's use in this indication. FDA reached the decision not to nominate quinacrine for this use based on both the 2016 503A reviews and the 2020 literature update, as summarized here.

"There were three articles identified in the previously described literature review related to quinacrine's use as a chemical sterilization agent. Lawrie (2016) updated the 2011 Cochrane Library review first published in 2002. Of the 19 randomized, controlled trials investigating techniques for the interruption of tubal patency for female sterilization, none involved the use of chemical inserts, including quinacrine. Jones et al. (2017, 2018) completed a retrospective cohort study of a population of Vietnamese women who underwent sterilization or contraception procedures between 1989 and 1996. These patients were interviewed regarding health outcomes approximately 16 years post exposure to compare the quinacrine pellet system (10503 interviews) versus intrauterine devices (9204 interviews) or tubal ligation (1333 interviews) for contraception. A 95% response rate based on the treated population resulted in a total of 21,040 interviews and found no significant excess of long-term risk of reproductive tract cancer, hysterectomy or ectopic pregnancy associated with quinacrine. These data updates do not provide adequate evidence regarding the safety profile for intrauterine quinacrine, and the potential effectiveness of drugs compounded from quinacrine for female chemical sterilization such that FDA would depart from DBRUP's 2016 findings and recommend adding quinacrine to the section 503B Bulks List for this use."

8 Division of Reproductive and Urologic Drug Products (DRUDP), 1998, Health Hazard Evaluation Summary of a
Kit for Intrauterine Insertion of Quinacrine Hydrochloride Pellets for Female Sterilization, log number DRUDP 137,
available at https://www.fda.gov/media/96263/download
9 https://apps.who.int/iris/handle/10665/70085
10 https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substancesnominated-use-compounding

June 7, 2021: 503B updated – link here
503B Category 1 – Bulk Drug Substances Under Evaluation: Quinacrine Hydrochloride (except for intrauterine administration)
503B Category 2: Bulk Drug Substances that Raise Significant Safety Risks: Quinacrine Hydrochloride for intrauterine administration

August 3, 2021: Dr. Lippes letter to Dr. Janet Woodcock FDA interim commissioner to review QS – link here

September 10, 2021: Patrizia Cavazzoni, MD, Director Center for Drug Evaluation and Research response to Dr. Lippes letter. – link here

September 28, 2021: Dr. Lippes response letter to Patrizia Cavazzoni, MD, Director Center for Drug Evaluation and Research. – link here

Date: October 20, 2021, at 10:18:50 AM PDT
Dear Dr. Lippes and Mr. Collins

> "Thank you for your letter to the Food and Drug Administration (FDA) dated September 14, 2021, and your letter to Dr. Cavazzoni, Director, Center for Drug Evaluation and Research (CDER) dated September 27, 2021 regarding quinacrine.
>
> We refer you to our previous correspondences regarding your IND (IND 074802) for your proposed quinacrine drug product, in which we explain the process for addressing the clinical hold deficiencies of your IND.
>
> FDA remains committed to fostering the development and availability of reproductive choices for women and is prepared to consider your development program for quinacrine through the pathway outlined to you in our previous communications.
>
> Sincerely,
>
> CDER Executive Operations"

The ISAF correspondence above fulfills Scott Monroe, M.D., Acting Director, Division of Reproductive and Urologic

Products, Office of Drug Evaluation III, Center for Drug Evaluation and Research requirements to lift the clinical hold.

"Clinical hold deficiency

Results from a two-year rat carcinogenicity study, in which quinacrine hydrochloride was administered directly into the uterus in a dosing study similar to that used in humans, have recently been reported to us. This study showed a dose related increase in malignant reproductive tract tumors, which was statically significant at the two higher doses. Because of these findings, we believe the women treated with quinacrine hydrochloride for non-surgical sterilization would be exposed to a significant risk of illness or injury.

Information needed to resolve the clinical hold deficiency

Long-term post treatment data from women previously treated with intrauterine quinacrine hydrochloride for non-surgical sterilization, which did not demonstrate an increased risk for the development of malignant reproductive tract tumors, would be required. The data will need to be obtained from an appropriate designed study, including sufficient duration of post treatment follow up and sufficient sample size to rule out an increased risk of the development of malignant reproductive tract tumors."

Also on March 24, 2021: FDA file on page 8

> "iii. Safety issues associated with non-oral use of quinacrine HCl.

As a female sterilizing agent, quinacrine HCl was originally studied using a slurry formulation that was instilled into the uterine cavity (Zipper et al., 1970). However, three deaths were reported (in the US and Bangladesh). It is unclear whether the deaths were due to erosion of the uterus and subsequent spillage of quinacrine HCl into the peritoneum or to effects of systemic exposure to quinacrine HCl. Quinacrine HCl pellets were subsequently used for female sterilization.

As regards the pellet formulation, on August 26, 1998, a safety assessment and Health Hazard Evaluation was conducted by FDA on a kit for uterine insertion of quinacrine HCl pellets for female sterilization [see Appendix 1]. In this evaluation, FDA raised concerns in three areas based on results from previously conducted toxicology studies on the oral formulation and the lack of adequate toxicology testing on the intrauterine pellet formulation:

> (1) possible carcinogenicity of quinacrine; specifically, quinacrine is a known mutagen and had tested positive in several genotoxicity tests, and the intrauterine administration of quinacrine pellets would result in significant tissue damage and the

presence of known mutagen could result in development of cancer of the reproductive tract;

(2) lack of sufficient pharmacokinetic data, specifically, concerns exist on the possible continuous exposure of the endometrium to the drug following intrauterine insertion; and

(3) pharmacodynamic issues, specifically, that intrauterine instillation of the cytotoxic agent had been noted to be unsuccessful for complete destruction of the endometrium and had resulted in neoplastic transformation of residual endometrial cells.

The evaluation noted that drugs with positive mutagenicity and cytotoxicity profiles, such as quinacrine HCl, were of concern with regard to increased cancer risks in humans. FDA concluded that the potential and known risks may outweigh any proposed advantages this procedure may have over surgical sterilization in the United States.

On October 14, 1998, FDA issued a warning letter regarding unapproved quinacrine HCl pellets labeled for non-surgical female sterilization [see Appendix 2]. In this letter, FDA highlighted many of the same safety concerns identified in the August 1998 Health Hazard Evaluation summarized above and concluded that non-surgical female sterilization is an unsafe use of quinacrine HCl pellets. Citing safety

concerns, FDA requested that the unapproved quinacrine HCl pellets for non-surgical female sterilization be immediately removed from the market. In October 2008, a WHO Panel recommended that "until the totality of safety, effectiveness and epidemiological data has been reviewed, quinacrine HCl should not be used for non-surgical sterilization of women in either clinical or research settings." To date, this interim statement has not been updated or removed."

As the FDA notes above, prior to the development of the QS pellet method described below, sadly, there were three deaths with the quinacrine 1500 mg slurry method, a woman in Nashville, TN, a woman in Canada, and a woman in Bangladesh. **There have been no deaths or serious side effects with the QS pellet method since its introduction in 1977.**

Robert Wheeler of University of North Carolina (UNC) and Family Health International1 researched and developed the initial quantity of 12,600, 36mg quinacrine pellets. Approximately 3300 were sent to Dr. Zipper in Chile, 3300 went to Dr. Bhatt in India, and 3300 went to Dr. Begum in Bangladesh. 3300 pellets are sufficient to do 235 cases. All 3 trials were stopped midway. Dr. Zipper performed 139 cases, Dr. Bhatt did 84 cases, and Dr. Begum did 79 cases. No more pellets were made at UNC.

Dr. Stephen Mumford's wife Judy was friends with the wife of a major Taiwanese pharmaceutical company who made the first 1 million pellets for the Center for Research on Population and Security (CRPS) in 1980. Dr. Lu in China got her first 2000 pellets from Taiwan. Many other researchers used these pellets from Taiwan successfully.

IAMANEH (the International Association for Maternal and Neonatal Health), a Geneva-based NGO made 1 million pellets for CRPS in 1990 all of which were sent to Dr. Hieu in Vietnam. A few of the team at Iamaneh, who made the pellets, left and went to SiPharm Sisseln AG another Swiss pharmaceutical company where they produced 1 million more pellets for CRPS in 2000. Dr. Lu in China got her second 2000 pellets from SiPharm. Many other researchers used these pellets from Swiss companies successfully.

To date, 3,010,000 quinacrine pellets have been produced for CRPS (enough for 215,000 cases) which have been used by over 1600 researcher around the world in hundreds of clinical studies published in many journals, none of which have been accepted by the FDA as proof of safety and efficacy. **Over 5 million patient years, with no deaths, no increase in cancer or ectopic pregnancy risk from a study larger and older than normal, proves QS is a safe and effective method, yet the FDA refuses to allow a U.S. clinical trial.**

These FDA concerns have been answered many times by ISAF. What powerful forces influence the FDA to do everything in its power to eliminate all avenues of QS through pharmacy Compounding and Investigational New Drug (IND) means ensuring U.S. women never gain access to QS despite its successful clinical trials in many other countries? As shown above, in February 2020, the FDA used $2.3 million and its power to prevent any drug company from making or distributing quinacrine in the future by using incorrect search terms and ignoring most of the peer-reviewed research on QS provided in this book.

If any of this hits a chord with you, click here to contact your member of Congress or call or email the best advocates for you (women leaders who work for you):

Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111
kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965

sf.nancy@mail.house.gov

We would love to hear from you too - send an email to donjr@quinacrine.org to let us know what you are thinking. Please take our survey.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 10 Dr. Clarence Gamble's 100 Year Legacy Helping Women and Families to Make "Every Child A Wanted Child"

1937 Clarence and Sarah Gamble at home with their children Dick, Walter, Judy, Sally, and Robert. (Credit: Gamble Family)

The Giving Impulse: One Family's Story by Maria Di Mento in *The Chronicle of Philanthropy* on April 2, 2019, tells "How generations of heirs to the Procter & Gamble fortune have nurtured a culture of philanthropy for more than a century."

"Judy Kahrl was a teenager when she realized not all families were like hers. Kahrl remembers typical dinner-table conversations included frank discussions about contraception, women's reproductive health, and the importance of family planning. This was in the 1930s and '40s, decades before the invention and FDA approval of the birth-control pill in 1960, and at a time when birth control of any sort was highly controversial.

Kahrl, who is 84, is the fourth of Clarence and Sarah Gamble's five children. Clarence was a physician and heir to the Procter & Gamble fortune. He received $1 million from his father when he turned 21 in 1915 (the equivalent of about $25 million today) with the caveat that he was expected to tithe 10 percent to charity. Clarence decided 10 percent wasn't enough and upped that amount to 30 percent.

Sarah was also from a wealthy family, and together the two became notable 20th-century family-planning and women's health activists. They helped start a number of U.S. maternal-health clinics in the 1920s. In the 1930s, they joined forces with birth-control pioneer Margaret Sanger and a prominent gynecologist and maternal health educator, Robert Latou Dickinson, to overturn the Comstock Laws, a series of 19th-century federal acts that outlawed the mailing of

contraceptives and information about them, among other things.

Clarence and Sarah eventually took their family-planning efforts overseas to Japan, India, and Indonesia. That work led to the couple's founding of what would become Pathfinder International in 1957. Today, Pathfinder has programs for maternal and reproductive health, family planning, and HIV/AIDS prevention and care throughout Africa, Latin America, Asia, and the Near East.

One of Clarence and Sarah's sons, the late Dick Gamble, led the organization until 1985, when its growing size and scope prompted him and his siblings to hire Dan Pellegrom, a seasoned nonprofit leader in the women's reproductive-health arena, who ended up leading the organization for 26 years. While Pathfinder was originally funded by Clarence and Sarah, today it receives most of its support from the U.S. Agency for International Development, and multiple generations of the family remain involved with the nonprofit.

Early Lessons

During their lifetimes (Clarence died in 1966, Sarah in 1984), the couple passed down to their children a deep commitment not only to Pathfinder's work and related

causes but to philanthropy more broadly. How they and successive generations of Gambles have made that commitment stick offers a road map for how to instill the philanthropic impulse into a wealthy family's DNA far into the future. The Gamble family declined to disclose its current net worth, but family members say theirs is a healthy but modest fortune when compared with other philanthropic families whose wealth carried over from the early 20th century.

Though rich, Clarence and Sarah were uncomfortable with showy displays of wealth, and those dinnertime conversations included talk about how much need there was in the world. Judy Kahrl says she doesn't know if that was by design or if it "was just sort of the air we breathed," but she says her father taught his children early on to manage their money wisely and to understand that a big part of having a lot of money included giving it away to those in need.

She remembers as an 8-year-old getting an allowance of 12 cents a week, 2 cents of which her father earmarked for her to donate to needy children. Those lessons blossomed in sophistication over the years so that by the time the first part of her inheritance kicked in, when she was 21, she was already giving healthy sums to some of her parents' projects and eventually to other charities. Clarence brought some of his

children on overseas trips to visit the clinics and other programs, and while he wasn't shy about asking his grown kids to support the family's charitable efforts, he didn't insist.

"There was always a kind of freedom for us to choose what we wanted to give to, and I think that was very wise," Kahrl says. "He realized we could evaluate our situation better than he could."

Virginia Esposito, president of the National Center for Family Philanthropy, who advises many modern-day philanthropists and their families, has high praise for families like the Gambles who take an immersive approach to giving. "Your chances go up exponentially of having your children and grandchildren involved in philanthropy if they get to sit with you and hear the stories and understand the family goals," says Esposito."

Richard B. Gamble, in September 1977 writes of his father in the Forward of the book *Every Child a Wanted Child*,

"My father's interest in birth control began in 1924 when he first met Dr. Robert L. Dickenson, the leading physician in the field of contraception, who urged him to "take up the work." From the earliest days that I can remember, his professional life was devoted

exclusively to "The Great Cause." He believed that there was no way a physician could do more for the health and happiness of women, and, in fact, of all people, then by making it possible to plan and space children.

The goals of his birth control work were three-fold: to make birth control services available to all people; to persuade leaders that birth control, or family planning as we call it today, should be part of every health system; and to develop safe, simple, and inexpensive contraceptives.

My childhood recollections of my father's work in the United States is hazy. I remember warmly some of the wonderful people he worked with – Margaret Sanger, Robert Dickinson, Edna McKinnon, and Phyllis Page, to name but a few. I recall his joy when things went well and his disappointment when opportunities, as he perceived them, were lost. Though my understanding of the substance of his work was limited, I clearly remember his burning desire to make it possible for every child to be a wanted child.

In 1953, upon my discharge from the Army, it was my privilege to become a partner in his work, sometime closely associated, sometimes only by telephone, by mail or through the occasional visit. Though we did not always agree on the best way to approach

problems or the best use of the resources available, I always had the satisfaction of knowing we shared the same goals. I was with him on his first and last international trips. The story of his first, his 1952–53 visit to Japan, India, and other countries in Asia is told in the text. In 1966 when he visited me in Nigeria, his dedication, his joys and his disappointments were once again demonstrated. Though civil strife was breaking out he insisted on making what might have been a dangerous drive to attend a population conference in Ibadan. On his return to Lagos, he persuaded the Minister of Health, a gynecologist, to let him help introduce family planning into the Lagos Maternity Hospital where there were 30,000 deliveries annually. It would have been a step many years ahead of its time in Africa. The next morning the Army moved to quell the unrest. Following a quick and peaceful coup, the civilian cabinet was dissolved and the Minister was no longer in office.

The Pathfinder Fund was established by my father in 1957, and following his death in 1966, has continued to carry on his work. In the eleven years since his death a greater understanding of the relationship between the health and happiness of families and appropriate child-spacing, coupled with a growing concern with respect to the imbalance between the world's population and its resources, stimulated popular

interest in birth control. Increased sums of money, from both the public and private sectors, became available for family planning programs. These greater resources have made it possible for Pathfinder, along with other organizations concerned with population issues, to grow substantially. The Pathfinder Fund, now located in Chestnut Hill, Massachusetts, a Boston suburb, became a public foundation in 1970. Today is has a headquarters staff of 25, five overseas offices, and an annual budget of $4,000,000, drawing its funds from private philanthropy and an annual grant from the United States Government under the Foreign Assistance Act. I was elected its full-time Executive Director in 1971, shortly after my return from Nigeria.

My father might not recognize the field of family planning today. So much has changed. In most countries it is no longer a question of whether to offer family planning services but how to do it so that as many people as possible can be reached effectively and efficiently. Increasing numbers of people are concerned about population size and growth. It may not be enough for every child to be a wanted child. The tradition for many people has been to want many children, but unless the average couple has only two children continued population growth may preclude successful economic development and make impossible an improved quality of life, both in the

United States and in other countries. Unless people, women in particular, can achieve happiness in ways other than having many children, excessive birth rates may well continue to be the norm. Women must be able to find fulfillment and satisfaction in roles other than being mothers of large families.

The Pathfinder Fund also has changed – in response to the changing needs. Though most of our work still promotes the availability of birth control services, our goals have become broader. We assist programs that help leaders understand the consequences of excessive rates of population growth so they can subsequently develop policies which directly or indirectly may lead to lower birth rates. Pathfinder's Women's Programs Division has been set up to stimulate those changes in the status and role of women that will eventually lead to a wider range of roles as alternatives to the exclusively maternal, a process which is underway but hardly complete in the United States and which has barely begun in many countries."

Introduction to the book *Every Child a Wanted Child*

"The contributions of Dr. Clarence James Gamble to population planning were essentially twofold: {1} As a missionary "spreading the good news" of family planning and often the first to "get something started" in many parts of the world. {2} As a tireless

experimentalist in search of a good contraceptive that the poor could afford to use. In sum, his objective was to show men and women the means of making conscious choices in determining the outcome of the sex act. In five trips around the world, Dr. Gamble missed no opportunity to make contraception both medically respectable and a dinner-table topic, accepting the risk that he might offend people, as he sometimes did.

Dr. Gamble was unusual in many ways. Born rich, he had the rare opportunity to answer for himself the question that so many dreamers ask themselves: "What would you do if you had a million dollars?" Recipient of his first million on his twenty-first birthday, and later many more as an heir to a fraction of the Procter & Gamble Company billions, Clarence Gamble invested himself and a substantial portion of his wealth in birth control.

Money, plus the natural endowments and scholastic aptitude of a man who graduated first in his class at Princeton (1914) and second in his class at Harvard Medical School (1920), gave Clarence Gamble security and independence. His position vis-à-vis life offered distinct advantages and some unsuspected disadvantages. He shared, as befitting his generation, in the local-boy-makes-good syndrome, but, being

denied self-generated earning power as a measure of success, he had more than the average man's difficulty in fulfilling the universal human need for the validation of one's work by society. He felt deeply that the privileges of education and wealth should be put to use to help those less privileged. The rendering of such service was to him a genuine obligation, as is witnessed to by the career choices and lifestyles of all five of his children. Not having to meet the challenge of economic survival, he looked on life as a different kind of contest: he continually followed a pattern of seeking risks and setting up obstacles to be overcome. They were sometimes needless hazards and he did not always overcome them, but he seemed compelled to test himself, he was often frustrated, yet he never stopped trying.

A conventional Republican and expert in the conservation and management of his own estate, he expressed little discontent with his country's economic system or political philosophy. Nevertheless, in his career as a physician and birth controller he was constantly at odds with the Establishment; perhaps he harbored a compulsion to defy authority figures, but it would be equally valid to speculate that, being able to afford it, he was in a unique position to pursue the course he thought best, since this course was almost always the shortest and most direct distance between

two points, he was anathema to the ponderous processes and ritualisms of organizations.

He did his own thing at some cost, although a cost he concealed in his intense desire for privacy. While Dr. Gamble achieved somewhat better than average life expectancy for white American males (he died at the age of seventy-two), he underwent an astounding variety of illnesses and injuries, requiring hospitalization some two dozen times. He suffered seven fractures and countless infections. A peptic ulcer gnawed at his duodenum for thirty years; angina pectoris clutched at his chest for twenty; leukemia bested him in his last two.

As an advocate for family planning, through the wise choice of Sarah Merry Bradley as his wife, he made his five children a model of a "real family"; friends not only of the parents but also of the children often marveled as the Gambles of Milton. Dr. Gamble's family was his island. Home was both a stage on which he was the leading man and an audience that he entertained with good news and amusing accounts of his many sorties against an often unfriendly and uncomprehending world.

Acquaintances viewed Clarence Gamble as a "frail person." Five feet seven inches in height and normally weighing one hundred thirty-five pounds, he had two

striking features; his brown eyes, as sharp and bright as a fox's, and a characteristic smile, sunny when he was a boy but, as a Korean doctor remarked, a "not so big one" in his later years. His classmates at Occidental Academy in Pasadena called him "Percy bright eyes." His brown hair turned to gray in his early forties; he wore a small mustache, glasses, and, in later life, a hearing aid.

Sarah Gamble and the children loyally defended him against his many critics, but the world of birth controllers saw him as a sharply two-sided personality, impulsively generous and kind in support of activities that he regarded as important but independent toward all else. He was frequently – and on occasion outrageously – unsympathetic, unperceptive, and unaccommodating to the other fellow's viewpoint – a characteristic, however, pandemic among his fellow birth controllers. He dealt with national and international birth control organizations for thirty-seven years {1929 - 1966}, but he never was an organization man and never understood the dynamics of organizational process; he was locked in conflict with their officers, who complained that he nagged and pestered them to distraction. Superficially polite and even-tempered, although sometimes angry and tense, he tended to be abrasive and inarticulate in his efforts to develop

warm, human relationships with these strangers. His family and close friends knew he had a sense of humor and saw his joy in his children, his shy warmth and thoughtfulness for those he loved. In early life he was afraid that others loved his money rather than himself. If it struck some of his colleagues in birth control that he did not care what they thought of him, they may have been wrong; from time to time, he asked Sarah why they disliked him. The fact that he did not understand, of course, suggested why. He chided his colleagues with putting the needs of organizations before the needs of women – especially the poor women they purportedly existed to serve.

Yet, when Clarence Gamble left the battlefield, the leaders whom he provoked and irritated came around to his ideas and modes of action sooner or later – sometimes much later. Perhaps this is a hallmark of a true pioneer. In the principles that he preached he was less the originator than the applicator. He was quick to act. In the introduction of birth control in out-of-the-way places and the staging of field trials of contraceptive techniques, he often moved ahead of the large, respectable birth control organizations, not only in his early testing of spermicidal jellies and condoms but in his acceptance of new methods – oral contraceptives pills and intrauterine devices (IUD's). In the course of time he became totally obsessed with

what he called "The Great Cause" and "my monomania." When he found himself at cross-purposes with natural allies who shared his commitment, he rationalized the difficulty by pointing out: "Birth controllers, being nonconformists, don't get along well with one another."

Overshadowing this truth was the larger fact that the pioneers of birth control did not get on well with the Establishment – the Church, government, police, business and industry, medical profession, foundations, or universities. In this realm, Dr. Gamble had touched all the right bases – family, fortune, religion, and education – but then deliberatively chose an unpopular career. Ironically, when the public and indeed the world had embraced the Great Cause and he asked, in small ways, to be recognized for his knowledge and experience rather than his money, birth control organizations denied him recognition and he remained unpopular with them to the end. Yet he had both recognition and respect from the two figures of greatest importance in the movement, Margaret Sanger and Dr. Robert Latou Dickinson.

Among Laymen, Margaret Sanger {1879 – 1966} is the one family planner who is universally remembered. Several biographies have been written about this dynamic, attractive, timeless heroine who introduced

the term "birth control" and the slogan, "Every child a wanted child." Mrs. Sanger began in New York City as a nurse, a feminist, and a Socialist. She challenged the Irish Catholic policemen who came to close the birth control clinics that she opened and to put her in jail for writing and lecturing on contraceptive methods.

Among physicians in family planning, the leading figure of the early part of the century was Dr. Robert Latou Dickinson {1861 – 1950}, a New York gynecologist and the first American sexologist. Dickinson quietly accepted the disdain of his profession in his efforts to convince it of the need for medical interest, research, and training in contraception, the only approved method then being the vaginal diaphragm of rubber laced with spermicidal jelly. The prudent general practitioner, in contrast, avoided any show of concern about sex in his women patients and would not think of examining the vagina for the repair and healing of nature's insults, lest fathers and husbands accuse him of concupiscent designs. Dickinson held that social condemnation of the possibility that the female, too, might find pleasure in sex was the predominant cause of mental strains and social maladjustments in women. He attacked the belief that it was a wife's duty to submit to her husband's lust whenever the man willed. This gentle

scholar had an aphoristic way of writing as when he said, "Birth control is simply self-control under various aliases."

Dr. Gamble became interested in the subject of conjugal relations, including contraception, in anticipation of his marriage in 1924. It struck him as logical that a young man going into a new field should read up on it. This interest led him to Dr. Dickinson, who advised him to plan and space his children, and made an effort to recruit him into the Great Cause: "Young men like you, who are also independent, ought to take up the work." The average practitioner dependent on community good will for his patients and his income feared to risk unpopularity. Drs. Stuart and Emily Mudd of Philadelphia, who became longtime friends of the Gambles, accelerated his interest when in 1929 they invited Clarence to head a maternal health group in Philadelphia and help them develop birth control clinics.

Both Mrs. Sanger and Dr. Dickinson took Dr. Gamble's side in his conflicts with birth control organizations, well knowing that pioneers may be seen by even their own kind as social misfits or troublemakers. They came to consider Gamble a kindred spirit and an important worker in their field. Dickinson ranked Clarence Gamble second only to Margaret Sanger as

an initiator of programs, although some leaders of organizations did not agree. These organizations included the American Birth Control League, Birth Control Federation of America, Planned Parenthood Federation of America, International Planned Parenthood Federation, Population Reference Bureau, and the Population Council, a rather imposing list surely confirming the fact that Gamble was not a good joiner. Indeed, he accepted most encounters with organizations as occasions for insistence that they do things differently – that is, his way. He had in abundance convictions and the courage of his convictions; but he was inept in explaining the reasons for his convictions, or perhaps he simply felt it was a waste of time.

He won the acceptance of small, select in-group as a private philanthropist, a lone prospector, and agent provocateur in the search for a good contraceptive and health and happiness for all the mothers of the world, as he liked to say. This makes him not only a subject for off-beat biographic scrutiny but also an appropriate vehicle for study of the birth control movement as medical social history.

Not destined to be hailed as a leader of men or even a defender of motherhood, Clarence Gamble saw it as his task so set an example for the organization

Goliaths. In the face of their insults and rebuffs, he remained cheerful, optimistic, and persevering, sometimes secretly hurt but always coming back for more. No David ever felt more challenged. In this role, he found his *joie de vivre*."

Learn about Dr. Clarence J. Gamble's extraordinary life here.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 11 Hero Sarah G. Epstein Continues Making the Case for Women

This picture is from an interview Sally gave to the Historic Chevy Chase DC organization on April 20, 2013 (Credit: Sarah G. Epstein)

QS would not exist without the efforts of Sarah G. Epstein. (Don Jr says about his stepmother) – I'm

grateful to have known her love and wisdom for three decades, and to serve with her on nonprofit boards.

The following is an essay from Marilyn Hempel's book, Facing the Population Challenge: Wisdom from the Elders (Blue Planet United, 2014). The book brings together the responses of fifteen giants in the field of human population and development, who were asked how they would advise an assemblage of the world's leaders on the future of humanity and the biosphere.

What Would I Say to World Leaders?

by Sarah G. Epstein

I have spent most of my life as a social worker in the field of family planning, so I am well aware of the advantages of contraception for families everywhere. Now my deepest concern is for the generation of my grandchildren and beyond. What kind of world are we leaving them? With world population today at more than seven billion and still growing, we are already robbing the future of fresh water, oil, adequate farmland, and the joy of untrammeled open spaces. We are already negotiating clogged roads, breathing smog-laden air, and losing somewhere near 100 species of animals and insects every day.

Each new disaster – flood, earthquake, fire – seems to kill and displace more people. And of course, the reason is that there are more people. If these ills are to be overcome, it will only be if there are far fewer people than are now here.

Therefore, our top priority should be to ensure that free contraception is available to everyone everywhere in all cities, towns, villages, and rural areas of the world. Trained doctors, nurses, and social workers, male and female, should make sure that all the world's inhabitants learn – through public meetings and discussions – about the health and economic benefits of small families with well-spaced children. Early marriage should be discouraged, and all children (especially girls) should be educated using a curriculum that includes health and sex education, food and nutrition, and ecology. And there should be emphasis on human rights for all, in order to eliminate religious strictures, especially those that affect women.

I ask all the world leaders to emphasize the need for a smaller population, brought about by educated people voluntarily choosing small families and a healthy lifestyle including good diet and exercise.

We live in a far different world than the one in which I grew up. I hope our external electronic brains and technological capabilities will help us reverse the

effects of climate change and leave a better world. Only by reducing population to a level where the world can sustain itself can we hope to pass on a stable and safe world to our grandchildren. Endless population growth is suicidal!

Sarah Louise Gamble Epstein was born in 1925 in Philadelphia, Pennsylvania, to Sarah Bradley Gamble and Dr. Clarence James Gamble. She attended Germantown Friends School (Philadelphia), Milton Academy (Milton, MA), Wellesley College for two years, Oberlin College (Class of 1948) and Simmons School of Social Work. Since her father, Dr. Clarence Gamble, was an advisor to Margaret Sanger, she grew up believing all children were planned and wanted. When she realized this was not the case, she decided to work in the field of family planning. Her father was the founder of Pathfinder International, an organization that pioneered the provision of family planning services.

After a summer in Austria (1949) with the Experiment in International Living, she met Lionel Charles Epstein, a student at Harvard Law School and a participant in the Experiment program. They were married in 1951 and moved to Washington, DC, where they raised five children. She remained active with the Experiment and volunteered with Planned

Parenthood, often counseling women in the maternity ward at the City Hospital. She was involved with Pathfinder International, and often traveled abroad to observe family planning programs at work.

She and Lionel were divorced in the early 1980s. She continued to travel and work in the family planning field. She met Donald Collins when he organized a group to go to Vietnam in 1993 to study a non-surgical permanent contraception for women method called QS, which is a safe, sure, inexpensive, and non-surgical permanent contraception for women. The QS procedure uses insertions of seven quinacrine tablets into the uterus. When they dissolve, they cause an inflammation inside the opening of the Fallopian tubes that results in a scar that seals the tubes closed. In Vietnam, they found that QS had been successfully used by thousands of women. Studies from around the world reports no deaths or life-threatening complications. However, after pressure from religious sources, the World Health Organization banned its use or further testing worldwide in 1993.

Shortly after returning from Vietnam, Sally married Don and they began work to have QS approved by the U.S. Food and Drug Administration. The FDA cancelled the Phase III trial for QS on the basis of an unscientific study that the FDA had designed, and

which (killed 1/3 of the rats within one month and which)* overdosed the rats with enough quinacrine to cause cancer (in 1/2 of the rats which survived the 1st month)*. Since then, they have been stalled despite numerous meetings with the FDA. *added by author

However, they do not intend to give up. Too many women in the world are seeking just such a method so they can easily stop having more children when their families are complete.

Sally stays involved with many other international family planning programs. For example, she has helped Molly Melching, the founder of Tostan, to succeed with her educational program in Senegal where villagers decided to abandon female genital cutting. The Tostan education program is spreading across Africa and now many more African villages are eliminating the practice. She has spirited wonderful books like *China 1908: Sidney D. Gamble & Brother Clarence Discover China* to be published.

Thank you Sally! You've been a source of strength and wisdom for so many decades for so many people and especially for me and my family.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 12 Joan Collins: Tribute by Hon. Nancy Pelosi of California in the House of Representatives

Shaker Heights, Ohio 1948 (Credit: ISAF)

15 July 1993

Ms. PELOSI. "Mr. Speaker, on July 1, the world lost an inspiring humanitarian, San Francisco resident Joan Freedheim Kraus Collins. My sympathy goes to her family and friends who will miss her deeply.

During her long association with both the Population Institute and Planned Parenthood, Mrs. Collins was a dedicated and tireless advocate of universal accessibility to modern, effective, and safe family planning. She travelled to many parts of the world to observe and evaluate efforts by developing countries to extend this basic human right to the poorest women in the world.

Joan Collins understood that when couples are unable to determine the number and spacing of their children, the results range from an exacerbation of poverty, misery and child and maternal morbidity and mortality to urban deterioration and environmental degradation.

She dedicated much of her time, her efforts, and her energy to doing whatever she could to avoid these unacceptable consequences.

Two blocks east of this U.S. Capitol building, the Joan F. Kraus Collins World Population Center, the headquarters of the Population Institute, stands as a most appropriate monument to her meaningful life

and distinguished career. Her deepest commitment was toward making a real difference in a world where complacency too often seems the norm. Mrs. Collins' obituary from the San Francisco Chronicle of July 2 follows:

Joan Freedheim Kraus Collins, a national leader in family planning, died yesterday of cancer at her home in North Beach. She was 64. Mrs. Collins, vice chairwoman and a longtime board member of the Population Institute, was honored by the organization three months ago when it named its new headquarters building in Washington, D.C., in her honor. Representative Nancy Pelosi, D-San Francisco, was among the public figures who paid tribute to her at that time. Mrs. Collins served Planned Parenthood for many years, first as president of the Marin chapter in the early 1960s, when the activities were expanded after the introduction of the birth control pill. She later became a member of Planned Parenthood's national board and executive committee. In 1990, she received the Marin Planned Parenthood's Margaret Sanger Award, named in honor of the pioneer birth-control advocate. More recently, Mrs. Collins was on the board of the International Services Assistance Fund, which produced the powerful prochoice film starring Sarah Weddington who as a 26-year-old attorney, appeared before the U.S. Supreme Court and

successfully argued Roe v. Wade. A native of Shaker Heights, Ohio, she attended Smith College and Case Western Reserve University, where she received a bachelor's degree.

The original version of "Whose Choice?" was aired on Turner Broadcasting System in prime time on September 21, 1992 just before the Clinton/Bush election that November. It was further shown on hundreds of community TV stations across the United States and had a real impact.

Don Jr. remembers, Joan as a loving stepmother who helped in so many ways through the years especially with my 3 kids. More evidence of Joan's matchmaking - flying home from her funeral, my assigned seat on Delta 824, San Francisco to Atlanta, June 6th, 1993 – was next to Terry Ellington, my future soul mate.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 13 Dr. Jaime Zipper Invents QS

Dr. Jaime Zipper (left) nominated Professor Emeritus of the University of Chile 2004 (Credit: ISAF)

16 March 2011

Dr. Valentín Trujillo Sibilla worked with Professor Dr. Jaime Zipper Abragan for decades and documented his wonderful life which was published in the Chilean Journal of Obstetrics and Gynecology On-line version ISSN 0717-7526 REV CHIL OBSTET GINECOL 2011; 76 (2): 61-63 and is reprinted below.

"Professor Dr. Jaime Zipper Abragan (Santiago, January 20, 1926 - Santiago, March 16, 2011), was son of Mr. Gustavo Zipper and Mrs. Juana Antonia Abragan, Jewish immigrants from Poland, who settled in Mulchén and then moved to Santiago.

He began his studies at the José Victorino Lastarria high school and at an early age his scientific spirit was manifested along with the unstoppable desire to know how things work. His sister Pearl remembers that one morning she did not find her new doll and went out looking for her desperately. Upon arriving at her mother's bedroom, she explained that her brother's scientific mind had been so impressed with the mechanism that made her talk and walk, that she tried by all means to locate this function, separating all its components. This story and many others, made their parents decide to finish their studies at the Barros Arana National Boarding School.

His first year of University was in the Faculty of Dentistry, where he met his wife, Mrs. Irma Latorre Vicentini. Then, he began his medical studies at the University of Chile, where he obtained the title of Surgeon in 1953. He had two children, Luisa (doctor-surgeon) and David (commercial engineer).

He was one of the leaders and pioneers in the worldwide development of contraception, creating in 1959 the first intrauterine device (IUD) made in Chile, the Zipper ring,

which consisted of a ring made by hand with fishing nylon, with which helped the most vulnerable population without access to effective contraception, especially in the maternity hospital Ramón Barros Luco, where he worked.

During the years 1961 and 1962 he completed a postgraduate degree in Reproductive Physiology at the Worcester Foundation for Experimental Biology, in the United States, directed by Professor Gregory Pincus, discoverer of the contraceptive pill. In 1963 he obtained the title of "Associate Professor of Physiology" in the Department of Physiology and Biophysics of the University of Chile. In the period 1967-1969 he served as Chief Physician of the Department of Human Reproduction of the World Health Organization, in Switzerland. In this position, he was able to assess in real magnitude the problem of maternal mortality, especially secondary to abortions due to unwanted pregnancies. Since 1967 he has been Associate Professor of Physiology in the Department of Physiology and Biophysics of the University of Chile and in 1971, he is appointed Professor of the same discipline.

Subsequently, and knowing the work of Grafenberg, who attributed the effectiveness of his ring with silver wire to this metal, he developed the concept of active IUDs with copper, discovering, after many animal tests, that the metal used by the German doctor was contaminated in 26% with

copper, this being the metal that really provided the contraceptive effect.

In 1970 he presented for the first time his device with copper in the Chilean Society of Obstetrics and Gynecology, receiving the support of the majority of his colleagues and the staunch criticism of a few, who did not perceive the future significance of this discovery. The same year he was honored in the United States by the American Fertility Society with the "The Samuel L. Siegler Lecture" award and is invited to exhibit on the control of human fertility through the use of endo-uterine metals, a subject that would be transcendent for World reproductive health.

Alongside his great scientific and intellectual capacity, Dr. Zipper possessed exceptional generosity, culture and sense of humor. In 1980, after being amazed at one of his classes, I had the honor of being accepted as his student assistant in the Department of Reproductive Physiology at the University of Chile. There I remember the visit of American doctors interested in their research. One of them asked him what his motivation was to develop the IUD with copper. Dr. Zipper, appealing to his sense of humor, replied, "I did it so that the Chilean copper mines had another item to export." Initially there was a silence from foreign colleagues to then laugh with us and then receive the formal response from Dr. Zipper.

IUDs with copper developed by Dr. Zipper continue to contribute significantly to the reduction of abortions and maternal mortality worldwide, with Chile being the first country to benefit from its work.

Parallel to the contribution made with copper IUDs, Dr. Zipper developed the method of non-surgical sterilization with quinacrine. This method, simple, outpatient and performed by transcervical route, was intended for women who had already completed the desired number of children. His motivation was the high mortality secondary to septic abortions in large multiparas. Its development required this brilliant mind, its great knowledge of the subject and the genius of associating different facts to invent something totally new. For this task he had the help of a whole team, among them Dr. Mario Medel, Dr. María Eugenia Bruzzone and the remembered Drs. René Guzmán-Serani, Alfredo Dabancens and Gianni Pinardi.

He obtained information from an ancient antimalarial (chinacrine), which was used in another use to treat pleural effusions of neoplastic origin. This drug fibrous both pleural leaves, controlling said pathology, so it inferred that it would have the same effect on the thin tubal epithelium. After much work in the laboratory, this hypothesis was proven true. The first non-surgical female sterilization method was born with successful results, which won the Grafenberg prize in Germany in 1983.

During 1998, Dr. Jack Lippes, inventor of the IUD that bears his name, became very interested in this method, and recalling the help that Dr. Zipper had given him, he decided to lead the studies in the United States. Dr. Lippes himself told us about the help he received from Dr. Zipper. The problem, apparently seemingly simple today, with its Lippes Loop IUD, had been how to control its location and easily remove it from the uterine cavity. It was Dr. Zipper, who advised him to tie 2 strands of nylon to his device. Made this modification, in 1962, Dr. Lippes presented his device at the First IUD World Conference, organized by the Population Council. From then on, the spiral of Lippes became the most prescribed IUD in the United States in the 1970s, replacing the Margulies device. The doctor, "His vital contribution to humanity will remain forever."

In 1999, he was awarded in the 10th at World Congress on Human Reproduction Brazil, for "his outstanding contribution in the field of human reproduction". In the same year, he was named Honorary Member of the National Health System of the Ministry of Health of Chile and in 2000 he was honored as one of the precursors of contraception in the world, by the Latin American Center for Health and Women (CELSAM) in Argentina. In 2003, he was honored at the XVII World Congress of Gynecology and Obstetrics (FIGO) held in Chile. The International Journal of Gynecology & Obstetrics dedicated a complete supplement to the topic "Quinacrine sterilization: reports

on 40,252 cases". In 2004 he received recognition from the Ministry of Health for "his tireless search and contribution in birth control" and the same year he was nominated Professor Emeritus of the University of Chile.

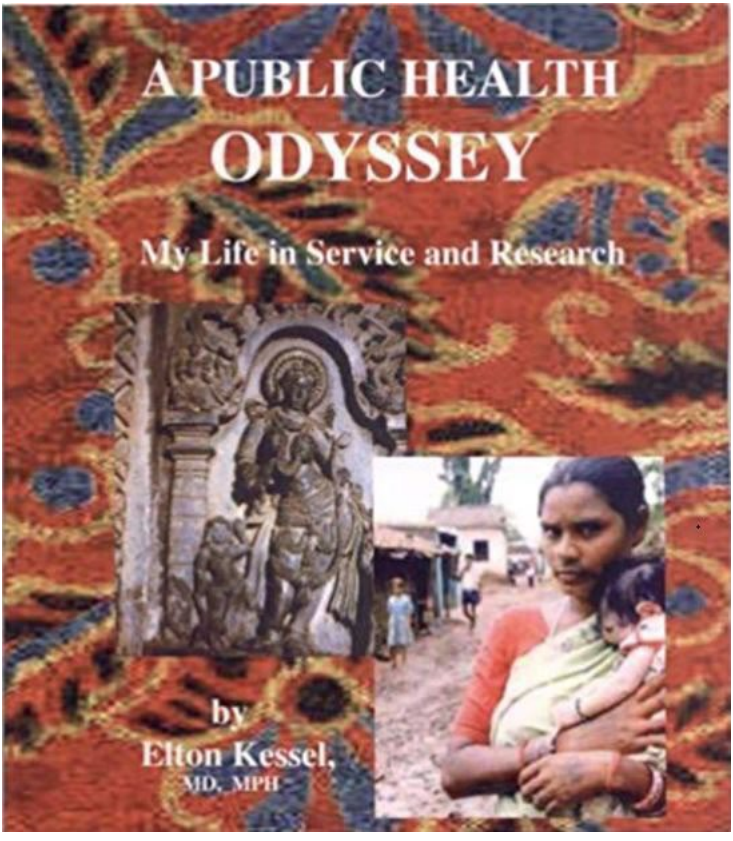
As Dr. Ramiro Molina described it very well in one of the many tributes he received: "Dr. Zipper was an innovator, a teacher and a teacher." He was an example of how to carry out quality scientific research with real weight in the medical community. He was also a deeply ethical professional, who put science at the service of man, and who had to bear the social costs of when people devote themselves to life issues. Nobel Prize recipient, as Dr. Pablo Lavín and many other colleagues publicly commented, after studying his scientific contributions.

I will greatly miss our conversations, their advice, their wisdom, their calls early in the morning telling me that I had read an article and had a hypothesis that we should corroborate when designing a scientific experiment. I will miss his talks about holograms or his special perception of the world, in which this would be a single great living being where everything we do influences others. His life, teachings and contributions will remain forever in our minds and in the place of excellence in the history of medicine.

Master of knowledge, master of life. Infinite thanks for allowing us to accompany him and be his disciples."

Here's to all the women in our lives! Thank you for your love. May we all work 42B= today in all of society.

Chapter 14 Dr. Kessel's Public Health Odyssey Spirited QS



Front cover of Dr. Kessel's book published 2007 (Credit: Daughter Louise Kessel)

30 April 2021

QS would not exist without the efforts of Dr. Elton Kessel who dedicated his life to helping women. This chapter is excerpted from A PUBLIC HEALTH ODYSSEY: My Life in Service and Research, a book published in 2007 by Elton Kessel, M.D., M.P.H., 1st first non-family President of Pathfinder and cofounder of International Fertility Research Programme IFRP, Family Health International (FHI) which became FHI360, and cofounder of IPAS. This is reprinted with permission.

CHAPTER NINE: THE INTERNATIONAL FEDERATION FOR FAMILY HEALTH (IFFH)

As national fertility research programs developed, two concerns led to the organization of IFFH. One was the need to diversify funding, which then was almost solely from USAID. As this agency is part of the State Department, and money awarded by Congress, with key senior conservative congressmen opposed to all artificial contraception, every election meant the threat of closing the Office of Population and the destruction of IFRP. It was for this reason that IFRP eventually changed its name to Family Health International (FHI) after the Nixon election in 1982.

In 1976 at a major regional scientific meeting in Bangkok the IFFH was formed, with Professor Hubert de Watteville chairing the Organizing Committee. The IFFH Secretariat would initially be in my office at IFRP but was later moved

to Bandung with Professor Sulaiman as Executive Secretary. The office was funded through a subcontract of IFRP and functioned in that way until it was returned to my office as an NGO established in North Carolina in 1977. IFFH easily obtained 503(c) nonprofit status with an Executive Committee made up primarily of leading developing country medical investigators.

IFFH was off to a good start when it received a grant from the United Nations Population Fund (UNFPA) to initiate Maternity Care Monitoring (MCM) in several developing countries. We set up a project office for this grant in Hyderabad, India, directed by Dr. Saroj Pachauri. Excellent plans were made to spread MCM, but the UNFPA required that support of the country projects come out of overall UNFPA funding and not be considered as additional moneys from their international or regional resources. All countries refused to do so. From my perspective, country funds were used primarily to supplement government support in their family planning programs. New UNFPA awards mainly covered salaries of present and recently retired government personnel. Some UNFPA funding for parts of projects were left unspent.

IFRP was welcomed into IFFH as an Associate Member. To my mind, they were complementary institutions, but IFRP

leadership including its Board Chairperson found them potentially competitive, ending that relationship.

It is well known that there is no shortage of health practitioners in almost every village in India. These indigenous technicians are the family physicians of the rural poor. Unfortunately, they are not well trained, but gain clinical skills through practice. The idea of preparing them to treat and prevent common illness in rural villages stems from my Sevagram experience.

An opportunity to experiment with this occurred by accident through my contact with Dr. Biral Mullick of Howrah, West Bengal, India. He was one of Dr. Clarence Gamble's data contributors, and I contacted him in order to explore his interest in an oral contraceptive (OC) delivery program through trained depot holders. He did this exceedingly well. Incidentally, during the program, he conducted a trial comparing acceptance of OCs distributed by homeopathic physicians in western packaging versus the small vials in which their medicines were usually distributed. No difference in acceptance was observed, and these practitioners asked to be included in the OC program, which markedly increased dispensing of the drug.

The implications for public health services were evident. The depot holders who dispensed the OCs were recruited and trained in an extraordinarily short period of time,

using Community Party of India (Marxist) cadres, who control political power in West Bengal. For the program to become financially self-sufficient, depot holders were obliged to share the income from small charges for OCs with the sponsoring organization, The Humanity Association, an NGO founded in 1924 by Dr. Mullick's father, Ajit Kumar Mullick. Initially, working in disaster relief, it had the blessing of Mahatma Gandhi, who had visited its headquarters in Howrah.

The Marxist cadre advised the depot holders to refuse to share their income, their rationale being that foreign support alone of the program would sustain the effort. But such funding was not available, and the program failed. Some 10 percent of the depot holders agreed to participate under the new rules. Unfortunately, West Bengal suffered a major flood just at this time, contributing to the program's collapse, as supplies of OCs at many depots were destroyed.

This distribution scheme had been part of the Indian government's pilot OC program, and from official statistical reports we learned that at the apex of the Humanity Association OC project, it distributed 50 percent of all OCs used in the state of West Bengal.

Another public health lesson was also learned. The original provision of OCs was made by Family Planning International Assistance from the USAID stock in a large

shipment of about 100,000 cycles. This supply ran out during the Bangladesh war with Pakistan, when relations between India and the United States were strained. India would not agree to a USAID-funded supply of OCs, claiming they themselves could provide for Humanity Association needs. However, this promise was not fulfilled, and about 2,000 women suddenly lost their source of low-cost OCs. Dr. Mullick undertook an evaluation of this development with guidance from Dr. I-Cheng Chi of IFRP. As I recall, Dr. Chi gave his advice from Dacca, Bangladesh, since we could not obtain Indian approval for his travel to Calcutta. This may be related to his being Chinese. The report was published (Mullick, Chi, Pachauri, Kessel 1976). Some women purchased OCs on the market, mostly smuggled from Bangladesh, but many became pregnant.

QUINACRINE STERILIZATION

IFRP first learned of quinacrine sterilization (QS) when Dr. Alfredo Goldsmith, our Latin America project monitor, met with Dr. Jaime Zipper on a trip to Santiago, Chile. He brought back news of this new procedure, which at the time involved instilling a slurry of quinacrine in water or xylocaine by syringe into the uterine cavity. Dr. Zipper had evidence from rat studies that such a slurry would cause an inflammation and scar that would occlude the

fallopian tube. We had no efficacy data at the time, only a verbal claim that the procedure was well tolerated.

I decided to support Dr. Zipper's work, although I doubted that the method would be effective, but on the other hand if it were, it would be the most significant development in contraceptive research.

We were interested in increasing contraceptive prevalence to slow the rapid population growth which contributed so heavily to morbidity and mortality in poor developing countries. Sociologists had warned against trying to convince couples about a particular contraceptive method, because of their preconceived ideas. The proper approach was to satisfy an unmet demand. It was logical to assume that a large unmet need for sterilization existed because of problems associated with surgical sterilization, including the skills for safe performance, its cost, and the fear of surgery.

IFRP encouraged Zipper by offering technical assistance in follow-up of cases while the actual trial remained his responsibility. With this support, a quinacrine slurry trial (one dose of 1500 milligrams) was completed and reported (Zipper, J. et al 1976). The early development has been summarized (Zipper - Kessel presentation 2003). A trial of this method was approved by the IFRP Institutional Review Board, but never conducted after a death was reported in Bangladesh. The patient was an uncontrolled

epileptic. Zipper assumed that the death was due to rapid absorption of the slurry. This was also suspected because of the known 2 percent complication of cortical excitation with the method. To avoid this rapid absorption, Zipper worked with Robert Wheeler, an IFRP engineer, to develop a (36 milligram) pellet (252 milligrams per dose) which would dissolve without pressure from a syringe. A first trial of introduction of the pellet using a Copper T insertion straw showed a 3 percent pregnancy failure rate and disappearance of the cortical excitation complication (Zipper 1980).

At a meeting with Zipper in Chapel Hill, North Carolina, we discussed the desirability of testing this quinacrine pellet method in a rural area of a developing country where the need for sterilization was greatest. I approached Dr. Biral Mullick, who had extensive contacts with indigenous practitioners in West Bengal, India. He agreed to sponsor this research, and in my capacity as Secretary General of IFFH I made quinacrine pellets available to him. He trained about 100 indigenous practitioners in the method. Some reports of this experience have recently been published (Pal 2003; Roy 2003).

A second project for a clinical trial of QS in Bandung, Indonesia and in Kuala Lumpur, Malaysia, was sponsored by the Government of Canada and successfully completed and reported (Arshat 1987; Agoestina 1992). The Malaysia

trial was smaller than planned, and we had reports that a nurse there told volunteers that the method had ill effects.

To expand QS experience required sufficient quinacrine pellets. A first supply was obtained by adding to the order of pellets in the Canadian supported trial by a donation from the Japanese affiliate of IAMANEH (the International Association for Maternal and Neonatal Health), a Geneva-based NGO which had been founded by Prof. Hubert de Watteville. In my capacity as Interim Director of IAMANEH after de Watteville's death, I communicated with the Japanese affiliate, sending Roger Bernard to Tokyo to make a personal appeal, which was successful. Many studies were initiated with the initial quinacrine pellet supply, including government trials in India and Indonesia.

The Indonesian trial directed by Dr. Tina Agoestina was successfully completed as a randomized trial comparing single and double insertions in six academic centers and reported (Agoestina et al 2003). The Indian trial was not successful — they used evidence of tubal occlusion by hysterosalpingogram (HSG) as endpoint, but failed to follow my advice to limit HSG pressure to below 100 mm Hg. Only six cases were done; HSG apparently opened tubes, which was reported as failure of the method in three of the six cases, and the study was terminated.

In my discussions of QS over many years with Dr. Badri Saxena of the Indian Council of Medical Research (ICMR), he was consistently opposed to a trial of the method, which however was finally ordered by the Director General of the ICMR. It was well known through these years that the WHO was opposed to trials of QS on the grounds that their Toxicology Panel felt additional toxicology studies were needed. It should be noted that on the day of Dr. Saxena's retirement he was hired as a consultant by WHO.

IFFH made supplies and technical assistance available for a large field trial in Vietnam after Dr. Do Trong Hieu was given materials for a pilot study at a WHO meeting in New Delhi. He became convinced of the safety and efficacy of QS, and as Director of Family Planning and MCH of the Ministry of Health of Vietnam, he proposed a large field trial of the method, which was approved by the Ministry. I made several consultant visits to Hanoi to guide the effort. IAMANEH also contributed pellets on the recommendation of Professor Otto Kässer, a leading Swiss gynecologist.

Dr. Hieu had originally described an insertion technique that deposited all pellets at the fundus. As demand for QS was very high, the trial was rapidly expanded and certain practitioners probably used a Copper T insertion technique resulting in a midline column of pellets, some extending far from the fundus.

A report (Hieu et al 1993) on over 31,000 cases in Lancet showed variation in efficacy among providers, but it was not possible to document their insertion techniques. A letter from WHO stating they would be surprised if quinacrine were not carcinogenic brought matters to a halt. An identical letter, signed by Dr. Giuseppe Benagiano, Director of the WHO Human Reproductive Research Program (WHO/HRP) (his father was dentist to Pope Paul VI), was sent to the Family Planning Coordination Board of Indonesia (BKKBN), but was rejected by the BKKBN Ethics Committee on the basis of known extensive human experience with QS. A phase III field trial was planned in Indonesia but not implemented, although it is currently under consideration.

On October 23, 2004, WHO confirmed to BKKBN their continued opposition to any clinical use of QS. IFFH supported clinical trials with supplies and technical assistance in two Chinese Provincial Family Planning Research Centers. The one in Jiangsu (Nanjing), China, received a letter from WHO advising discontinuation, making it difficult to complete the trial. The other center, in Guizhou Province, conducted 300 cases under the direction of Dr. W. Lu and with IFFH funding through the State Family Planning Commission of China (SFPC). A detailed analysis of data with a comparison group of 300 women accepting surgical sterilization was carried out and reported (Lu et al 2003). But before these favorable results

were known, officials of the SFPC at a meeting in Washington, DC requested support for a large field trial of QS. IFFH paid for translations of key articles for Committee review to approve the trial. Because of the large number of cases, sanction was needed from the Department of Public Health. The Center for Research on Population and Security (CRPS) completed an elaborate form for their review and approval.

There was a sudden change in attitude for the field trial with expressed doubts about QS safety. A review committee was formed to make a recommendation, organized by Dr. Her. In her presentation to the review committee, she claimed it was illegal to use quinacrine in China — a somewhat disingenuous statement, as although the drug was not on any approved list, it was nevertheless widely used as an anti-malarial. Printed information on QS was not distributed before the meeting. Following her recommendation, the committee voted to abort the planned field trial. It should be noted that some members of the review committee, including Dr. Her, are consultants with WHO, which provides their main income.

Consultant fees for trials conducted in China are similar to those paid in industrialized countries. The trials are well conducted, as follow-up is easy — China knows where everyone lives. We received indirect word from one member of the review committee that she did not dare vote

in favor of the QS trial for fear of losing her WHO consultancy.

I criticized the decision of the review committee and requested an opportunity to address them. The SFPC agreed, but when I arrived a group was hastily put together to hear my critique, and only one person in that group was a member of the review committee. No questions were asked after my presentation. Most of the audience consisted of clerical people brought in to fill the room.

On another trip to China, I was given an opportunity on June 12, 2001, to meet with Mrs. Hao Limma, Deputy Director General, SFPC, Department of International Cooperation, and other members of the SFPC. I explained at that time the conflict of interest in having WHO consultants make recommendations on a QS trial. I also demonstrated that switching to QS from surgical sterilization would save the Government more financially than all foreign support to the SFPC, assuming patient compensation for QS would be twice that of an IUD insertion, as two insertions are required. This was to no avail. Technical people at the SFPC who are WHO consultants are able to block needed policy decisions of the SFPC.

In 1978 I gave a lecture for the OHSU OB/GYN Department on quinacrine sterilization which attracted the attention of

Dr. Amy Thurmond, a radiologist in that Department. She did a rabbit study of the method (Ross et al 1994) and applied to the National Institutes of Health (NIH) for a phase I trial of QS, but it was not accepted. She later attempted and was able to open the tubes of two QS patients in Calcutta. However, neither patient became pregnant. Dr. Thurmond has had excellent success in opening corneal blockage by intratubal catheterization. The attempt in Calcutta was published (Thurmond et al 1995).

Unlike Odysseus, on my journey I have been privileged to meet and work with a number of remarkable women. Some of these physicians have already been mentioned. Among others are: Altaf Bashir of Pakistan; Pouru Bhiwandiwala of India; Cláudia Ferreira of Brazil; Rohinee Merchant of India; Khairia Omran of Egypt; Ashi Sarin of India; and Sheitaneh Soroodi-Moghaddam of Iran.

WHO MEETING

I had a long dialogue with the World Health Organization (WHO) concerning their reluctance to consider a clinical trial of quinacrine sterilization. At my request and with a recommendation by Dr. Ralph Henderson, Assistant Director General of WHO, a meeting was set for May 8, 1997, to discuss a "way forward." We met at a Human Reproduction Programme office at WHO. Dr. Giuseppe Benagiano, Director of the Special Programme on

Research, Development and Research Training in Human Reproduction and three of his senior staff were present: Drs. Paul van Look, Frank Webb and Patrick Rowe.

Dr. Benagiano explained their requirement for approval of their Toxicology Panel before they could consent to any clinical trial. I summarized our discussions in a letter dated 9 May 1997 to Dr. Benagiano and he agreed with my summary in a letter to me dated 20 May 2007. Dr. Webb observed that he did not think sterilization was a proper family planning method. When no one objected to that statement, I reminded them that, at that very moment, a committee in another room of WHO was finalizing guidelines for female sterilization as a family planning method.

What is reprehensible about this situation is that the four top personnel of WHO/HRP are Caucasian men from European countries and at least three of the four are Roman Catholic. They made decisions on reproductive health involving women of color in developing countries who are primarily non-Christian. No Director General of WHO has attempted to correct this situation. It appears that the Vatican controls the votes of a group of Catholic countries whose approval any Director General needs for adoption of policies by the General Assembly of WHO.

The author notes: In 2009, WHO Department of Health and Reproductive Research including Human

Reproductive Planning issued their interim statement: The safety of quinacrine when used as a method of non-surgical sterilization in women which could not conclude that QS causes cancer, but WHO recommended that, "Until the totality of safety, effectiveness and epidemiological data has been reviewed, quinacrine should not be used for non-surgical sterilization of women in either clinical or research settings."

INDIAN RURAL MEDICAL ASSOCIATION (IRMA)

It was while visiting the Humanity Association OC pilot distribution centers in Urban, Rural and Slum areas as reported in Studies in Family Planning (Majamdar et al 1972) that I noted the need to train rural practitioners in treatment and prevention of common illness, which Dr. Mullick developed with the Indian Rural Medical Association. It was found that these practitioners are willing to pay tuition for the instruction. No doubt important motivating factors are the certificate they receive at the end of the course and being able to pass an examination, which they feel give them some protection from authorities.

The courses are mainly in two parts: Community Medical Services (CMS) covers anatomy, body functions, sanitation, vaccines and environmental health. This course lasts one year with weekly meetings on Sundays. The second course, Essential Drugs (SD), follows a WHO

manual entitled Essential Drugs for Primary Health Care, including treatments using 112 allopathic drugs (WHO 2000). WHO recommends these be available in every village. This course lasts six months with weekly meetings each Sunday. IRMA charges a registration fee and an examination fee. All tuitions go to an Organizer who advertises the course and arranges a meeting place, usually in a school building that is vacant on Sundays. Large classes are encouraged so that the Organizer can make a living through this activity. But the examination is thorough, and only about 70 percent of trainees pass it to obtain the certificate issued by IRMA with a 3-year expiration date, when a refresher course is needed to extend the certificate. The training has spread to over 100 training centers with 5,000 trainees at one time.

Contacts with the Indian homeopaths led to the idea of training them in allopathic (western) medicine. Initial instruction involved IUD insertion, MR and QS. Only about 100 completed the training for QS. A busy MR clinic in Howrah was the venue for practical clinical training. Also, some homeopaths brought in patients to the Humanity Association Family Planning Clinic in Calcutta, where Dr. Mullick would supervise their training on their own patients.

These 100 MR trainees purchased quinacrine pellets from the Humanity Association Clinic in Calcutta. They were

required to show a QS Register detailing previous cases before being issued additional supplies. Quinacrine pellets were donated by IFFH, generally hand carried from Geneva to Calcutta. The QS procedures became popular in this community where patients paid for the procedure. Early on, the Humanity Association and later the IRMA conducted QS as research under definite protocols. Some of these were reported in the October 2003 issue of the International Journal of Gynecology and Obstetrics (Pal 2003; Roy 2003).

Originally, the forms were kept in a file cabinet filed by center number, but when controversy developed regarding QS, the reports were deposited in a cardboard box where they were destroyed by a paper eating insect. Few investigators kept copies of their experience. Once IRMA had become convinced of the safety and effectiveness of QS, its members were encouraged to include QS in their services. Approximately 30,000 QS cases were performed by these practitioners in their private practices without a reported death or complication requiring hospitalization. Several of the research trials have been reported, perhaps the most important documenting improved efficacy of the Hieu insertion technique (Bairagi et al 1995).

Despite the favorable results of clinical trials showing safety superior to that of surgical sterilization and efficacy

similar to surgical sterilization (Kessel, Zipper, Mumford 1985), the method remained controversial, primarily due to the insistence of WHO/HRP that further toxicology studies be carried out before any clinical experience is to be initiated. Publication by Dr. Hieu of the Vietnamese field trial in Lancet (Hieu et al 1993) increased concern, as this trial was terminated by a letter from WHO/HRP claiming they would be surprised if quinacrine did not turn out to be carcinogenic. The political significance of this has been described by Hieu (2003 presentation), and the financial and health implications by Sarin (2003 presentation) and Agoestina (2003 presentation).

DR. JACK LIPPES QS TRIAL

Early in 1998 I requested what is known as a Pre-IND meeting with the FDA in anticipation of an application for a clinical trial of QS. A date was set for May 8th. Dr. Jack Lippes and Steve Mumford accompanied me to their office. Besides the customary FDA scientists, officers from their Compliance Division were present, unusual for a Pre-IND meeting.

The FDA informed us that an approved IND application is needed for any trial in this country and that a 2-year carcinogenicity test might be demanded before this could occur. There were several other requirements, such as details on the level of impurities in the quinacrine pellets, degradation and stability, good manufacturing practices

(GMP), and measures of shelf-life of the administered drug.

Shortly after the meeting, Dr. Susan Allen was assigned to review the safety and efficacy of QS. A copy of her report appeared on the FDA website. Mumford carefully reviewed it and found several errors. If this paper were to represent FDA policy, it is unlikely that they would approve a Phase III trial.

We learned from an anonymous source that the FDA planned to seize our supply of pellets, and they were therefore removed from the United States. Mumford and I also received a Warning Letter from the FDA Compliance Division stating that all supplies of quinacrine pellets should be destroyed.

The FDA shared the Warning Letter with the Columbia Broadcasting System (CBS), which was preparing a report on QS for its program 60 Minutes. However, CBS produced the program without mention of the letter.

The FDA had also sent a copy of the Warning Letter to Alix Freedman of The Wall Street Journal. This led to (after) a front page "yellow journalism" article in the Journal in June 1998 describing her travels to Bangladesh and Vietnam. Mumford and I had traveled with Freedman on some of her visits to those countries, were therefore distressed to learn how much misinformation the article

contained, including implications of interviewing people Freidman actually never met. The article was widely distributed internationally and influenced policymakers in several countries.

With this negative publicity for QS, we were advised to meet with the Office of the Ombudsman of the FDA, and Mumford communicated with Amanda Norton there on December 9, 1998. Dr. Lippes, Mumford and I later met with her to evaluate the FDA paper prepared by Susan Allen. Ms. Norton admitted that some of Allen's statements could not be supported and agreed to call this to the attention of the FDA Commissioner, Dr. Jane Henney. Ms. Norton later advised us that the Commissioner recommended that we submit an IND application and that only she, the Commissioner, would be permitted to reject it.

With this assurance, we submitted an IND application with Dr. Jack Lippes as principal investigator in a trial of 10 cases. It was approved by the FDA and completed and reported (Lippes 2003).

IFFH is cooperating with the International Services Assistance Fund (ISAF) to complete the FDA application for a phase III QS trial. Once approved, this IFFH priority will be completed.

The negative impact of population growth on socioeconomic development has been described by scientists and a committee of the parliament of the United Kingdom. (Ottaway 2007). But focusing on QS alone reflects the importance of this method in terms of morbidity, mortality and health services expenses. There are obvious cost savings for QS compared to tubal ligation (TL). Estimates for TL in developing countries range from $40 to $100 per case. This is due to the need for a surgical team, an operating theater, hospitalization of the patient, and complications of the procedure. For a country like India with 40 million TLs per year, this is an important part of health expenditures, without even considering the case of treatment of TL poor sequelae. No one denies that morbidity is lower for QS compared to TL. After all, QS requires only a technician in an outpatient setting, with the patient able to resume her activities at once. Sterilization is the most prevalent contraceptive method today, and access to QS would increase contraceptive prevalence and lower the incidence of unwanted pregnancies, including those leading to abortion. The greatest savings in mortality and finances of wider use of QS is in the estimated reduction in abortions.

The objections to QS in terms of potential coercion and lack of full knowledge that it is in an early stage of development – pale in comparison to its advantages.

MY SPARATION FROM IFRP/FHI

I was asked to resign from FHI in 1982. I will first describe the general setting for this action, then the complex events leading up to it.

I attempted to mask USAID support to IFRP while being grateful for it. Such funding tended to diminish the concept of independence of a nongovernmental organization (NGO), and in some cases hiding this funding helped to prevent exposure of USAID to controversial issues. I enjoyed the full confidence of the USAID director, Dr. Reimert Ravenholt, but others — including our program monitors, Dr. Joseph Speidel and Dr. James Shelton — examined my every action suspiciously. I needed their written approval for each expenditure. At times I did not give them information requested when I thought they should obtain it from Dr. Ravenholt, who was always fully informed. So my relationship with the monitors was somewhat strained.

Then Peter Donaldson joined the staff. Jesuit-trained at Fordham University, he carefully planned a coup to get rid of me; the monitors accepted the scheme. Engineering this action was Donaldson's primary activity at IFRP. Although we had many data sets in need of analysis, he did not produce a single scientific paper based on IFRP data during his eight-year tenure.

Collection of data critical of Kessel as Executive Director of IFRP occurred in several ways. Against my wishes, a senior researcher, Judith Fortney, carried on a dialogue with Dr. Speidel, in which she described a number of staff persons as "deadwood". Her targets were staff who were weak in data analysis but who had other useful skills, such as expertise in the culture of specific countries in which we worked. I had presented the arguments for keeping one of these people, and Speidel decided to keep him.

In an attempt to democratize staff relations, I asked Dr. Charles Ausherman (who had been appointed Deputy Director to assist me) to form a Staff Advisory Committee which could meet to address staff complaints. Board members were permitted to attend such meetings, where some overworked staff complained of their work loads, although they were loyal to the organization. At this time, in the late 1970's, the position of Dr. Ravenholt at USAID was weakening, as political influence increased to remove him as Director of the Office of Population. Later, he described the influence of the Vatican and the Roman Catholic bishops in this process (Ravenholt 1991).

USAID conducted a review of IFRP in preparation for a contract renewal. Chairing this review committee was Dr. Elizabeth Connell, a person qualified to replace me and who was also recently unemployed. The review was very critical of my proposal to take over the Population Library

of the Carolina Population Center (CPC) of the University of North Carolina (UNC). My objective was to save this valuable resource, which was scheduled to close due to lack of funding. This was seen by the review committee as overly ambitious and not focused on research, and denied for this reason.

Another major objection was our conducting "programmatic" studies, which monitored service programs of contraception delivery. I had demonstrated to Dr. Ravenholt that as a cost of recruitment to these studies, payment based on receipt of data forms was lower than the recruitment of contraceptors by the International Project of the Association of Voluntary Sterilization (IPAVS), another major USAID funded program. The review committee felt this was not valuable research, and recommended the deletion of programmatic studies. The staff was in favor of this, as they wanted to be senior authors of published studies, but this was not permitted for research involving a single center. The volume of forms was very large and a chore to process, although we had worked out a system to automatically clean data by eliminating questionable data entries. The loss of these data in the process was of little importance in such large data sets. It should be mentioned that some of the most significant publications of IFRP were based on programmatic study data, including all by our qualified epidemiologist, Dr. I-Cheng Chi.

The review committee felt that more sophisticated data analysis was needed, whereas I and others thought that what the statistics needed to demonstrate was fairly simple — whether the failures of a contraceptive method were too high, or acceptable. Nevertheless an additional statistician was added to the contract, as recommended. And now again, as was usual, USAID complained that the requested budget for the new contract was too high. This fitted into Peter Donaldson's plan for a massive reorganization and my removal as Executive Director.

At about this time a name change from International Fertility Research Program (IFRP) to Family Health International (FHI) had been implemented when, with the ushering in of a conservative Republican administration, it was feared that the Population Office of USAID might finally be eliminated. A shift of name and focus would ensure that in that case, funding could continue by applying to the USAID Office of Health.

One final financial crisis was fabricated to precipitate the reorganization. At the recommendation of our computer staff, we had purchased a Burroughs computer. Before signing the contract, I had asked Harvey Lucas, our administrator, if he had an agreement with the USAID Contract Officer to cover all costs of service of the computer, including the payments. He said that he did, but unfortunately, I did not ask to review such an agreement

in writing. I was told later that the agreement was verbal, and the Contract Officer denied the existence of any such agreement. The only other way to pay for the computer was through depreciation expenses. We calculated these on a five-year depreciation schedule, which was customary for a computer, and adequate to cover the payments. At this point however a USAID audit occurred, deciding on an eight-year depreciation schedule, which was inadequate to cover the payments. We were headed for bankruptcy if a revised contract with Burroughs could not be worked out. Gaines Turner, our senior administrator, initiated these negotiations, and conducted them in a way that irritated the Burroughs people. In a memo dated March 13, 1978, Chris Whitner of our computer staff states: "I assume he (Turner) proposed an invalid method to Burroughs intentionally."

It should be noted that Turner was the person who had implemented my separation from executive authority at the Pathfinder Fund. However it had been my view that he had engineered a delicate but necessary situation, and it was I who later chose him to join IFRP in North Carolina. He was of course aware of plans to replace me as Executive Director of IFRP. I later learned in a statement by Dr. Ravenholt in the presence of Dr. Speidel that Turner had proposed himself as my replacement.

These were the internal politics of the coup that resulted in the staff reduction of 30 persons on March 14, 1978. All staff with close personal ties to me were included. No doubt it was the intention of the reorganizers to get rid of me altogether, but as Chairman of the Board, I drafted the reorganization showing a new Executive Director, but maintaining my position as President. Sharon Camp, Chairperson of the Board, suggested that I could be retained for one year at 50 percent salary level, and I accepted. The Board asked me to continue negotiations with Burroughs, and within a week of the reorganization Burroughs agreed to my renewed payment schedule consistent with our proposed depreciation costs. I was also asked to remain on the Board as I had excellent relationships with many key researchers in developing countries, but I resigned later when it became clear that the new Executive Director Malcolm Potts and Sharon Camp felt that IFFH was a competitor to FHI.

It is not possible to prove the rationale for my removal as Executive Director of FHI. But a clue can be discerned in the role of the Vatican and the Roman Catholic Church in the removal of Dr. Rei Ravenholt as Director of the Office of Population of USAID. First, it should be noted that Randy Engil, national director of the U.S. Coalition for Life, presented to President Reagan a list of USAID -supported persons who should be removed, and my name was on that list, as well as Ravenholt's. Second, was the recruitment of

the overly qualified Jack Ganley in 1980 as a senior FHI administrator; he had held senior political appointments in previous Republican administrations. He immediately became a close personal friend of Peter Donaldson; they both were Roman Catholic. They collaborated to implement a new direction for FHI, away from family planning toward family health.

Did Church influence play a role in the FHI coup? Will we ever know? In any case, it was the saddest episode in my life.

THE DALKON SHIELD CONTROVERSY

I was now unemployed, although my office expenses were reimbursed by the International Association for Maternal and Neonatal Health (IAMANEH). This Geneva-based NGO had been founded by Professor Hubert de Watteville, who also established FIGO, the International Federation of Gynecologists and Obstetricians. He was a member of the Board of IFRP and appointed me as his Deputy. Upon his death I had become their interim Secretary General. This was at the time of widespread publicity regarding dangers of the Dalkon Shield intrauterine device (IUD) as a risk for pelvic inflammatory disease (PID). Over a long period I had had an interest in IUD clinical trials and had noted no increased risk of PID for IUDs, including the Dalkon Shield.

Essentially, all of the Dalkon Shield evidence of increased risk was from case-control studies. I began to thoroughly investigate a possible bias in this research and described the detected bias in a report in Fertility and Sterility (Kessel 1985). These case control studies were conducted by major medical institutions that were referral centers for a network of surrounding clinicians. Because of the publicity and litigation regarding Dalkon Shield use, clinicians preferred to send such cases to referral centers if symptoms of possible PID were present. This caused an increased prevalence among these Dalkon Shield users, resulting in bias of their studies. As a result of this publication, I was recognized knowledgeable in IUD research and was hired by lawyers as an expert witness in litigation, including the Robbins company bankruptcy trial.

Besides the income earned from this, the greatest benefit was the interest and cooperation I received from another unemployed colleague, Dr. Stephen Mumford.

DR. STEPHEN MUMFORD

I had hired Stephen Mumford in 1977. He had earned a Doctor of Public Health from Houston, Texas with a special interest in vasectomy decision-making (Mumford 1977). At IFRP, he spent his time mainly on analyses of clinical data sets, resulting in publications in peer review journals, actually more often than any other researcher at IFRP.

Despite this excellent record, he was fired in 1983, after publishing a paper on abortion. USAID was very sensitive to any publications that defended "choice." Their principle funders came from Congress where influential Catholic congressmen like Henry Hyde of Illinois were opposed to all artificial methods of contraception, sterilization, and abortion.

We learned that the then director of IFRP, Dr. Malcolm Potts, was called into USAID's Washington office, where he met with a senior official who had a copy of Mumford's article on his desk. Dr. Potts was informed that Mumford was to be fired or IFRP would lose its USAID contract. Dr. Potts did the needful to preserve the organization. Because Mumford was in the process of completing analyses of three data sets at the time, Dr. Potts permitted him to remain to complete this work as a volunteer with computer support provided by IFRP. The results of these analyses appeared in three reports in peer review journals.

My association with Stephen Mumford led to a fruitful collaboration in other research areas which continue to this day. He is the author of a significant book on U.S. Population policy (Mumford 1994).

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 15 Inventor and Entrepreneur - Dr. Lippes got his IUD to the World and he also Championed QS

Dr. Jack Lippes (center) receiving the European Society of Contraception and Reproductive Health's Medal at the Hague, Netherlands July 24, 2007 (Credit: ISAF)

24 July 2007

Dr. Jack Lippes was the first American to receive the European Society of Contraception and Reproductive Health's annual medal, awarded to him in a ceremony at the Hague, Netherlands.

Dr. Jack Lippes was the Chief Investigator for the FDA Phase I and Phase III clinical trials of non-surgical permanent contraception for women (QS). He has been a steadfast advocate for women's reproductive rights for more than 50 years. At 38 years old, Dr. Jack Lippes, invented and got his Loop intrauterine device (IUD) to the world through Ortho Pharmaceuticals and the Population Council. He flew around the world training doctors and nurses and ultimately tens of millions of Loops were used making it a resounding success for women. Now at 98 he wants to Bring Back the Loop.

Jack once told me that he was at work in his Planned Parenthood Buffalo, NY office one day, when a stranger walked in and said, "Would a blank check help?" It was Dr. Clarence J. Gamble who helped Jack pay for the plastic injection molding tooling to produce the three parts involved in his IUD. A few days later, Jack attended a speech that Dr. Gamble and his nurse were giving at the YWCA, when the nurse said, "you should call your IUD the Lippes Loop."

Frank W. Notestein, Foreign Affairs, Vol. 46, No. 1 (Oct. 1967), pg. 175 - The Population Crisis: Reason for Hope

"It has been only in the last two or three years that the programs have had much substance. Now they are getting under way, and by the end of this year India will apparently

have inserted more than two million I.U.D.s and Pakistan nearly one million. . .

The Population Council alone has filled requests for some 2.6 million Lippes loops from the governments or medical institutions of 39 developing countries, and has helped governments in South Korea, Taiwan, Hong Kong, India, Pakistan, Egypt and Turkey to establish local manufacturing."

23 July 1965 - India: The Loop Way, Time Magazine

"The grey-haired spinster waved a delicate, S-shaped twist of plastic at her audience of newsmen in New Delhi last week and announced triumphantly: "It's foolproof." What Dr. Sushila Nayar, India's Health Minister, held aloft was a contraceptive device. She was opening Family Planning Week, the start of a new government campaign against the nation's severest problem: overpopulation.

The problem is everywhere to behold—in fly-filled villages, along dusty bullock paths, in the dismal density of city tenements—millions of people trapped in desperate squalor. In the hope of ending all this, India has struggled ineffectually for years to promote family planning. The rhythm method proved too complicated for a 75% illiterate population. To help women keep track of the days of the month, the government devised a handy string of beads (green for safe days, black for unsafe). Children upset the

arithmetic by toying with the beads. Some women mistook the strings for a charm against conception; others shunned them because they resembled the necklaces Hindus hang around the necks of cows as decoration. Other methods—even the pill—proved too costly or required too much medical supervision. More than 800,000 persons have submitted to voluntary sterilization since 1956, but this has not substantially reduced the country's birth rate.

Subsidized Control. Though Dr. Nayar herself had long been a birth-control skeptic in the Gandhi tradition (she was once his private physician), she agreed three years ago to test the Lippes loop, a U.S.-designed intrauterine contraceptive device that prevents the development of a fetus in the womb. Only eleven of the 2,839 Indian women fitted with them last year became pregnant, and five of these conceived after their little white loops had been removed. That convinced her, she said last week, that Lippes loops are "the answer" to India's problem.

The loops cost so little to manufacture (1¢ each) that the Indian government expects to give away 1,000,000 within a year, 2,000,000 a year by 1967, and 5,000,000 a year after that. While the country prepares a plant to produce its own, it will rely on 1,200,000 gift loops from the Manhattan-based Population Council. Radio broadcasts, movies and roving clinics will explain the device in thousands of villages, and the government will divide a $1-per-insertion subsidy

among midwives who bring women to the clinics, doctors who insert the loops, and local agencies that administer the program. Tradition may be against it, but last week the Municipal Corporation of Delhi bought newspaper space to advertise: "A small family is a happy family. Plan your family the 'loop' way."

With loops, continuing sterilization and other contraceptive methods, Dr. Nayar hopes to cut India's soaring birth rate almost in half in a decade—from 40 to 25 births per 1,000 population per year. Many Indian leaders agree that the nation must do something of the kind or live on the brink of chronic famine. Despite a 10% gain in this year's grain crop, the country cannot feed itself, must depend on 600,000 tons of U.S. wheat a month to avert a recurrence of last year's food riots. Mindful of this, Prime Minister Lal Bahadur Shastri, who, as the father of six, jokes that he is no expert on the subject, last week called family planning "a matter of the highest importance . . . for the individual and for the nation."

Sons as Insurance. It will be years before family planning can slow India's 12 million-a-year population growth enough to let its creaky economy gain. No religious opposition thwarts birth control in India, but tradition does. The average Hindu, unprotected by social security, old-age pensions, unemployment or sickness benefits, considers sons to be his best insurance against impoverished old age.

Beyond this, a gain in the economy can be a mixed blessing. Of the 40% of the world's population that normally goes hungry, about one-fourth are Indians. Even a slight increase in their standard of living means that they would eat better food and grow healthier—and that would send their birth rate up."

Thomsen, Russel J., 1982, Hemisphere Publishing Corporation, pg. 3 - An Atlas of Intrauterine Contraception.

> "The Lippes loop IUD was introduced to the 1962 IUD conference by Dr. Jack Lippes, its inventor. Its early and major use and promotion made it the standard by which other IUDs are judged. More than 25 million Lippes Loops have been used since 1962. It was the first plastic IUD to utilize transcervical nylon strings to check placement and facilitate its removal."

1908 – 1988, Ann Dugdale, PhD thesis, University of Wollongong, Australia, 1995, pg. 175 - Devices and Desires: constructing the intrauterine device.

> "Within three years, Robins had sold 2,2 million Dalkon Shields domestically, and a further 2 million for overseas use." "In its first year of promotion, [1970] sales of the Dalkon Shield displaced the Lippes Loop as the number one brand of intrauterine devices."

Scholar, Dr. Stephen Mumford, proved that the Dalkon Shield IUD "was indeed safe and effective when inserted by a skilled and experienced clinician", but confidence in IUDs waivered in the U.S., and they dropped in usage for decades. Now it is time to Bring Back the Loop. Please help Jack.

Dr. Jack Lippes, 2011 Distinguished Medical Alumnus of University of Buffalo, MD 1947, has made fundamental contributions to the field of obstetrics and gynecology. In 1959, as a private practitioner, he invented the Lippes loop, an intrauterine contraception device. He later promoted the use of quinacrine sterilization as a simple, inexpensive non-surgical method of sterilization. In this endeavor, Lippes is the Chair of the Medical Advisor Board of the International Services Assistance Fund. He also conducted extensive research into the physiology of human oviductal fluid, which resulted in improved pregnancy rates through in vitro fertilization. Lippes taught in the UB Department of Obstetrics and Gynecology from 1952 to 1999. He served as medical director of Planned Parenthood of Buffalo from 1962 to 1978, and clinical chief of the obstetrics/gynecology department at Deaconess Hospital of Buffalo from 1975 to 1981. He helped to open and directed the first in vitro fertilization clinic in Buffalo in 1981. Internationally, Lippes has received numerous awards and has served as a family planning and population consultant to health care organizations, corporations, and governments, including

South Korea, Taiwan, Pakistan, Tunisia, Turkey, India, Afghanistan, and Iran. UB bestowed its Distinguished Alumni Award on Lippes in 1982, followed by its Lifetime Achievement Award in 1999. In 2010, Lippes became the first American to receive the European Society of Contraception and Reproductive Health's annual medal, awarded to him in a ceremony at the Hague, Netherlands (picture above).

Dr. Lippes has been an important medical expert, tireless supported, and advocate for QS. He also writes letters periodically to influencers. Here is the latest example:

November 25th, 2021

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

Dear Speaker Pelosi,

I have so admired your work in Congress. I am hoping you can champion Quinacrine Sterilization (QS). QS is a simple, safe, inexpensive office procedure. However, in the United States the FDA bans QS, because the FDA with Family Health International believe that the drug

Quinacrine, used in QS, is carcinogenic. This is based on a single flawed study on rats. In this study, Quinacrine was placed in a slurry in the rat's uterus, whereas in women, 7 pellets of Quinacrine containing 36 mg each are inserted into the uterus using an IUD inserter. This is done twice. The first dose is inserted 6 to 12 days after the start of the menstrual period. The second dose is inserted 28 days later. The dose of Quinacrine used in the study on rats was 83 times the dose of Quinacrine used for QS in women.

With the history of QS, we know that when 3.1 million soldiers who were stationed in the South Pacific during WW II received 100 mg of Quinacrine daily for three years to prevent malaria, the army medical corps found no medical deaths and no serious adverse events (SAE) related to Quinacrine. Furthermore, after the war, the Veterans Administration reported no lingering SAEs due to quinacrine. This is certainly strong evidence that Quinacrine is a safe drug.

This FDA ban makes it impossible for women to have QS. Therefore, in the United States, if a woman wants to be sterilized, she must resort to surgical tubal ligation (STL), at a cost of $5000 each. In the United States there are 750,000 STLs annually, for the price of $3.75 billion. The Center for Disease Control (CDC) once counted 21 deaths within that 750,000.

In Vietnam more than 31,000 women had QS under the supervision of Dr. Do Trong Hieu where each treatment cost $1.06. There were no deaths reported and no SAE were reported. Just think, if suddenly the FDA approved of QS, 100 million women around the world would use QS per year. If the FDA approved QS, we would annually save 21 lives and billions of dollars for the United States. Concurrently, there would be an increase in the education and the use of all contraceptives. There would be a drop in population.

Please, Nancy Pelosi, convince President Biden to appoint a new director to the FDA with instructions to approve QS and expel the antichoice lobby from the FDA. When the new director, he or she, approves of QS, that would be a world changing event. Now, humanity would know that by only limiting population we can control climate change.

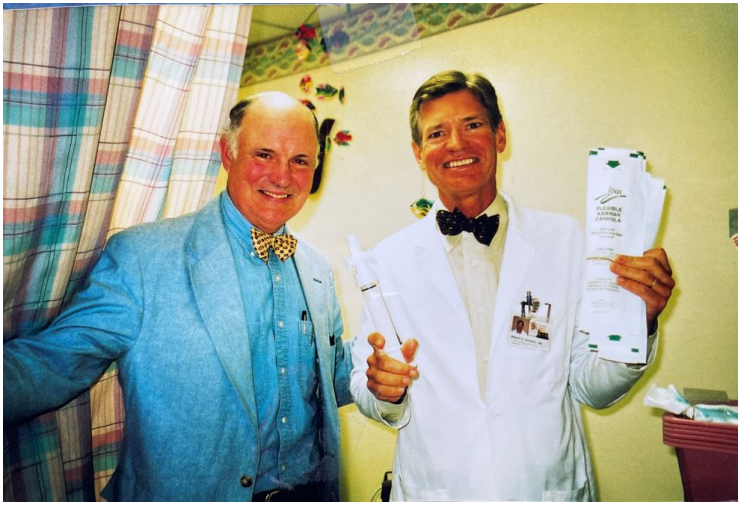
Thank you for your consideration,

Jack Lippes, MD

Professor emeritus of Gynecology and Obstetrics at SUNY at Buffalo, School of Medicine

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 16 Donald Collins, Sr. Helped Many Women to Get Contraception



Don Collins (left) and Dr. Phil Darney in San Francisco July 2001 (Credit: ISAF)

15 May 2014

My father has written five books so there is more than a whole book that could be put into this chapter. Many have said, he was an effective and tireless warrior for women's reproductive rights for more than 50 years.

The following is an essay by Donald A. Collins from Marilyn Hempel's book, Facing the Population Challenge: Wisdom from the Elders (Blue Planet

United, 2014). The book brings together the responses of fifteen giants in the field of human population and development, who were asked how they would advise an assemblage of the world's leaders on the future of humanity and the biosphere.

The Pioneers

by Donald A. Collins

I recall some of the pioneers on whose shoulders our leaders should be standing but sadly are not. It is too bad current leaders have forgotten the ardor of their betters, who in the 1960's and early 70's understood population issues, and were committed to solving core problems, rather than tinkering at the edges. Now it is too late to do so without much pain.

My advice is simple. Ensure the human rights of all women by providing free of charge all reproductive services, as only by so doing can the deadly population bulge be slowed and brought into balance with the rest of nature so that human life on our planet can be sustained.

That advice comes as the result of a long career in family planning. In September 1965, at age 34, armed only with a liberal arts BA and MBA, I was hired as a program officer by a foundation group in Pittsburgh, PA, whose major interests included family planning, then a rather arcane

subject which had few devotees or non-profit entities to do the work. India's population was under 500 million, the United States under 200 million, total world population was 3.3 billion vs. only 2 billion people in the world when I was born in 1931.

Now world humans number over 7 billion en route to a projected 9 or 11 billion by 2100, while most world leaders still whine about the need for endless growth, which a few prescient observers have dubbed "the behavior of cancer cells". Defining "growth" has often been focused on JOBS, which the Sunday September 8, 2013, CBS 60 Minutes segment showed are not coming back in any great numbers to the U.S. after this recession, due to automation and cheaper labor elsewhere.

Ignoring population growth by U.S. and other world leaders was not always so, as the late Lawrence Lader opined in his classic 1971 book, Breeding Ourselves to Death. The book recounted a history of strong support from a bipartisan cross-section of Americans including a past a present American President, both convinced about the dangers of world population expansion beginning to burgeon wildly.

One of our principal bosses at my new 1965 job was an immensely rich, retiringly shy, but forcefully committed population / family planning partisan named Cordelia Scaife May, whose Mellon forebearers had left her one of

America's wealthiest women. (Her wonderful charitable legacy was briefly covered in a July 25, 2013, Los Angeles Times article.) At her urging, the several charitable entities that she influenced sought ways to extend family planning services to all women in the U.S. and around the world. There were few non-profit foundations when actively involved in providing such services, although the International Planned Parenthood Federation's network of affiliates around the world included its U.S. affiliate Planned Parenthood Federation of America (PPFA). PPFA was then as now, certainly the leading U.S. family planning service provider. PPFA had been founded by Margaret Sanger. Cordelia May, "Cordy" as she was known, had come to know Sanger through her mother and was greatly influenced by her.

Early in my tenure at being a philantropoid (vs. being a philanthropist – one who actually has the money), my workaday boss, the chief foundation manager, showed me a funny plastic item. "Do you know what this is?" I didn't. "It's an intrauterine device and you are going on the board of National Planned Parenthood". Oops, talk about a naïf in training.

I spent the next seven years on the PPFA board, meeting a who's who of family planning pioneers of that era: Bill Draper Sr. Hugh Moore, Alan and Leonore Guttmacher, Fred Jaffe, Bernie Barrelson, Frank Notestein, Paul Todd,

Stewart Mott, Rei Ravenholt, Malcolm Potts, Julia Henderson, Al Moran, Bud Harkavy, Elton Kessel, Tim Black, Phil Harvey, George Dennison, and many more far too little lauded people who came forward to help facilitate more reproductive services for all women. There are so many more whose advice and council were so generously and freely given to me that I apologize for not having space to bless them all.

My first international family planning meeting in Santiago, Chile in 1966, convened by International Planned Parenthood, was attended by many of those named above, plus Dr. M.C. Change, the co-developer with Gregory Pincus, of the famous birth control pill approved by the FDA in 1960. I asked Dr. Chang how they knew how much progesterone to put in their initial Pill, to which he replied, "We really didn't know exactly". Over the years, of course, doses were minimized, and one could rightly argue that The Pill was by far the most important invention of the last century. When combined with other methods, it brings the world the potential to be the greatest solution possible to save our plundered planet.

A major place to invest charitable funds for family planning in those early years was the Population Counsel (PC), founded in 1952 by John D. Rockefeller, III. PC was willing, but only with approval from a sovereign government, to fund contraceptive services in foreign

countries. A major initial effort in IUD distribution in Taiwan got Cordy's approval and had proved very successful by the time I joined the Pittsburgh charitable staff.

Cordy subsequently toured Asia with PC President Frank Notestein, gaining first-hand knowledge of conditions on the ground, which helped inspire later more daring philanthropy. To her, the numerous weighty formal studies of population trends and methods had by then already proved the obvious: the real work was to provide specific birth control services as rapidly and widely as possible. Those services included providing safe, early, if possible, abortions. Of course, abortions were not available in the U.S. on demand until the historic Roe v Wade Supreme Court decision of January 23, 1973. We now know that this ruling triggered a full-scale attack on family planning led by the Roman Catholic Church, which has proved to be one of the most dangerous and effective attacks on basic human rights mounted in the 20th Century and continued today.

Well before the passage of Roe v Wade, there were states that could do abortions and I was dispatched to find abortion funding service opportunities, which were provided by all too few around the nation. When New York State passed its abortion on demand law in July 1971, the CEO of NYC's PPFA affiliate Alfred Moran, took up the

cudgel and quickly stabled substantial services, again aided by substantially with Cordy's money. Her funds also created a revolving loan fund at PPFA to set up abortion clinics at any PP affiliate which wished to do so.

My own extensive tour of South America with an official of IPPF-Western Hemisphere in the late 1960's was where I observed women in hospital wards dead from septic abortions. This sealed my fervent commitment to fostering safe services.

In 1971, Dr. Ravenholt, the head of the U.S. government Office of Population (1965 to 1979) asked me if I could get my trustees to grant $50,000 to start an early abortion non-governmental organization (NGO) to work overseas. He hoped once begun he could get sustaining support form USAID. Senator Helm's amendment in 1973 stopped that source of money in its tracks. However, International Pregnancy Advisory Services, now called IPAS, was already underway with an office and small staff. I got elected Chairman and President only because I was connected to its startup money.

Fortunately, my boss, Cordy, continued to support this fledgling startup and overtime gave IPAS over $1.5 million ($12 million in today's dollars). Without her resolve, IPAS would likely not be here today. It took my chief fund-raising colleague on the IPAS board, Dr. Leonard Laufe, a distinguished Pittsburgh OB/GYN, and I many years to

gain enough support from brave donors to bring IPAS forward. Celebrating 40 years of effective training and service this year, IPAS now enjoys major support from a growing number of large private donors, but still the Helms Amendment keeps our government from being involved.

Another hugely successful abortion services provider, UK headquartered Marie Stopes International, was started by Dr. Tim Black and Philip Harvey in the mid 1970's. They also started Population Services International (PSI) another major family planning commodity provider funded early by my then employer.

As former USAID Administrator, Duff Gillespie, writes, "As director of USAID Office of Population from 1965 to 1979, Dr. Reimert T. Ravenholt created a family planning juggernaut that still provokes both praise and disdain. Ravenholt was a remarkable leader, full of perplexing contradictions. He dazzled people with his brilliance one moment and shocked them with his myopic ethnocentrism the next. He could be strategically wise and tactically reckless. Ravenholt's controversial reputation masks his many contributions, which are still evident 20 years after he was forced from his leadership of USAID's population program."

One of Ravenholt's many creations was International Fertility Research Programme (IFRP), under the founding

leadership of Elton Kessel, MD, MPH, in 1971, again with critical startup money from Cordy's trusts which allowed IFRP to become independent of the University of North Carolina where it originally functioned, much to the delight of Senator Jesse Helms who sought its departure. Again, as a possible funding representative, I was asked to join its initial board where I served until 2004. Now known as FHI360 (formally Family Health International or FHI) and operating with a wide development and family planning mandate, its staff numbers thousands and its total yearly revenue approach $800 million.

FHI's second President Dr. Malcolm Potts, now Bixby Professor of Population and Family Planning at UC Berkeley, sent a proposal in 1985 to USAID and obtained its first major grants to curb the HIV/AIDS epidemic. Then, a few years ago, at US Berkeley, along with his wife, Dr. Martha Campbell, Potts helped found Venture Strategies, which assists a growing number of developing nations to better cope with the fatalities to mothers associated with postpartum bleeding.

While in Pittsburgh, my charitable fund employers approved my recommendations for start-up funding for a number of other family planning entities including Population Services International, Guttmacher Institute, Population Institute, Religious Coalition for Reproductive Choice, Population Dynamics, and others who have gone

on to make family planning movements stronger and more widely effective.

At present, as founder and President of International Services Assistance Fund, I and my colleagues, which include Dr. Jack Lippes, Dr. Stephen Mumford, and Dr. Elton Kessel, are seeking FDA approval to market an inexpensive permanent method of female contraception, known as QS (invented by distinguished Chilean MD, Dr. Jaime Zipper) using a now well-established standard protocol. QS has been provided by over 1900 practitioners in over 50 countries to over 175,000 women, some for over 30 years, with no reports of death or major complications.

Thus, as noted initially, my message to world leaders is very simple. Leaders! You must use your full influence to work to insure basic human rights for all the world's women. Those rights must include the absolute right to decide when and under what circumstances they choose to bear children. That right can only be achieved with the full availability of safe, free or very inexpensive, modern contraception, including abortion. With over 40 million abortions occurring yearly worldwide, we can only assume that contraceptive failure will continue. Thus, providing safe, preferably early – on demand if needed – services must accompany any family planning program to be effective and in keeping with offering women their full human rights.

As we now know, unless such programs are urgently initiated, a sustainable and humane habitation of our planet will continue to deteriorate. Failing to provide family planning, we can with certainty expect the growing disruptions presently visited on so many countries to spread globally as the 21st Century unfolds. Constant articles about various human disasters in the press seem to make no impression. And so, the future remains cloudy.

Donald A. Collins is a former U.S. Naval officer, banker, and venture capitalist. He is now a free-lance writer living in Washington, DC. He spent over 50 years working for women's reproductive health as a board member and/or officer of numerous family planning organizations including Planned Parenthood Federation of America, Guttmacher Institute, Family Health International and IPAS.

Mr. Collins holds a BA from Yale University and an MBA from Ney York University. He served with the U.S. Navy from 1953 to 1956. Subsequent to the U.S. Navy, Collins entered the commercial banking business in NYC. Thereafter, he became CEO of a Pittsburgh based small business investment company. In 1965, he became Chief Administrative Officer of a Pittsburgh charitable foundation, which focused on community development, plus serving as a program officer of two other charitable entities with broad domestic and international mandates.

In this connection for 10 years, Collins helped develop a number of charitable programs concerned with forming public policy and service-based actions in the population and environment fields, including serving on the original boards of Advocates for Youth (then Center for Population Options), Alan Guttmacher Institute, International Projects Assistance Services, Family Health International (now FHI360) and others.

In 1976, Collins moved west and formed his own firms, Donald A Collins Associates and International Services Assistance Fund, through which he engages in consulting activities for both for-profit and non-profit entities. His clients include several private foundations, for-profit corporations as well as individuals who seek advice on policy, program, organization and operational management.

His primary interests remain in the fields of family planning and immigration reform. As an active volunteer, he encourages the use of a major new method of non-surgical female sterilization known as non-surgical permanent contraception for women (QS) for which he seeks advocates and funders. The same is true for immigration reform where he served for years on the board of the Federation for American Immigration Reform (FAIR), now serving as Co-Chair of its National Advisory Board.

Don also contributes OP ED pieces and letters to the editors on these issues to newspapers, journals and blog sites.

His 1976 marriage to Joan F. Kraus Collins ended with her death in 1993.

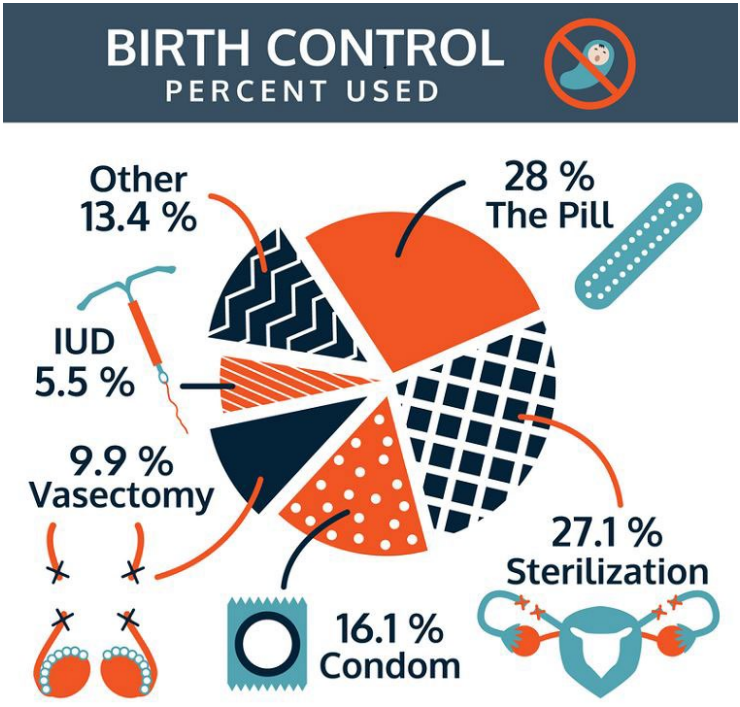
In November 1994, he married Sarah Gamble Epstein (the daughter of Dr. Clarence Gamble who founded Pathfinder International). Together they have been pursuing the task of seeking FDA approval for QS and other family planning work. They are still indefatigable travelers. Their most recent trip to Patagonia and to the Iguassu Falls, seeing 275 separate waterfalls.

In his 90th year, Dad has published four more books which are available with his 5th book for purchase on his Amazon Author page here.

- Vote: Your grandchildren's lives and your country will be defined by how (if) you vote in the 2022 midterms and in the 2024 presidential race
- What Can Be Done Now to Save Habitable Life on Planet Earth? Leaders Commit to Reduce Human Population
- We Humans Overwhelm Our Earth: 11 or 2 billion by 2100?
- Trump Becoming Macbeth: Will Our Democracy Survive?

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 17 Why isn't the Safest Permanent Method Used by More Men?



(Credit: Dreamstime.com)

28 March 2019

An article in the NY Times by Christina Caron asked the question, *Why Don't More American Men Get Vasectomies?*

> "In the United States, female sterilization is twice as prevalent as vasectomy, according to 2015 estimates from the United Nations — despite the fact that vasectomy is equally effective, less invasive and carries a lower risk of complications. Why?"

Great question. And the answer she gives is,

> "It's a blend of cost, misconceptions and fears about the procedure, and cultural expectations about what truly defines a man."

A man interviewed for the article said,

> "Looking ahead 20 years, will he and his wife still be married? Will she even be alive? Maybe, I meet a younger woman or something like that and she wants to have kids"

Caron gives more information,

> "Vasectomy is covered either partially or in full under most insurance plans, but the procedure may require a referral from a primary care provider. Without insurance, the price is usually about $1,000. Vasectomy reversals, however, are not covered by insurance, and the procedure is cumbersome and expensive."

"By contrast, the Affordable Care Act required insurance companies to cover 18 types of contraception used by women, including sterilization surgery, and no co-payment is required.

Aside from cost, getting a vasectomy often requires multiple visits to the doctor — first to establish consent, then to have the surgery and later to figure out when the sperm has been purged from the ejaculate. The entire process can take three months or more.

Dr. Anuj Khattar, a fellow with Physicians for Reproductive Health who practices in the Seattle area, estimated that after the initial consultation, 20 to 30 percent of his patients end up either changing their minds or simply not showing up for the procedure."

"I think part of the fears around vasectomy is that it's so permanent," Dr. Khattar said, adding that some men worry about "losing some of their virility and their ability to enjoy sex."

But 'physiologically, it doesn't affect any of those functions," he said. "There's just a lot of misinformation.'"

According to Wikipedia,

> "In nearly every way that vasectomy can be compared to tubal ligation it has a more positive outlook. Vasectomy is more cost effective, less invasive, has techniques that are emerging that may facilitate easier reversal, and has a much lower risk of postoperative complications."

In another good article Why He Doesn't Want a Vasectomy (And What You Can Do About It) 5 myths are debunked by Edwin Risenhoover, MD, a family medicine physician with Banner Health Center in Loveland, CO.

Myth #1: It will shut down my sex drive. Truth is…

Your sex drive won't be interrupted … well, maybe before you've medically recuperated from the procedure. Dr. Risenhoover said:

> "Libido, or sex drive, is both psychological and physiological. The physiological aspect of libido is often associated with testosterone levels. Testosterone is made in the testes and transported through the body in the bloodstream. Sperm is also made by the testes and transported during ejaculation through the genitourinary tract, beginning in the vas deferens tubes.

> A vasectomy interrupts the flow of sperm along the vas deferens, but it does not change the blood flow to or from the testes. Therefore, vasectomy does not change testosterone level or libido."

Myth #2: Most vasectomies fail anyways. Truth is…

You won't accidentally get your spouse pregnant if you follow doctor's orders. Dr. Risenhoover said:

> "Most pregnancies occur, however, when the patient has unprotected intercourse before completing a test to confirm that the vasectomy has worked.
>
> The overall failure rate for vasectomy is 1 in 2,000, or 0.05%. That rate actually ranges from 0.02% to 29%, depending on the technical method of vasectomy used by the surgeon. The most commonly accepted method today, cautery of the prostatic end and fascial interruption (burning one end and tying a tissue barrier between the two ends), affords the lowest failure rate. So, ask your surgeon what method they plan on using."

Myth #3: I won't be able to ejaculate or have an erection.

Truth is…

It won't affect your ability to perform in bed. Dr. Risenhoover said:

> "The ejaculate fluid volume comes almost entirely from the prostate gland, not from the sperm in the vas deferens. Vasectomy interrupts the flow of sperm, but it does nothing to the fluid from the prostate gland. In fact, multiple ejaculations are required before performing a post-vasectomy semen analysis.
>
> When it comes to sexual desire, research has shown that vasectomies don't impact a man's interest in sex, his ability to get or keep an erection or the quality of his orgasms. An erection depends on blood flow to and from the penis and has nothing to do with the area operated upon during a vasectomy."

Myth #4: Vasectomies can cause prostate cancer. Truth is…

They won't increase your risk, but they don't protect against sexually transmitted diseases. Dr. Risenhoover said:

> "Many studies have assessed whether there is any association between having a vasectomy and developing prostate cancer later in life. Most studies show there is no increased risk of prostate

> cancer after vasectomy. However, a few studies indicate a weak increased risk may be present. Even in those few studies, no causal relationship between vasectomy and prostate cancer exists. If this small risk is a concern for the patient, you should consider other options of permanent birth control.
>
> Vasectomies don't, however, protect you from STDs, so make sure you use additional means for protection, such as latex condoms."

Myth #5: Vasectomies are painful and have a long recovery.

Truth is…

It is actually quite painless, thanks to numbing medication, but you won't want to run a marathon the next day. Dr. Risenhoover said:

> "Most vasectomy patients recover quickly, if they follow their surgeon's instructions. There are cases that fall outside of the norm, and the patient has a complicated or protracted recovery or may even have long-lasting pain. However, most men feel back to normal in just a few days. They can usually resume light work within two to three days, heavy

> work or exercise in a week and normal sexual activity after one week."

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 18 The Root of all Evil in Family Planning

Roman Catholic Pope John Paul II in 1991(Credit: Wikipedia)

22 January 2022

"What's good for the goose is good for the gander", a 17th century saying from the UK (what applies to a woman applies to a man) is still relevant today. Biologically, once a gander's sperm is in a goose, it's her embryo. If human men were child bearers (like male seahorses), things might be better for society and especially women and children. The grandeur of sporting events, pickup trucks, and rocket ships dominates American TV. Would it be like that if women were equal?

Human Family Planning implementations fall short for almost 2 billion women worldwide as it has since Adam and Eve. No surprise that the World Health Organization (WHO) in 2020 reported 270 million women have an unmet need for contraception. Or that yearly, there are 211 million pregnancies globally, 121 million (57%) are unintended, and 46 million (22%) end in induced abortions according to The Lancet Global Health, and WHO reports that 529,000 (0.25%) lead to maternal death. With a CDC reported 3.6/100,000 mortality rate in the U.S., the most common contraceptive method, used by 219 million women of reproductive age (15 – 49 years), is surgical tubal ligation (STL) according to The United Nations.

Even worse, in 2019, the United Nations reported worldwide only 44% of women use birth control at all. It is a humanitarian disaster that fewer than 65% of American

women use birth control as reported in 2018 by the U.S. Centers for Disease Control and Prevention (CDC).

With all our democracy, capitalism, and high tech, what is keeping America from setting the standard for the highest usage of the best contraceptive methods (as determined by women and their doctors) provided at the lowest cost?

Abortion should not be considered a contraceptive. It should never happen except in rare circumstances.

Certainly, pharma companies must get paid for their research and must be able to cover unexpected circumstances with high insurance premiums, but is it legitimate for them to charge women so much for their products, especially in the U.S. market, where the average cost as shown in the table in chapter 4 is $549 per year (excluding the Loop and QS).

It's well documented that for decades; family planning methods and availability have been and continue to be hampered by **Vatican leaders' religious doctrine which has been politically weaponized in the U.S. with the worst effects upon women.**

The Wall Street Journal published Tuesday January 11, 2022,

> "The pope said that effective multilateral diplomacy requires the recognition of what he describes as

> fundamental values: 'The right to life, from conception to its natural end, and the right to religious freedom.'
>
> Instead, he said, many international organizations practice 'ideological colonization,' a term he previously has used to **describe efforts by rich nations to promote contraception**, same-sex marriage, and progressive concepts of gender in developing nations."

WSJ columnist William McGurn wrote in his November 29th, 2021, article entitled, *What Pro-Lifers Want From the Supreme Court* days before the Supreme Court heard oral arguments about a Mississippi law banning abortions after the first 15 weeks of pregnancy:

> "It bears notice here that since Roe was decided, those who oppose it have played by the rules. They have done the hard work of proposing legislation, compromising to reach a bill that can pass, and then working to get laws enacted by their elected representatives in statehouses around the country. They have diligently worked to elect Republican presidents who campaigned on the promise of nominating Supreme Court justices who would uphold the Constitution instead of legislating from the bench. And they have supported these justices

through ugly nomination fights—often at bottom over Roe."

As Dr. Mumford reported decades ago, "On November 20, 1975, the American Catholic bishops issued their ***Pastoral Plan for Pro-Life Activities***" posted here by Notre Dame, posted here by Dr. Mumford, and later posted by The United States Conference of Catholic Bishops here. Dr. Mumford provided detailed analysis of the Bishop's plan here, with praise by reviewers here, which has been read almost 2 billion times. In mid-2022, we will see fruits of the Vatican's labor when the Supreme Court overturns Roe v Wade. Of course, the Vatican has already succeeded in changing the U.S. at the state level shown by a map from @guttmacherinstitute @rewirenewsgroup and @sarah.epperson above.

The IRS issued a press release IR-2007-190, Nov. 19, 2007 with more detail here. How is it that the RCC maintains its nonprofit tax status despite its enormous political, social, and economic power?

NYTimes editorial by David Burnham July 29, 1988 explained an attack to, *Alter the Catholic Church's Tax Status?* Also, Fulani v. League of Women Voters Education Fund, 882 F.2d 621 (2d Cir.1989) dismissed for "lack of subject matter jurisdiction for lack of standing." So, no law breaking here.

LA Times columnist Michael Hiltzik reported July 1, 2021 in Column: How the University of California outfoxed Catholic hospitals on religious medical restrictions,

> "Catholic doctrine is embodied in a document titled Ethical and Religious Directives for Catholic Health Care Services. It's a product of the U.S. Conference of Catholic Bishops, is enforced by bishops at the local level and prohibits numerous medical procedures at Catholic hospitals, including most abortions, sterilization procedures such as tubal ligations, hysterectomies for transgender patients, and end-of-life care such as assisted suicide."

Over decades this Catholic doctrine has become economically advantaged throughout America supported by our tax dollars, and is winning over disadvantaged competitors.

NY Times Katie Hafner reported August 10, 2018, in As Catholic Hospitals Expand, So Do Limits on Some Procedures

> "One in six hospital patients in the United States is now treated in a Catholic facility, according to the Catholic Health Association, a membership organization that includes 90 percent of the Catholic hospitals in the United States. In a 2016 report, MergerWatch, a nonprofit group in New York that

> tracks hospital consolidation, found that in 10 states, 30 percent or more of the acute-care hospital beds were under Catholic ownership, or in a hospital affiliated with a Catholic health care system. In a growing number of rural areas, a Catholic hospital is the sole provider of acute care."

The NY Times Op-Ed by Jamie Manson, who has a master's in divinity, is the president of Catholics for Choice, and a former columnist for The National Catholic Reporter on May 27, 2021 reported in, The Catholic Church's Reproductive Fight Is About Controlling Women's Freedom:

> "But Catholics should ask themselves whether the church's anti-abortion fight is less about babies and more about controlling women's fertility and, with that, women's freedom. Bishops have notably little to say about methods to control male sexuality. They never turn vasectomies into a culture war issue.
>
> Virulent anti-abortion rhetoric from on high has kept the majority of pro-choice Catholics silent — including the president of the United States. Now that the Supreme Court, with its six Catholic justices (five of whom espouse extremely conservative religious views), has decided to take up a case that is a direct challenge to Roe v. Wade, there has never been a more urgent moment to speak out boldly as

> people of faith who support the right to access abortion."

There are actually 7 Catholic Justices including the Justice from Puerto Rico.

As Margaret Talbot said her The New Yorker, February 7, 2022, article *Amy Coney Barrett's Long Game*:

> "The remaining question was whether a majority of the conservatives would accept Mississippi's request to throw out Roe and Casey altogether. Alito, Thomas, and Gorsuch appeared ready to do so. Kavanaugh . . . also seemed on board,
>
> Barrett may be pursuing her goals more slowly, and more cautiously, than Alito. But what's the hurry? She has plenty of time."

If the U.S. Supreme Court overturns Roe v. Wade enacted 49 years ago in 1973, the reproductive rights for American women will not improve. See what has already happened in many U.S. states tending toward the Latin American model described below.

US News Kaia Hubbard reported February 25, 2021,

> 45 States Have Enacted Abortion-Related Laws in Recent Years, States enacted 256 laws relating to

> abortion between January 2017 and November 2020, a new study finds.

When a group is disadvantaged, competition wanes, and in this case, women have no choice but to pay for bad products and services. Is this Catholic doctrine also promoted throughout U.S. state and federal governments, schools, media, and in other countries around the world?

Where can women of reproductive age (15 – 49 years) turn? Good for the goose is good for the gander, should mean that women and men both get their choice of free birth control.

Medical experts at The American College of Obstetricians and Gynecologists (ACOG) issued a committee report titled, Access to Contraception, reaffirmed in 2017, recommend that,

> "All women should have unhindered and affordable access to all U.S. Food and Drug Administration-approved contraceptives."

Women ignore the church teachings as "89% of Catholic women use a contraceptive, while 90% of Protestant women use one." For a far better treatise on this subject by scholar Dr. Stephen D. Mumford, one of 200 Critics of the Catholic Church, wrote Why the Church Can't Change, published in the Winter of 2000 in Free Inquiry Magazine.

As an electrical engineer I've used integrated circuits based on the technology of a 30 doubling (1,000,000,000 times) numbers of transistor increase per chip shown in this chart.

Much of that successful progress occurred because competitors and their scientists, engineers, customers, manufacturers, experts, and regulators communicated with each other and laid down rules for progress that each contributor agreed to. Here is an example from IPC and JEDEC.

As always, competitors of various sizes tried to beat each other, but they worked together so that all customers' boats rose in the tide of progress. Imagine if the U.S. government had been against semiconductors. How slow might have been the advance of technology. Instead, the U.S spirited this growth and now we have smartphones, the inside of which looks like military hardware.

Has this powerful Catholic doctrine sabotaged method development and availability of birth control for decades, so women are unfairly biologically disadvantaged compared to men? Look at women's reproductive rights in Latin America where this Catholic doctrine reigns supreme. A U.S. woman was recently convicted of misdemeanor manslaughter for having a miscarriage at 15 - 17 weeks of pregnancy. This routinely happens in El Salvador and other countries south of the U.S. border.

As further evidence, surgical tubal ligation (STL), still the most common method, highlights FDA failure to approve a viable non-surgical permanent contraception method for women like QS.

Non-surgical permanent contraception for women (QS) has been proven to be a simple, safe, effective, and inexpensive method. Dr. Jaime Zipper invented QS in 1976 in Santiago, Chile. QS is accomplished by inserting seven (7) pellets, 36 milligrams each (252 milligrams total) into the uterus of women in two (2) doses. The first dose is inserted within 6 to 12 days after a woman's menstrual period starts. The second dose is inserted 1 month later. The lifetime dose is 504 milligrams. QS has been used by 200,000 women in over 50 countries.

With FDA approval a consultant to USAID said, "QS is expected to be used by hundreds of millions of women worldwide." The QS method is a safe and effective contraceptive used for 45 years prescribed by 1600 health practitioners who conducted 100 clinical trials and produced scores of peer reviewed articles. More than 5 million patient years of experience with no deaths proves QS is a safe and effective method.

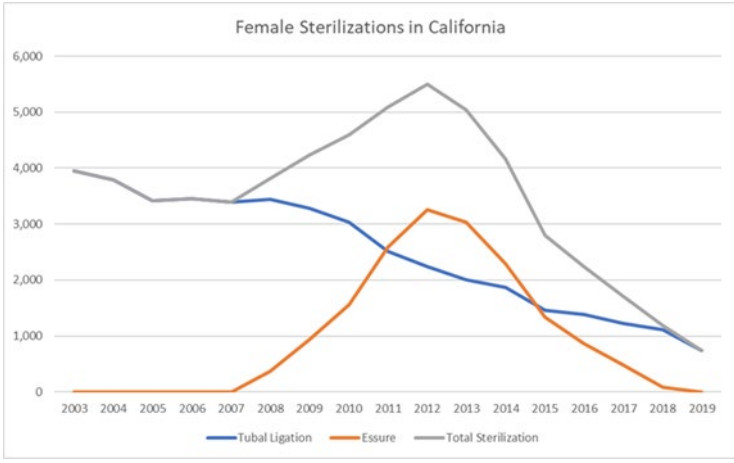
FDA could reduce maternal deaths, unintended pregnancies, and abortions worldwide by approving QS. U.S. Pharmacopeia approved the use of quinacrine for non-surgical permanent contraception for women (QS) from

1993 - 1999. FDA ended QS in 2016 and paid to have quinacrine removed from the U.S.

If QS was available to women in California from 2003 until 2019 instead of tubal ligation and Essure, the state would have saved $11 million. Note in the graph below, when non-surgical method Essure was available, sterilizations per year more than doubled. During this time there were an average of 3,477 procedures with an average reimbursement per client of $330. If QS, at $125 per woman was instituted, then California could save conservatively $434,603 per year.

Have the powerful forces that promote this religious doctrine infiltrated states too? What else might explain the drop in female sterilization in CA? Maybe women don't want surgery. Could it be an unwritten provision in CA Family PACT? A practicing physician in CA reports that:

> "A woman is no longer eligible to receive Fam PACT services (UTI, STI, Vaginitis, contraceptive) if she has become sterilized. However, she may still be covered by Medi-Cal (depends on her circumstances) for these services. Fam PACT is very specific covering STIs (male and female), Urinary tract infections, vaginal infections and contraception."



(Credit: ISAF)

Women are half of humanity, and they have been brutally controlled by religious doctrine for centuries. Like men, they should have the right to control their bodies and to have freely available birth control with minimal side effects.

Listed below are instances in this book where religion is mentioned and someone was fired, a group stopped supporting QS, or an NGO's funding was threatened if they supported QS:

1) NPR report, page 18, religious objections to contraceptives
2) NPR report, page 18, Fed rules don't require all health plans to cover all contraceptives
3) Clarence Gamble, page 26, Comstock Laws

4) Clarence Gamble, page 39, Church did not get along with family planning pioneers
5) Sarah G. Epstein, page 45, religious strictures affect women
6) Sarah G. Epstein, page 47, pressure from religious sources
7) ACOG, page 55, not provide sterilization because of religious beliefs
8) PP NMC, page 59, forces push even Planned Parenthood to withdraw from QS clinical trial
9) Dr. Hieu, page 81, ministry funding threatened if they didn't stop QS
10) Elton Kessel, page 122, Vatican control WHO
11) Elton Kessel, Page 130, removal of Dr. Ravenholt
12) Elton Kessel, page 133, removal of Dr. Ravenholt by Vatican, 30 fired at FHI reorg,
13) Elton Kessel, page 137, FHI funding removed if Mumford not fired
14) Donald Collins, page 152, Roe caused full scale attack by RCC
15) Root of all Evil, page 168, Vatican doctrine
16) Dr. Mumford, page 169, Catholic bishops plan
17) NYTimes, page 169, Catholic Church tax status
18) NYTimes, page 171, Catholic Church's reproductive fight
19) Root of all Evil, page 175, Family Pact corrupted to reduce sterilizations in CA
20) Needed: Scientific Endorsers, Vatican in QS report

Sadly, the above list is dwarfed by the Vatican's (a foreign country's) tax exempt weaponization of various religious groups with its 1975 ***Pastoral Plan for Pro-Life Activities*** to limit and eliminate legal contraception, sterilization, and abortion in the U.S. by taking over local, state, and federal governments we can only imagine to obtain and maintain power over women.

Printed in its entirety below is Chapter 11 of THE LIFE AND DEATH OF NSSM 200, How the Destruction of Political Will Doomed a U.S. Population Policy by Dr. Stephen D Mumford one of 200 Critics of the Catholic Church, explains why the Vatican will never change its stance on contraception.

"THE ONLY way to solve the problem of contraception is to solve the problem of infallibility."[97]

-- Hans Küng; Catholic theologian; 1979

THE CROSS OF PAPAL INFALLIBILITY

For me, no other single statement better summarizes the world population problem. To protect the dogma of infallibility, the Vatican has been forced to undermine the political will of governments which have been striving to deal with overpopulation. It has been largely successful in killing the political will to deal with this problem in all countries (where it exists) except in China. And, political will is vital to halting rapid population growth. Thus the dogma of infallibility lies at the very heart of the overpopulation dilemma.

There is wide agreement that the world population problem cannot be successfully dealt with unless we solve the contraception problem. However, there is a nearly total lack of awareness that the problem of contraception is related to the problem of papal infallibility, as noted by Hans Küng above.

There is a time warp involved here -- a decisive action, or event, that occurred more than a century ago. It had a direct bearing on the mushrooming of population that didn't really get up to speed until the 1930s. The event was the action of Pope Pius IX and Vatican Council I in 1870. Understanding the principle of infallibility and how it came to pass is essential to understanding the world population problem. This

Chapter is devoted to how and why this principle was created and its implications.

For decades, Americans have been subjected to pseudo discussion of the population problem as American writers and speakers have gone about deflecting attention from the only population issue that really matters -- that the Papacy is threatened with annihilation as civil authorities make contraception and abortion legally available to their constituents. We are all deeply indebted to both Hans Küng, arguably the world's leading Catholic theologian, and certainly the best known, and to August Bernhard Hasler, for his book, *How the Pope Became Infallible*.98 In this Chapter, the wisdom of Dr. Küng's statement will become evident.

THREAT TO THE PAPACY

In Chapter 6, I cite a paragraph from the minority report of Pope Paul VI's Commission on Population and Birth authored in 1966 by the man who later became Pope John Paul II. This paragraph shows with great clarity the real motivation of the Papacy: institutional survival. It is so important; I repeat it here:

"If it should be declared that contraception is not evil in itself, then we should have to concede frankly that

the Holy Spirit had been on the side of the Protestant churches in 1930 (when the encyclical Casti connubii was promulgated), in 1951 (Pius XII's address to the midwives), and in 1958 (the address delivered before the Society of Hematologists in the year the pope died). It should likewise have to be admitted that for a half a century the Spirit failed to protect Pius XI, Pius XII, and a large part of the Catholic hierarchy from a very serious error. This would mean that the leaders of the Church, acting with extreme imprudence, had condemned thousands of innocent human acts, forbidding, under pain of eternal damnation, a practice which would now be sanctioned. The fact can neither be denied nor ignored that these same acts would now be declared licit on the grounds of principles cited by the Protestants, which popes and bishops have either condemned or at least not approved."[43]

The pope's claim that "morality" demands that the Church maintain its current position on contraception is merely deception. This will become evident as we discuss the doctrine of papal infallibility and the doctrine of primacy of the pope, and why they are vital to the survival of the institution of the Papacy itself.

HISTORY OF THE POPE'S INFALLIBILITY

Two dogmas were proclaimed at Vatican Council I on July 18, 1870, and they are linked. The dogma of the primacy of papal jurisdiction means that the pope has universal jurisdiction. He has "direct sovereignty over the entire church":99 "The pope can intervene authoritatively at any time in any situation in any diocese, and in every instance where the pope intervenes the bishops are obliged to obey and submit to his decisions."100 The bishops were at that moment, according to Küng, reduced to mere lackeys of Rome,101 and this arrangement continues to this day.

The second dogma proclaimed that day, the dogma of papal infallibility, means that the pope is incapable of error when he makes *ex cathedra* decisions on matters of faith and morals. However, virtually all matters, including political, social and economic, can be framed in terms of faith and morals. Hasler describes this dogma as elastic, meaning that it expands and contracts. Whenever it seems opportune, infallibility, thanks to its vagueness, can be stretched far beyond the limits of *ex cathedra* decisions. The ordinary papal teaching now becomes infallible too. In a sense, such "infallible" decisions are much more important to the Vatican and the Church's bureaucratic machine than the rare *ex cathedra* declarations. The aura of infallibility counts more than its actual use.102 Papal infallibility means that the pope has an interpretive

monopoly. He no longer needs the Church's approval. His decisions are beyond appeal.

Infallibility was first attributed to the pope in 1279 by a Franciscan priest.103 In 1324 Pope John XXII condemned this idea as the work of the devil104 (which may explain why Pope John XXIII chose this name, the first in 550 years, and then set about ignoring the dogma of infallibility). Later on, in their struggle against Protestantism, popes once more considered infallibility a practical weapon.105 In 1800, papal infallibility was still generally rejected except in Italy and Spain.106 Pope Gregory XVI (1831-46) was the first pope to claim that popes were infallible. His encyclical, *Mirari*, also viewed freedom of conscience as "a false and absurd concept," indeed a mad delusion. According to him, freedom of the press could never be sufficiently abhorred.107

Pope Pius IX (1846-78) was absolutely committed to making papal infallibility a dogma. Indeed, it is unlikely that it would have ever become a dogma had it not been for this man. In his first encyclical letter (1846), he laid implicit claim to infallibility.108 In 1854 Pius IX, on his own authority, elevated the doctrine of Mary's Immaculate Conception -- the belief that the mother of Jesus was born without any stain of original

sin -- to the status of dogma.109 With this act, he had de facto demonstrated his own infallibility.

PAPACY FACED EXTINCTION IN 1870

The times set the stage for Pius IX to act. The Papacy seemed to be facing extinction.110 The Church was under siege from many different forces: secularization, liberalism, rationalism and naturalism. The French Revolution had changed the Catholic world permanently.

Pius IX was responding to several events of the times. It is believed that he wished to extend his spiritual jurisdiction as compensation for his loss of secular power because of the loss of the Papal States.111 He believed that the principle of authority would counteract the principles of the French Revolution. He desperately needed to contain the forces of unbridled journalism which were wreaking havoc.112 There was a hope that this principle of authority would bring about the return of lands already lost by the Papacy. The French Revolution destroyed centuries old patterns of Church government, 113 threatening the very existence of the Church.

The Church no longer had at its disposal the option of physical coercion that ranged from detention to annihilation, which was not infrequently used by the

pope. For example, in "1868 Pius IX ordered the Italian revolutionaries, Monti and Tognetti beheaded in the Piazza del Popolo for attempting to blow up a papal barracks. And just two weeks before Rome was taken by storm, a certain Paolo Muzi was hanged in Frosinone, the last citizen of the Papal States to be executed."[114] This hanging took place just 6 weeks after papal infallibility became a dogma. With great disappointment, the pope knew the power he derived from the threat of annihilation was rapidly coming to an end.

Professor Vaillancourt, cited in Chapter 6, states, "...it has become increasingly difficult to enforce unpopular decisions through coercion and exclusion. Consequently, the Vatican must now try to exercise its control over Catholics through normative and manipulative means (e.g., through socialization and co-optation) rather than through coercive and repressive power.... The declaration of papal infallibility...was an important milestone in that direction. The stress on the absolute authority of the pope in questions of faith and morals helped turn the Church into a unified and powerful bureaucratic organization, and paved the way for the establishment of the Papacy-laity relationship as we know it today."[115]

In his encyclical Quanta Cura (1864), Pius IX had listed eighty contemporary errors and condemned them. This is referred to as the Syllabus of Errors. In it he condemned many of the freedoms Americans hold dearest: freedoms of conscience, speech, the press, and religion. He rightfully recognized that American style democracy gravely threatened the Papacy. (If Americans are permitted to exercise these rights, American democracy may yet bring about the extinction of the Papacy.) The Syllabus was the definitive challenge to the modern state.116

With the Syllabus and numerous actions, the pope set the stage for his counterattack against the modern world and all that was threatening the Church. Now he needed the authority to carry out his wide-ranging plan.

Pius IX felt that he must acquire absolute authority over the entire Church if the Papacy was to survive. Even in the early days of his Papacy, he was untrusting of his bishops to hold the line against these threats, so he forbade the formation of national bishops' conferences and directed that there be as little contact as possible between bishops. They were to communicate with Rome. For this reason, Pius IX introduced the obligation of regular visits to the Holy See, a practice that still continues. Control was the

objective. All bishops had to administer their diocese in strict subordination to the pope under the threat of coercion.117

PIUS IX, THE MAN

To understand what really brought about proclamation of the dogmas of papal primacy and infallibility, we must take a close look at the man himself. Hans Küng describes Pius IX as follows: "Pius IX had a sense of divine mission which he carried to extremes; he engaged in double-dealing; he was mentally disturbed; and he misused his office."118

Hasler describes Pius IX in detail. In 1850, Pius IX branded freedom of the press and freedom of association as intrinsically evil. He determined that liberalism (out of which American democracy grew) was the mortal enemy of the Papacy and the Church. His rule was reactionary and dictatorial. His followers' practices bordered on papolatry. The most eminent bishops of the time viewed him as a great disaster for the Catholic Church.119 He struck "many people as dangerous above all because he wished to dogmatize a teaching which, from a historical standpoint, was worse than dubious and which overturned the Church's basic organization."120 In their eyes, these dogmas "would deprive the Catholic Church of the last shred of credibility."121 In the end, it looks as if this

assessment of these bishops is proving to be correct. (More on credibility later.)

According to Hasler, Pius IX had surrounded himself with mediocre, unbalanced, sometimes even psychologically disturbed people.122 His fury in private audiences would become so violent that older prelates might suffer heart attacks. He was described as having a heart of stone and at times normal feelings of affection, gratitude, and appreciation would be totally absent -- heartless indifference.123

Hasler describes a series of bizarre incidents: "In all these episodes Pius IX showed quite clearly how out of touch he was with reality.124 Many bishops had the impression that the pope was insincere, that he was striving to get infallibility approved by the use of trickery and cunning. In the presence of many witnesses, one bishop called him false and a liar.125

The historian Ferdinand Gregorovius noted in his diary, "The pope recently got the urge to try out his infallibility.... While out on a walk he called to a paralytic: `Get up and walk.' The poor devil gave it a try and collapsed, which put God's vicegerent very much out of sorts. The anecdote has already been mentioned in the newspapers. I really believe that he's insane." 126

Hasler states, "Some, even bishops, thought he was mad or talked about pathological symptoms. The Catholic Church historian Franz Xavar Kraus noted in his diary: `Apropos of Pius IX, Du Camp agrees with my view that ever since 1848 the pope has been both mentally ill and malicious.'"127

The most distinguished bishops viewed Pius IX as "the greatest danger facing the Church...." They felt powerless struggling with a pope who was possessed by his monomania and not accessible to rational arguments. "'Oh, this unfortunate pope,' wrote Felix Dupanloup in his diary. `How much evil he has done!...I mean, he has delivered the Church into the hands of these three or four Jesuit professors who now want to inflict their lessons on him!...This is one of the greatest dangers the Church has ever known.'"128

Hasler asked the question: Was the pope mentally competent during Vatican Council I? "Many of his personality traits suggest that this was not the case. The unhealthy mysticism, the childish tantrums, the shallow sensibility, the intermittent mental absences, the strangely inappropriate language...and the senile obstinacy all indicate the loss of a solid grip on reality. These features suggest paranoia."129

THE LEGACY OF PIUS IX

The leadership entrusted the future of the Church to this man. But as we continue to permit papal influence in public policymaking to spread worldwide, we are allowing Pius IX's legacy -- the legacy of an unbalanced man -- to determine the future of our planet even as we approach the end of the 20th century. In significant ways, our behavior today is being determined by the actions of Pius IX of 125 years ago.

Furthermore, the dogmas of infallibility and papal primacy ended any semblance of democracy in the church, and no self-correction can be expected, no matter how insane the Church policy on overpopulation has become.

THE DOGMAS' IMPORTANCE TO SOME CATHOLICS

Infallibility made Roman Catholicism even more attractive to many. People often seek religion because of their fear of uncertainty and the unknown in their lives and in death. It provides emotional relief. According to Hans Küng, "Infallibility performed the function of a metadogma, shielding and insuring all the other dogmas (and the innumerable doctrines and practices bound up in them). With infallibility -- and the infallible aura of the `ordinary,' day-to-day magisterium is often more important than the

relatively rare infallible definitions -- the faithful seemed to have been given a superhuman protection and security, which made them forget all fear of human uncertainty...In this sense the dogma of infallibility has undoubtedly integrated the lives of believers and unburdened their minds..."130 So now the Church offers a final, unsurpassable guarantee of security to believers. This is a powerful attraction to all who fear insecurity -- which includes most of us. Infallibility provided many believers with a great sense of religious security all through life, imparting stability and freedom from anxiety, relieving emotional pressure and softening the cruel blows of reality.131

On the other hand, the dogma of infallibility is binding on the conscience of the entire Catholic world. According to Hasler, "For the Roman Catholic Church, the dogmas defined by the Council are strictly obligatory. Anyone who doesn't accept them is threatened with excommunication, that is, with exclusion from the Catholic community."132

INFALLIBILITY'S IMPORTANCE TO THE POPE

The dogma of Papal infallibility was important to the pope and the Vatican in many ways. States Küng, "[It] most effectively furthered the unity, uniformity, and power of Roman Catholicism."133 Enhancement of the

power of the Church was an important motivating factor. Indeed all three of these outcomes were vital if the Papacy was to avoid extinction. He says, "What could be better for legitimizing, stabilizing, and immunizing this system against criticism than the dogma of the infallibility of its highest representative(s)?"134

The Church still derives enormous power from the claim of infallibility. "Paul VI laid aside his tiara" writes Hasler. "Both his successors, John Paul I and John Paul II, dispensed with the throne and crown. But the pope's claim to infallibility has remained, and hence so has their position of power. For power was the issue in 1870..."135 But, if the essential foundation of the Church laid by the dogma of infallibility is destroyed, faith collapses and the whole Church will crumble.136 For this reason, it is imperative to the Vatican that this dogma be protected.

Hasler describes in two paragraphs137 why infallibility was important to both the leadership and their followers. "...in the Middle Ages there was a conspicuous trend to look for an infallible authority, whether it be pope or council, to buttress the great edifice of the Catholic system. Its original religious power had been lost, and yet the entire social structure still rested on religion as much as ever. Behind the

perfectly intact facade doubts and uncertainty began to spread. Signs of disintegration became apparent in philosophy and theology. The old spontaneity and unquestioning naturalness of the faith were largely gone. The quest for infallibility looks like a desperate attempt to recover a lost sense of security.

"The endeavor to shore up doctrinal structures was unusually momentous because religion still played such a unique part in most people's lives. Their personal happiness depended on it, first of all in this world, and still more in the next. The great majority of the population had neither the skill nor the desire to judge questions of faith: They wanted to rely on authorized teachers. This only heightened the power and influence of the religious elite, which held the fate of so many in its hand. This arrangement thoroughly suited the mutual interest of both groups. Only those who could offer certainty in matters of salvation would be of any use to the people of that time. And so it didn't sound like blasphemy when men of the Church appeared, claiming they had been given all power in heaven as well as on earth (Boniface VIII)."

The promoters of the infallibility dogma believed that by raising the pope's authority to its upward limit they could gradually break society of its liberal and democratic tendencies.138 A bishop of that day

describes the advocates' position, "The great evil of our day is that the principle of authority lies prostrate. Let us strengthen it in the Church and we shall save society." Stated one supportive newspaper of the day: "The infallible pope must counteract and cure the prevailing abuses of unbridled freedom of the press, thanks to which journalists daily spread lies and calumny."[139]

THE POWERLESS PRESS

According to Hasler, "The plan was to enhance the pope's authority as much as possible, not only in hopes of strengthening the old hierarchical order within the Church but, above all, in society at large."[140] This objective was largely achieved, especially in the United States, as bishops and lay Catholics marched in lock-step until 1968 when the encyclical *Humanae Vitae* was issued. During the period 1870 to 1968, the American press was almost completely tamed.

The Knights of Columbus, the largest organization of Catholic laity in the world, was founded soon after the dogma of infallibility was adopted (1882) by a priest in New Haven, Connecticut. The mission: protect the faith. By 1914, the Knights had evolved into a national organization with considerable capability to intimidate those who spoke out against the Church regardless of whether the criticisms were justified.

They created the Commission on Religious Prejudices, chaired by Patrick Henry Callahan, to shut down the press criticism of the Church. According to their 1915 report, the Commission sponsored an education campaign by "informing and correcting editors and journalists who allowed religious prejudices to surface in their newspapers." Callahan pointed out that between August 1914 and January 1917, the number of publications which published material critical of the Church dropped nationwide from 60 to two or three.141

Until this time, the American press was free to be critical of the pope, the Vatican and the bishops, who are undeniably agents of a foreign-controlled power. But since the days of Callahan's Commission, the American press has not been free to report on the considerable political activities, and, most important, the motivations behind those activities. As a result, few Americans are aware of just how much their access to information is restricted by the Church. For example, recently, New York's *Newsday*, following an investigation, reported that at least 83 percent of the income of the New York City Archdiocese comes from local, state and federal taxes.142 Separation of Church and State? How did this come to pass? We will never know. But the pope's authority in both New York and Washington was vital. There was never any follow-up.

And this article never appeared in any other newspaper in the country or in the news on television or radio. Is this a state church or a church state? It seems like one or the other. Eighty-three percent of the budget surely makes this so. The American press is not free to discuss these matters.

Mainstream media never identify arson and bomb attacks against abortion clinics as domestic terrorism. Doing so would be greatly to the disadvantage of the bishops. Since 1982, according to the Bureau of Alcohol, Tobacco and Firearms, there have been 169 such attacks in 33 states on women's health centers where abortions were performed. On April 20, 1995, the *New York Times*, reporting on the Oklahoma City Federal Office Building bombing, ran a list headlined "Other Bombings in America," which spanned four decades and included some attacks that claimed no injuries or lives. But none of the 40 officially documented bombings that have targeted women's clinics in that period were mentioned. Why?

For the year before the Oklahoma City bombing, Planned Parenthood's Fred Clarkson had communicated their research findings on anti-abortion militants and extremist militias. Just after the bombing, when it became evident that this was an act of a domestic terrorist, Clarkson was invited by a major

cable network to appear in their broadcast. Just four hours before his scheduled appearance, the invitation was rescinded by the news producer. Clarkson told EXTRA!: "He said they couldn't have someone from Planned Parenthood on about militias, because they'd have angry pro-life viewers calling in and they didn't want to take that heat."142a

Another example is Oliver North's religious affiliation. The press has gone to great lengths to give the impression that Oliver North is a Protestant fundamentalist. Everyone I have ever asked "knew" that he is a Protestant. Most of his political support in Virginia is coming from southern Protestants and if he is elected to the Senate this year, it will be because of that support. But North is a devout Catholic. This fact was reported by both the Wall Street Journal143 and The Christian Science Monitor144 in 1986. Other newspapers and the electronic media have avoided this fact. North would lose many votes and support if this fact becomes widely known and many voters do want to know. But the press is not free to ask Mr. North how his conservative Catholic views might affect his voting behavior in the Senate, and this Fall's voters won't know. Infallibility did dramatically strengthen the pope's authority in the United States. The American press is very reluctant to resist his authority.

Chapters 13 and 14 are devoted to the documentation of this reality.

The free presses of Europe and North America were gravely undermining papal authority. The proponents of the doctrine of papal infallibility were convinced that this doctrine would lead to control of the world press on matters vital to papal authority. The control of individuals in the press, as well as individuals who could be used to manipulate the press in various ways, including intimidation, in order to protect papal authority, was a key argument for adoption. The proponents were correct on this account as we shall see in Chapters 13 and 14.

The dogma of infallibility is important because it shields the entire doctrinal structure of the Catholic Church from criticism. According to Hasler, "This claim extends not to one doctrinal statement but to all of them; it covers every single one. Papal infallibility -- the formal principle, as it were, of Catholicism -- becomes the crowning conclusion of the system. The insurance policy is flawless: There can be no appeal from the pope to any other authority....Presupposing the fundamental principle of infallibility, the Church's entire operation can run smoothly."[145]

Absolute control of the entire Church structure by a despotic pope was made much easier by this dogma.

The majority rule on questions of dogma that had existed for nearly 2000 years ended the day infallibility officially became dogma.146

A NEW IMAGE FOR THE POPE

Papal infallibility and universal jurisdiction resulted in a new image for the pope -- which was quite intentional. He became God's representative on earth. Pius IX also became an idol and papolatry came so much into vogue that even many of his supporters were embarrassed.147 He was now referred to as "exalted king," "most beloved of kings," "supreme ruler of the world," king of kings," and "vice-God of humanity."148 This of course was the desired outcome. One journal wrote, "When the pope meditates, it is God who thinks in him." St. John Bosco referred to the pope as "God on earth" and asserted: "Jesus has put the pope on the same level as God."149

The school of thought that worked so diligently to achieve a favorable vote of the bishops at Vatican Council I was referred to as the Infallibilists. It was their view that "the Church, as a community incapable of erring in matters of faith, had to have an infallible leader and judge. Otherwise it would not be safe from error, it would lack both unity and order, and it would be vulnerable to fragmentation, as could be seen so clearly in Protestantism."150 And they had a second

line of thinking similarly based on papal primacy. "Since the pope had a universal jurisdiction and therefore the supreme teaching authority, he had to be infallible. Otherwise he might lead all the faithful into error, carrying the entire Church with him into the abyss, since all Catholics were obliged to obey him on questions of faith."151

The Jesuits were the chief manipulators in the campaign for papal infallibility.152-[155] Apparently, the Jesuits felt that their never ending political agenda would be best served if the pope became an infallible despot. The Jesuits were chosen to write the official history of Vatican Council I some 20 years later.156-[157]

More than anything else, even the manipulation of the bishops by the Jesuits, it was the fear of schism, that was considered a worse misfortune than infallibility, that kept the bishops in line.158 A schism did occur but unfortunately for America and the rest of humanity it was small, resulting in the creation of what is known today as the Old Catholic Church.159

THE DISSENTERS' PREDICTIONS COME TRUE

Negative reactions to the two new dogmas was extensive -- and most telling. The impact of these two dogmas in 1994 on virtually everyone on this planet,

Catholic and non-Catholic, is enormous and will be discussed later. These reactions at the time are important to us today and should be examined. The apocalyptic predictions of the dissenters are now coming true.

Hasler notes that even at the Vatican Council some individuals perceived this claim of infallibility -- this claim to total truth -- would ultimately be self-destructive: "The Papacy, they thought, had gone down a blind alley from whence there could be no escape without a critical loss of authority. `The results of the Vatican decree of 1870 are only now beginning to come to light,' the Catholic Church historian Franz Xaver Kraus noted in his diary on February 9, 1900. `Rome has locked the door leading to its only way out. There seems to be nothing left but for the whole papal system to break down.'"160

The Swiss theologian Hans Urs von Baltha called the Vatican dogma a "gigantic disaster."161 One bishop described the pope as "an authority subject to no other control than his own whims and preferences. The new dogma, he felt, must lead to despotism." 162 Wrote Henri Icard, a priest, "This is truly a difficult situation for the Church. The most absolute power -- in the hands of a man who will only listen to the people who think -- or, rather, speak -- the way he does."163 The

French bishops, in a minority petition, wrote, "The new dogma, which must lead to such grave consequences, is demanded of a Council which is both deeply divided and not free."164 Different bishops referred to the new dogmas in the following way: "the Vatican farce," "the pope is devouring us," "we have to eat what we have vomited up," "a crime against the Church and humanity."165 Says Hasler, "For them [the Council minority], the credibility of the Church was on the line."166 Professor Friedrich Michelis described Pius IX as a "heretic and devastator of the Church." Neither his cardinal nor his bishop contradicted him.167

An English bishop wrote, "The bishop of St. Gall was so violent in his speech against infallibility that through the very force of his enunciation he lost a false tooth. He had to pick it up from the ground and put it back into place before he could go on."168 One archbishop "viewed the fetishist adoration of the Church's hierarchy (and especially of the pope) as the chief error of Catholicism....It had, he said, transformed the office of the supreme shepherd into a despotic sultanate of Mohammed and Christ's sheepfold into a herd of slaves."169

In German-speaking countries alone, twenty professors of theology and clerical teachers of

philosophy were excommunicated within a short time after the Council. Two-thirds of all Catholic historians teaching at German universities left the Church." 170

But there is no turning back. Says Icard, "To affirm that the Council lacked the freedom necessary to validate its ordinances is impossible....Under no circumstances would God abandon his Church in such a way that we should one day be justified in going back and questioning what the great majority of the bishops, together with the pope, decided on matters of faith!...Can we run the risk of such a scandal? And what would then become of the Holy Church?"171

Objections to the adoption of the dogmas of papal primacy and infallibility were extensive, thoughtful and loud but to no avail. We can be certain that the Church, as an institution, will become extinct before these two dogmas are terminated.

CONSEQUENCES FOR CATHOLICISM AND HUMANITY

These two dogmas produced vast consequences for both the institution and for virtually all of us who now inhabit this planet. Had these two dogmas not been proclaimed, life on this earth would be both far less threatened and less threatening. There is much

evidence that rational responses to these threats would have begun occurring decades ago.

In a couple of paragraphs, Hasler provides an overview of these consequences: "The Church not only missed its chance for a rapprochement with scientific scholarship... [it became] an obstacle to cultural evolution and an enemy of the unprejudiced search for truth. It is hard to deny the justice of such complaints -- the way the dogma came to be defined would be proof enough.... The dogma of infallibility was not just one more doctrine among many others. It took a comprehensive position on the issue of truth. It involved a very broad claim, namely, that the pope could pronounce on questions of faith and morals with guaranteed certainty. The truth was no longer to be brought to light by laborious research and investigation but by the determination of an infallible authority."172

"The Church does indeed gain, at first, in unity and uniformity, but it blocks off its own free access to the real world and ultimately stands in danger of losing touch with reality completely.... On the one hand, Catholicism gains in...political muscle; on the other, its conflict with science grows more intense. Its dogmatic commitments make it harder for the Church to adapt to circumstances; they lessen its flexibility and the

chances for reform. The Church loses its credibility with many people and draws in on itself. This increases the danger of its stiffening into a sect and forfeiting its potential for social renewal. The machine may still remain intact, and the power structure may continue to stand firm, but the life has gone out of it."173 Hasler has described the Church as we find it in 1996.

The Church did gain in unity and uniformity. At least this applies to all those people who really matter: those who blindly support the pope, either because of faith or opportunity, including all cardinals and bishops, most priests and a relatively small fraction of the laymen. The Papacy has acquired enormous political muscle as a result of these two dogmas. The political muscle that was needed to halt NSSM 200 in its tracks and bury it for almost two decades is truly impressive. In the April 25, 1993, issue of The Independent On Sunday published in London, Mark Hertsgaard states, "The Vatican has managed to derail every international effort to curb the population explosion," despite the fact that we are overwhelmed with evidence that the population explosion gravely threatens almost everything we value. This accomplishment has required enormous political muscle.

Indeed, the machine remains intact and the power structure continues to stand firm in significant part because of the influence through Catholics within the U.S. government and its ability to use the U.S. government as an instrument to impose papal policy on the UN system and other international organizations and on many national governments either through rewards, punishment or threat of force. The fact that the Church has been permitted to accumulate enormous wealth has also been vital to keeping its machine and power structure intact. In the 1980s, the Chicago Sun newspaper, following an investigation, estimated the net worth of the Church in the U.S. at more than $200 billion. Its worth worldwide has been estimated at $2 trillion.

Science and the Vatican are enemies. The Church ignores the findings of science when their acknowledgment threatens to undermine papal authority. The best examples are the innumerable findings of science which show that overpopulation is causing often permanent degradation of our planet and reducing the number of people Earth can support on a sustainable basis. The Church sets about deliberately undermining the credibility of science in its desperate attempt at institutional survival. As a result of the Vatican's efforts to survive the onslaught of these findings, we are all continuously bombarded

with disinformation which seeks to throw these findings into question. But science continues, on nearly a daily basis, to produce alarming evidence that the Church's position on family planning and contraception is indefensible.

Each day the physical potential for human life support is diminished by abuse of our planet, and much of this loss is probably permanent. As a result, every day the number of people that Earth ultimately will be able to support on a sustainable basis grows smaller. This fact alone makes the bishops' claims of "concern for human life" and defense of "right-to-life" absurd. Their policies are destroying the earth's physical ability to provide for human needs.

The charge by Hasler that these dogmas have stifled intellectual development by Roman Catholics is supported by two prominent Catholics in the United States. On November 11, 1988, Jesuit theologian Father Avery Dulles spoke to the Washington Chapter of the Catholic League for Religious and Civil Rights. Says Dulles (son of John Foster Dulles), himself widely regarded as a leading light in U.S. Catholic intellectual life for more than three decades, "In spite of our many Catholic schools, colleges and universities we have as yet very few eminent Catholic intellectuals on the national scene....Catholics, whether clerical or lay, are

not prominent in science, literature, the fine arts, or even, I think, in the performing arts and communications."[174]

Dulles reopened a theme first argued in depth in the mid-1950s by Church historian Msgr. John Tracy Ellis: "That U.S. Catholics have failed to achieve a leadership stature in U.S. intellectual and public life commensurate with their numbers, wealth and organizational strength." Ellis said he "would basically agree" with Dulles's analysis of the current situation and that the influence of Catholic leaders has increased substantially in the business and political worlds since the 1950s. But in the field of culture and intellectual life, "I fail to find for the last 35-40 years any widespread love of learning for learning's sake in Catholic circles. I say this with great regret." He went on to say "there is a decided emphasis in Catholic circles on money...[with the result that]...the United States is now teeming with Catholic millionaires."[175]

It is reasonable to assume that the Catholic educational system is devoted to the advancement of the papal agenda in America through the growth of influence in the political system. Advancement in science (which frequently threatens Catholicism) and encouragement of the "love of learning for learning sake" (which also threatens it) are not part of the papal agenda in

America. Given the observations of Father Dulles and Msgr. Ellis, it is apparent that the priorities of Catholic schools reflect the papal agenda.

Hasler observed, "...the life has gone out of it."176 By this he means that the Church no longer has a conscience. Referring to the Church's teaching on contraception, *Humanae Vitae*, Küng states, "This teaching...has laid a heavy burden on the conscience of innumerable people, even in industrially developed countries with declining birthrates. But for the people in many underdeveloped countries, especially in Latin America, it constitutes a source of incalculable harm, a crime in which the Church has implicated itself."177 The widespread premature death and suffering that the Church has wreaked upon developing world women because of their position on birth control has been a clear indication to millions that the Vatican does not really give a damn about "the little people." Institutional survival, political muscle, and authority dominate the attention of the Church leadership -- not "the little people" they claim to protect, many of whom reached this conclusion on their own. For them, the hypocrisy has been too much to stomach and they have left the Church by the tens of millions. The Church's position cannot be reasonably defended.

The evidence supporting Hasler's assessment that these dogmas are resulting in a loss of credibility is overwhelming. The number of young men entering American seminaries has dropped 35 percent since 1977.177 In 1966, there were 42,767 seminarians. Today, while the Catholic population has increased by more than 50 percent, they number only slightly more than 6,000 in the U.S.177a During the 1993-1994 school year there were 6,244 candidates for the priesthood; this year there are 6,030, a drop of 3.4%. For those closest to Ordination, the number of candidates for the priesthood fell over the past year from 2,915 to 2,817.177b No end is in sight. Only three percent of American nuns are under age 40 and 37 percent are over age 70.178 The average age of priests here is 65 years. There are now 20,000 ex-priests -- one-half of all U.S. priests quit the priesthood before reaching retirement age,179 and they represent the best and brightest. Membership in Catholic orders has fallen 40 percent since 1962, while the nation's Catholic population grew by 36 percent.180 The Vatican now regards North America as a missionary region. Younger priests from Eastern Europe, Africa, Asia and Latin America are being brought in to protect papal interests because American men are shunning the priesthood.181

The number of Catholic grade and high schools is down by 30 percent since 1960.182 This does not bode well for the future of the Church because Catholic schools provide over 90 percent of bishops, 90 percent of sisters and over 85 percent of priests.183 The number of Catholic general hospitals is down 22 percent in the same period.184 Only 28 percent of Catholics attend mass on a typical Sunday while 30 years ago mass attendance was more than 70 percent.185 Catholics contribute only 1.1 percent of their income to the Church while Protestants contribute 2.2 percent; 20 years ago they gave about the same.

In Latin America, Protestant churches are growing swiftly, with as many as 20 percent of Catholics abandoning their church to become members. Latin America represents 48 percent of all Catholics in the world, but it provides only one percent of the missionaries.186 While Bolivia has been occupied by the Catholic Church for 500 years, yet only five percent of its priests are natives. In Europe, the credibility of the Catholic Church is plummeting. Italy has the lowest birth rate in Europe. Less than 25 percent of the vote is now controlled by the Vatican, compared to a substantial majority in the decades after World War II, and state funded abortions are available to all who want them. In France, only one percent of the

population attends mass regularly. In the summer of 1995, a petition calling for drastic changes in the Church collected half a million signatures in Austria, about half of their Catholic churchgoers.186a In November 1995, millions of Catholics across Europe -- in Germany, Poland and Ireland -- sent powerful messages to the Vatican demonstrating that they were prepared not merely to ignore the Church's teachings, but to defy them openly. Poland elected an ex-Communist whom Church leaders called a "neo-pagan." Ireland legalized divorce. In Germany 1.5 million out of five million practicing Catholics signed a petition modeled after the Austrian one.186b

Just as predicted in 1870 by the dissenting bishops, the credibility of the Church has been greatly diminished. These statistics are compelling evidence. Likewise, the predicted loss of touch with reality has also come true.

LOSING TOUCH WITH REALITY

Perhaps the most important outcome described by Hasler, the most dangerous outcome, is that the Church has lost touch with reality. There is much evidence of this but none more convincing than Pope Pius XII's proclamation on November 1, 1950 of the new dogma that Mary was assumed into heaven body and soul. In this dogma, the pope declared that "the immaculate Mother of God and ever Virgin Mary was

at the end of her life assumed into heaven body and soul." This dogma is based entirely on mythology. The myth was never mentioned in the first five centuries of the Church's existence.

The myth of Mary first appeared in the sixth century in a text. The myth was loaded with grotesque accounts of miracles. According to Hasler, the story goes something like this: "Mary lives in Bethlehem. The archangel Gabriel makes known to her that her end is nigh. At her request all the apostles are brought from all the different countries of the world on a wondrous journey through the clouds to Bethlehem. Numerous miraculous cures take place at Mary's sickbed. Since danger threatens from the Jews, the Holy Spirit carries Mary and the apostles off on a cloud to Jerusalem..."[187] The story goes on and on.

There were no other historical sources for Mary's Assumption. There was no serious opposition to this infallible proclamation by Pope Pius XII. The story is quite simply preposterous. It is frightening to think that such a thing could happen in 1950. Consider the fact that the entire leadership of the Church in 1950 went along with such nonsense. It is more frightening to recognize that these men, the leadership of the Church in 1996, are making critical decisions that affect all of humanity. It is shocking to be faced with the fact

that this leadership was permitted to impose a policy which undermined U.S. political will to deal with the mounting overpopulation threat to U.S. and global security.

After reading the complete 6th century myth which was accepted by the entire leadership of the Church as truth (in my lifetime), I better understand how the Church can continue to ignore the growing mountain of evidence that the planet and humanity are gravely threatened by overpopulation. Bishops in 1870 saw this coming and voiced their concerns. In the last section I quoted Hasler, "...but [the Church] blocks off its own free access to the real world and ultimately stands in danger of losing touch with reality completely."188 Indeed, it has.

DESPOTIC AUTHORITY

Just as predicted in 1870, these two new dogmas created a system of concentrated despotic authority. The implications for scientific findings and scientific advancement became evident almost immediately. In his 1903 book, *The Church and the Future*, leading English theologian George Tyrell explored the relationship between science and the Church's magisterium or teaching authority. Do science and its representatives enjoy autonomy even within the Church or must they remain forever subordinate to the

magisterium? What should be done in case of conflict? Who and what decides when science has come up with unequivocal results which contradict the doctrine or decisions of the Church?189 These are vital concerns for everyone who seeks a humane solution to the overpopulation problem. Science does have unequivocal results on this question. Who decides? The pope does and he has. He possesses despotic authority and today he is permitted to exercise it.

Catholic insiders are well aware of the despotism of the Papacy, and that the practice of it brings rewards. In 1954, Pius XII canonized Pius X, who had authorized an elaborate system of spies and informers "to ward off modernist errors."190 His covert methods, including espionage, were discussed at his canonization proceedings. According to Hasler, the prevailing attitude was: "Since the faith of the Church was threatened, all such means seemed justified."191

Americans are frequently reminded that the pope's authority is despotic. Wrote Ignaz von Dollinger on March 1, 1887, to the archbishop of Munich, "The new dogmas have come into being thanks to force and coercion. They will also have to be maintained by the constant use of force and coercion."192 Since the encyclical *Humanae Vitae*, the press with regularity has exposed Americans to acts of repression by the Vatican

as it has silenced all of its dissenters, the mark of a successful despot.

INFALLIBILITY COLLIDES WITH CONTRACEPTION

Apparently until the reign of Pope John XXIII, the dogma of infallibility went unchallenged. It appears that John XXIII had plans for this dogma. As noted earlier, even the selection of his name John was suggestive in that Pope John XXII, who had ruled in the early Fourteenth Century, had condemned the concept of infallibility as the work of the Devil. When John XXIII created his Commission on Population and Birth, it was a signal to the world that the Church *could* change its position on birth control. But this would have to be at the expense of the principle of infallibility.

To review the sequence of events discussed in Chapter 6. Pope Paul VI inherited the Commission from Pope John. The Commission consisted of 2 parts -- 64 laymen in one group and 15 cardinals and bishops in the other. The laymen voted 60 to four and the clerics 9 to 6 to change the Church's position on birth control even though they recognized that this change would diminish papal authority. This vote was leaked to the press, so the whole world knew the outcome of the vote. However, Paul VI rejected the majority position,

and accepted the minority view which insisted that to make this change regarding contraception would destroy the fundamental principle of infallibility and with it, the Church itself. Paul VI then issued his encyclical, *Humanae Vitae* (1968), in which the pope condemned practically every form of birth control as morally reprehensible. According to Hasler, "After the promulgation of the encyclical...the Church conducted a massive purge of its key personnel wherever it could."[193]

Thus, contraception represents the first serious threat to the principle of infallibility to emerge. It also represents a great crisis of authority. Though the Vatican would like to think this issue has already been decided, the vast majority of Catholics (and non-Catholics) reject the teaching of *Humanae Vitae*. In 1968 Dutch Bishop Franceos Simons had argued that faith in infallibility was theologically dubious, raising the issue for the first time in decades. Soon after, papal infallibility was questioned by Küng in *Infallible? An Inquiry*.[194] As a result, Küng fell victim to papal repression and was silenced as a Catholic theologian.

Contraception is bringing about an implosion in papal authority. Contraception has resulted in the greatest crisis in the Church since the loss of the Papal States during the time of Vatican Council I in 1870. Very few

people are aware of the real motivation for *Humanae Vitae*. But they do recognize that the behavior demanded by this encyclical is not in their best interests -- behavior that in the long run will be suicidal for humanity. Contraception has initiated a collapse of the institution from within.

CHANGING THE AMERICAN VIEW OF THE BISHOPS

But more important to us as Americans, this despotic authority exercised by the pope has serious implications for the way in which we should view bishops who serve in America. As mentioned earlier, Küng acknowledged that the dogma of infallibility reduced all bishops to mere lackeys of the pope. Since American security-survival interests, as explored in NSSM 200, and the security-survival interests of the Papacy, as defined by Pope Paul VI and Pope John Paul II, are squarely in conflict, the American bishops cannot possibly represent the interests of both. It is evident they have chosen, without exception, to protect the security interests of the Papacy at the expense of the security interests of the United States. This is not a satisfactory exercise of American citizenship. More accurately, the bishops' behavior is outrageous and unacceptable. Indeed, it is impossible to imagine how a Catholic bishop could successfully

argue that he should be permitted to retain his American citizenship.

This is a dangerous predicament. Andrew M. Greeley is a Roman Catholic priest, best-selling novelist and sociologist at the University of Chicago's National Opinion Research Center. He recently assessed the Vatican's hierarchy appointments in America for the Religion News Service as reported in the *National Catholic Reporter*: "With unrelenting consistency in recent years, the Vatican has appointed to the American hierarchy men who are mean-spirited careerists -- inept, incompetent, insensitive bureaucrats who are utterly indifferent to their clergy and laity. In all its 200-year history, the American hierarchy has never been in worse shape. This same policy has been implemented all over the Catholic world in the name of restoring to the church the loyalty of the clergy and people."194a

Americans can learn an important lesson from Argentina, a lesson described for the world on March 4, 1995 by a retired Argentinian naval captain, Adolfo Scilingo. During the 1976-1983 "dirty war," which was an uprising against the country's right-wing government and the Catholic Church, an estimated 4,000 dissidents were killed and 10,000 disappeared. Capt. Scilingo reported to an investigating tribunal

that between 1,500 and 2,000 dissidents were thrown alive, one at a time, from airplanes at high altitudes into the ocean during 1976 and 1977 on orders from the military high command. He described in chilling testimony how he and another officer helped detainees -- many weak from torture -- to board the planes. Scilingo revealed that Catholic chaplains comforted military commanders after they flung political dissidents into the ocean from airplanes and that Catholic Church officials provided moral justification for the torture and murder of dissidents during the conflict.194b

Hebe de Bonafini, director of the Mothers of the Plaza de Mayo, a human rights group, said the church has much to repent of: "The Church has a great responsibility in everything that happened, because the Church knew that the military chaplains were paid salaries by investigating judges to participate and act in the jails extracting confessions from the prisoners." Church officials have repeatedly denied any involvement in the "dirty war." However, in April 1995, five bishops issued a statement of regret for their roles in the war.194b

The same Vatican officials who chose these Argentinian bishops have selected nearly all the bishops serving in the U.S. today -- using the very

same criteria. Father Greeley's description of the men thus appointed is most revealing. Security-survival of the institution of the Papacy is the most prized ethical value of the men in power (as has been the case for a least a millennium) and all bishops are selected because they rank this ethical value above all others. The Argentine bishops were responding to the threat posed by these dissidents to the security-survival interests of the Vatican.

Throwing young people alive out of airplanes, one by one, over the ocean was justified because this served to protect the interests of the Holy See.

Frances Kissling, president of Catholics for a Free Choice, has followed Cardinal John O'Connor's career for more than two decades: "This is a man who longs for the imperial papacy -- a papacy where you had the power to burn people at the stake. When it comes to matters of internal church discipline, he is the toughest, and the meanest."194c The New York Times reports, "As the Archbishop of the media and cultural center of the United States, Cardinal O'Connor has extraordinary power among Catholic prelates. He travels to Rome and has lunch with the pope on Church business about once a month, and is widely acknowledged to have a great deal of say in the appointment of American bishops."194c

Are the bishops in the United States really different from their colleagues in Argentina? Given the descriptions of these men offered by Greeley and Kissling, we wonder. If this could happen in Argentina within the last 20 years, is it not possible in the U.S. today? Are American bishops not responding to dissidents in this cruel manner only because they have not yet acquired sufficient power? They have not ventured to criticize the behavior of their Argentinian counterparts because the Vatican has not instructed them to do so. There can be no doubt that the Argentinian bishops look to Rome for guidance. But after all is said and done, there was no outcry -- no condemnation -- from the Vatican when their role became public.

A more recent example comes from Rwanda which is predominantly Catholic. Human rights groups have charged that Catholic priests actively encouraged the murderers of more than 500,000 Tutsis in the 1994 warfare.194d According to a report issued by the London based Africa Rights seeking the rewards of an intimate relationship with the majority Hutu government, the bishops chose to remain silent.194e

KÜNG RECAPS WHERE THINGS STAND NOW

The Church is on an inevitable course of self-destruction as some bishops, theologians and

historians predicted in 1870, at the time of the invention of papal infallibility. The Church has reached a dead end, as they predicted, and there is no way out. For 25 years, such a way has been sought. Millions of intelligent sincere Catholics have tried to identify a way out of a position that nearly everyone agrees has become indefensible. No one has succeeded. The Papacy as it exists today is coming to an end.

Küng summarizes where things stand: "There is no dodging the fact that in the Catholic world church history, exegesis, dogmatics, moral theology, and catechesis have all had to pay a high price...for this infallibility, which allowed for no genuine corrections and revisions....It brought on a continual conflict with history and the modern world which profoundly shook the credibility of the Catholic Church; a continual defensiveness towards new information and experiences, towards all scientific criticism, towards all possible enemies, real or imagined. And it created a gap between the Church and modern science.... Enormous sacrifices were also indirectly demanded of the `little people' -- in the interests of authority, continuity, and doctrinal infallibility. The ban on contraception is only a particularly striking example of all the burdens placed on the individual conscience by the teaching presented as de facto infallible in

catechisms, confessionals, religious instruction, and sermons. The exodus of countless intellectuals, the inner alienation of many believers, the lack of creative people and initiatives in the Church...the psychic disturbances, the loss of touch with reality, the mighty religious machine whose operations very often conceal the absence of inner life...Was all that necessary?"195

Küng is describing an institution in an advanced stage of self-destruction. Can this self-destruction be postponed, and if so, how, and for how long? This will be the subject of the next chapter. No doubt, the leadership of the Church will do everything possible to survive. The Church has enormous resources, energy, organization, direction, and commitment. Paranoia has already set in. We can expect an ugly defense that will know no bounds until the very end. "This is God's institution and it must be saved at all costs," will be the battle cry in their holy war to insure institutional survival. Should we hasten the self-destruction and how?"

If you can help, contact your member of Congress, or Vice President Kamala Harris, or Speaker of the House Nancy Pelosi and ask them to ask President Joe Biden:

1) to make all birth control free for every person in America for their lifetimes, and

2) to have the FDA approve the Lippes Loop and QS for immediate use, and

3) to promote ***A simple idea*** to make women's lives better and to help women to become equal to men faster.

If any of this hits a chord with you, click here to contact your member of Congress or call or email the best advocates for you (women leaders who work for you):

Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111
kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

Grassroot efforts from concerned, protesting, voting citizens are what changes politicians minds when their re-election campaigns are funded by business (big Pharma) or religious groups (the Vatican by way of the U.S. Catholic

bishops) who historically may not have the best interests of women at heart.

Families could save money, live happier and safer lives by convincing their politicians to provide free contraceptives to them for life, asking the FDA to approve the Lippes Loop and QS, and by following ***A simple idea***. Please take our survey.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 19 Needed: Scientific Endorsement of QS by Brave and Independent - Nature Loving Folks?

(Credit: Dreamstime.com)

15 April 2016

BRUCE SUNDQUIST REMEMBERED by Peter Wray, Allegheny Group, Sierra Club

"Bruce Sundquist: Scientist, Outings Leader, Publisher, and Conservationist, 1936 - 2016

In the early morning of April 15, 2016 Bruce Sundquist died quietly in his bed at the age of 79, a fitting end for a modest and peaceful man.

Immediately after obtaining his Ph.D. from Illinois Inst. of Technology in 1960 Bruce Sundquist accepted a job at U.S. Steel's research laboratory in Monroeville, PA. The young man from Minnesota soon enjoyed hiking in the Appalachian Mountains and when he joined the West Virginia Highlands Conservancy he began a long career of voluntary conservationism. When the Allegheny Group of the Sierra Club was formed in 1970 Bruce was one of its first members, becoming a regular outings leader and eventually chair of the Outings Committee. In the late 70s he joined Sam Hays and Dick Pratt as they explored areas on Allegheny National Forest for potential inclusion in the National Wilderness Preservation System, leading to designation of the Hickory Creek Wilderness Area in 1984. In West Virginia he was a regular visitor to the Dolly Sods area, working towards designation of that unique spot as a federal wilderness area in 1975.

To help the public enjoy and protect the natural areas around Pittsburgh, Bruce began the production of guides, first with the American Youth Hostels of Pittsburgh, and then with the Allegheny Group and the Keystone Trails Association. He organized volunteers to scout and map the trail systems in various areas and over a period of thirty

years he authored or co-authored a series of guides. He started in 1974 with "Allegheny National Forest Hiking Guide", followed by "Hiker's Guide to Laurel Highlands Trail", "Monongahela National Forest Hiking Guide", "Ski-Touring in Western Pennsylvania", "Hiking Guide to Western Pennsylvania", "Canoeing Guide to Western Pennsylvania", and "Laurel Highlands Hiking Guide (sixth edition Part 2, 2004).

Initially Bruce printed the guides using a mimeographing machine in his basement. And that same machine he used to print the early editions of the Allegheny Group's newsletter. His home was a combination office and storehouse.

Bruce was a year-round outdoorsman. For many years he led the annual January cross-country skiing trip to West Virginia, and he introduced to Sierra Club members the joy of tube floating on the Youghiogheny.

When he retired from Westinghouse's Blairsville lab in 1991 Bruce was able to devote more of his scientific training to the topic that had attracted his interested in the mid-eighties - the Earth's carrying capacity. The scope of this interest is reflected in the list of his writings at the Website he created at http://www.bsundquist.civilizationsfuture.com. Not only did he cover the topics of the degradation of soils and crop lands, forests, gaming lands and fisheries, but he did

research on globalization and Third World issues. Population growth was a major concern, and as recently as 2008 he wrote a paper titled "Could Family Planning Cure Terrorism".

In addition to a long tenure as chair of the Allegheny Group's Outings program, Bruce was for some years chair of the Conservation Committee and in 1995 and 1996 he was Group Chair.

It is not often that a person like Bruce Sundquist comes along, but when they do, the world is better for it."

I never had the pleasure of meeting Bruce, but I grew up in western PA in Greensburg, hiked the Allegheny trail, rock climbed, and my father took me to shoot the Yough when I was 11. Bruce's perspective on the world and the salient things he said about QS are here. The most poignant below:

> "What is crucial here is to ask what criteria ought to define any standard of safety for a medical procedure or drug. Consider the following example. In some regions of Southeast Asia the probability of dying as a result of an abortion is about one in two. Yet women still seek out abortions in a desperate attempt to avoid worsening the already extreme wretchedness born of earning a dollar or two per day and feeding an already unaffordable number of children. A tubal

ligation surgery is likely unavailable, and unaffordable if it were available. Failure to get a QS means another one or two abortions at least, and hence a chance of dying during an abortion of well over 50%.

All those tens of thousands of follow-ups done on past QS recipients possibly were not done with all the scientific rigor required of FDA Phase III clinical studies. So when these earlier studies report no risks of cancer and other deadly ailments as a result of a QS, a risk as high as perhaps 10% of some deadly ailment might have slipped through the cracks. Had a Phase III clinical study been done, the uncertainty of the conclusions would be far smaller. The question for the developing world woman faced with a one-out-of-two chance of dying during an abortion is not whether a Phase III study on QS has been done, but whether the risks of a QS procedure exceed the risks of another abortion or two. We already know the answer to that question, so what possible sense is there in Southeast Asian country demanding a FDA Phase III clinical study before it legalizes QS procedures?

In the developed world, the risks associated with an abortion or two is one in several thousand, so it is perfectly reasonable then to demand an FDA

Phase III clinical study of QS, since that is the only way of making sure that the risks associated with a QS procedure are less that the risks of the various alternatives to a QS. So the answer to the question raised above as to what criteria ought to define any standard of safety for a medical procedure or drug is simply a question of balancing risks. The risks inherent in the alternatives to a QS procedure in the developing world are far higher than in the developed world. Hence an FDA Phase I or II clinical study of QS is all that can be logically justified for the developing world, while an FDA Phase III clinical study is needed to do the risk-balancing in the developed world. All this has nothing to do with callously setting two different standards. The difference in risks inherent in alternatives to QS are much different in the two worlds, and this alone is all that is needed to decide on the appropriate and justifiable level of clinical study to be required. The tragedy is that holding off approval of QS until Phase III has been completed (a delay of a decade or more) achieves nothing but a huge increase in maternal deaths, a huge increase in motherless children, and a huge increase in abortion rates among the poorest, and most powerless, of developing world women."

QS pioneers are forever grateful to the thousands of doctors and health professionals who recognize and have proven the safety and efficacy of the QS pellet method and have supported QS.

To bring QS to the world, ideally it should be approved by the FDA and used by American women. If a country or U.S. state is interested in conducting a clinical trial, ignoring WHO/FDA "guidance" as being politically biased, please contact me at donj@quinacrine.org and we will help you to conduct a clinical trial. If you have advice that would help women to gain access to QS, please send it. Please take our survey.

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Chapter 20 What's Next and What Can You Do?

Women's March in Washington on January 21, 2017 (Credit: Wikipedia)

8 March 2022

Huge progress has been made for women and families in the last 70 years with the allowance and use of contraception. Soon, the U.S. Supreme Court may overturn Roe v. Wade putting 49 years of nationwide legal abortion at risk of being taken away or severely limited by many states. Whereas abortion is the last battlefield for women's reproductive rights, good free contraception for women should be the tip of the spear for an offensive attack for the good of women. Why isn't this happening?

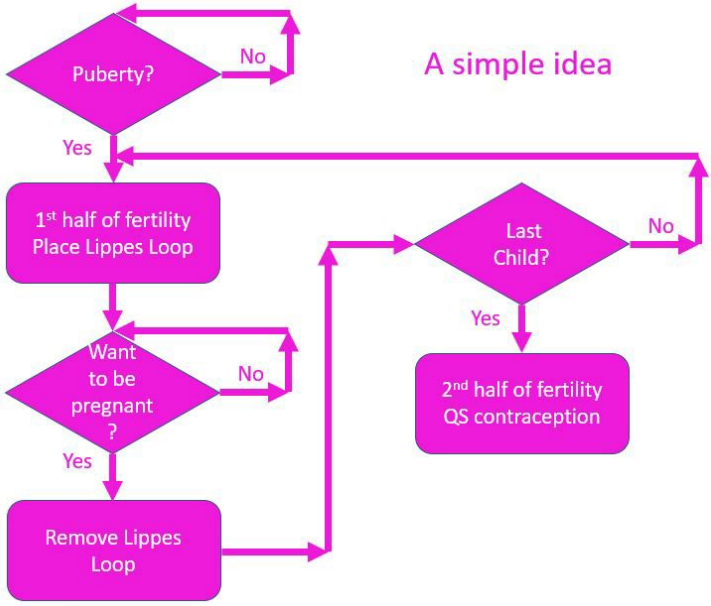
I hesitate to use the words *War on Choice* as brave American Gloria Feldt, past president of Planned Parenthood did, but women really do need our help to gain equality.

When Roe falls, or even if it doesn't, we humbly request President Biden to direct his HHS Secretary to declare the following Public Health Emergency:

As a result of the continued consequences of the lack of national freely available contraceptives (and abortion) including the education in their use, over 2.8 million unintended pregnancies and more than half a million abortions, both medically preventable conditions, occur annually, affecting our nation, particularly those most vulnerable women and families in weaker economic positions (before SARS-COV-2), on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby declare that a public health emergency exists nationwide as a result of the consequences of the shortfall in free deployment and education of and about contraceptives (and abortion) creating a severe crisis and undue financial and emotional hardship for women and their families.

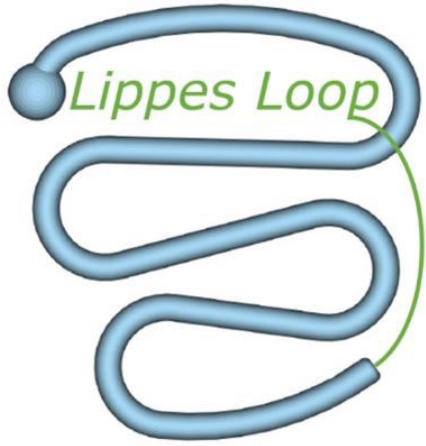
We hope you can persuade politicians to make contraceptives freely available. Jack Lippes, the MD who invented the first commercially successful

intrauterine device (IUD) called the Lippes Loop in 1962, and we suggest that medical and economic experts in the U.S. adopt this ***A simple idea*** flowchart as the ideal recommendation for all women who are of childbearing age (15 – 49 years) and beyond.



Unfortunately, neither method in this flowchart is FDA approved. So that is where we need your help.

1) Please hit the link below and take our survey to Bring back the



2) And call your member of Congress and demand they adopt ***A simple idea*** including asking the FDA to approve the Lippes Loop and QS or authorize a QS Phase III clinical trial today. Please take our survey.

No other action you can take will more effectively bring equality to women in the U.S. Once the rest of the world sees what U.S. women have, then they will want it too.

If any of this hits a chord with you, call or email the best advocates for you (women leaders who work for you):

Vice President Kamala Harris
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500
(202) 456-1111

kamala.harris@wh.gov

The Honorable Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515
(202) 225-4965
sf.nancy@mail.house.gov

Here's to all the women in our lives! Thank you for your love. May we all work 4♀2B=♂ today in all of society.

Epilogue

Phil Harvey Sep 28, 2015 (Credit: YouTube)

8 December 2021

This article was written by Donald A. Collins, Sr. posted on the Church and State Website which has permitted us to reuse it here.

On December 2nd a major leader in the too often attacked issue of providing women's reproductive services Philip D. Harvey died at 83 here in the Washington DC area. Much of his brilliant approaches to the concept of Social Marketing, the core of his philosophy, can be read in this interview.

His life certainly confirmed the effectiveness of social marketing which can be defined as an approach used to

develop activities aimed at changing or maintaining people's behavior for the benefit of individuals and society as a whole.

His passing comes at a time when central to reproductive rights, the legality of abortion, has come under serious and lethal attack against Roe/Casey in our ideologically stricken Supreme Court. But one of the many enterprises he initiated is Carafem, which will continue work for women's choice under the leadership of its chief operations officer, Melissa Grant. Read about this agency here.

I first met Phil Harvey in about 1972 when I was the program officer in charge of seeking birth control investments for a charitable organization.

Harvey had by then founded two corporations, one a commercial venture called Adam and Eve, the other a non-profit, Population Services International (PSI), both highly illustrative of his broad understanding of human nature and human needs for responsible freedom without an overly intrusive government.

The first business began selling condoms but realized that market led to erotica or soft porn, which inspired government attacks which Phil, a staunch libertarian, defended with its profits to defeat these ridiculous prudish anti free speech lawsuits. Started in 1972 it is still going strong and is now the largest employer in Hillsborough, NC.

You can read about those here.

His web site allows you to learn about his social marketing modus operandi. Read here.

When I learned he and I were both born in Evanston, Illinois it probably biased and initiated my long affection for this brilliant caring avatar for human rights.

Of the two only PSI qualified for a charitable grant, but I found very positive his willingness with its co-founder Dr Tim Black, his co-collaborator, here to challenge sexual hypocrisy. As I investigated his application, I learned that they had not gotten major funding from others, probably due to ownership of Adam and Eve. Thus, I was delighted when my charitable employer made a sizable grant, perhaps the initial one of that size to PSI.

Phil's other kindred spirit, Dr Tim Black, a UK OB/GYN, in the mid-1970s took over a largely moribund London NGO called Marie Stopes and turned it into an early abortion operation in which Phil was also involved. While Tim died some years ago, this agency still continues its vital work.

Subsequently I got to know Tim well and frequently sought his wise counsel when I served as the founding Chairman and President of Ipas, which widely used new non-surgical devices, called menstrual regulation kits which safely

enabled trained midwives to perform early abortions worldwide.

Then as you can read here, he and Tim founded DKT which has had an enormous international impact in providing women with means to prevent unwanted pregnancies (and avoiding abortions). You can read the story of this powerful family planning agency here.

In short, while many talk about and even vigorously advocate full women's reproductive rights, no one in my long career in family planning has done more than Phil and Tim in making such services safe, inexpensive and legally available.

Phil's wife, Harriet Lesser, an artist of huge talent, was his powerful soulmate who doubtless facilitated his tremendous accomplishments.

What a life well lived with a legacy that will continue to make choice in all options better for women and their families.

Phil Harvey's last words in his video say it all, "Education becomes possible when you have 3 kids instead of 7, so that the impact of giving people the right to control their own fertility is very significant. Anyone who opposes it is a fool and probably an evil fool at that it seems to me."

The author has the least amount of experience with QS, and is merely a scribe to document instances of pioneer's greatness. Many in the battle are dead. The only hope for success to gain free contraceptives for all lies in the youth of America. I hope they realize what they may lose as we return to Comstock Act-like dark times.

Here's to all the women in our lives! Thank you for your love. May we all work 4  2B=  today in all of society.

Appendix 1 – Stepping Through History of Women's Rights

20 January 2017

Anything in quotes in this appendix is excerpted from a U.S. News & World Report: *A timeline of women's rights from 1769 to the 2017 Women's March on Washington* by Susan Milligan Senior Politics Writer Jan. 20, 2017.

"Historians describe two waves of feminism in history: the first in the 19th century, growing out of the anti-slavery movement, and the second, in the 1960s and 1970s. Women have made great strides – and suffered some setbacks – throughout history, but many of their gains were made during the two eras of activism in favor of women's rights. Some notable events:

1769 – The colonies adopt the English system decreeing women cannot own property in their own name or keep their own earnings.

1777 – All states pass laws which take away women's right to vote.

1809 – Mary Kies becomes the first woman to receive a patent, for a method of weaving straw with silk.

1839 – The first state (Mississippi) grants women the right to hold property in their own names – with permission from their husbands.

1848 – At Seneca Falls, New York, 300 women and men sign the Declaration of Sentiments, a plea for the end of discrimination against women.

1866 – The 14th Amendment is passed by Congress, with "citizens" and "voters" defined as "male" in the Constitution.

1869 – Arabella Mansfield is granted admission to practice law in Iowa, making her the first woman lawyer. Ada H. Kepley becomes the first woman in the United States to graduate from law school.

1872 – Victoria Claflin Woodhull becomes the first female presidential candidate in the United States, nominated by the National Radical Reformers.

1873 – The Supreme Court rules that a state has the right to exclude a married woman from practicing law.

1887 – Susanna Medora Salter becomes the first woman elected mayor of an American town, in Argonia, Kansas.

1890 – The first state (Wyoming) grants women the right to vote in all elections.

1900 – By this year, every state had passed legislation granting married women the right to keep their own wages and to own property in their own name.

1916 – Jeannette Rankin, of Montana, is the first woman to be elected to the U.S. House of Representatives

1918 – Margaret Sanger, two years after opening a birth control clinic in Brooklyn, wins her suit in New York to allow doctors to advise their married patients about birth control for health purposes. The clinic, along with others, becomes Planned Parenthood in 1942.

1920 – The Nineteenth Amendment to the Constitution is ratified, ensuring the right of women to vote.

1923 – The first version of an Equal Rights Amendment is introduced. It says, "Men and women shall have equal rights throughout the United States and every place subject to its jurisdiction."

1932 – Hattie Wyatt Caraway, of Arkansas, becomes the first woman elected to the U.S. Senate.

1932 – The National Recovery Act forbids more than one family member from holding a government job, resulting in many women losing their jobs.

1933 – Frances Perkins becomes the first female cabinet member, appointed secretary of labor by President Franklin D. Roosevelt.

1953 – Jerrie Cobb is the first U.S. woman to undergo astronaut testing. NASA, however, cancels the women's program in 1963. It is not until 1983 that an American woman gets sent into space."

1957 - FDA approved the use of the pill to regulate menstruation.

1962 - The Lippes Loop quickly became the most widely prescribed IUD in the United States.

"1963 – The Equal Pay Act is passed by Congress, promising equitable wages for the same work, regardless of the race, color, religion, national origin or sex of the worker.

1964 – Title VII of the Civil Rights Act passes, prohibiting sex discrimination in employment. The Equal Employment Opportunity Commission is created.

1965 – The Supreme Court establishes the right of married couples to use contraception.

1968 – President Lyndon B. Johnson signs an executive order prohibiting sex discrimination by government contractors and requiring affirmative action plans for hiring women.

1969 – California adopts the nation's first "no fault" divorce law, allowing divorce by mutual consent.

1972 – Title IX of the Education Amendments prohibits sex discrimination in all aspects of education programs that receive federal support.

1973 – Landmark Supreme Court ruling Roe v. Wade makes abortion legal. The Supreme Court in a separate ruling bans sex-segregated "help wanted" advertising.

1974 – Housing discrimination on the basis of sex and credit discrimination against women are outlawed by Congress.

1975 – The Supreme Court denies states the right to exclude women from juries.

1978 – The Pregnancy Discrimination Act bans employment discrimination against pregnant women.

1980 – Paula Hawkins of Florida, a Republican, becomes the first woman to be elected to the U.S. Senate without following her husband or father in the job.

1981 – Sandra Day O'Connor becomes first woman to serve on the Supreme Court.

1982 – The ERA falls short of ratification.

1983 – Dr. Sally K. Ride becomes the first American woman to be sent into space.

1984 – Geraldine Ferraro becomes the first woman to be nominated to be vice president on a major party ticket.

1985 – EMILY's List is founded, its mission to elect Democratic, pro-abortion rights women to office.

1986 – The U.S. Supreme Court held that a work environment can be declared hostile or abusive because of discrimination based on sex, an important tool in sexual harassment cases.

1989 – The Supreme Court affirms the right of states to deny public funding for abortions and to prohibit public hospitals from performing abortions.

1992 – The Year of the Woman: Following 1991 hearings in which lawyer Anita Hill accused Supreme Court nominee Clarence Thomas of sexual harassment, record numbers of women are elected to Congress, with four women winning Senate elections and two dozen women elected to first terms in the

1994 – The Violence Against Women Act funds services for victims of rape and domestic violence and allows women to seek civil rights remedies for gender-related crimes. Six years later, the Supreme Court invalidates those portions of the law permitting victims of rape, domestic violence, etc. to sue their attackers in federal court.

1997 – Madeleine Albright become the first female secretary of state.

2005 – Congress passes the Partial-Birth Abortion Ban Act, the first law to ban a specific abortion procedure. The Supreme Court upholds the ban the following year.

2007 – Nancy Pelosi becomes the first female speaker of the House.

2008 – Alaska Governor Sarah Palin becomes the first woman to run for vice president on the Republican ticket. Hillary Clinton loses the Democratic nomination to Barack Obama.

2009 – The Lily Ledbetter Fair Pay Restoration Act allows victims, usually women, of pay discrimination to file a complaint with the government against their employer within 180 days of their last paycheck.

2012 – The Paycheck Fairness Act, meant to fight gender discrimination in the workplace, fails in the Senate on a party-line vote. Two years later, Republicans filibuster the bill (twice).

2013 – The ban against women in military combat positions is removed, overturning a 1994 Pentagon decision restricting women from combat roles.

2016 – Hillary Rodham Clinton secures the Democratic presidential nomination, becoming the first U.S. woman to lead the ticket of a major party. She loses to Republican Donald Trump in the fall.

2017 – Congress has a record number of women, with 104 female House members and 21 female Senators, including the chamber's first Latina, Nevada Sen. Catherine Cortez Masto."

2017 - Nikki Haley became the first Indian American to serve in a Cabinet-level position as U.S. ambassador to the United Nations.

2020 - 100th Anniversary of Women's Right to Vote in the United States. Rulings by the Supreme Court came in three cases of employees being fired because they were gay or transgender thus prohibiting discrimination based on sexual orientation and gender identity.

2021 – Kamala Harris becomes the first woman to serve as Vice President of the United States, and the first Black and Asian American person in this high office. Vice President Kamala Harris became President of the United States for 85 minutes while President Joe Biden was sedated for a colonoscopy.

Appendix 2 – QS Brochure - p1

Quinacrine Sterilization

What is Quinacrine Sterilization (QS)?

Quinacrine Sterilization (QS) is a permanent method of contraception. There is no surgery. Instead, a drug called quinacrine (originally taken orally to treat malaria) is inserted into the uterus. Researchers began to study quinacrine sterilization in humans in the 1970s. Since then, over 125,000 women in 30 countries have used QS as a method of sterilization.

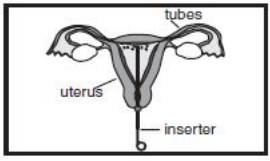
Because it is a relatively new method and many women do not know much about QS, this brochure is provided to answer some questions.

How safe is QS?

Research has been done around the world to find out how safe quinacrine is. What is known is that QS is safer in terms of complications than surgical sterilization especially in parts of the world where hospitals and clinics are poorly equipped.

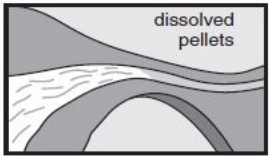
What happens during an insertion?

1



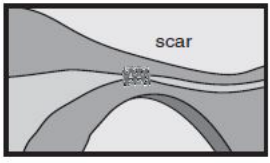
Using a modified IUD inserter, the healthcare provider (a midwife, nurse or doctor) places 7 small pellets (pills) of quinacrine in the uterus on two separate visits.

2



In half an hour, the pellets dissolve and the liquid quinacrine flows into the tubes. The quinacrine causes inflammation of the lining of the fallopian tubes.

3

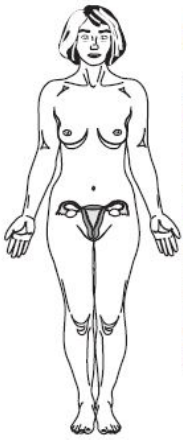


Over the next 6-12 weeks, the quinacrine causes plugs of scar tissue to form at the first part of the tubes. These plugs close the tubes and block the egg's path to the uterus.

Appendix 2 – QS Brochure - p2

How many insertions are necessary?

Two insertions greatly increase the chance that the quinacrine sterilization will be successful and are therefore always part of a QS insertion.



What happens after the first insertion?

Because it takes 6-12 weeks for the scar tissue to form, you must use another contraceptive method in addition to QS, starting the day of the first insertion. Examples of contraceptives to use are condoms, foam, pills, IUDs or injectables. To make sure that the scar tissue has formed and that the patient will not become pregnant, she must return for a second insertion one month later. She must continue using the other method for 2 more months after the second insertion.

Does QS ever fail?

Yes. QS fails if the tubes are not blocked completely after two insertions. However, it is becoming more effective with improved technique. Studies conducted 10-20 years ago reported higher failure rates than we see today. Since the adoption of a new insertion technique in 1993, the failure rates reported have been less than 2 out of 100 women after 2 years. Because of improvements in the technique, it is estimated that after ten years, fewer than 5 of 100 women will be become pregnant.

When must the insertions be done?

QS must be done 6-12 days after the onset of the woman's period. (To increase chances of success, there must be no blood in the uterus during the first or second insertion.)

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

days of menstrual period
days to have QS

What are the side effects of QS?

Nearly half of all women report experiencing at least one side effect. If there is a side effect, it usually goes away within a few hours to a few days. Here is a list of the most common side effects, and the number of women out of every 100 who get them:

Symptoms	Number of Women
menstrual pattern changes	20 to 29
lower abdominal pain	9 to 25
headache and dizziness	9 to 20
backache	1 to 21
vaginal itching or irritation	1 to 23
discharge	5 to 16
fever	9 to 10
pain during urination	≤ 1
pain during sex	≤ 1

Some women have menstrual changes after the insertions. This means that they either do not have their period or there is a change in the amount of flow of their period or the number of days it lasts. This usually lasts no more than a few months. In rare cases, it may last a year or more.

Appendix 2 – QS Brochure - p3

What are the advantages of QS?

The main advantages of QS are:

- no surgery, which means less risk of infection, injury or death
- no hospitalization
- less pain than surgical sterilization
- many types of trained healthcare providers, not just doctors, can perform the method
- requires no anesthetic

What are the disadvantages of QS?

The main disadvantages of QS are:

- it has never been successfully reversed (QS may be much less reversible than surgical methods)
- some women may still get pregnant even after they have a QS
- QS is still a new method; there may be risks which are not yet known
- it requires two visits to the clinic
- it does not completely protect against tubal pregnancy
- It does not protect against sexually transmitted diseases (STD's)

Is tubal pregnancy possible?

As with other methods of contraception, tubal pregnancy (a pregnancy which occurs outside of the uterus), though rare, can still occur. Tubal pregnancy may still occur after QS, but it is not caused by this method. The tubal pregnancy rate with this method is lower than the rate in women who use no contraceptive method. Tubal pregnancies are very dangerous. In some countries, 1 out of 20 women with a tubal pregnancy dies. If a woman believes she is pregnant and has any of these signs, she should call or go to her healthcare provider right away:

- a missed period
- severe pain in the lower abdominal area
- dizziness, fainting or weakness
- vaginal bleeding other than a normal menstrual period

A potential QS client should be encouraged to consider the following:

1 Some questions to ask your healthcare provider

- Can I change my mind after the first insertion?
- Are there women in my community who have had QS? Can I contact them?
- What do I do if my side effects last longer than a few days?
- Can I return to all my normal activities right after QS?
- What kind of contraception do you suggest I use for the first 3 months?
- When can I start having sexual relations after QS?
- What happens if I find out I am pregnant?

2 Some questions to ask yourself

- Why am I having this procedure?
- Are there other methods of contraception I can use that will work better for me and my husband at this time?
- Most importantly, am I certain that I never want any more children?

3 Tell your healthcare provider

- if you know or think you might be pregnant
- if you have seizures (fits), cancer or any vaginal infections
- how long it has been since your last child's birth
- if you have doubts about being sterilized
- about any other concerns you have

Appendix 2 – QS Brochure - p4

QUESTIONS FREQUENTLY ASKED BY WOMEN

Questions and Answers for Family Planning Providers

Q. Will I be sterile immediately?

A. No. It takes 6-12 weeks for the scar tissue to develop. You should use another method of contraception for 12 weeks.

Q. Will I be sterile after one insertion?

A. Maybe. Research has shown that women who have two insertions are half as likely to become pregnant as women who have only one.

Q. What will happen if I cannot or do not return for my second insertion after one month?

A. If you cannot return for the second insertion, go to the clinic as soon as possible to find out what to do next. Until you return, continue to use another contraceptive method. If you do not return, your QS procedure is not complete and there is a higher chance you may become pregnant.

For more information on QS see:
http://quinacrine.org
Questions can be directed to:
info@quinacrine.org
or
Quinacrine Information
P.O. Box 13067
Research Triangle Park, NC 27709 USA
Phone - (919) 933-7491
Fax - (919) 933-0348

ISAF

QS

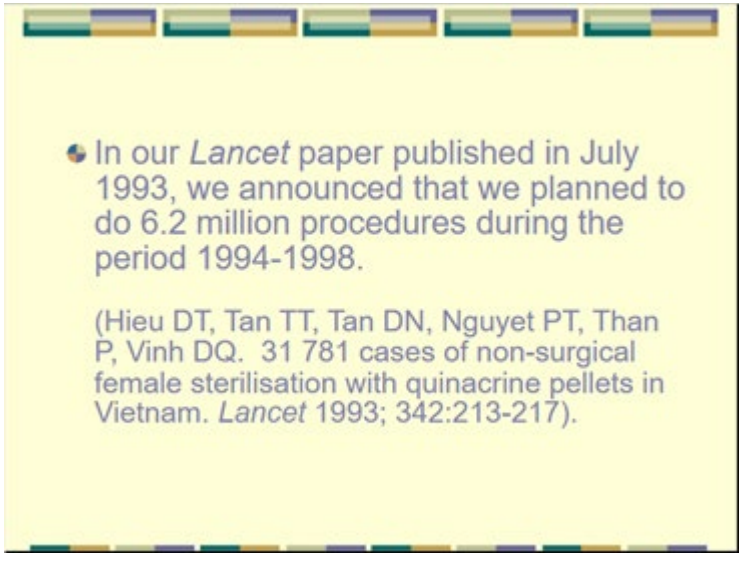
Permanent Contraception for Women ®

Female Voluntary Non-surgical Sterilization:

The Quinacrine Sterilization Method

Appendix 3 – XVII FIGO World Congress of Gynecology and Obstetrics in Santiago, Chile Presentations

Dr. Do Trong Hieu, Former Director Department of Maternal and Child Health and Family Planning, Ministry of Health, Hanoi, Vietnam presented his paper **The Future of Quinacrine Sterilization: Vietnam** the 1st of a dozen talks developed at the XVII FIGO World Congress of Gynecology and Obstetrics in Santiago, Chile, November 2 to 7, 2003 dedicated entirely to QS. Get Dr. Hieu's entire presentation here.



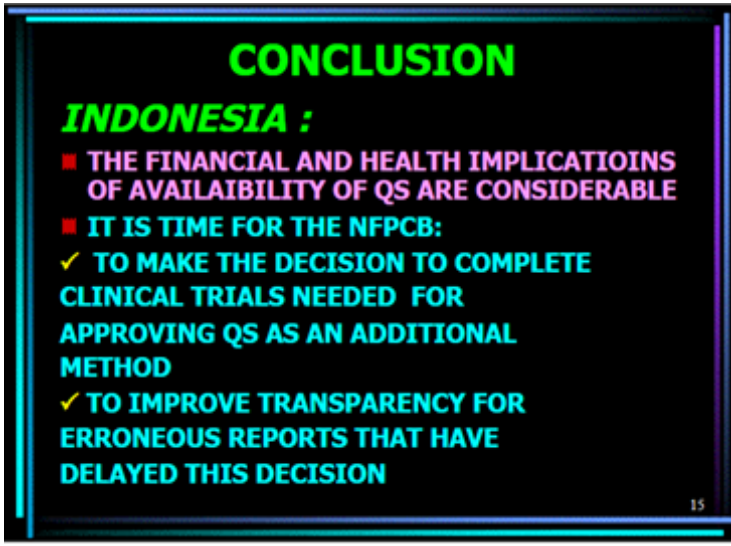
- In December 1993 WHO HRP sent a letter to Vietnam stating: "WHO experts and FDA officials have said that they would be surprised if quinacrine did not turn out to be carcinogenic." The Vietnam QS program was immediately brought to a halt for reevaluation.

- By February 1994, we had determined that this statement could not be substantiated. The preponderance of scientific evidence suggested that this statement was without merit. We wanted to resume our QS program.

- Immediately, in the hallways of the Ministry, several threatening rumors from international and UN agencies were heard: If the QS program is resumed, support for family planning in Vietnam could be suspended/ withdrawn.

- Ministry officials feared that international and bilateral programs would terminate their financial support to Vietnam (especially when WHO and UNFPA departed). The decision was made not to resume our highly popular QS program.

The Future of Quinacrine Sterilization: Indonesia Tina Agoestina Rumah Sakit Ibu Dan Anak Sukajadi – Bandung, Indonesia. Get the entire presentation here.



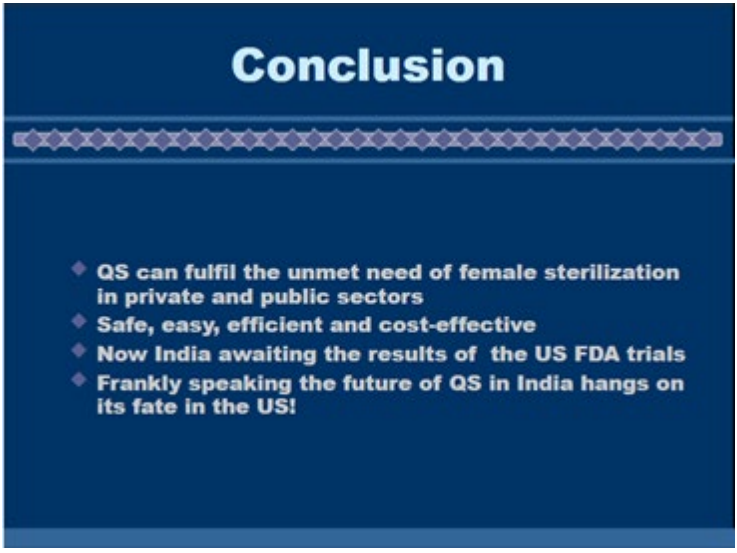
Quinacrine Sterilization: A retrospective Jaime Zipper, Elton Kessel, International Federation for Family Health Otis, Oregon, USA here.

Experience in Chile Valentin Trujillo S., Jaime Zipper San Jose Hospital, Santiago, here.

The Role of Vaginal Ultrasonography Cláudia Ramos de Carvalho Ferreira Universidade Federal de Minas Gerais, Bel Horizonte, Brazil here.

Five-Year Follow-up of 300 Cases in Guizhou Province, China Lu Weiqun Guizhou Research Institute for Family Planning, Guiyang, P.R. China here.

The Future of Quinacrine Sterilization: India Ashi R. Sarin Aastha Medical Center, Patiala, India Get the entire presentation here.



Experience in Faisalabad, Pakistan Bashir Ahmed Mother & Child Welfare Association, Faisalabad, Pakistan here.

An Option for Women in Libya M.S. El Mahaishi Misurata, Libya here.

A Private Practice Experience in the United States Randall B. Whitney Daytona Beach, FL, USA here.

FDA-Approved Trial of Quinacrine Sterilization and the Future of Quinacrine Sterilization: USA Jack Lippes State University of New York at Buffalo, Buffalo, NY, USA here.

Appendix 4 - 44 Peer-reviewed Publications on the QS Method

QS was invented in Chile in 1977, and has undergone rigorous scientific study, producing scores of peer reviewed articles attesting to its safety and efficacy.

In clinical trials globally, more than 200,000 women in 50 countries have chosen QS as their method of permanent contraception, with no serious side effects and no deaths reported.

Here are ISAF's most important 44 peer-reviewed publications on the QS method:

1. Lippes, Jack, (2015) Quinacrine sterilization (QS): time for reconsideration, Contraception, Volume 92, Issue 2, 91–95,
   DOI: 10.1016/j.contraception.2015.06.005

2. Stephen D. Mumford, (2021) What happened to quinacrine non-surgical female sterilization? Regulatory Toxicology and Pharmacology, Volume 124, August 2021, 104968,
   DOI: 10.1016/j.yrtph.2021.104968

3. Judith K. Jones, Arlene Tave, John C. Pezzullo, Sharon Kardia & Jack Lippes (2017) Long-term

risk of reproductive cancer among Vietnamese women using the quinacrine hydrochloride pellet system vs. intrauterine devices or tubal ligation for contraception, The European Journal of Contraception & Reproductive Health Care, 22:2, 123-130, DOI: 10.1080/13625187.2017.1285880

4. Judith K. Jones, Arlene Tave, John C. Pezzullo, Sharon Kardia & Jack Lippes (2018) Long-term risk of hysterectomy and ectopic pregnancy among Vietnamese women using the quinacrine hydrochloride pellet system vs. intrauterine devices or tubal ligation for contraception, The European Journal of Contraception & Reproductive Health Care, 23:2, 105-115, DOI: 10.1080/13625187.2018.1449823

5. Ernest E. McConnell, Jack Lippes, Roger G. Growe, Patricia Fail, Michael I. Luster, Errol Zeiger, (2010) An alternative interpretation of, "A lifetime cancer bioassay of quinacrine administered into the uterine horns of female rats", Regulatory Toxicology and Pharmacology, Volume 56, Issue 2, Pages 166-173, ISSN 0273-2300, DOI: 10.1016/j.yrtph.2009.12.007

6. Joseph K. Haseman, Roger G. Growe, Errol Zeiger, Ernest E. McConnell, Michael I. Luster,

Jack Lippes, (2015) A critical examination of the mode of action of quinacrine in the reproductive tract in a 2-year rat cancer bioassay and its implications for human clinical use, Regulatory Toxicology and Pharmacology, Volume 71, Issue 3, Pages 371-378, ISSN 0273-2300, DOI: 10.1016/j.yrtph.2015.02.006

7. Roger G. Growe, Michael I. Luster, Patricia A. Fail, Jack Lippes, (2013) Quinacrine-induced occlusive fibrosis in the human fallopian tube is due to a unique inflammatory response and modification of repair mechanisms, Journal of Reproductive Immunology, Volume 97, Issue 2, Pages 159-166, ISSN 0165-0378, DOI: 10.1016/j.jri.2012.12.003

8. Lippes, J. (2002), Quinacrine sterilization: the imperative need for American clinical trials. Fertility and Sterility, Volume 77, Issue 6, Pages 1106–1109, DOI: 10.1016/s0015-0282(02)03089-3

9. Lippes, J., Brar, M., Gerbracht, K., Neff, P. and Kokkinakis, S. (2003), An FDA phase I clinical trial of quinacrine sterilization (QS). International Journal of Gynecology & Obstetrics, 83: S45-S49. DOI: 10.1016/S0020-7292(03)90089-0

10. Lippes, J. (2003), Forward. International Journal of Gynecology & Obstetrics, 83: S3-S5. DOI: 10.1016/S0020-7292(03)90083-X

11. Hieu, T., Vinh, Q., Tong K., Waszak C., Katz K., Hanenberg R., Sokal D., (1995), A Retrospective Study of Quinacrine Sterilization in Vietnam, Conducted by The Ministry of Health Hanoi, Vietnam, Presentation at the Quinacrine Sterilization Dissemination Meeting in Hanoi, Vietnam, link

12. Jones, et al., (2012) Comparison of Long Term Cancer Risk Between Vietnamese Women Undergoing QS vs. IUD Contraceptive Procedures, 7th Asian Conference on Pharmacoepidemiology, October 26-28, 2012, Bengaluru, India, link

13. Feldblum, Paul J. et al., (2012) Pelvic surgery and hospitalization among Chilean women after nonsurgical sterilization with quinacrine pellets between 1977 and 1989, Contraception, Volume 86, Issue 2, 106 – 109, 10.1016/j.contraception.2011.11.072

14. Sokal DC et al., (2010) Quinacrine sterilization and gynecologic cancers: a case-control study in

northern Vietnam, Epidemiology, 2010 Mar;21(2):164-71. DOI: 10.1097/EDE.0b013e3181cb41c8

15. Sokal, David C. et al., (2009) Cancer risk after sterilization with transcervical quinacrine: updated findings from a Chilean cohort, Contraception, Volume 81, Issue 1, 75–78, DOI: 10.1016/j.contraception.2009.07.006

16. David C. Sokal, Do Trong Hieu, Nguyen Dinh Loan, David Hubacher, Kavita Nanda, Debra H. Weiner, Trinh Huu Vach, (2008) Contraceptive effectiveness of two insertions of quinacrine: results from 10-year follow-up in Vietnam, Contraception, Volume 78, Issue 1, Pages 61-65, ISSN 0010-7824, DOI: 10.1016/j.contraception.2008.02.010

17. Agoestina, T. (2003), 8-year follow-up in a randomized trial of one vs two transcervical insertions of quinacrine pellets for sterilization in Indonesia. International Journal of Gynecology & Obstetrics, 83: S129-S131. DOI: 10.1016/S0020-7292(03)90104-4

18. Alfonso, L. and Albano, H. (2003), Quinacrine sterilization (QS) experience in the Philippines: a

preliminary report. International Journal of Gynecology & Obstetrics, 83: S121-S123. DOI: 10.1016/S0020-7292(03)90102-0

19. Alpizar, F. (2003), Quinacrine sterilization (QS) in Costa Rica: 694 cases. International Journal of Gynecology & Obstetrics, 83: S141-S145. DOI: 10.1016/S0020-7292(03)90107-X

20. Bashir, A., Bashir, M. and Afzal, S. (2003), The effect of special training for quinacrine sterilization (QS) in Faisalabad, Pakistan: a report on an 1833-women subset of 11,000 cases. International Journal of Gynecology & Obstetrics, 83: S67-S71. DOI: 10.1016/S0020-7292(03)90092-0

21. Bhatt, R. (2003), Quinacrine nonsurgical female sterilization in Baroda, India: 23 years of follow-up of 84 women. International Journal of Gynecology & Obstetrics, 83: S31-S33. DOI: 10.1016/S0020-7292(03)90087-7

22. Bhattacharyya, S. (2003), Quinacrine sterilization (QS): the ethical issues. International Journal of Gynecology & Obstetrics, 83: S13-S21. DOI: 10.1016/S0020-7292(03)90085-3

23. Bilgrami, M. and Shah, L. (2003), Marie Stopes Society, Pakistan: 1000 cases of quinacrine sterilization (QS). International Journal of Gynecology & Obstetrics, 83: S125-S127. DOI: 10.1016/S0020-7292(03)90103-2

24. El Mahaishi, M. and Azzidani, A. (2003), Quinacrine sterilization in Libya: 200 cases. International Journal of Gynecology & Obstetrics, 83: S113-S115. DOI: 10.1016/S0020-7292(03)90100-7

25. El Sahwi, S., Kamel, M., El Faham, M. and El Makhzangy, I. (2003), Hysteroscopic and hysterosalpingographic study after intrauterine insertion of quinacrine pellets for non-surgical sterilization: results in 180 women. International Journal of Gynecology & Obstetrics, 83: S101-S106. DOI: 10.1016/S0020-7292(03)90098-1

26. Ferreira, C., Magalhães, D., Ferreira, D., Hanan, M. and Camargos, A. (2003), Quinacrine female nonsurgical sterilization (QS): endometrial assessment by vaginal ultrasonography in 128 women. International Journal of Gynecology & Obstetrics, 83: S59-S66. DOI: 10.1016/S0020-7292(03)90091-9

27. Garabedian, V. (2003), Quinacrine sterilization (QS) in Syria: a preliminary report on 297 cases. International Journal of Gynecology & Obstetrics, 83: S133-S135. DOI: 10.1016/S0020-7292(03)90105-6

28. Giugni Chalbaud, A. and Plaza Mora, G. (2003), Female sterilization with quinacrine using hysterosalpingography (HSG) as an endpoint after a single-insertion protocol in Caracas, Venezuela. International Journal of Gynecology & Obstetrics, 83: S107-S111. DOI: 10.1016/S0020-7292(03)90099-3

29. Hieu, D., Luong, T., Anh, P., Ngoc, D. and Duong, L. (2003), The acceptability, efficacy and safety of quinacrine non-surgical sterilization (QS), tubectomy and vasectomy in 5 provinces in the Red River Delta, Vietnam: a follow-up of 15,190 cases. International Journal of Gynecology & Obstetrics, 83: S77-S85. DOI: 10.1016/S0020-7292(03)90094-4

30. Hieu, D. and Luong, T. (2003), The rate of ectopic pregnancy for 24,589 quinacrine sterilization (QS) users compared to users of other methods and no method in 4 provinces in Vietnam, 1994–1996. International Journal of Gynecology & Obstetrics, 83: S35-S43. DOI: 10.1016/S0020-7292(03)90088-9

31. Informed Consent Working Group, (2003), Quinacrine sterilization (QS): Informed consent. International Journal of Gynecology & Obstetrics, 83: S147-S159. DOI: 10.1016/S0020-7292(03)90108-1

32. Kessel, E., (1996) 100,000 quinacrine sterilizations. Advances in Contraception 12:69-76. DOI: 10.1007/BF01849629

33. Lu, W. , Zhu, J. , Zhong, C. and Zhao, Y. (2003), A comparison of quinacrine sterilization (QS) and surgical sterilization (TL) in 600 women in Guizhou Province, China. International Journal of Gynecology & Obstetrics, 83: S51-S58. DOI: 10.1016/S0020-7292(03)90090-7

34. Pal, S. (2003), Quinacrine sterilization of 1997 women in Daharpur, Midnapore, West Bengal, India: a comparison of 3 protocols. International Journal of Gynecology & Obstetrics, 83: S97-S100. DOI: 10.1016/S0020-7292(03)90097-X

35. Roy, A. (2003), A 22-year experience with quinacrine sterilization in a rural private clinic in Midnapore, India: a report on 5 protocols and 1838 cases. International Journal of Gynecology & Obstetrics, 83: S87-S91. DOI: 10.1016/S0020-7292(03)90095-6

36. Sarin, A. and Sarin, R. (2003), Quinacrine sterilization (QS) among high-risk women: a study of 134 cases. International Journal of Gynecology & Obstetrics, 83: S73-S76. DOI: 10.1016/S0020-7292(03)90093-2

37. Sarin AR, (1999) Quinacrine sterilization: experience among women at high risk for surgery., Adv Contracept. 15(3):175-8. DOI: 10.1023/A:1006757914435

38. Shelton, James D. et al., (1993) Non-surgical female sterilization, The Lancet, Volume 342, Issue 8875, 869 – 871, DOI: 10.1016/0140-6736(93)92732-9

39. Soroodi-Moghaddam, S. (2003), Quinacrine sterilization (QS) in Iran and the use of HSG as a measure of success. International Journal of Gynecology & Obstetrics, 83: S93-S96. DOI: 10.1016/S0020-7292(03)90 96-8

40. Suhadi, A., Anwar, M. and Soejoenoes, A. (2003), 10-year follow-up of women who elected quinacrine sterilization (QS) in Wonosobo, Central Java, Indonesia. International Journal of

Gynecology & Obstetrics, 83: S137-S139.
DOI: 10.1016/S0020-7292(03)90106-8

41. T Hieu, D & T Tan, T & N Tan, D & Nguyet, Pham & Than, P & Q Vinh, D. (1993). 31781 cases of non-surgical female sterilisation with quinacrine pellets in Vietnam. Lancet. 342. 213-7.
DOI: 10.1016/0140-6736(93)92302-A

42. Whitney, R. (2003), Quinacrine sterilization (QS) in a private practice in Daytona Beach, Florida: a preliminary report. International Journal of Gynecology & Obstetrics, 83: S117-S120.
DOI: 10.1016/S0020-7292(03)90101-9

43. Zipper, J. and Trujillo, V. (2003), 25 years of quinacrine sterilization experience in Chile: review of 2,592 cases. International Journal of Gynecology & Obstetrics, 83: S23-S29.
DOI: 10.1016/S0020-7292(03)90086-5

44. Zipper, J. and Kessel, E. (2003), Quinacrine sterilization: a retrospective. International Journal of Gynecology & Obstetrics, 83: S7-S11.
DOI: 10.1016/S0020-7292(03)90084-1

Appendix 5 - 204 Articles Supporting the QS Method

1. Access to Contraception, Committee Opinion, Committee on Health Care for Underserved Women, The American College of Obstetricians and Gynecologists, number 615, January 2015, Reaffirmed 2017.

2. An Agent for the Palliative Treatment of Neoplastic Effusions Quinacrine (Atabrine) Hydrochloride, Journal of the American Medical Association March 28, 1966; Vol 195, No 13

3. Agoestina T, Hoesni RH, Purwara BH, Santoso BI, Siswanto P, Dasuki D, Samsulhadi A, Surya GP. Department of Obstetrics and Gynecology, Dr. Hasan Sadikin Hospital/Medical School, Padjadaran University., Bandung, Indonesia. Fertil Steril 2002 May;77(5):1065-8

4. Agoestina, T. and Kusuma, I., Clinical evaluation of quinacrine pellets for chemical female sterilization, Department of Obstetrics and Gynecology, Hasan Sadikin Hospital, 38 Jalan Pasteur, Bandung 40161, Indonesia, Advances in Contraception 1992; 8:141-51.

5. Allen, S.S., Medical Officer, Letter to, Lisa Rarick, Division Director DRUDF, Subject: Health Hazard Evaluation Summary of a kit for intrauterine insertion of Quinacrine Hydrochloride pellets for female sterilization. August 26, 1998.

6. Ames, B.N., Gold, L.S., Chemical carcinogenesis: Too many rodent carcinogens, Proceedings of the National Academy of Sciences October 1990; 87:7772-6.

7. Archer, J.D., The FDA Does Not Approve Uses of Drugs, Editorial, Journal of American Medical Association 1984; 252(8):1054-55.

8. Arshat, H., Suan, A.E., Kim, K.S., Nonsurgical Female Sterilization with Quinacrine Pellets: Malaysian Experience, Malaysian Journal of Reproductive Health 1987; 5:61-9.

9. Atabrine dihydrochloride: quinacrine hydrochloride [an expanded discussion of package insert information]. New York Monograph undated.

10. Atabrine hydrochloride (brand of quinacrine hydrochloride): for chemotherapy of giardiasis,

tapeworm and malaria. Package insert from Winthrop-Breon Laboratories 1985; 6 pp.

11. Bairagi, N.R., Mullick, B.C., Kessel, E., Mumford, S.D., Comparison of the efficacy of intrauterine diclofenac and ibuprofen pellets as adjuvants to quinacrine nonsurgical female sterilization, Advances in Contraception 1995; 11:303-308.

12. Barka, J., Popinchalk, A., Ganatra, B., Moller, A., SunCal, O., Beavin, C., et al., Unintended pregnancy and abortion by income, region, and the legal status of abortion: estimates from a comprehensive model for 1990–2019. The Lancet Global Health, VOLUME 8, ISSUE 9, E1152-E1161, 2020, DOI:10.1016/S2214-109X(20)30315-6

13. Bashir, A., Quinacrine: non surgical female sterilization, Advances in Contraception Delivery Systems 1993; 9:37-42.

14. Bashir, A., Mustansar, M., Chcema, M.A., Akram, S., Naheed, R., Quinacrine, Non Surgical Female Sterilization, The Gynecologist 1993; 3:129-36.

15. Bashir, A., Quinacrine Sterilisation: A Community Service, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.16

16. Bauer, F., Quinacrine hydrochloride drug eruption (tropical lichenoid dermatitis), Special Article, Journal of the American Academy of Dermatology 1981; 4:239-248.

17. Begum, R., Bhuiyan, S.N., Quinacrine-Non Surgical Tubal Occlusion, Indian Progress in Family Welfare: Proceedings of IXth Indian Conference on Family Welfare & Voluntary Sterilization, Ahmedabad 13-15th November, 1992; pp. 239-42.

18. Benedek, T, History of Malaria Chemotherapy, 2010, http://www.antimicrobe.org

19. Benoit, A., Melancon, J., Gagnon, M.A., Chemically Induced Tubal Occlusion in the Human Female using Intrauterine Instillation of Quinacrine, Contraception 1975; 12:95-101.

20. Bhatt, R.V., Aparicio, A., Laufe, L.E., Parmley, T., Ring, T.M., Quinacrine-Induced Pathologic Changes in the Fallopian Tube, Fertility and Sterility 1980; 33:666-7.

21. Bhatt, R.V., Jariwala, K.M., Bhiwandiwala, P., Laufe, L.E., Editors, Hingorani, V., Pandit, R.D., Bhargava, V.L., Chemical Female Sterilization

using Quinacrine Pallets, Proceedings of the Third International Seminar on Maternal and Perinatal Mortality. Pregnancy Termination and Sterilization, New Delhi, October 3-5, 1980, eds.; pp. 370-7313.

22. Bhatt, R.V., Waszak, C.S., Four-year follow-up of insertion of quinacrine hydrochloride pellets as a means of nonsurgical female sterilization, Fertility and Sterility 1985; 44:303-6.

23. Bhatt, R.V., Camp Laparoscopic Sterilization Deaths in Gujarat State, India, 1978-1980, Asia-Oceania Journal of Obstetrics and Gynaecology 1991; 17(4):297-301.

24. Bhatega, S., Kini, P., Rajgopal, K., Quinacrine Pellet Non-surgical Female Sterilization: A Two Year Review of Cases in South India, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.58.

25. Bhuiyan, S.N., Begum, R., Quinacrine non-surgical female sterilization in Bangladesh, Department of Obstetrics and Gynecology, Chittagong Medical College, Chittagong, Bangladesh, Contraception 2001 Nov;64(5):281-6.

26. Bjarkman, S., Elisson, L.O., Gabrielsson, J., Pharmacokinetics of Quinacrine after Intrapleural Instillation in Rabbits and Man, Journal of Pharmacy and Pharmacology 1989; 160-3.

27. Black, T., The Quinacrine Imperative, Marie Stopes International 1995

28. Blake, D.A, Dubin, N.H., Diblasi, M.C., Parmley, T.H., Stetten, G., King, T.M., Female Transcervical Sterilization, Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 71.

29. Cancel, A. M., Dillberger, J. E., Kelly, C. M., Bolte, H. F., Creasy, D. M., Sokal, D.C. 2010. A lifetime cancer bioassay of quinacrine administered into the uterine horns of female rats. *Regul. Toxicology. Pharmacol.* 56:156-165.

30. Carignan, C.S., Rogow, D., Pollack, A.E., The Quinacrine Method of Nonsurgical Sterilization: Report of an Experts Meeting, Advances in Contraception July 1994; AVSC Working Paper No. 6.

31. CFR: Code of Federal Regulations: The clinical investigation of an off-label use of a drug such as

quinacrine that is lawfully marketed in the United States. Food and Drug Administration: Code of Federal Regulation (4-1-96 Edition) 312.1-2; p.72.

32. Chandra, H., Malaviya, B., Toxic Effects of Quinacrine Hydrochloride in Rhesus Monkeys, Contraception 1981; 24:269-74.

33. Choudhury, I.R., Frittering of utopian WHO, Indian Medical Tribune, New Delhi 1992.

34. Choudhury, I.R., WHO Lacks Transparency: Members Cautious, Indian Medical Tribune February 15, 1995.

35. Ciak, J., Fiatin, F.E., Quinacrine (Atebrin): Mode of Action, Science 1967; 156:655-56.

36. Coates, J.B., Havens, W.P., Internal Medicine in World War II: Vol II: Infectious Diseases: eds., Chapter 15, The Suppression of Malaria, Baker, B.M., M.D., Medical Department, Department of the Army Washington, D.C. 1963; p 465.

37. Conant, E.B., Quinacrine: Of Medicine, Politics, and Vested Interests - Where is the Woman in the Equation? Speak Out Magazine of the PRO-

CHOICE NETWORK OF WESTERN NEW YORK 1995; Summer.

38. Contraceptive Use by Method: Data Booklet, 2019, United Nations, Department of Economic and Social Affairs, Population Division (ST/ESA/SER.A/435)

39. Current Trends Deaths Attributable to Tubal Sterilization - United States, 1977-1981, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, May 20, 1983 / 32(19);249-50.

40. Dabamens, A., Zipper, J., Guerrero, A., Quinacrine and copper, compounds with anticonceptive and antineoplastic activity. Contraception September 1994; 50:243-51.

41. Dabamens, A., Rivera, M., Sokal, D.C., Zipper, J., Pruyas, M., Prevalence and standardized incidence rates of preclinical cervical pathology among 1061 women sterilized with transcervical quinacrine hydrochloride pellets. Fertility and Sterility 1995; 64:444-446.

42. Daniels, K., Abma, J., Current Contraceptive Status Among Women Aged 15–49: United States,

2015–2017, NCHS Data Brief, no 327. Hyattsville, MD: National Center for Health Statistics. 2018.

43. Davidson, O.D., Wilkins, C., Chemically Induced Tubal Occlusions in the Human Female Following a Single Instillation of Quinacrine, Contraception 1973; 7:333-9.

44. Davidson, O.D., Quinacrine-induced tubal occlusion, New York: Harper and Row, 1976; pp. 200-7.

45. Destefano, F., Greenspan, J.R., Dicker, R.C., Peterson, H.B., Strauss, L.T., Rubin, G.L., Complications of Interval Laparoscopic Tubal Sterilization, Obstetrics and Gynecology 1983; 61:153-158.

46. Detailed description of Atabrine (quinacrine). Physicians' Desk Reference 1993.

47. Dickinson, J.G., Deceptions alleged in FDA attack on quinacrine, Dickinson's FDA REVIEW: pp, 9-10, Volume 5, NO. 12. December 1998.

48. DiConsiglio, J.M, Risks and rewards: family planners weigh quinacrine. Family Planning World 1994; January/February, pp. 19-20.

49. Drug Information for the Health Care Professional. Quinacrine, United States Pharmacopeia of Drug Information (USP DI) 1997; 17th edition: p. 2489 - 2490

50. Dubin, N.H., Blake, D.A., Diblasi, M.C., Parmley, T.H., King, T.M., Pharmacokinetic studies on quinacrine following intrauterine administration to cynomolgus monkeys. Fertility and Sterility 1982; 38:735-40.

51. Dubin, N.H., Strandberg, J.D., Craft, C.F., Parmley, T.H., Blake, D.A., King, T.M., Effect of intrauterine and intravascular quinacrine administration on histopathology, blood chemistry, and hematology in cynomolgus monkeys. Fertility and Sterility 1982; 38:741-7.

52. Dubin, N.H., Parmley, T.H., Diblasi, M.C., Ghodgaonkar, R.B., Jiffry, M.T., Blake, D.A., King, T.M., Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 60.

53. Dubin, N.H., Parmley, T.H., Ghodgaonkar, R.B., Pharm, B., King, T.M., Comparative effects of intrauterine instillation of analogues of quinacrine

and tetracycline on uterine morphology in the rat. Contraception 1984; 29:553-59.

54. Duncan, G.W., 2006. External review of USAID's Current and Future Role in Contraceptive Research and Development. Links Media LLC, pp.12-13

55. Dunn, R.L., Cowsar, D.R., Lewis, D.H., Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 128.

56. Eddy, C.A., Pauerstein, C.J., Anatomic and physiologic factors affecting the development of transcervical sterilization techniques. Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 7-23.

57. Edouard, L., Non-surgical female sterilisation. Lancet Oct. 2, 1993; Vol. 342.

58. Edwards, S., Quinacrine sterilization method found effective among women in Vietnam. International Family Planning Perspectives 1993; 19:157-8.

59. Ehsanian, R., Van Waes, C., Feller, S.M., 2011. Beyond DNA binding – a review of the potential mechanisms mediating quinacrine's therapeutic activities in parasitic infections, inflammation and cancers. *Cell Commun. Signal.* 9, 13. DOI: 10.1186/1478-811X-9-13

60. El Kady, A.A., Mansy, M.M., Nagib, H.S., Kessel, E., Histopathologic changes in the cornual portion of the fallopian tube follow a single transcervical insertion of quinacrine hydrochloride pellets. Advances in Contraception 1991; 7:1-9.

61. El Kady, A.A., Nagib, H.S., Kessel, E., Efficacy and safety of repeated transcervical quinacrine pellet insertions for female sterilization. Fertility and Sterility 1993; 59:301-4.

62. ESTERILIZACIÓN VOLUNTARIA NO QUIRÚRGICA DE LA MUJER: EL MÉTODO DE LA QUINACRINA, Manual in Spanish, Revised, July 2002, Copyright 2002 Center for Research on Population and Security. All rights reserved

63. Fail, P.A., Martin, P., Sokal, D.C., 2000. Comparative effects of quinacrine and erythromycin in adult female rats: A non-surgical sterilization study. Fertil. Steril. 73:387-94.

64. Family planning/contraception methods: Key facts, 2020, World Health Organization.

65. FDA letter: Nomination and Review of Clinical Need for Quinacrine Hydrochloride to be Included on the 503B Bulk Drug Substances List (except for intrauterine use).

66. FEMALE VOLUNTARY NONSURGICAL STERILIZATION: THE QUINACRINE METHOD, Manual Revised: April 2002, Copyright 2002 Center for Research on Population and Security. All rights reserved

67. Feuerstein, M.T., Family Planning in Vietnam [Lancet Commentary on Hieu, et al paper in same issue]. Lancet 1993; 342:188.

68. FHI quinacrine studies. Contraceptive Update May 1994; Vol. 14, p. 27.

69. FHI Quinacrine Studies, Family Health International's role in quinacrine female sterilization research. Contraceptive Update. Vol. 16, September 1995, p. 27.

70. FHI's Decision to Halt Development of Quinacrine: Why and How, Sokal, D, Haneke K, Robinson E, Katz K, Dorflinger L, Family Health International, Research Triangle Park, NC, Abstracts / Contraception 76 (2007) 157–178

71. FHI 360's experience: A nonsurgical permanent contraception stakeholder advisory committee, Katz,K., Nanda, K, Contraception 92 (2015), p139-142

72. Fitzhugh, G., Nelsok, A.A., Calvery, H., The chronic toxicity of quinacrine (Atabrine). Journal of Pharmacologic Experimental Therapy 1945; Volume 85, pp. 207-21.

73. Ghosh, A.K., Hazra, A., Non Surgical Female Sterilization With Quinacrine Vis-A-Vis Laparoscopic In Rural India. A Comparative Evaluation. Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.59

74. Goldsmith, A., Laufe, L.E., King, T.M., Discussion: Research and Clinical I Experience With Quinacrine, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 141.

75. Guzman-Serani, R., Bernales, A., Cole. L.P., Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row; 1983.

76. Guzman-Serani, R., Bernales, A., Cole. L.P., Quinacrine Hydrochloride Pellets: Three-year Follow-up on a Nonsurgical Method of Female Sterilization, Contraception Delivery Systems 1984; 5:131-5.

77. Guzman-Serani, R., Pott, M., Wheeler, R.G., Non-Surgical Tubal Occlusion, Advances in Contraception Delivery Systems 1985; 1:146-9.

78. Heywood, R., Toxicological requirements for sclerosing agents or other chemicals for female sterilization, International Journal of Gynecology and Obstetrics 1995; 51(Suppl):S41-S45.

79. Hieu, D.T., Tan, T.T., Tan, D.N., Nguyet, P.J., Than, P., Vinh, D.Q., Non-surgical female sterilisation, Lancet Oct. 2, 1993; Vol. 342.

80. Hieu, D.T., Tan, T.T., Tan, D.N., Nguyet, P.J., Than, P., Vinh, D.Q., 31781 cases of non-surgical

female sterilisation with quinacrine pellets in Vietnam, Lancet 1993; 342:213-7.

81. Hieu, D.T., Tan, D.N., Quinacrine nonsurgical female sterilization, Current Science 1994; 67:706-9.

82. Hieu, D.T., Quinacrine method of family planning, Lancet 1994; 343:1040.

83. Hieu, D.T., Quinacrine Sterilization: Risk of Ectopic Pregnancy, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.17

84. Hoogenboom, H., Quinacrine sterilization, Lancet October 22, 1994; 344:1160.

85. Humphreys, F., Marks, J.M., Mepacrine and pregnancy. British Journal of Dermatology 1988; 118:452.

86. ICH Harmonized Tripartite Guideline. Guidance for Industry: S1C(R2) Dose Selection for Carcinogenicity Studies. Current Step 4 Version, Parent Guideline Dated 27 October 1994, (Addendum on a Limit Dose Dated 17 July 1997 and Incorporated in November 2005), Revised on

11 March 2008, This Guideline Has Been Developed by the Appropriate ICH Expert Working Group and Has Been Subject to Consultation by the Regulatory Parties, in Accordance with the ICH Process. At Step 4 of the Process, the Final Draft Is Recommended for Adoption to the Regulatory Bodies of the European Union, Japan, and USA.

87. Informed Consent Working Group, Quinacrine Sterilization (QS): Informed Consent, International Journal of Gynecology and Obstetrics 83 Suppl. 2 (2003) S147–S159

88. Israngkun, C., Phaosavadi, S., Neuwirth, R.S.., and Richart, R.M., Clinical evaluation of quinacrine hydrochloride for sterilization of the human female. Contraception 1976; 14:75-80.

89. Jensen, J.T., Rodriguez, M.J., Liechtenstein-Zabrak, J., Zalany, S., 2004. Transcervical polidocanol as a nonsurgical method of female sterilization: a pilot study. Contraception 70, 111-5.

90. Joseph, A.A., Kincl, F.A., Toxic and antifertility effects of quinacrine hydrochloride in rats,

American Journal of Obstetrics and Gynecology 1974; 119:978-81.

91. Kessel, E., Mumford, S.D., Potential demand for voluntary female sterilization in the 1980s: the compelling need for a nonsurgical method, Fertility and Sterility 1982; 37:725-33.

92. Kessel, E., Zipper, J., Mumford, S.D., Quinacrine nonsurgical female sterilization: a reassessment of safety and efficacy, Fertility and Sterility 1985; 44:293-8.

93. Kessel, E., Prospects for Nonsurgical Female Sterilization, International Journal of Gynecology and Obstetrics 1989; 29:1-4.

94. Kessel, E., Zipper, J., Mumford, S.D., Surgical vs. nonsurgical female sterilization. MCI newsletter January 1991; No. 16 pp. 1-2.

95. Kessler, D.A., Regulation of investigational drugs: unapproved uses of approved drugs - role of Food and Drug Agency (FDA). The New England Journal of Medicine 1989; 320:285-6.

96. Kessel, E., Response to AVSC Technical Statement of concerning Quinacrine pellets for nonsurgical female sterilization. Memorandum Nov. 5, 1993.

97. Kessel, E., Cost-effectiveness of Interventions to Lower Maternal Mortality: The Role of Quinacrine Pellet Nonsurgical Female Sterilization, Pan African Maternal and Child Health International Conference, Cairo May 25-27, 1994.

98. Kessel, E., Quinacrine sterilization revisited. (Commentary) (A critique of the WHO position on the quinacrine method). Lancet 1994; 344-698.

99. Kessel, E., Quinacrine sterilization, Lancet November 19, 1994; 344:1434.

100. Kessel, E., Zipper, J., Hieu, D.T., Mullick, B., Mumford, S.D., Quinacrine pellet method of non-surgical female sterilization. Advances in Human Reproduction. Proceedings of the VIIIth World Congress on Human Reproduction and IVth World Conference on Fallopian Tube in Health and Disease, Bali, Indonesia. April 1993, The Parthenon Publishing Group London 1995; pp. 501-512.

101. Kessel, E., Ectopic pregnancy, Letters to the Editor. American Journal of Obstetrics and Gynecology December 1996; p. 1675.

102. Kessel, E., 100,000 quinacrine sterilizations, Advances in Contraception 1996; 12:69-76.

103. Kessel, E., Quinacrine acceptance spreads, Newsletter report of the 11th Indian Conference on Family Welfare and Voluntary Sterilisation and Family Welfare of India, Oct. 30 1996; p. 2.

104. Kessel, E., Letter to the Editor: Quinacrine Sterilization in the United States? Fertility and Sterility March 1996; Vol. 65, No. 3 p. 679-80

105. Kessel, E., 100,000 quinacrine sterilizations, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.16

106. Kessel, E., Quinacrine sterilization: an assessment of risks for ectopic pregnancy, birth defects and cancer, Advances in Contraception 1998; 14:81-90.

107. Kessel, E., Laparoscopic Sterilization: An Obsolete Procedure? Proceedings of The World

Congress of Gynaecological Endoscopy, Bombay, India 2-5 December 1993; pp. 34-6.

108. King, T.M., Dubin, N.H., Blake, D.A., Parmley, T.H., Quinacrine Hydrochloride: Future Research, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ. Philadelphia, Harper and Row 1983; p 138.

109. King, T.M., President, CEO Family Heath International, Presentation given at the experts panel discussion on Quinacrine as a method of female sterilization held at the Association for Voluntary Surgical Contraception (AVSC) offices in New York City, December 2, 1993 (unpublished) ; 11pp.

110. Kini, P., Bhatega, S., Rajgopal, K., Quinacrine Pellet Nonsurgical Female Sterilization: A Non-governmental Service Initiative in South India, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.58

111. Klitsch, M., Sterilization without surgery: Special Report. International Family Planning Perspectives 1982; 8:101-104.

112. Kumar, S., Sterilisation by quinacrine comes under fire in India, Lancet 1997; 349:1460.

113. Laufe, L.E., Cole, L.P., Nonsurgical Female Sterilization, International Journal of Gynaecology and Obstetrics 1980; 18:333-9.

114. Laufe, L.E., Wheeler, R.G., Quinacrine IUDs, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia: Harper and Row 1983; p 115.

115. Laufe, L.E., Sokal, D.C., Cole, L.P., Shoupe, D., Schenkens, R.S., Phase I prehysterectomy studies of the transcervical administration of quinacrine pellets. Contraception 1996; 54:181-6.

116. Lawrie, TA, R Kulier and JM Nardin, 2016, Techniques for the Interruption of Tubal Patency for Female Sterilisation, Cochrane Database Syst Rev, CD003034.

117. Lippes, J., What is the future for quinacrine sterilization? Letter to the Editor, Fertility and Sterility 2001;75:1244-45.

118. Long, P.H., CHAPTER XVII, Treatment of Malaria, Internal Medicine in World War II: Vol II:

Infectious Diseases: Editors, Coates JB, Havens WP, Washington, D.C. Medical Department, Department of the Army 1963; p 493.

119. Malaviya, B., Chandra, H., Kar, A.B., Chemical occlusion of monkey oviducts with quinacrine: antagonism and reversal with estrogen. Contraception 1975; 12:31-6.

120. Merchant, R.N., Doctor, V.M., Thaku, S.S., Sinha, M., Jhaveri, L., Kessel, E., Mumford, S.D., Clinico- pathological study of Fallopian tubes after transcervical insertion of quinacrine hydrochloride pellets, Advances in Contraception 1986; 2:79-90.

121. Merchant, R.N., Prabhu, S.R., Clinicopathologic Study of Fallopian Tube Closure After. Single Transcervical Insertion of Quinacrine Pellets, International Journal of Fertility 1995; 40:47-54.

122. Most, H., CHAPTER XVIII, Clinical Trials of Antimalarial Drugs, Internal Medicine in World War II: Volume II: Infectious Diseases: Editors, Coates JB, Havens WP, Washington, D.C. Medical Department, Department of the Army 1963; p 525.

123. Mullick, B., Kessel, E., Mumford, S.D., Studies of quinacrine and of tetracycline for non-surgical female sterilization, Advances in Contraception 1987; 3:245-54.

124. Mullick, B., Kessel, E., Mumford, S.D., A potential single insertion protocol for quinacrine pellet non-surgical female sterilization. Advances in Contraception 1995; 11:239-244.

125. Mullick, B., Bairagi, N.R., Quinacrine Sterilization: Medroxyprogesterone as Adjuvant, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.17

126. Mumford, S.D., Letter to Sarah G. Epstein, RE: Petition to Planned Parenthood Federation of America Board Members on Quinacrine Sterilization January 6, 2000, CENTER FOR RESEARCH ON POPULATION AND SECURITY

127. Mumford, S.D., Kessel, E., Sterilization needs in the 1990s: The case for quinacrine nonsurgical female sterilization, American Journal of Obstetrics and Gynecology 1992; 167:1203-7.

128. Mumford, S.D., Quinacrine sterilization, Lancet November 19, 1994; 344:1434.

129. Mumford, S.D., Vatican control of world health organization population policy: an interview with Milton P. Siegel. The Humanist 1993; 53:21-25.

130. Nisa, F., An Early Experience with Nonsurgical Female Sterilization, Maternal and Child Care in Developing Countries: Kessel E, Awan AK, eds., Thun, Switzerland, Ott Publishers 1989; p 273.

131. Oshman, C., Institute for Development Training, 1995, Quinacrine sterilization: non-surgical permanent birth control for women. Questions and answers for family planning clients., Brochure 1995

132. Ogilvie, B.M., Scott, I.G., The Wellcome Trust population initiative. Human Reproduction, 12 National Supplement, The British Journal of Fertility and Sterility 1997; 2(2). pp. 95-98.

133. Parmley, T.H., Dubin, N.H., Strandberg, J., Laufe, L.E., Histologic Changes Following Intrauterine Administration of Quinacrine Hydrochloride, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A,

Sciarra JJ, Philadelphia, Harper and Row 1983; p 89.

134. Patek, E., Sterilant Action of Quinacrine, Fertility and Sterility 1977; 28:692.

135. Peterson, H.B., Lubell, I., DeStefano, F., Ory, H.W., The Safety and Efficacy of Tubal Sterilization: An International Overview, International Journal of Gynaecology and Obstetrics 1983; 21:139-144

136. Peterson, H.B., Xia, Z., Hughes, J.M., Wilcox L.S., Tylor, L.R., Trussell, J., The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization, American Journal of Obstetrics and Gynecology April 1996; 174:1161-70.

137. Peterson, H.B., Xia, Z., Hughes, J.M., Wilcox L.S., Tylor, L.R., Trussell, J., The Risk of Ectopic Pregnancy after Tubal Sterilization, The New England Journal of Medicine March 13, 1997; Vol. 336 Number 11: 762-67.

138. Pies, C., Potts, M., Young, B., Quinacrine Pellets: An Examination Of Nonsurgical

Sterilization, International Family Planning Perspectives 1994; 20:137-141.

139. Post-Congress symposium on nonsurgical female sterilization, Bandung, September 15, 1991. MCI newsletter January 1992; No. 19 p. 2.

140. Potts, M, Wheeler, R, The Quest for the Magic Bullet, Family Planning Perspectives v. 13(6):269-271, 1981.

141. Potts, M, Quinacrine Method of Family Planning, Lancet, Vol 343, March 12, 1994, p662

142. Potts, M., Benagiano, G., Quinacrine sterilization: a middle road, Contraception. 2001 Nov;64(5):275-6.

143. Quinacrine Hydrochloride: Review and mode of action of an antimalarial, used as an occlusive agent for transvaginal human sterilization, Acta Obstetricia et Gynecologia Scandinavica (Copenhagen) 1979; 58:561-4.

144. Quinacrine Non-Surgical Female Sterilization (QS) Introduction and Summary, QS Consent, Version Date: 5/28/2002

145. Quinacrine. The Pharmacological Basis of Therapeutics. Second Edition. New York, Macmillan 1960; pp 1167-73.

146. Quinacrine acceptance spreads at NAVSFWI meeting, The 11th Indian Conference on Family Welfare and Voluntary Sterilisation and Family Welfare of India: Newsletter Report Oct. 30, 1996; pp. 1-2.

147. Quinacrine pellets have potential for simple, low-cost female sterilizations. Contraceptive Technology Update. (A monthly newsletter) April 1994.

148. Quinacrine Non-Surgical Female Sterilization (QS) Introduction and Summary, QS Consent in Spanish, Version Date: 6/12/02

149. Quinacrine for female sterilization. Current Science (India) 1994; 67:631-2.

150. Raj, A., Chakravarty, S., PERMANENT FEMALE STERILZATION BY CHEMICAL METHOD TRANSCERVICAL INSERTION OF QUINACRINE, Proceedings of the Third International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and

Sterilization: Hingorani V, Pandit RD, Bhargava VL, eds., New Delhi, India 3rd to 5th October 1980. Bombay, India 1981; 476-80.

151. Randic, L., Haller, H., Sojat, S., Nonsurgical female sterilization: comparison of intrauterine application of quinacrine alone or in combination with ibuprofen, Fertility and Sterility 2001;75:830-31.

152. Randic, L., Non-surgical female sterilization with quinacrine pellets [Abstract only]. Program Book of Abstracts. Second Congress of the European Society of Contraception. Athens, Greece. 6-9 May 1992, p 74.

153. Rashidah Abdullah, Anjung Felda. Jalan Makvab, Letters to the Editor, AslanPacific Resource & Research Centre for Women, 54000 Kuala Lumpur, Lancet 1994; 343:1425-7.

154. Richart, R.M., Female Sterilization Using Pharmacologically Active Agents, Research Frontiers in Fertility Regulation: Editors, Zatuchni GI, Labbok M, Sciarra JJ, Hagerstown, Harper and Row 1980; p. 262.

155. Richart, R.M., Sterilization using chemical agents. New Trends in Female Sterilization: D. A. F. van Lith, L. G. Keith, E. V. van Hall eds., Chicago 1980; Chap. 14, pp. 150-53.

156. Richart, R.M., Female Sterilization using Chemical Agents, Research Frontiers in Fertility Regulation 1981; 1:1-12.

157. Richart, R.M., The Use of Chemical Agents in Female Sterilization, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 24.

158. Rosca, A., Surcel I.V., Toader, S., Rotaru, O., Non-surgical female sterilization using Mepacrine (quinacrine). Obstetrica si Ginecologia. UNFPA 1996; XI(VI):221-4.

159. S., Jadwani, K., Goyal V., Chemical Sterilisation with Quinacrine, Fourth transaction of scientific papers at the India FRP Contributors' Conference held at the West End Hotel, Bombay, February 24, 1977 Pachauri S, ed., Calcutta, India Fertility Research Programme September 1977; p 167-70.

160. Sarin, S.R., Quinacrine Sterilizations: Experience Among High Risk Women, Acta Obstetricia et Gynecologica Scandinavica 1997; Vol 76: Sup. 167:4 p.16 (Abstract).

161. Sarin, A.R., Mohindroo, A., Chandra, P., Gill, S.S., Histologic Changes in the Fallopian Tubes after Lower Dose of Transcervical Quinacrine Insertion. Fertility and Sterility 1998; 70:Suppl. 1 (abstract p-121)S164.

162. Sarin, A.R., Department of Obstetrics and Gynecology, Government Medical College, and Aastha Medical Center, Patiala, India. Quinacrine sterilization: experience among women at high risk for surgery, Advances in Contraception, 1999; 15: 175-178.

163. Sciarra, J.J. Moderator of Discussion: Feasibility and acceptability of transcervical sterilization. Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983; p 56-59.

164. Shelton, J.D., Non-surgical female sterilisation, Lancet Oct. 2, 1993; Vol. 342.

165. Sherman, I., Drugs That Changed the World: How Therapeutic Agents Shaped Our Lives, 1st edition, 2016, CRC Press, Taylor & Francis Group, Florida, ISBN 9781315366739, DOI: 10.1201/9781315366739

166. Sivin, L., Non-surgical female sterilisation, Lancet Oct. 2, 1993; Vol. 342.

167. Sokal, D., Hieu, D.T., Weiner, D.H., Vinh, D.Q., Vach, T.H., Hanenberg, R., Long-term follow-up after quinacrine sterilization in Vietnam. Part I: interim efficacy analysis, Fertility and Sterility 2000;74:1084-91.

168. Sokal, D., Hieu, D.T., Weiner, D.H., Vinh, D.Q., Vach, T.H., Hanenberg, R., Long-term follow-up after quinacrine sterilization in Vietnam. Part II: interim efficacy analysis, Fertility and Sterility 2000;74:1092-1100.

169. Sokal, D.C., Dabancens, A., Guzman-Serani, R., Zipper, J., Cancer risk among women sterilized with transcervical quinacrine in Chile: an update through 1996, Fertility and Sterility 2000 Jul;74(1):169-71

170. Sokal, D.C., Quinacrine family planning method: Letters to the Editor. Lancet 1994; 343:1425-7.

171. Sokal, D.C., Zipper, J., Guzman-Serani, R., Aldrich, T.E., Cancer risk among women sterilized with transcervical quinacrine hydrochloride pellets, 1977 to 1991, Fertility and Sterility 1995; 64:325-34.

172. Sokal, D.C., Zipper, J., King, T., Transcervical quinacrine sterilization: clinical experience, International Journal of Gynecology and Obstetrics 1995; 51 Suppl: S59-S69.

173. Soroodi-Moghaddam, S., Quinacrine Pellet Method of Nonsurgical Female Sterilization in Iran: Preliminary Report on a Clinical Trial, International Family Planning Perspectives 1996; 22:122-123, 127

174. Steck, E.A., The Chemotherapy of Protozoan Diseases. Walter Reed Army Institute of Research 1972; p. 3.121.

175. Sterile arguments. The Economist: Science and Technology March 19, 1994; pp. 99-100.

176. Suhadi, A., Soejoenoes, A., One year experience using quinacrine pellets for non-surgical female sterilization. Indonesian Journal of Obstetrics and Gynecology 1996; 20:39-43.

177. Suhadi, A., Soejoenoes, A., Quinacrine pellet nonsurgical female sterilization in Wonosobo, Indonesia. Fertility and Sterility 1997; 67(5):966-8.

178. Suhadi, A., Anwar, M. and Soejoenoes, A. Four-year clinical evaluation of quinacrine pellets for non-surgical female sterilization. Advances in Contraception 1998; 14: 69-77

179. Tennant, R.W., Margolin, B.H., Shelby, M.D., Zeiger, E., Haseman, J.K., Spalding, J., Caspary, W., Resnick, M., Stasiewicz, S., Nderson, B.A., Minor, R., Prediction of Chemical Carcinogenicity in Rodents from in Vitro Genetic Toxicity Assays. Science 1987; 236:933-41.

180. Thakur, P.S., Quinacrine sterilization in Tripura, India. Tripura Branch, Indian Rural Medical Association, Agartala 799 001, Tripura, India. Contraception 2001 Nov;64(5):277-9.

181. The FDA's Rigged Drug Committees. A case study in how the agency gets the advice it wants

to hear. The Wall Street Journal, Editorial, updated Dec. 30, 2016

182. The Lancet editorial, Death of a study: WHO, what, and why, Lancet 1994; 343:987.

183. The Lancet editorial, Fortress WHO: breaching the ramparts for health's sake, Lancet, Vol. 345 1995, Jan. 28; pp. 203-4.

184. The World health report: 2005 make every mother and child count. World Health Organization, ISBN 9241562900.

185. Thurmond,, A.S., Jones, M.K., Mullick, B., Kessel, E., Reversal of 'Sterilization due to Application of Quinacrine by Means of Transcervical Tubal Catheterization, Journal of Vascular and Interventional Radiology 1995; 6:147-9.

186. Tice, R.R., Griffith, J., Recio. L., An Evaluation of the Mutagenicity and Carcinogenicity of Quinacrine, Unpublished report of Family Health International June 22, 1990; 32pp.

187. Tice, R.R., Cavender, F.L., Carson, B.L., Haneke, K.E., Is Quinacrine a Human

Carcinogen? Unpublished report of Mutation Research, July 13, 1999

188. Trujillo, V., Zipper, J., Viel, B., Rivera, M., Sterilisation feminine, non chirurgic'ale avec I'emploi de quinacrine: efficacite de deux insertions de pellets de quinacrine. Gynecology and Obstetrics 1993; 88:147-50.

189. Trussell, J. (2011) Birth Control Guide, "Contraceptive failure in the United States." Contraception 83(5):397-404.

190. Weld, M., Out of the Public's View: The Battle for Quinacrine, Humanist in Canada 1996, Autumn; pp. 31-2.

191. Wheeler, R.G., Delivery Systems for Applying Quinacrine as a Tubal Closing Agent, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia, Harper and Row 1983.

192. Whitney, R, Quinacrine Non-surgical Female Sterilization (QS) in a Private American Office Practice, presentation given at the F.I.G.O Conference in Santiago, Chile , Nov 2003.

193. Will American women want Quinacrine? Contraceptive Technology Update. (A monthly newsletter) April 1994.

194. Wilson, E.W., The development of new technologies for female sterilization: conclusions and recommendations for research, International Journal of Gynecology & Obstetrics 51 Suppl. 1 (1995) S71 -S74

195. Wu, Y.H., Qian, P.L., Tien, S.P., Nonsurgical procedures for manual instillation of a phenol-Atabrine paste (PAP) for female tubal occlusion. Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia: Harper and Row 1983; p 151.

196. Yoon, S., Gianturco, S., Pavlech, L., Storm, K., Yuen, M., Mattingly, A., Quinacrine: Summary Report, The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), 2020, http://hdl.handle.net/10713/12349

197. Zaneveld, L.J.D, Goldsmith, A., Evaluation of Slow-Release Quinacrine Pellets in the Pig, Female Transcervical Sterilization: Editors, Zatuchni GI,

Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia: Harper and Row 1983; p 122.

198. Zaneveld, L.J.D, Goldsmith, A., Lack of tubal occlusion by intrauterine quinacrine and tetracycline in the primate. Contraception 1984; 30:161-7.

199. Zatuchni, G.I. Moderator of Discussion: Chinese Techniques for Chemical Sterilization, Female Transcervical Sterilization: Editors, Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, Philadelphia: Harper and Row 1983; p 172.

200. Zipper, j., Medel, M., Prager, R., Alterations in fertility induced by unilateral intrauterine instillation of cytotoxic compounds in rats. American Journal of Obstetrics and Gynecology 1968; 101:971-78.

201. Zipper, J., Stachetti, E., Medel, M., HUMAN FERTILITY CONTROL BY TRANSVAGINAL APPLICATION OF QUINACRINE ON THE FALLOPIAN TUBE, Fertility and Sterility 1970; 21:581-9.

202. Zipper, J., Insunza, S., Pharmacological agents that potentiate or inhibit the occlusive action of

quinacrine in the rabbit tube and rat uterus. Female Sterilization: Prognosis for Simplified Outpatient Procedures. (Proceedings of a workshop held at Airlie, Virginia, December 2-3, 1971): Editors, Duncan CW, Falb RD, Speidel JJ, New York: Academic Press 1972; p 151-8.

203. Zipper, J., Medel, M., Stachetti, E., Pastene, L., Rivera, M., Prager, R., CHEMICAL AGENTS FOR TRANSVAGINAL STERILIZATION, Human Sterilization. Proceedings of the conference, Cherry Hill, New Jersey, October 28-31, 1969: Editors, Richart RM, Prager DJ, Springfield, Illinois: Charles C. Thomas 1972; p 339-352.

204. Zipper, J., Prager, R., Medel, M., BIOLOGIC CHANGES INDUCED BY UNILATERAL INTRAUTERINE INSTILLATION OF QUINACRINE IN THE RAT AND THEIR REVERSAL BY EITHER ESTRADIOL OR PROGESTERONE, Fertility and Sterility 1973; 24:48-53.

Appendix 6 - 37 Lippes Loop Clinical Studies and Patents

Here are Clinical Studies of the Lippes Loop archived at the National Institute of Health (NIH), National Library of Medicine, Center for Biological Information and two patents on the method.

1. Christopher Tietze and Sarah Lewit, Evaluation of Intrauterine Devices: Ninth Progress Report of the Cooperative Statistical Program, Studies in Family Planning, Vol. 1, No. 55 (Jul., 1970), pp. 1-40 Published by: Population Council Stable URL: https://www.jstor.org/stable/1965076 Accessed: 12-12-2020 17:16 UTC

2. Chompootaweep S, Reinprayoon D, Virutamasen P, Somboonsuk A, Dusitsin N. A comparative study of Lippes loop and Delta loop intrauterine devices in early postpartum. Contraception. 1983 Nov;28(5):399-404. doi: 10.1016/0010-7824(83)90072-0. PMID: 6673899.

3. Randic L, Haller H, Perovic M, Farr G. The effect of adding copper onto Lippes Loop IUDs: results from a ten-year study in Yugoslavia. Contraception. 1991 Mar;43(3):229-39. doi: 10.1016/0010-7824(91)90142-3. PMID: 2036794.

4. Behlilovic B, Etman S, Laufe LE, Dixon B. Comparison of the Lippes Loop D and tapered Lippes Loop D intrauterine devices. Contraception. 1982 Mar;25(3):293-8. doi: 10.1016/0010-7824(82)90052-x. PMID: 7075196.

5. Farr G, Amatya R, Acosta M, Ekwempu C, Kisninci H. Clinical performance of the TCu380A and Lippes Loop IUDs in three developing countries. Contraception. 1995 Jul;52(1):17-22. doi: 10.1016/0010-7824(95)00119-u. PMID: 8521710.

6. Brenner PF, Roy S, Mishell DR Jr. A randomized comparison of the Ypsilon-Y and Lippes loop D intrauterine devices in parous women. Obstet Gynecol. 1978 Mar;51(3):327-9. doi: 10.1097/00006250-197803000-00015. PMID: 628535.

7. Interval iud insertion in parous women: a randomized multicentre comparative trial of the Lippes Loop D, TCu220c and the Copper 7. Contraception. 1982 Jul;26(1):1-22. doi: 10.1016/0010-7824(82)90167-6. PMID: 7128130.

8. Fakhr MM, Fakhr DM, Hassan AA, Nasser NM. A clinical study comparing the performance of three IUCDs (Multiload Copper 250, Copper T 200, and

Lippes Loop C). Popul Sci. 1988;8:39-53. PMID: 12316112.

9. Díaz J, Díaz MM, Pastene L, Araki R, Faúndes A. Randomized clinical study of the T-Cu 380A and the Lippes loop C, in Campinas, Brazil. Contraception. 1982 Sep;26(3):221-8. doi: 10.1016/0010-7824(82)90071-3. PMID: 6756774.

10. Chi IC, Wilkens LR, Siemens AJ, Lippes J. Syncope and other vasovagal reactions at interval insertion of Lippes Loop D--who is most vulnerable? Contraception. 1986 Feb;33(2):179-87. doi: 10.1016/0010-7824(86)90083-1. PMID: 3516567.

11. Thiery M, Laufe L, Parewijck W, van der Pas H, van Kets H, Derom R, Defoort P. Immediate postplacental IUD insertion: a randomized trial of sutured (Lippes Loop and TCu22OC) and non-sutured (TCu22OC) models. Contraception. 1983 Oct;28(4):299-313. doi: 10.1016/0010-7824(83)90032-x. PMID: 6365448.

12. Chi IC, Wilkens L, Rogers S. Expulsions in immediate postpartum insertions of Lippes Loop D and Copper T IUDs and their counterpart Delta devices—an epidemiological analysis. Contraception. 1985 Aug;32(2):119-34. doi:

10.1016/0010-7824(85)90101-5. PMID: 3907964.

13. Comparative multicentre trial of three IUDs inserted immediately following delivery of the placenta. Contraception. 1980 Jul;22(1):9-18. doi: 10.1016/0010-7824(80)90112-2. PMID: 7418410.

14. Sastrawinata S, Farr G, Prihadi SM, Hutapea H, Anwar M, Wahyudi I, Sunjoto, Kemara KP, Champion CB, Robbins M. A comparative clinical trial of the TCu 380A, Lippes Loop D and Multiload Cu 375 IUDs in Indonesia. Contraception. 1991 Aug;44(2):141-54. doi: 10.1016/0010-7824(91)90114-u. PMID: 1893708.

15. Kisnisci H, Champion CB. A study of delta intrauterine devices in Ankara, Turkey. Int J Gynaecol Obstet. 1985 Feb;23(1):51-4. doi: 10.1016/0020-7292(85)90011-6. PMID: 2860033.

16. Shaw ST Jr, Andrade AT, Paixão de Souza J, Macaulay LK, Rowe PJ. Quantitative menstrual and intermenstrual blood loss in women using Lippes Loop and Copper T intrauterine devices. Contraception. 1980 Apr;21(4):343-52. doi: 10.1016/s0010-7824(80)80013-8. PMID: 7389355.

17. Guillebaud J, Bonnar J, Morehead J, Matthews A.

Menstrual blood-loss with intrauterine devices. Lancet. 1976 Feb 21;1(7956):387-90. doi: 10.1016/s0140-6736(76)90216-6. PMID: 55650.

18. IUD insertion following termination of pregnancy: a clinical trial of the TCu 220C, Lippes loop D, and copper 7. Stud Fam Plann. 1983 Apr;14(4):99-108. PMID: 6351364.

19. Mccarthy TG, Lim LS, Chew SC, Heng SH, Ratnam SS. A randomized comparative trial of the Lippes Loop D, Gravigard and TCu 220C IUDs. Adv Contracept Deliv Syst. 1985;(1):113-21. PMID: 12267106.

20. Batár I, Thomas MN. One year's experience with the Ypsilon-Y IUD. Int J Gynaecol Obstet. 1978-1979;16(4):333-8.doi: 10.1002/j.1879-3479.1979.tb00458.x. PMID: 35399.

21. Dennerstein G, Langley R, Zimmerman M. A controlled intrauterine contraceptive device trial. Med J Aust. 1977 Mar 5;1(10):322-4. PMID: 323659.

22. Stumpf PG, Lenker RM. Insertion technique, not design, affects expulsion rates of postpartum intrauterine device. Contraception. 1984 Oct;30(4):327-30. doi: 10.1016/s0010-7824(84)80024-

4. PMID: 6509985.

23. Aznar R, Lara R, Zarco D, González L. The effect of various contraceptive hormonal therapies in women with normal and diabetic oral glucose tolerance test. Contraception. 1976 Mar;13(3):299-311. doi: 10.1016/s0010-7824(76)80040-6. PMID: 55331.

24. Chi IC, Farr G, Thompson K, Acosta M, Alvarado G, Rivera R, Bandaragoda J, Delgado Betancourt J. Is the copper T 380A device associated with an increased risk of removal due to bleeding and/or pain? An analysis. Contraception. 1990 Aug;42(2):159-69. doi: 10.1016/0010-7824(90)90099-h. PMID: 2085967.

25. Cole LP, Edelman DA, Potts DM, Wheeler RG, Laufe LE. Postpartum insertion of modified intrauterine devices. J Reprod Med. 1984 Sep;29(9):677-82. PMID: 6387112.

26. Theron F. 'n Vergelyking tussen die Multiload Cu 250- en die Lippes lus-intraüteriene kontraseptiewe toestelle [A comparison between the Multiload Cu250 and the Lippes loop intrauterine contraceptive devices]. S Afr Med J. 1980 Jul 12;58(2):64-5. Afrikaans. PMID: 7404184.

27. Oyelola OO, Okonofua FE, Adediran TO. Menstrual bleeding pattern and iron status in women fitted with copper and non-medicated intrauterine contraceptive devices. East Afr Med J. 1994 Apr;71(4):268-70. PMID: 8062778.

28. Andrade AT, Pizarro E, Shaw ST Jr, Souza JP, Belsey EM, Rowe PJ. Consequences of uterine blood loss caused by various intrauterine contraceptive devices in South American women. World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction. Contraception. 1988 Jul;38(1):1-18. doi: 10.1016/0010-7824(88)90091-1. PMID:3048870.

29. Arowojolu AO, Otolorin EO, Ladipo OA. Performances of copper T 380A and multiload copper 375/250 intrauterine contraceptive devices in a comparative clinical trial. Afr J Med Med Sci. 1995 Mar;24(1):59-65. PMID: 7495202.

30. Pizarro Orchard E, Gómez Rogers C. Evaluación clínica del dispositivo intrauterino "T de progesterona" [Clinical evaluation of the progesterone T intrauterine device]. Rev Chil Obstet Ginecol. 1980;45(2):87-98. Spanish. PMID:

6765370.

31. Pedron Neueo N. Cuantificación del sangrado menstrual en mujeres portadoras de dispositivos intrauterinos (DIU's) [Quantification of menstrual bleeding in women using intrauterine devices (IUDs)]. Gac Med Mex. 1992 Sep-Oct;128(5):597-604; discussion 604-5. Spanish. PMID: 1307733

32. Guillebaud J, Bonnar J. Longer though lighter menstrual and intermenstrual bleeding with copper as compared to inert intrauterine devices. Br J Obstet Gynaecol. 1978 Sep;85(9):707-12. doi: 10.1111/j.1471-0528.1978.tb14951.x. PMID: 698154.

33. IUD insertion following spontaneous abortion: a clinical trial of the TCu 220C, Lippes loop D, and copper 7. Stud Fam Plann. 1983 Apr;14(4):109-14. PMID: 6351363.

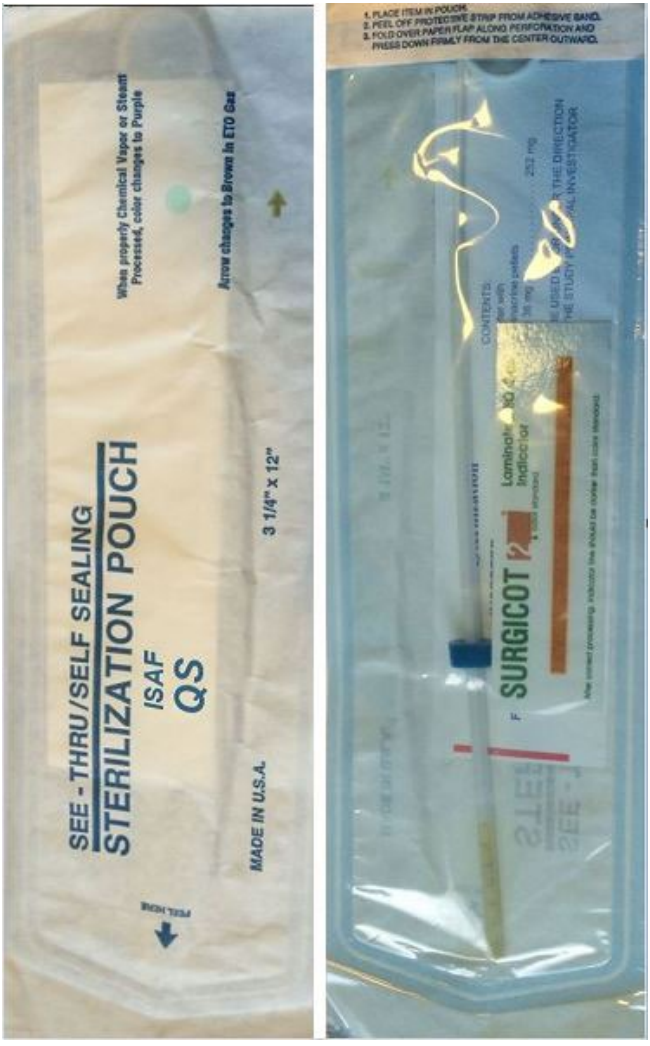
34. Bounds W, Hutt S, Kubba A, Cooper K, Guillebaud J, Newman GB. Randomised comparative study in 217 women of three disposable plastic IUCD thread retrievers. Br J Obstet Gynaecol. 1992 Nov;99(11):915-9. doi: 10.1111/j.1471-0528.1992.tb14442.x. PMID: 1450143.

35. Somboonsuk A, Israngkum C, Siriwongse T, Dusitsin N, Onthuam Y, Chaudhury RR, Fuchs F, Grossman R, Gray R. A comparative controlled trial in rural Thailand of three intrauterine devices. Contraception. 1978 Aug;18(2):137-50. doi: 10.1016/0010-7824(78)90089-6. PMID: 688751.

36. Howard J Tatum, 1968, Intrauterine contraceptive device, US Patent 3533406A, see Table

37. Jack Lippes, 1963, Intrauterine device, US Patent 3250271A

Appendix 7 – QS Kit



Appendix 8 – Lippes Loop Kit

About The Author

Mr. Collins, Jr. is a senior level engineering manager in the computer industry and holds 62 patents. His research and development teams designed and supported production and sale of over a million products installed worldwide. He is on the board of several nonprofits, President of International Services Assistance Fund (ISAF) a 501(c)(3) founded in 1976 by his father, is an undergraduate of Temple University, and holds his Master of Science degree in Electrical Engineering from National Technological University.

Chief Collaborator

Dr. Stephen D. Mumford is the founder and President of the Center for Research on Population and Security. He has his doctorate in Public Health. His principal research interest has been the relationship between world population growth and national and global security. He has been called to provide expert testimony before the U.S. Congress on the implications of world population growth.

Dr. Mumford has decades of international experience in fertility research where he is widely published. In 1981, he received the Margaret Mead Leadership Prize in Population and Ecology. He has been recognized for his work in advancing the cause of reproductive rights by the Feminist Caucus of the American Humanist Association, and has addressed conferences worldwide on new contraceptive technologies and the

stresses to the security of families, societies and nations that are created by continued uncontrolled population growth. He has written extensively on the pivotal role of the Catholic hierarchy in thwarting efforts to tackle the world's burgeoning population.

In 1974, President Richard Nixon requested the authoritative interagency study that came to be known as NSSM 200 (National Security Study Memorandum 200). The NSSM 200 report states: "There is a major risk of severe damage [from continued rapid population growth] to world economic, political, and ecological systems and, as these systems begin to fail, to our humanitarian values." However, the implementation of NSSM 200 recommendations that were already approved by President Ford was blocked by the swift action of the Vatican. As CIA Director, George H.W. Bush was in the position most concerned with such a grave threat to the United States and global security. Just days after leaving his post at the agency, he told Dr. Mumford, author of *Population Growth Control* (1977), "I agree with everything you are saying here," referring to the book, "and I can assure you the folks at the CIA agree with you too."

As president of the Center for Research on Population and Security, Dr. Mumford continues his work of more than four decades as lead scientist in the development and evaluation of contraception methods and

advancing the cause of reproductive rights. Collaborating with health providers and scientists in more than 20 countries, his office is in North Carolina where he makes his home. His wife of 40 years, a Chinese immigrant and leading cancer researcher, focuses much of her investigation on environmental cancers affecting large populations of poor women.

In addition to his books on biomedical and social aspects of family planning, as well as scientific articles in more than a score of journals, Dr. Mumford's major works include American Democracy and the Vatican: Population Growth and National Security (Amherst, New York: Humanist Press, 1984), The Pope and the New Apocalypse: The Holy War Against Family Planning (Research Triangle Park, North Carolina: Center for Research on Population and Security, 1986), and The Life and Death of NSSM 200: How the Destruction of Political Will Doomed a U.S. Population Policy (Research Triangle Park, North Carolina: Center for Research on Population and Security, 1996).

The following is a sampling of some of the articles, excerpts and presentations by Dr. Mumford that we feature on this site. There is a much wider selection available here.

How far is the Vatican willing to go to insure its survival?

Why the Catholic Church has survived for 2000 years while all other tyrannies have failed

The Catholic Church and Sex

How the undemocratic activities of the Catholic Church silences critics

Catholicism – both a religion and an ambitious, arrogant political institution

The Roman Catholic hierarchy: a cabal of power that moves under the guise of benevolence

Postponing Self-Destruction of the Catholic Church

Overcoming Overpopulation: The Rise and Fall of American Political Will

What happened to American political will to deal with the overpopulation problem?

The Vatican's Role in the World Population Crisis: The Untold Story

Vatican Control of World Health Organization Policy: An Interview with Milton P. Siegel

NSSM 200, the Vatican, and the World Population Explosion

Eight kinds of power the Vatican exercises to control Catholics

Why The Pope Can't Change The Church's Position On Birth Control: Implications For Americans

About the Book

This book is a thank you to women highlighting a century of key pioneers in the women's reproductive movement, with a brief history to help explain why the fight for women's equality is so critical to men and for all of humanity.

As a first step in leveling the playing field for women to be equal to men (4♀2B=♂), we all must fight for:

1) complete control over our bodies (as opposed to control by anyone else, e.g., religious leaders, politicians, or businesses), and;

2) access to the best, safe, and most effective contraceptive methods that people like, and that they will use like the Lippes Loop and QS all free for our lifetimes. Please take our survey, and;

3) a gameplan for economic success like ***A simple idea*** so that we can save time and money and have the healthiest and happiest of families.

This book, referring to hundreds of publications proving the safety and efficacy of non-surgical permanent contraception for women (QS) would never have happened without thousands of healthcare providers who recognized the value to women of QS and the undying

support chiefly of ISAF CEO Dr. Stephen D. Mumford, Dr. Jack Lippes, Sarah G. Epstein, and Donald Collins, Sr. Thank you!