

## IN THE MATTER OF

## NME HOSPITALS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF  
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-3317. Complaint, Dec. 31, 1990—Decision, Dec. 31, 1990*

This consent order requires, among other things, a corporation based in Santa Monica, Ca., that owns a medical center in Boca Raton, Fla., that operates an infertility clinic, to possess a reasonable basis for any future success rate claims for its *in vitro* fertilization procedures, and for claims of success in terms of either live births or pregnancies achieved through any of its infertility treatments.

*Appearances*

For the Commission: *Michael A. Katz* and *Michael C. McCarey*.

For the respondent: *Milton McKay*, Tampa, FL.

## COMPLAINT

The Federal Trade Commission, having reason to believe that NME Hospitals, Inc., d/b/a West Boca Medical Center, a corporation (“respondent”), has violated certain provisions of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. 41 *et seq.*, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. NME Hospitals, Inc., is a Delaware corporation with its principal office and place of business located at 2700 Colorado Avenue, Santa Monica, California. Respondent owns and operates West Boca Medical Center, a hospital, which is located at 21644 State Road 7, Boca Raton, Florida.

PAR. 2. Through West Boca Medical Center (“the Center”), respondent is now, and for some time last past has been, engaged in offering for sale and the sale of services in connection with the treatment of infertility in the human reproductive system. The Center dispenses its infertility services to the public under the trade name, “The Fertility Institute of Boca Raton”, (“FIBR”). The address of FIBR is the same as the Center.

PAR. 3. Since at least 1987, the Center, acting under the authority

and control of respondent, has placed, or caused to be placed, advertisements in various periodicals that are in general circulation to the public and has mailed letters to potential patients that contain information about FIBR and its services.

PAR. 4. The acts and practices of respondent alleged in this complaint have been and are in or affecting commerce.

PAR. 5. The Center's advertisements and mailings have contained representations through January, 1989, as to the past success rates of achieving pregnancies for patients who purchase FIBR's services in treating infertility, including use of In Vitro Fertilization ("IVF") and Gamete Intrafallopian Transfer ("GIFT"). Typical of these advertisements, but not necessarily all-inclusive thereof, are the attached Exhibits A and B. The aforesaid advertisements, which appeared in publications dated September, 1988 (Exhibit A) and January, 1989 (Exhibit B) contain the following statements:

1. "The Fertility Institute of Boca Raton is producing some very satisfactory results.

In fact, four of our first twelve patients participating in our In Vitro Fertilization program have achieved pregnancy, and our first 'test tube' baby is due in October." [Exhibits A and B]

2. "Our success rate is an impressive 30%, well above the national average." [Exhibit A]

PAR. 6. Through the use of the statements referred to in paragraph five, respondent has represented, directly or by implication, that, as of the date that the advertising containing said statements appeared:

1. FIBR had achieved pregnancies for at least four of its patients who had undergone IVF procedures at its clinic.

2. FIBR's success rate in achieving pregnancies for its patients through IVF procedures has been higher than the national average.

PAR. 7. Through the use of the statements and representations referred to in paragraphs five and six, respondent has represented, directly or by implication, that at the time respondent made those representations, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 8. At the time respondent made those representations, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph seven was and is false and misleading.

PAR. 9. The acts and practices of respondent alleged in this

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complaint constitute unfair and deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

Commissioner Starek not participating.

## EXHIBIT A



## The Fertility Institute of Boca Raton is producing some very satisfying results.

In fact, four of our first 12 patients participating in our In Vitro Fertility program have achieved pregnancy, and our first "test-tube" baby is due this October. Our success rate is an impressive 30%, well above the national average.

Amazing as it seems, couples with serious fertility problems are now able to realize the joys of parenthood. Through IVF (In Vitro Fertilization), GIFT (Genetic Intrafollicular Transfer), and state-

of-the-art laser and microsurgery many women can now fulfill their dream of becoming pregnant.

At the Fertility Institute of Boca Raton our experienced team of specialists is dedicated to the comprehensive evaluation and treatment of infertile couples.

Under the direction of reproductive endocrinologist Moshe R. Poros, M.D., and embryologist Joseph E. Solotowski, formerly senior embryologist at the prestigious Cleveland Clinic, you are assured complete care in a private and

thoroughly comfortable environment that is part of the full-service facility of West Boca Medical Center. And since most procedures are performed on an outpatient basis, your home life remains undisturbed. If you are seriously interested in learning more about these programs - call us in confidence. The results could be quite gratifying!

The Fertility Institute of Boca Raton at West Boca Medical Center, 29644 State Road 7, Boca Raton, FL 33428-8222.

The Fertility Institute of Boca Raton  
At West Boca Medical Center

## EXHIBIT B



## The Fertility Institute of Boca Raton is producing some very satisfying results.

In fact, four of our first 12 patients participating in our In Vitro Fertilization program have achieved pregnancy, and our first "test-tube" baby is due this October.

Amazing as it seems, couples with serious fertility problems are now able to realize the joys of parenthood. Through IVF (In Vitro Fertilization), GIFT (Genetic Intra-Uterine Transfer), and state-of-the-art laser and microsurgery

many women can now fulfill their dream of becoming pregnant.

At the Fertility Institute of Boca Raton our experienced team of specialists is dedicated to the comprehensive evaluation and treatment of infertile couples. Under the direction of reproductive endocrinologist Moshe R. Peron, M.D. and embryologist Joseph E. Sokolozki, formerly senior embryologist at the prestigious Cleveland Clinic, you are assured complete care in a private and thoroughly comfortable

environment that is part of the full-service facility of West Boca Medical Center. And since most procedures are performed on an outpatient basis, your home life remains undisturbed. If you are seriously interested in learning more about these programs - call us in confidence. The results could be quite gratifying!

The Fertility Institute of Boca Raton at West Boca Medical Center, 29844 State Road 7, Boca Raton, FL 33428 - 488-8222.

**The Fertility Institute of Boca Raton**  
At West Boca Medical Center

## DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such an agreement on the public record for a period of sixty (60) days now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent NME Hospitals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2700 Colorado Avenue, Santa Monica, California.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

## ORDER

## I.

*It is ordered,* That respondent, NME Hospitals, Inc., a corporation, its successors and assigns, and respondent's officers, agents, repre-

sentatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale or offering for sale of services relating to the treatment of infertility through *in vitro* fertilization, do forthwith cease and desist from representing, directly or by implication:

A. That its success rate in achieving pregnancies for its patients is higher than or compares favorably with the success rates of other providers of these services, unless at the time of making such representations, it possesses and relies upon a reasonable basis for making such comparison which shall, at a minimum, consist of results for its own patients that are based upon either the same or essentially equivalent test procedures for determining pregnancy that were used to produce the results with which the comparison is made.

B. That any of its patients have achieved pregnancies through respondent's treatment unless at the time of making such representation, respondent possesses and relies upon a reasonable basis for making such representation. Such reasonable basis shall consist of competent and reliable scientific evidence substantiating the representation. For any test to be "competent and reliable" it must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession to yield accurate and reliable results and shall not consist solely of measuring or evaluating human chorionic gonadotrophin (hCG) risings.

## II.

*It is further ordered,* That respondent, NME Hospitals, Inc., a corporation, its successors and assigns, and respondent's officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale or offering for sale of services relating to the treatment of infertility, do forthwith cease and desist from misrepresenting, directly or by implication, the number or percentage of respondent's patients that give birth or achieve pregnancy, or have given birth or achieved pregnancies, or otherwise misrepresent respondent's past or present success rate in achieving births or pregnancies.

## III.

*It is further ordered,* That respondent shall maintain for a period of three (3) years after the date the representation was last made, and make available to the Federal Trade Commission upon request, business records supporting any claims of success in connection with its infertility treatment programs.

## IV.

*It is further ordered,* That, for a period of five years after the date of entry of this order, respondent shall notify the Commission at least thirty (30) days prior to any proposed change in respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in respondent which may affect compliance obligations arising out of this order.

## V.

*It is further ordered,* That respondent shall, within (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with all requirements of this order.

Commissioner Starek did not participate.



IN THE MATTER OF

FERTILITY INSTITUTE OF WESTERN  
MASSACHUSETTS, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF  
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-3318. Complaint, Dec. 31, 1990—Decision, Dec. 31, 1990*

This consent order prohibits, among other things, a Springfield, Ma., fertility institute and its proprietor from misrepresenting: the number or percentage of patients that achieve success in overcoming infertility, including the number or percentage of patients that give birth or achieve pregnancy; the success rate of any infertility procedure, without competent and reliable scientific evidence to substantiate the claims; or the cost or expense of any infertility test or procedure. The order also prohibits respondents from misrepresenting their qualifications or ability to provide infertility treatments, and any beneficial or therapeutic aspects of any test or procedure relating to the treatment of infertility.

*Appearances*

For the Commission: *Sara V. Greenberg* and *Phoebe D. Morse*.

For the respondents: *M. Elizabeth Gee*, Winston Salem, N.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that the Fertility Institute of Western Massachusetts, a sole proprietorship, and Dr. Ronald K. Burke, M.D., individually, hereinafter referred to as respondents, have violated Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45(a), and that an action by it is in the public interest, issues this complaint and alleges that:

PARAGRAPH 1. Respondent Fertility Institute of Western Massachusetts is a sole proprietorship with its principal office and place of business located at 130 Maple Street, Springfield, MA.

Respondent Ronald K. Burke is the sole proprietor of Fertility Institute of Western Massachusetts.

PAR. 2. Respondents are, and have been, engaged in offering and providing services for the treatment of infertility under the name Fertility Institute of Western Massachusetts.

PAR. 3. Respondents have placed, or caused to be placed, and have disseminated or caused to be disseminated, advertising and promotional materials including, but not limited to, the promotional materials referred to herein, promoting the services they provide in treating infertility.

PAR. 4. The acts and practices of respondents alleged in this complaint are, and have been, in or affecting commerce, as "commerce" is defined in the FTC Act.

PAR. 5. In the course and conduct of its business, respondents have disseminated or caused the dissemination of advertisements and promotional materials relating to their infertility services by various means, including *inter alia*, advertising in yellow pages and mailing promotional materials across state lines to prospective infertility patients, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of respondents' infertility services.

PAR. 6. Respondents' promotional booklet entitled "Understanding Your Fertility" contains representations as to respondents' success in achieving live births and pregnancies for patients who purchase their infertility services. "Understanding Your Fertility" is attached hereto as Exhibit A. The aforesaid promotional materials contain the following statements:

1. "As of 1988, the success rate for GIFT procedures performed by the Fertility Institute was 35%...Today, in order to avoid confusion, and in order to maintain standards, "success" should be defined only in terms of **take home live babies.**" (emphasis in original) [Exhibit A at p.34]

2. "Today, in order to avoid confusion, and in order to maintain standards, "success" should be defined only in terms of **take home live babies.** Defined in this way...the finest IVF centers report about 10-15% success, while GIFT yields an enviable 35% success rate." (emphasis in original) [Exhibit A at p.34]

3. "In vitro fertilization...the success rate is less than 20 percent and requires a commitment to at least six treatment cycles. Thus, a procedure offering less than a one-in-four chance for success, entails a financial liability of between \$30,000 and \$50,000." [Exhibit A at p.36]

4. "Fortunately, medical knowledge of reproductive physiology—and medical ability to successfully treat infertility—has increased dramatically in recent years. With proper care, 80 to 90 percent of infertile couples can be helped." [Exhibit A at p.2]

5. "Unfortunately, between five and ten percent of couples undergoing an infertility evaluation do not achieve a pregnancy within one year." [Exhibit A at p.27]

PAR. 7. Through the use of the statements referred to in paragraph six, respondents have represented, directly or by implication, that:

1. As of 1988, Fertility Institute of Western Massachusetts' success rate for the GIFT procedure was 35%, when success is defined as the ratio of the number of patients taking home babies compared to the number of patients entering the program.

2. IVF offers a 10-15% success rate while GIFT offers a 35% success rate, when success is defined as the ratio of the number of patients taking home babies compared to the number of patients entering the program.

3. Multiple treatment cycles of IVF produce a success rate of less than 20% and cost \$30,000-\$50,000.

4. Through proper care, 80-90% of infertile couples can be helped with their infertility problem.

5. 90-95% of couples undergoing an infertility evaluation will achieve a pregnancy within one year.

PAR. 8. In truth and in fact, as of 1988, the Fertility Institute of Western Massachusetts' success rate for the GIFT procedure was not 35%, when success is defined as the ratio of the number of patients taking home babies compared to the number of patients entering the program. Therefore, respondents' representation, as set forth in paragraph seven (1) was, and is, false and misleading.

PAR. 9. Through the use of the statements and representations referred to in paragraphs six and seven above, respondents have represented, directly or by implication, that they possessed and relied upon a reasonable basis for the representations set forth in paragraph seven, above, at the time such representations were made.

PAR. 10. In truth and in fact, respondents did not possess and rely upon a reasonable basis at the time such representations were made. Therefore, the representation set forth in paragraph nine, above, was, and is, false and misleading.

PAR. 11. The dissemination by respondents of the aforesaid false and misleading representations as alleged in this complaint constitutes unfair and deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

Commissioner Starek not participating.

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## EXHIBIT A

## UNDERSTANDING YOUR FERTILITY

A User's Manual Produced by  
**FERTILITY INSTITUTE OF WESTERN MASSACHUSETTS**  
and the  
**REPRODUCTIVE DIAGNOSTIC CENTER FOR RESEARCH AND TESTING**  
A Comprehensive Center  
for the Evaluation and Treatment  
of the Infertile Couple

## Directors

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Infertility, Gynecology,  
Microsurgery, and Pelvic  
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UNDERSTANDING YOUR FERTILITY

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#### UNDERSTANDING YOUR FERTILITY:

##### PREFACE

Who we are:

Fertility Institute of Western Massachusetts and its laboratory facilities, The Reproductive Diagnostic Center for Research and Testing provide a complete and comprehensive evaluation and treatment of the infertile couple. Our professional staff offers a multi-disciplinary approach to the treatment of infertility, incorporating the latest advances in the psychological, medical, surgical, microsurgical, and microlaser treatment of infertility.

The Directors:

Ronald K. Burke, M.D.—A recognized authority in the diagnosis and treatment of infertility, Dr. Burke has authored numerous articles in scientific journals, and has won international recognition for his clinical research and for the development of new methodology in the diagnosis and treatment of infertility. A respected lecturer, Dr. Burke has conducted and participated in numerous postgraduate courses in infertility for physicians throughout the United States and abroad. Dr. Burke is credentialed in gynecological microsurgery at both Baystate Medical Center and Mercy Hospital, and in operative laser surgery, laser laparoscopy, and laser microsurgery at Mercy Hospital and the University Hospital in Worcester. A consultant to several manufacturing corporations, Dr. Burke has pioneered in developing new instrumentation for pelvic laser surgery and operative laparoscopy.

Dr. Burke holds faculty appointments at the University of Massachusetts Medical School and Tufts University Medical College, and membership in the American

Fertility Society, the International Andrology Society, the American Association of Gynecologic Laparoscopists, the Fallopius Society, and The Gynecologic Laser Society. In addition, he is certified by the American Board of Obstetrics and Gynecology, and is a Fellow of the American College of Obstetricians and Gynecologists and the prestigious Society of Reproductive Surgeons. Dr. Burke is a consultant to the National Institute of Health Special Study Section on Reproductive Endocrinology and is particularly known for his clinical research in sperm physiology and for his contributions to the field of Andrology.

A Springfield native, Dr. Burke received his M.D. degree from the University of Kentucky College of Medicine, and completed his postgraduate training in Obstetrics and Gynecology at Thomas Jefferson Medical College and Temple University Health Sciences Center in Philadelphia. In addition, Dr. Burke completed postgraduate preceptorships with internationally renowned infertility specialists, and has developed expertise in microsurgery and pelvic laser surgery.

Paul David Shore-Suslowitz, Ed. D.—A licensed clinical psychologist, Dr. Shore-Suslowitz has developed an extensive interest and expertise in infertility and couples counseling, as well as in reproductive psychology.

Dr. Shore-Suslowitz has been actively involved in the field of psychology since 1970. He served as Consultant to the John F. Kennedy School of Government at Harvard University, as Outpatient Director of the Springfield Community Care Mental Health Center, and as psychotherapist at Northhampton State Hospital.

A Columbia University graduate, Dr. Shore-Suslowitz received his doctorate in counseling psychology from the University of Massachusetts. He is listed in the National Register of Health Service Providers in Psychology.

Eileen K. Burke, B.A.—A graduate of the City College of New York, Ms. Burke's initial experience was in the field of education. Since 1973, she has been deeply involved in the field of medical management and has been extensively trained in the case management of infertility problems as well as infertility counseling. A member of the National Association of Female Executives, Ms. Burke has had extensive postgraduate training in the specialty of reproductive endocrinology and medical counseling.

#### INTRODUCTION

About 3.8 million babies were born in the United States in 1987. An increasing number of these babies were born to couples who required medical assistance from a fertility specialist in order to overcome their infertility.

We have designed this manual to help you understand the procedures we will use to determine why you have had difficulty achieving a successful pregnancy—and the treatments we may use to help you.

Understanding the causes of your difficulty enables us to take proper measures to increase your fertility. Please study carefully the information we have prepared for you—and make a list of any questions you may have. Ask us to explain or clarify anything which seems unclear or confusing to you. The better you understand the significance of each factor and the purpose of each test or study, the better we can help you attain your goal—a healthy pregnancy culminating in the birth of a beautiful, healthy baby.

## The Problem of Infertility

Approximately 20 percent of married couples in this country experience some infertility problem. Sad to say, the number of infertile couples is sharply on the rise—particularly among young people. The National Institute of Health estimates over four million infertile couples in the United States, while more recent estimates by the American Fertility Society place the number at ten to twelve million! According to a 1983 article in the Journal of the American Medical Association, there were 900,000 fertility-related visits to physicians in 1980—alarming statistics, indeed. Another alarming statistic is that 101.2 out of every one hundred thousand of all patient-physician visits were fertility related in 1983.

## What is Infertility?

Medically, we define **infertility** as the inability of a couple to conceive after twelve months of intercourse without contraception (or within six months, for women over thirty). Why this time limit? Medical research observes that 85 percent of couples who reach pregnancy without medical help will do so within six months, and another ten percent in the following six months.

If you have never been pregnant, you have **primary** infertility. If you have been pregnant—regardless of the outcome—and have subsequent difficulty conceiving, you have **secondary** infertility. This distinction is an important one, since we associate each situation with different factors. According to a 1988 National Survey of Family Growth, primary infertility doubled from 500,000 in 1965 to 1 million in 1982, while secondary infertility declined from 2.5 million in 1965 to 1.4 million in 1982. Part of this decrease in secondary infertility can be explained by the increase in voluntary surgical sterilization for contraceptive purposes (from 15.8 percent in 1965 to 38.9 percent in 1982). This contraceptive sterilization masks those women who might otherwise discover that they were infertile, particularly those women over the age of 30. [2]

Within the general population, black couples are more likely than white to be infertile. In 1982, the risk of infertility for black couples was 1.5 times that for white couples.

On the bright side, an ongoing study of the epidemiology of infertility by the Centers for Disease Control reveals that this medical definition of infertility is a poor predictor of future conception. Only 16 to 21 percent of couples meeting the medical definition of infertility actually remain infertile throughout their lives.

## Some Causes of Increasing Requests for Infertility Services in the 1980's

## More couples with primary infertility

- Aging of the baby boom generation
- Delayed childbearing; more people in higher risk age groups
- Childbearing condensed into shorter intervals
- Delayed conception due to prior use of oral contraceptives

## Increasing proportion of infertile couples seeking care

- Decreased supply of infants available for adoption
- Heightened expectations
- Larger number of people in higher income brackets with infertility problems
- Larger percent of infertile couples are primarily infertile

## Increasing number of physicians providing infertility services



- Greater demand from private patients
  - More sophisticated diagnosis and treatment
  - At least 169 sites in the United States offering in vitro fertilization or gamete intrafallopian tube transfer
- More conducive social milieu
- Baby-boom generation expects to control their own fertility
  - Profamily movement
  - Increased discussion of sexual matters due to the AIDS epidemic
  - Extensive media coverage
- Evolution of new reproductive technologies
- Artificial insemination
  - Intrauterine insemination
  - Surrogate motherhood
  - In vitro fertilization (IVF)
  - Gamete Intrafallopian Tube Transfer (GIFT)
  - Cryopreservation

(SOURCE: Infertility, Medical and Social Choices, Congress of the United States, Office of Technology Assessment. Adapted from S.O. Aral and W. Cates, Jr., "The Increasing Concern With Infertility: Why Now?" Journal of the American Medical Association, 1983)

Fortunately, medical knowledge of reproductive physiology—and medical ability to successfully treat infertility—has increased dramatically in recent years. With proper care, 80 to 90 percent of infertile couples can be helped. [3]

What causes infertility?

While we have no simple answer to this question, we do know quite a bit about the causes of infertility. For example, the older the partners, the longer it may take them to achieve a pregnancy. The optimum time for reproduction—for both men and women—is between the ages of 22 and 26. In fact, of all women attempting to become pregnant, only about 25 percent over 35 and 22 percent over 40 succeed.

The following table presents the different factors contributing to infertility in order of frequency. We will discuss each factor in greater detail in subsequent chapters.

<u>Factor</u>	<u>%</u>
Male factors	50
Female factors	50
Combined factors	85
Cervical factors	33
Peritoneal factors	35-40
Tubal Abnormalities	20-30
Failure to Ovulate	10-15
Unexplained infertility	10
Luteal phase defects	5
Emotional factors	5
Sperm allergy & immunologic factors	1-5

You may wonder why the total exceeds 100 percent. While any single abnormal factor may prevent a pregnancy, most often infertility evaluation reveals a number of problem areas which contribute to the infertility problem. In order to successfully

treat infertility, we must address each of these problem areas. For this reason, we consider you and your partner as a single biological unit.

Although this chart links “emotional factors” with only five percent of infertility cases, in reality it plays a much more significant role. While medical research directly relates “emotional factors” to infertility in approximately five percent of the couples, specialists have begun to realize that the secondary psychological components of infertility affect many more couples. The emotional difficulties caused by infertility compound the problem for as many as 90 percent of couples, leading to a vicious cycle. Because of this, we at the Fertility Institute of Western Massachusetts always incorporate the emotional dimension of infertility. How you feel—about yourselves, about each other, about your difficulty in attaining a successful pregnancy—figures significantly in our evaluation and treatment.

Because of this definitive although less than clear and causal relationship between “emotional factors” and infertility, you, as a couple, will be asked to spend an “intake” session with our reproductive psychologist. The session is largely informative and educational, as well as a review of the salient issues that seem to contribute to infertility. Although this session is not “mandatory”, recent research indicates that those couples who participate in this session are three times as likely to achieve a pregnancy as those who do not! [4]

#### Who Provides Infertility Services?

Providers of medical and surgical infertility treatment services typically fall into three categories:

- Primary care physicians
- Infertility subspecialists practicing in centers that offer a complete a range of infertility services including IVF/ET and/or GIFT
- Other centers offering infertility treatment

According to the National Survey of Family Growth, Primary Care Physicians are the front-line providers of infertility treatment. Most female patients initially discuss their concerns about infertility with their obstetrician/gynecologist, while most male patients initially seek out a urologist. A survey of 100,000 private physicians conducted by the Alan Guttmacher Institute (AGI) at Mount Sinai in New York City, determined that infertility care is provided by other physicians as well. Of the 45,600 primary care physicians who indicated that they treated infertility, there were 17,500 general/family practitioners, 1,400 general surgeons, 20,600 obstetrician/gynecologists and 6,100 urologists. 96 percent of the obstetrician/gynecologists and 92 percent of the urologists offered “entry-level” infertility services, although this was not their area of specialization or greatest expertise.

Although general ob/gyns indicated that they provided basic diagnostic services, including clomiphene (91 percent), hysterosalpingograms (89 percent), and laparoscopies (85 percent), they were more likely to make referrals to infertility centers or infertility specialists than the other primary care physicians. This was felt to be due to the ob/gyns superior familiarity with the need for specialty referrals and the relatively complex services required.

The second category of infertility management is provided by Infertility Subspecialists consisting of ob/gyns who have received additional formal training beyond their basic ob/gyn residency programs. These subspecialists practice in fertility center settings and provide a complete range of services including IVF and/or GIFT. In 1987

there were 169 such centers offering IVF or gamete intrafallopian tube transfer, but proficiency in these techniques were found to vary widely. The trend in most modern centers was to offer a variety of the well established infertility diagnostic and treatment services, including artificial insemination and intrauterine insemination. Such centers tended to evaluate and treat both the male and female in the infertile couple, with the exception that male microsurgery was referred to urologists specifically interested in those procedures. This is the approach taken at the Fertility Institute.

The last category of providers includes Family Planning Agencies in hospitals, health departments and Planned Parenthood facilities. According to the AGI survey, 70 percent of family planning agencies provide at least some basic infertility services (e.g. physical exams, counseling, infection investigation and basal body temperature instruction). However, at least half of the family planning agencies said that they see fewer than ten infertility patients per year. Lack of demand, lack of appropriately trained staff and lab facilities, and the high cost of infertility services are among the reasons that this type of agency accounts for a minimal amount of infertility services.

[5]

#### Quality Assurance in Infertility Care

Quality assurance, quite simply, involves protecting infertile couples and assuring that they receive medical treatment in keeping with accepted standards of care. Quality assurance includes protecting individuals from being offered experimental treatments under the guise of therapy and from the inappropriately enthusiastic use of procedures not yet shown to be safe and/or effective. In addition, some procedures are accepted medical practice for certain indications but not for others. For example, IVF was originally offered only to women with damaged fallopian tubes, but has more recently been used for other types of infertility. GIFT, as well, originally performed only in very long standing infertility; with increasing success its indications have expanded to the point where numerous specialists are now recommending GIFT as "routine" with repeat laparoscopic procedures.

Differences in success rates among fertility centers is another area which cannot yet be fully explained. Although there are over 150 centers performing IVF and/or GIFT, the vast majority of these centers have yet to achieve a pregnancy with these advanced technologies!

Professional societies influence the research and treatment protocols of medical practitioners. The American College of Obstetricians and Gynecologists, the American Board of Obstetrics and Gynecology, the American Fertility Society, the Society of Reproductive Endocrinologists, the Society of Reproductive Surgeons, the American Andrology Society and the American Association of Gynecological Laparoscopists are a few of the more prominent and influential societies that pertain to the management of infertility.

The American Board of Obstetrics & Gynecology has established subspecialty certification in the field of Reproductive Endocrinology as recognition for those ob/gyns who have completed additional formal training beyond the general residency and have subsequently demonstrated proficiency by passing both a written and oral examination.

While membership in the American Fertility Society (AFS) is open to any physician professing an interest in treating infertility and applying for membership, the AFS

has established two select and prestigious organizations, the Society of Reproductive Endocrinologists, and the Society of Reproductive Surgeons. These societies promote research, set standards and differentiate through formal recognition those physicians qualified as subspecialists in the field of infertility management. The reason for these two societies lies in the practical realization that not all formal fellowship programs are equally strong in the postgraduate training of ob/gyns in both the medical and surgical treatment of infertility. Some programs, for example, primarily train physicians to be experts in running an IVF program, others emphasize research and minimize clinical care; still others are quite strong in microsurgery and operative laparoscopy, while a precious few are well rounded in all aspects of fertility treatment.

Fellowship in the Society of Reproductive Endocrinologists is primarily open to subspecialists limiting their practice to medical infertility. Fellowship in the Society of Reproductive Surgeons recognizes the fact that not all reproductive endocrinologists are proficient in the surgical treatment of infertility. Fellowship in the Society of Reproductive Surgeons requires both certification following completion of formal postgraduate training in reproductive endocrinology as well as formal documentation and marked proficiency in microsurgery and operative laparoscopy. In 1988 there were slightly less than 300 infertility specialists certified by the Society of Reproductive Endocrinologists and slightly less [6] than 300 infertility specialists certified by the Society of Reproductive Surgeons in all of the United States. In 1988, Massachusetts had approximately 5 subspecialists certified by each respective society.

#### How to Use this Manual

We have written this manual in order to provide you with a clear and comprehensive guide to the evaluation and treatment of infertility. The manual contains a great deal of information about some very complex issues and procedures. Do not expect to read and understand it all in one sitting.

We strongly advise you and your spouse to read through this manual prior to your initial office consultation. Make a list of questions you would like to ask us. The more you understand, the more productive you will find your consultation visit.

As your treatment progresses, use the manual as a reference guide. Consult appropriate sections as we perform various pertinent tests and procedures. Together, all of us—the two of you, and the highly trained professional staff at Fertility Institute of Western Massachusetts—form a team. The better you understand all aspects of your evaluation and treatment here, the better our chances for success.

Ronald K. Burke, M.D.  
Director [7]

#### THE EMOTIONAL ASPECTS OF INFERTILITY

by Paul Shore-Suslowitz, Ed. D.

“A baby is God’s opinion that the world must go on”....Carl Sandburg

Facing the possibility of infertility exacts an enormous psychological toll. Couples confronting this prospect feel significant stress and anxiety—on many fronts. The prospect of infertility strikes deep, threatening some very important ideas we hold about ourselves, our spouse, our marriage, our world. At Fertility Institute of Western Massachusetts, we recognize the importance of addressing the psychological impact which infertility has on your life. Couples come to us feeling anxiety-ridden,

frustrated, often depressed. We believe that effective treatment of infertility must address your emotional needs during this life crisis. We have designed our comprehensive team approach with this in mind.

As with all aspects of the evaluation and treatment of infertility, the more you become aware of your own emotional reactions—and the more you come to understand your emotional needs—the better your chances are for a successful treatment. While we can discuss your particular feelings only after meeting you, we can point out some problems most infertile couples share.

#### Identity and Self-Esteem

Most couples grappling with infertility experience some troubling thoughts about their identity. We all grow up assuming we can bear children. When this proves difficult, we may question our worth. Infertility can affect our sense of our own sexuality. Often, a man confronting the possibility will question his “masculinity” because of a low sperm count. A woman may question her “femininity” because she cannot conceive. These self-deprecating thoughts can be devastating to one’s self-esteem.

To cope with the emotional stress of infertility, you must confront and express these fears, rather than harboring them deep inside of you. Recognize that fertility is no measure of masculinity or of femininity, nor does your worth as a human being hinge on it. We encourage you to share your fears with each other, and with our highly skilled professional staff.

#### Control

At heart, most of us believe that our good efforts will be rewarded. We believe we can control our lives and reach our goals if we try hard enough. When we fail, we often hold ourselves responsible.

The experience of infertility shatters our sense of control. Coping with infertility involves acknowledging our lack of control over our own destiny. The experience may evoke profound feelings of powerlessness.

Many infertile couples feel great anger because of this—anger which they must confront and work through, lest it prove destructive. Sometimes, the man or woman searches [8] for a past event or “guilty deed” responsible for the infertility. Many people, for example, blame their infertility on past abortions, sexual promiscuity, or use of birth control. These feelings of guilt often reflect the individual’s refusal to accept a lack of control over his or her life. Without realizing it, the infertile person attempts to regain a sense of control by blaming himself or herself. Unfortunately, like anger, such guilt feelings usually prove counter-productive.

#### Trust and Intimacy

Dealing with infertility places great stress on a couple’s relationship. Sometimes a husband will lay all the blame for the problem squarely on his wife; sometimes a wife will blame her husband. This divisive fault-finding causes bitter feelings, sometimes anger, alienation, and other counter-productive emotions. Often the spouse with the more obvious physiological contribution to infertility will begin to dwell on his or her sense of responsibility for the problem. The feeling of guilt or failure which may ensue often leads the person to withdraw from the relationship, for fear of rejection by his or her spouse. This mixture of anger and alienation, guilt and isolation, distance and recrimination, takes a severe toll even on healthy, close relationships. For couples with

pre-existing difficulties in communication, trust, and sexual intimacy, the crisis of infertility can be devastating.

Furthermore, the infertility investigation itself has a deep impact on many aspects of intimacy. Procedures intrude on areas usually deemed most private. The infertility investigation requires intensive and often prolonged focus on sexual functioning, including masturbation for semen analysis, scheduled sex, obsession with basal body temperature, and the like. The anxieties and frustrations which this evokes may prove to be more than a couple can handle. For some couples, this leads to further alienation, depression, anger, and conflict. If ignored, these feelings can lead to a deterioration in the couple's sexual relationship, even a total breakdown in the marriage itself.

#### Isolation

Because people find infertility so painful to discuss, members of an infertile couple often find that they isolate themselves from friends and family. Seemingly innocent situations become threatening. A friend's pregnancy can evoke ambivalent feelings—envy and sadness, bitterness and anger—which seem too threatening to discuss openly. Well-intentioned relatives may unwittingly offer insensitive, intrusive advice.

Not surprisingly, many people facing the prospect of infertility become depressed. However, when couples withdraw—in anger, in fear, in shame, in despair—they cut themselves off from potentially valuable support. Sadly—and all too understandably—many couples suffer alone.

#### A Team Approach

The team approach of Fertility Institute addresses the needs—medical, surgical, and emotional—of the couple struggling with infertility. We realize that the psychological stresses associated with infertility can precipitate a vicious cycle, in which the emotional reactions to infertility can actually decrease the possibilities for successful treatment. We recognize the deep sense of loss—of potential, of hope—which accompanies the experience of infertility. Our highly-trained professional staff works together with you to break this destructive cycle. [9]

#### Background

Twenty-five years ago, medical science knew relatively little about fertility. This lack of knowledge led medical practitioners to attribute infertility—as well as many other diseases with unknown causes—to “psychological factors.” Psychiatrists told the infertile woman that she did not truly want children, blaming her difficulty on her “ambivalence” about motherhood. The scientific literature abounded with articles about women who sought medical attention to conceive children they did not truly desire.

As medical science uncovered the physiological factors responsible for fertility—the discovery, for example, of LH, FSH, and their relationship to ovulation and fertilization—we came to a better understanding of the biological causes of infertility. A backlash then developed against the concept of psychological treatment for infertility. While experts recognized that couples experiencing infertility suffered great emotional stress, they saw the emotional difficulties purely as a result of infertility, never as a cause.

Recent advances in the understanding of the neuro-endocrinologic pathways (the relationship of the chemicals produced in the brain) which affect male and female

hormone production have refined our thinking. We know, for example, that heightened anxiety affects the levels of serum prolactin, an important female hormone.

We know, for example, that emotional factors can sometimes be a primary or a secondary cause of infertility. In fact, published studies at Yale Medical School, as well as others, suggest that psychological assessment and counseling alone—in the absence of any other medical treatment—may significantly improve reproductive potential.

#### The Psychological Component

We have designed the psychological component of Fertility Institute to respond sensitively and effectively to the emotional needs of the infertile couple. Our approach proceeds through several phases.

At the initial stages of the Fertility Institute infertility investigation, you will meet with an experienced psychologist who will address the emotional impact of infertility upon you and your spouse. If necessary, the psychologist will recommend ongoing professional counseling to address some of the conflicts and feelings associated with infertility and its treatment.

In many instances, Fertility Institute refers couples to Resolve, a national organization which offers support and information to infertile people. In addition, support groups for infertile couples and individuals have been established in the Springfield area. Our psychologist will often suggest that infertile couples contact these valuable resources in our community.

Because of our commitment to the integration of emotional support with the medical and surgical management of infertility, Fertility Institute sees you and your spouse as a unit. We work together with you as a team to develop a plan for infertility investigation and treatment which takes into account your needs—as individuals and as a couple. We augment the physician's specialized medical expertise with the services of both a skilled psychologist and a highly trained case management coordinator. Thus, we offer our patients a comprehensive program providing emotional support, education, and sensitivity. [10]

We believe that the multi-disciplinary approach of Fertility Institute enables us to respond sensitively and effectively to both the medical/surgical and the emotional needs of our patients. [11]

#### THE PHYSIOLOGY OF FERTILITY

by Ronald K. Burke, M.D.

In order to understand the significance of the procedures followed in the infertility investigation at Fertility Institute, you must understand the different aspects and mechanisms involved in the complex process of fertilization. Do not expect to absorb and remember all the information that follows in one reading. Make a note of any questions which occur as you read, and ask a member of our professional staff to answer them for you when you come to see us.

#### The Brain-Ovary Hormonal Cycle

Because of the intricate and essential role hormones play in reproduction—and because hormonal irregularities both cause and signal fertility problems—many studies test for their proper functioning in the reproductive cycle.

What is a hormone?—A hormone is a chemical messenger carried in the bloodstream from one part of the body to another. Hormones transmit information to specific organs, and cause those organs to react in specific ways. The two major female reproductive hormones—progesterone and estrogen—are essential to fertility, but they do not act alone. Several hormones produced in the brain play a vital part in the process.

The orchestration of the hormonal cycle begins with the hypothalamus, a part of your brain which acts as a sort of thermostat. Right after your menses (or period), the hypothalamus senses that the female hormones are at their lowest level. The hypothalamus responds by producing hormones called releasing factors (RF) or Gonadotropin Releasing Hormone (GnRh). These hormones travel to the nearby pituitary gland—another part of the brain—and stimulate this gland to produce three very essential hormones: follicle stimulating hormone (FSH); leuteinizing hormone (LH); and prolactin; FSH governs development of the egg follicles, LH stimulates the release of the ripened egg at midcycle and prolactin synchronizes and maintains the proper relative concentrations of FSH and LH.

The pituitary hormones, FSH and LH exert their effect at the ovary where they regulate and stimulate the production of the two important ovarian hormones—estrogen and progesterone. FSH travels through the bloodstream from the pituitary gland to the ovaries. Once there, it stimulates the growth of an egg follicle, consisting of an ovum (egg) and a surrounding halo of cells. In response to FSH, the follicle begins to produce the female hormone estrogen. As the ovum or egg follicle grows, it produces more and more estrogen.

The rising level of estrogen inhibits further production of FSH. When it reaches a critical level, estrogen triggers the pituitary gland to release a burst of a second hormone, luteinizing hormone (LH). LH travels to the ovary, and causes the now-mature egg to break out of the follicle—what we call ovulation. Ovulation usually (but not always) occurs at midcycle—approximately 14-16 days before the onset of your next period.

LH also converts the ruptured follicle into a gland called the corpus luteum—Latin for “yellow body,” which is how it appears. The corpus luteum produces the second important female hormone, progesterone. [12]

Estrogen stimulates the lining of the uterus, or endometrium, to grow. In turn, progesterone brings the endometrium to maturity. Progesterone also affects the pituitary gland, inhibiting further production of LH and FSH.

The corpus luteum has a life-span of about 15 days. If pregnancy does not occur within this time, the corpus luteum automatically stops functioning. The endometrium, no longer stabilized and supported by progesterone, breaks down. It sheds its rich and vascular lining as menstrual blood—your period.

The final pituitary hormone important to the reproductive process is prolactin. The initial function attributed to prolactin was to stimulate the production of breast milk in the post partum period. Simultaneously, prolactin was found, understandably, to prevent the further release of FSH and LH during breast feeding. When prolactin levels are too high in a woman attempting to become pregnant, the ratios of LH and FSH are abnormally affected and ovulation may not occur.

Each segment of this complex and inter-related hormonal cycle must perform precisely in order for ovulation to occur. The interruption of this cycle may affect



subsequent cycles as well. Sometimes a woman may require medical treatment to restore ovulation. For this reason, we pay close attention to hormonal function.

#### The Genital Tract. A Brief Anatomy

##### *The Female Genital Tract*

The main components of the female reproductive system are: the uterus and its cervix, the vagina, the fallopian tubes with their delicate fimbria, and the ovaries.

The uterus is a pear-shaped, muscular structure deep in the abdomen. It connects to your vagina by means of a small nubbin, the cervix. Through the center of the cervix runs a small canal—the endocervical canal—which communicates with the endometrial cavity—or the space inside the uterus.

The two fallopian tubes attach to the upper portion of the uterus, on either side. These tubes, hollow canals about three inches long, flare out into fine tentacles. The tentacles—the fimbria—end just near the ovaries.

You have two ovaries, one on each side of the uterus. The ovaries contain the eggs, and produce important female hormones, estrogen and progesterone. During ovulation, the fimbria delicately caresses the ovary, as though milking the egg from the ruptured follicle. The egg then travels down the tube to the uterus.

##### *The Male Genital Tract*

The main components of the male reproductive system are: the penis, the scrotum and testes, the seminal vesicles, the epididymis, the vas deferens, the prostate gland, and Cowper's glands.

The scrotum—or male “sac”—contains the testes. The male testes plays a role in reproduction similar to the female ovaries. The testes produce the male hormones, including testosterone. In addition, the testes produce sperm in small seminiferous tubules. While the average woman produces one mature egg each month, the average man produces [13] approximately 180 million sperm during each ejaculation. Only one of these sperm will actually fertilize the egg.

The sperm travel from the testes through a long tiny convoluted tube, the epididymis, where they undergo maturity, and then through a small tunnel, the vas deferens. (In a vasectomy—the male operation for permanent sterilization, the vas deferens is surgically divided.)

The sperm pass from the vas deferens into the prostate gland. This gland, along with the seminal vesicles and Cowper's glands, produce most of the liquid secreted in the male ejaculate. A drop or two of sperm mix with about a teaspoon full of these secretions, and pass through the penis via the urethra.

While it takes approximately 14 days for a female egg to mature, sperm take about six months to mature into “adult” sperm capable of fertilizing an “adult” egg. The brief 28-day menstrual cycle can be more easily studied than the lengthier male cycle. Because of this, we know more about female infertility.

#### Fertilization

Fertilization occurs when sperm released from the penis during ejaculation meets and fertilizes a mature egg.

The sperm, deposited in the vagina, must make their way through the endocervical canal, up to the uterus, and out into the fallopian tubes. Simultaneously, the mature egg, picked up from the ovary by the fimbria at about the 14th day of an ideal cycle, wafts down one of the fallopian tubes.

Out of the millions of sperm deposited in the vagina during intercourse, only one will finally fertilize the egg. The fertilized egg makes its way down the fallopian tube. At about the 23rd day of an ideal cycle, the egg reaches the plush endometrium lining of the uterus. The egg then burrows into the endometrium—a process which sometimes causes a slight amount of implantation bleeding.

#### Early Pregnancy

This fertilized egg and its developing placental tissue, gently implanted in the soft endometrial lining, produces human chorionic gonadotrophin (HCG)—the pregnancy hormone. The urine test and the more sensitive blood test determine pregnancy by detecting the presence of this hormone. While older urine tests were not able to detect the presence of HCG until approximately two weeks after the first missed period, modern urine tests can actually detect a pregnancy before the missed period. Moreover, the newer blood tests can actually confirm a pregnancy within several days after implantation. HCG levels rise rapidly until the twelfth to fourteenth week of pregnancy, at which point they actually begin to fall off normally. This rapid rise allows us to quantitatively measure the ongoing health of an early pregnancy and is particularly useful in diagnosing an ectopic pregnancy or a miscarriage, or whether progesterone supplementation is indicated.

HCG prolongs the life of the corpus luteum, which continues to produce progesterone until the eighth to twelfth week of pregnancy. This progesterone stabilizes the endometrium and prevents bleeding.

This progesterone also allows the fragile young embryo to develop until it can produce progesterone on its own. A pregnancy which is not viable will not be able to sustain [14] itself once the corpus luteum stops functioning. For this reason, most spontaneous miscarriages occur between the eighth and twelfth week of pregnancy.

In some cases, a defective corpus luteum will be unable to produce enough progesterone to sustain an otherwise normal pregnancy. This is particularly true in pregnancies which result from ovulation induced cycles. In order for the pregnancy to progress normally, the woman must obtain progesterone in the form of medication—either by vaginal suppositories, the usual and more convenient route, or by injections.

Sometimes, a slight drop in the progesterone level marks the shift of progesterone production from the corpus luteum to the embryo and placenta. This drop may cause a small amount of “transitional bleeding”—perfectly normal and no cause for alarm.

At around the twelfth to fourteenth week of pregnancy, a heartbeat is first audible. Once we hear the heartbeat, you can rest assured that you have a healthy and viable pregnancy.

#### The Fertility Evaluation

Your fertility evaluation at Fertility Institute investigates whether all the inter-related factors necessary for fertilization occur normally and in proper sequence. Once we determine the problem or problems which underlie your infertility, we can map out appropriate treatment and make specific recommendations.

#### Your Initial Consultation

The diagnosis and treatment of infertility begins with a thorough, meticulous, and intimate history. Before undertaking the detailed evaluation described below, you and your partner meet with us for an initial joint consultation. The information and insight you provide at this interview helps us map out your future course of treatment.

In addition, at this meeting we can begin to address—and reverse—the psychological toll which infertility may have exacted on you and your relationship. Studies—as well as our own experience—show that this type of visit substantially increases the success rate of infertility regimens.

Prior to this visit, we urge both of you to read this brochure thoroughly. Set aside enough time to review the material, so that we can discuss it together.

We recommend that you transfer to our office any gynecological or urological records or previous infertility evaluations. In this way, we can incorporate the results, make appropriate referrals for treatment, and avoid any unnecessary delay in the woman's subsequent evaluation.

#### Fertility Factors and Procedures

##### The Male Factor

The man must deposit a sufficient number of normal, healthy sperm into the vagina in order for the woman to become pregnant. Nearly one half of all infertile couples may be attributed, in part, to the male factor; and 30% of all infertility is limited to the male factor. [15]

Male reproductive medicine and infertility have become important areas of clinical concern that are now classified under the specialty referred to as Andrology. Traditionally, male factor infertility has been a relatively neglected field which was within the purview of the urologist. Fortunately, a number of important medical discoveries, newer diagnostic tests and treatment modalities have significantly improved the fertility specialist's ability to benefit the subfertile male. In addition, treatment programs originally devised to treat female infertility, such as GIFT, IVF and intrauterine insemination have been shown to benefit certain types of male infertility as well. Finally, the "new age" Aquarian male, educated and less prone to equate infertility with masculinity, is more willing to participate in the evaluative process.

##### The Male Examination

As with the female, the male will undergo a thorough history and physical examination, with emphasis on those systems and factors which might have a direct bearing on reproduction. The examination will include a review of the heart, lungs, endocrine, abdominal, neurological and male reproduction system, with emphasis on the scrotum and prostate, the latter requiring a rectal exam. Scrotal temperature, important in sperm viability, will be taken. The scrotum will be examined with emphasis on the detection of epididymal, testicular or varicocele abnormalities. It is important to let us know if you have had any testicular disease or surgery such as varicocele repair, vasectomy reversal, mumps, gonorrhea or other sexually transmitted diseases. It is likewise important to let us know if you have had any endocrine disorders such as hypo or hyperthyroidism, as well as any malignancies, particularly if chemotherapy has been used.

In the event that you are suspected of having a varicocele, a large, dilated vein leading from the testicle, you will be scheduled for a scrotal ultrasound. This is a painless, non-invasive procedure in which high frequency sound waves are used to generate pictures which can demonstrate the presence or absence of varicoceles with much greater accuracy than was available prior to the advent of this new technology.

In addition to the history and physical examination, you will be asked to submit two

semen specimens for microcomputerized analysis. Further testing involving immunological or endocrinological factors may be required if indicated.

#### Microcomputerized Semen Analysis

A sperm count or semen analysis directly evaluates the ability of sperm to successfully fertilize the egg. This procedure tests male fertility, NOT masculinity or potency. An infertile may be a potent and effective sexual partner, but may simply not produce sperm of adequate quantity or quality. [16]

#### Sperm Velocity

Fertility Institute has pioneered research in a superior method of semen analysis which now permits the actual measurement of sperm speed or sperm velocity. Traditionally, the semen analysis measured primarily for sperm concentration, and involved a significant margin of error. Although sperm counts have fallen from an "average" of 60 to 80 million in the 1950's to 20 million in the 1980's, we now know that the actual sperm count is the least important predictor of male fertility; indeed, men with sperm counts varying from 2 million to 200 million sperm per milliliter are capable of fathering a child. Sperm velocity is now recognized as one of the most important predictors of male fertility, and we at the Fertility Institute are proud of the part we have played in the research and development of this new and rewarding concept. The newly developed Multiple Exposure Photography method at Fertility Institute provides exceptionally accurate measurements utilizing microcomputerized techniques and a specially designed sperm counting chamber.

Prior to the semen analysis, we will provide you with detailed instructions for the proper collection of semen. The Fertility Institute semen analysis determines the following:

- sperm velocity
- sperm concentration
- sperm motility concentration
- percentage of motility
- motility index
- individual and average sperm velocity
- percentage of abnormal forms
- sperm morphology

In addition, the new method incorporates the most recent findings in Andrology (the study of male fertility). While 95 percent of all pregnancies result from men with "normal" sperm counts (at least 20 million sperm per cc), recent studies have established that sperm concentration is the least important factor in male infertility.

Far more significant than the number of sperm is the concentration of motile, or active, sperm. This specialized chamber allows us to calculate motile sperm concentration, percentage of motility, and the motility index (a measurement of active versus inactive sperm).

Most importantly, this new computerized methodology enables us to measure what experts now deem the primary attribute of fertile sperm—velocity, or how fast the sperm can travel. Utilizing the sperm counting chamber, a revolving strobe disk, a special microscope and a camera, we obtain actual pictures of moving sperm at split-second intervals. These pictures can then be transferred to a digitizing tablet and a micro computer and the actual sperm velocity determined.

Research now indicates that sperm travelling less than 20 microns per second are highly unlikely to fertilize a human egg. (In case you are wondering, "How big is a micron?" .... A sperm is about 6 microns in diameter, and the human eye can barely begin to see something that is 150 to 200 microns). [17]

These pictures also enable us to accurately evaluate sperm morphology—the actual shape of the sperm. We can thus determine the percentage of abnormal sperm forms.

#### Treatments and Recommendations

Based upon the results of sperm analysis and medical history, we can make specific recommendations to compensate for or treat the male factor in infertility.

Thermal factors, for example, adversely affect semen quality. Sauna, steam baths, thermal underwear, even Jockey shorts may be implicated in male infertility. There are some devices on the market designed to raise scrotal temperature.

A varicocele (or swelling of the vein in the scrotum leading from the testicle) is an extremely common and important cause of male infertility which may reduce the paternity rate to less than 10 percent. Surgical correction increases the sperm motility and sperm velocity in 80 percent of patient's varicoceles, accounting for a 55 percent higher pregnancy rate. A varicocele may be suspected in men with normal sperm counts where there is low motility or low sperm velocity. Once suspected, the presence of a varicocele can be detected either by palpation or, in the case of smaller yet clinically significant varicoceles, by doppler (ultrasound) detection. A radioisotope scan is also available for detection of varicocele. If present, a varicocele can be readily repaired by relatively simple surgical technique. Should a varicocele be detected, you will be referred to a urologist for surgical correction.

Any number of conditions can produce sperm abnormalities—for example, severe past illnesses, infections, dietary deficiencies, abnormal thyroid function, low testosterone, inappropriate pituitary hormones (male FSH or LH), genetic defects.

Male infertility factors which can be identified on the semen analysis include oligospermia (excessively low sperm count), decreased motility, asthenospermia (excessively slow sperm velocity), azoospermia (a total absence of sperm), abnormal sperm morphology (shape), and various infections of the testicles or prostate gland. Should the sperm analysis disclose any of these factors, we will ask you for another semen specimen to confirm our findings.

Unfortunately, with the exception of the indicated varicocele repair (varicolectomy), most medical regimens for the correction of male infertility, including clomiphene, testosterone, thyroid and pergonal, have simply not been successful. Sperm washing or capacitation, therefore, has been a welcomed and successful method of overcoming male infertility due to slow sperm or the presence of sperm antibodies, as will be discussed below.

#### Sperm Antibodies

Other than sperm dysfunction such as low counts, low motility or low velocity, and varicoceles, the most common male factor causing infertility is the presence of anti-sperm antibodies. The presence or absence of sperm antibodies is best suspected through the post-coital or Sims Huhner test. The actual presence of sperm antibodies can be accurately detected now through the recently developed Immunobead Antisperm Antibody Test.

Actually, there are many types of antisperm antibodies, some more serious than

others. There are antibodies that the male produces in his own body against his own [18] sperm, and there are antibodies that the female produces against the male's sperm. The Immunobead Antisperm Antibody Test, developed by Dr. Bronson and perfected at the Fertility Institute, involves obtaining blood from both the male and the female, processing the serum from the blood in a special way so as to extract that portion that would contain any antibodies, and mixing the serum with the sperm and specially treated, microscopic latex beads. These "beads" are coated with substances called antigens. Antigens are proteins to which antibodies bind. Therefore, if you have antisperm antibodies, the immunobeads will bind to the sperm during the test and will be visible under a "phase contrast" microscope. The Fertility Institute is one of the few centers in the United States capable of performing this extremely important and sophisticated test.

Who should be tested for anti-sperm antibodies? Infertile couples in whom the presence of anti-sperm antibodies should be suspected include those with:

1. Persistently poor post coital tests, or post coital tests in which there is clumping of the sperm or a "crooked neck" appearance to the sperm.
2. Low sperm motility or slow sperm velocity.
3. Males who have had a vasectomy reversal.
4. Males who have had a testicular biopsy.
5. Unexplained infertility (where everything else appears normal).

If antibodies are found to be present, is there a treatment? Yes. In the event that significant antisperm antibodies are discovered, this condition can be treated either with a short course of high dose steroids, with various anti-inflammatory medications or by intrauterine insemination with the sperm washing process to "wash off" the antibodies. An older and less successful method of treating sperm antibody production was the use of condoms for several months.

How do antisperm antibodies form? Normally, sperm do not get into the bloodstream. In the event that sperm do get into the bloodstream, as in the case of surgery on the testicles or vas deferens, they may be attacked by the body's immune system, causing the formation of antibodies. During subsequent intercourse or sperm formation, the body's host defenses will mistake the sperm for bacteria or other "foreign" material and produce antibodies against the sperm. Other ways of the sperm finding their way into the male's bloodstream would be through infections or injuries. The production of female antisperm antibodies may be induced by the sperm entering cuts in the female vagina, open veins in the uterus or through rectal fissures or hemorrhoids during anal intercourse.

#### Intrauterine Insemination with Enhanced Sperm

Fertility Institute and the Reproductive Diagnostic Center for Research and Testing have developed a particularly effective technique for treating male infertility. This technique, called intrauterine insemination using washed, enhanced, capacitated sperm, actually improves (enhances) and concentrates the husband's sperm, then injects the sperm directly into the uterine cavity.

Of particular importance because of the resistance of male infertility to medication, the technique offers an alternative to adoption or artificial insemination using donor sperm. Many couples who required artificial insemination with donor sperm to achieve

a pregnancy prior to the development of in-vitro sperm treatment have subsequently achieved successful subsequent pregnancies with their husband's treated sperm. [19]

Artificial insemination using fresh, untreated husband's sperm (AIH) has simply not been successful. Semen ejaculated from the penis contains only a drop or two of pure semen. The major volume of the semen represents secretions from the prostate gland, containing bacteria, chemicals harmful to the uterus, white blood cells, and other impurities left behind in the vagina during normal intercourse. For this reason, injection of untreated semen directly into the uterine cavity can be harmful.

In addition, before it can fertilize a mature egg, the sperm must undergo a maturation process called capacitation. The process, which entails a physical alteration of the sperm, normally takes place as the sperm travels towards the egg, through the endocervical canal, uterus, and fallopian tube. Fresh sperm has not yet matured—or capacitated.

The procedure pioneered at Fertility Institute washes the husband's sperm, separates out impurities, and incubates the sperm long enough for the healthy sperm to be capacitated. The process has also proven successful in the treatment of sperm antibodies. The final step decants a concentrated solution of pure "super sperm"—washed, highly motile (active) sperm with markedly increased velocity. In a way, you can think of the process as sending the sperm to a health spa.

We can then safely inject the enhanced sperm directly into the uterine cavity.

In the past two years, this new treatment—used in cases of previously intractable infertility—has yielded a success rate of over 35 percent, and almost always within the first four treatment cycles. In addition to being the first really effective method of treating male infertility, sperm enhancement has also proven effective in overcoming various forms of female factor infertility.

What conditions can be helped by Intrauterine Insemination with washed, capacitated sperm?

<u>Indications</u>	<u>Success Rate (%)</u>
1. Male factor, including oligo and asthenospermia	18.5
2. Sperm antibodies, both male and female.	25.0
3. Unexplained infertility.	35.0
4. In conjunction with ovulation induction	75.0
5. Persistently poor cervical mucous.	35.0
6. Prior to GIFT or IVF/ET	35.0

In fact, if we may be fanciful, the technique has proven so successful that we like to refer to it as WISH—for Washed, Intrauterine insemination with Sperm by Harvesting.

#### Other Male Factor Tests

A second test also measures the adequacy of sperm. The post-coital or Sims-Huhner test evaluates the number and quality of sperm which reach the cervical mucous.

One additional important male factor which can be suspected through the post-coital test is the presence of sperm antibodies. [20]

#### Female Factor

##### 1. The Vagina

The vagina receives the penis and the sperm. Sometimes the vagina harbors an

infection which can injure or damage the sperm. In addition, changes in the cells lining the vagina reflect the changing hormonal levels of the menstrual cycle.

*Tests and Procedures:*

**Wet Mount**—We observe under a microscope a drop of vaginal secretion mixed with saline solution. This small sample enables us to detect and identify a vaginal infection, even though you may have no symptoms. The most common vaginal infections—bacterial, yeast, and trichomonas—respond readily to medication.

**Vaginal Cytology**—At different times of your menstrual cycle, we swab cells from the lining of the vaginal walls. Because these cells respond to changing hormonal levels, observing them under the microscope enables us to determine whether your body is undergoing the normal hormonal sequence.

## 2. The Cervix

The cervix—the lowermost portion of the uterus which projects into the vagina—receives, and preserves sperm on its upward journey to meet the egg. Evidence suggests that the sperm remain in crypts in the cervix until they mature—or capacitate—and gain the capacity to fertilize the ripe egg.

The cervix also contains endocervical glands which secrete mucous. These glands respond to the cyclic fluctuations of the female hormones, especially estrogen. At ovulation, the mucous secretions are clear, sticky, and abundant. You may even notice an increased discharge at midcycle due to this. At this point the mucous also becomes more alkaline—or basic, in pH—something that can easily be measured with litmus paper.

This endocervical mucous fluid plays a key role in fertilization. Successful sperm penetration into the uterus depends on it. In addition, the mucous fluid responds to changing hormonal levels of the menstrual cycle.

*Tests and Procedures:*

**Sequential examination of cervical mucous**—Adequate estrogen stimulation, along with the proper balance of electrolytes (such as sodium and potassium), effects the structure of the mucous. Dried cervical mucous forms fernlike patterns which we can observe under a microscope. This process, known as ferning, becomes most intense at ovulation. After ovulation, the predominance of progesterone changes the structure of the mucous. Instead of ferning, we observe a bead-like pattern in the dried mucous. This difference in pattern helps us pinpoint the time of ovulation.

Cervical mucous can also reveal signs of cervicitis—cervical infection—which we can treat with appropriate medication. Persistent cervicitis or cervical erosion may call for cryosurgery. This benign procedure, performed in our office, freezes the infected [21] cervical tissue. The frozen tissue then sloughs off, allowing healthy cervical tissue to grow in its place.

In certain cases, we may prescribe small doses of estrogen to improve the quality of cervical mucous. Certain studies attribute up to a third of female infertility factor to abnormal cervical mucous.

**Post-coital (PC) mucous test**—This test, also called the Sims-Huhner test, examines the cervical mucous after intercourse. The test is performed during ovulation, when the cervical mucous is abundant and healthy. The recent availability of urine tests to determine the LH surge has significantly improved the value of this test, inasmuch as the timing of ovulation is more precise.



In general, it is not necessary to refrain from intercourse prior to this examination. You must have intercourse the night of the LH surge (In circumstances where this is too inconvenient, intercourse may take place the morning following the LH surge). Lie on your back with your knees elevated for about twenty minutes after intercourse, so that the cervix can bathe thoroughly in the seminal fluid. Do not use any chemicals—such as douches, or lubricants.

When you arrive at our office on the day of the post-coital test, we will ask you to place your feet in the stirrups. We will then remove a small amount of endocervical mucous—a painless procedure.

What can we find out from this test? Quite a bit. Examining this sample under the microscope helps us to evaluate the quality of your mucous, the number of sperm which have reached the mucous, sperm motion and anatomy, and the interaction between your mucous and your partner's sperm.

The quality of the mucous—Cervical mucous should be clear and copious, like a mountain stream. Opaque, cloudy mucous with red and white blood cells suggests cervical infection. A small supply of mucous indicates inadequate estrogen stimulation. Both of these common conditions respond well to appropriate therapy. In addition, we measure the pH of the mucous. Since the pH at ovulation is normally alkaline, an acid mucous can signal infection—or it may indicate that ovulation has not occurred.

The number of sperm—Using a high-powered microscope, we will calculate the number of sperm, along with the percentage of motility (active sperm), the quality of motility, the percentage of abnormal sperm, and the forward progression of the sperm.

The sperm-mucous interaction—In some cases, an allergic or antigen-antibody reaction between your mucous and your partner's sperm can cause infertility. When this occurs, the sperm tend to form clumps—which we can observe under the microscope, or sperm with “crooked” appearing neck/tail junctions may be seen. If the test results lead us to suspect an allergy or antibody, we perform additional tests, such as the Immunobead Antibody Test to confirm the possibility. [22]

### 3. The Uterus

The uterus, a pear-shaped, muscular structure deep in the abdomen, connects to your vagina at the cervix. Estrogen, produced in increasing amounts as the menstrual cycle progresses, causes the endometrial lining to grow. Progesterone, produced by the corpus luteum after ovulation, causes the endometrium to mature and stabilize.

#### *Tests and Procedures:*

Endometrial biopsy—Microscopic examination of a thin sliver of endometrial tissue—a biopsy—taken after a presumed ovulation, will confirm whether or not ovulation has occurred, the quality of ovulation, whether ovulation is too early or too late, as well as if there is any inflammation or infection of the uterine lining. A properly interpreted endometrial biopsy can even indicate if there is a likelihood of pelvic scarring and/or endometriosis...

The endometrial biopsy is usually performed during the last week of the menstrual cycle, or on the first day of your period (day 1 of the cycle). Using a small instrument called a curette, we obtain a tiny piece of tissue from the uterus. Although the procedure requires no anesthetic, you may feel a slight cramping or discomfort. Recently, at the Fertility Institute, we have introduced the use of a “pipelle” plastic

biopsy catheter, which significantly reduces the amount of discomfort while actually increasing the sample of the tissue biopsied.

In addition to confirming the time of ovulation, the biopsy also detects infection or inflammation of the uterine lining. Uterine inflammation and infection are linked to infertility—particularly repetitive miscarriages—and usually respond well to appropriate antibiotic therapy.

In addition, recent research at Fertility Institute enables us to use the endometrial biopsy to target women who may have pelvic adhesions or endometriosis. Certain biopsy results strongly suggest the presence of these conditions. Armed with this knowledge, we can pinpoint those women who should undergo a laparoscopy to confirm the diagnosis. Prior to our research, fertility specialists tended to perform laparoscopy much later in the course of an infertility evaluation. This needlessly delayed the time it would take for some women to conceive.

Finally, specific changes in the endometrium are associated with each day of the “ideal” menstrual cycle. Normally, the appearance of the biopsy sample matches the actual day of your cycle (within three days) when the biopsy was taken.

Sometimes, however, the appearance of the biopsy reflects a significantly earlier or later point of your menstrual cycle than the actual date of the test leads us to expect (a greater than two day discrepancy is considered “significant”). For example, a biopsy taken on day 28 of your cycle reveals the characteristics of a 24th-day tissue. If a second biopsy confirms the same time lag, then this may indicate that the corpus luteum produces too little progesterone. The reason that a second biopsy is required is the event of such a discrepancy is based on the statistical observation that while 95% of women may have a single “out of phase” endometrial biopsy, less than 10% of women will have such a finding on two or more occasions. A blood sample taken on the same day as the second biopsy allows us to correlate the actual progesterone levels with the biopsy findings. [23]

A corpus luteum defect is associated with approximately five percent of infertility. We can correct this condition with supplemental progesterone, in the form of vaginal tablets or injections. Clomiphene—a “fertility drug”—can also treat this type of defect, by stimulating the formation of a more effective corpus luteum. Should you require such treatment, we will provide you with a more detailed explanation of Clomiphene or other appropriate medication.

#### 4. The Fallopian Tubes

After passing through the uterus, the sperm meet the egg which has been picked up from the ovaries by the fallopian tubes. Here fertilization takes place—usually on the day after ovulation. The fertilized egg then slowly makes its way down the fallopian tube. After several days, the fertilized egg reaches the uterus where nidation (implantation) occurs.

#### *Tests and Procedures:*

Hysterosalpingogram (HSG) or X-Ray test—This procedure is performed by Dr. Burke who will meet you in the radiology department during the week following your period (after the menstrual flow has stopped but prior to ovulation). The timing of the test avoids x-ray exposure during the early part of a possible pregnancy, forcing of menstrual blood through the fallopian tubes, or causing an ectopic pregnancy.

At Fertility Institute, the HSG is performed in two stages. First, a water soluble dye is injected into the uterus and out the fallopian tubes. This dye is very safe. The water

soluble dye allows us to see if the tubes are open and if there are any uterine abnormalities, but has no therapeutic effect. Once we have determined that both fallopian tubes are indeed open, a second kind of oil soluble dye is injected. This second dye, according to studies at Yale and elsewhere, as well as our own experience at Fertility Institute, increases the pregnancy rate by 40-50% in the four to six months following the HSG.

The test reveals any anatomic abnormality in the uterus, and any obstruction or deformity of the tubes. In addition, for some women the test itself has therapeutic value. The dye may "wash through" any accumulated debris which partially clog the tubes.

Should the tubes be blocked, you may require minor surgery. However, no major surgery to correct tubal problems should ever be performed until all other factors are found normal. In addition, prior to surgery, the abnormalities suggested by the HSG should be substantiated by a diagnostic laparoscopy. At times, the HSG may indicate tubal blockage when in fact the tubes are actually patent but only appear blocked at the time of the HSG because of spasm. You may experience some vaginal discharge or bleeding following this procedure which is normal and is to be expected. [24]

#### 5. The Ovaries

The egg (or ovum) grows in the ovaries before its release at ovulation. Because ovulation occurs approximately 15 days prior to menstruation, we normally predict the time of your next ovulation based upon prior months.

The short life-span of the released egg makes accurate forecasting of ovulation critical. An unfertilized egg will die within 24 to 48 hours after ovulation. If the sperm does not meet the egg during that interval, you cannot conceive until your next menstrual cycle. The dead egg passes out of the body with the menstrual blood.

#### *Tests and Procedures:*

The Basal Body Temperature Record (BBT)—Once the only predictor of ovulation, the BBT has now been supplanted by more accurate measurements. However, because we may ask you to chart your BBT as part of our research protocol or for one month to correlate the BBT with several other events in a general sort of way, a brief description of the test follows.

As you recall, after ovulation, the corpus luteum begins producing progesterone. In addition to its other effects, the hormone triggers a slight rise in body temperature—about 0.5 to 0.8 degrees F. For this reason, women usually have slightly lower body temperature in the first half of the cycle—before ovulation—and a generally higher temperature after ovulation. In addition, the temperature drops slightly just prior to ovulation and its accompanying rise in temperature—a phenomenon called the thermal nadir. When examining a graph of normal basal body temperature, one pinpointed the time of ovulation at approximately 18 hours after the last thermal nadir.

As you can see, the BBT served at best as a rather crude indicator of ovulation. Recent evidence reveals it to be in error up to 60 percent of the time. More to the point, at best, the BBT worked retroactively—that is, it indicated last month's ovulation, too late to be of real practical value.

In addition, many women found the temperature record keeping burdensome and intrusive. The BBT exacted an enormous emotional toll on many infertile couples, whose mornings anxiously revolved around the ritual temperature measurement.

Fortunately, today we have at hand more accurate means of predicting ovulation.

Enzyme-Immunoassay of the LH Surge (EIA)—As you recall, the pituitary gland located in the brain produces a surge of luteinizing hormone (LH) approximately 30 hours before ovulation. In fact, LH triggers ovulation. It travels from the pituitary gland to the ovary, and causes the egg to break out of its follicle.

A recent breakthrough in fertility research has resulted in a new technique for accurate measurement of LH. Until recently, we could only detect the LH surge using a relatively expensive and cumbersome method. The new method—simpler but just as precise—has proven to be so reliable that In-Vitro Fertilization centers have adopted it. [25]

Monoclonal Urine LH Surge Test—Even more recently, fertility researchers have designed a simple, at-home urine test to detect the LH surge. Less expensive and more convenient than tests performed at the laboratory or office, the LH urine test offers some women a precise prediction of ovulation. If we find it appropriate for you, we will train you to perform this accurate and sensitive test. (A word of caution. Numerous “over the counter” LH kits are based on “polyclonal” technology which is not as accurate as the “monoclonal” based LH kits. Monoclonal LH determination kits are 85-90% accurate in predicting ovulation while polyclonal LH determination kits may be only 65-70% accurate.)

Ultrasound Sector-Scan—A more complex—and hence, more expensive—technique for determining the precise timing of ovulation utilizes pictures obtained with specially generated waves.

In this procedure, high frequency, harmless sound waves are directed inside the body. Tissues of different density and thickness reflect the sound waves differently. These reflected sound waves, converted into light waves, generate a picture of the interior of the body.

One form of ultrasound—the sector scan—has particular value in the treatment of infertility. Aiming the sound waves at the ovary containing the ripening egg follicle gives us a precise measurement of the size of the follicle. A series of sector-scans records the progressive growth—and sudden decrease—in follicle size, an excellent indicator of ovulation.

Fertility Institute now utilizes the highly sophisticated and most modern ADL vaginal probe, a “state-of-the-art” ultrasound unit which allows for the precise measurement of follicles so as to pinpoint ovulation and safely monitor ovulation induction with some of the more potent medications.

Once we know the size your follicle reaches just prior to ovulation, we can use the sector-scan to predict subsequent ovulation to within several hours.

Should the various tests determine that you do not ovulate, you may require medication to stimulate ovulation.

Numerous medications have proven useful in treating infertility. These drugs include Clomiphene, Pergonal, Human Chorionic Gonadotrophin, progesterone, estrogen, and Premarin. Fortunately, medical science has acquired much experience and expertise in fertility medication. Multiple births occur far less frequently today than in the early days of “fertility pills.”

Will “fertility pills” help me? If your infertility evaluation indicates a course of medical therapy, we will explain to you the risks and benefits of each appropriate medication. An extensive and thorough counseling session is conducted for all patients

requiring ovulation induction. Once you have begun taking medication, you must resolve to remain on the medication for at least six treatment cycles. [26]

#### 6. The Peritoneum

The peritoneum—or pelvic sac—contains the female genital organs (the uterus, ovaries, fallopian tubes).

Scars or adhesions may block or kink the fallopian tubes, impairing the free motion by which the tubes pick up the egg. In addition, previous infection can damage or swell the tubes. Scars on the ovaries can prevent ovulation. If your medical history or physical examination leads us to suspect and of these conditions, we may perform a diagnostic laparoscopy.

#### Diagnostic and Operative Laparoscopy

Diagnostic Laparoscopy—An invaluable technique in evaluating and treating infertility, a laparoscopy allows your physician to actually see various internal organs by means of a small, telescope-like instrument called a laparoscope. A laparoscope is a type of lighted telescope which can be placed through the umbilicus (belly button), into which the physician can look in order to see all of the pelvic structures.

A laparoscopy can be considered diagnostic, in which only a diagnosis is made; or operative, in which the various diseases causing infertility, such as fibroids, scars and/or adhesions, endometriosis or ovarian tumors, as well as other abnormalities can be cured right through the laparoscope. At the Fertility Institute we can cure up to 70% of problems that used to require major surgery right through the laparoscope with “same day surgery”.

Infertility specialists now strongly urge an early diagnostic laparoscopy for the following patients:

- women over the age of 30 and infertile for at least two years.
- women who have been infertile for at least three years.
- infertile women with a history of pelvic inflammatory disease, venereal disease, or infection following childbirth.
- former IUD users.
- women with unexplained pain or painful intercourse.
- women whose endometrial biopsy reveals subacute focal inflammation.
- women whose infertility evaluation revealed no cause for infertility.
- women requiring artificial insemination, who suspect the presence of an anatomical factor
- patients who suspect endometriosis.

Laparoscopy requires a light general (gas) anesthesia, or a spinal anesthetic. The surgeon makes a small incision in the navel and inserts a special needle. He then fills your abdominal cavity with a gas—either nitrous oxide or carbon dioxide. Through this same incision he introduces into the pelvic area the laparoscope—a long instrument similar to a telescope.

Frequently, your physician will make another small incision, directly above your pubic bone. Through this second incision, he introduces a metal wand, which aids in [27] moving internal structures to maximize visibility. The doctor also places a cannula—a special metal tube—into the vagina and through the cervix. Using the

cannula, your doctor can move your uterus during the laparoscopy, to obtain a clearer view of the various pelvic structures.

In addition to visualizing internal structures for diagnostic purposes, your physician can perform certain procedures during the laparoscopy, and can even treat certain conditions. For example, your doctor can also biopsy through the laparoscope a small piece of ovary and examine it under the microscope.

Your physician can also pass a special pair of scissors through the center of the laparoscope or through the second incision. Using these scissors, the doctor can cut through small delicate adhesions—bands of scar tissue resembling gossamer webbing. In addition, your doctor can inject a harmless blue dye through the cannula during the laparoscopy. The dye flows through the endocervical canal, up the uterine cavity and through the fallopian tubes. If we suspect a blockage in your fallopian tubes, then this procedure will determine whether they are, in fact, obstructed. Studies show that when a previous HSG suggests blocked tubes, 40 percent of the time the tubes are open and normal. We attribute the abnormal HSG tests to a muscle spasm which clears the relaxing effect of a general anesthetic. The dye itself may also wash through any accumulated debris clogging the tubes.

Laparoscopy, on the other hand, may confirm the results of the HSG and other tests, revealing the need for major corrective surgery. Only laparoscopy can provide us with a firm diagnosis of endometriosis or pelvic infection. In addition, laparoscopy will reveal the cause—often correctable—for half the cases of previously unexplained infertility.

Perhaps the most exciting and significant advance involves the use of laser through the laparoscope. This often eliminates the need for further major surgery.

#### The Investigative Conference

After completing the diagnostic evaluation described above, we will hold an investigative conference with both you and your husband together. At this conference, we will thoroughly review and analyze the results of the evaluation.

We often find that couples have achieved a pregnancy by the time we schedule the conference. However, if you have not yet become pregnant, we will recommend possible treatments to correct whatever deficiencies your infertility analysis has uncovered.

Will you ever achieve a pregnancy and, if so, how long will it take for you to become pregnant? Unfortunately, between five and ten percent of couples undergoing an infertility evaluation do not achieve a pregnancy within one year. If you are among these couples, we wish to stress that there are two possible reasons for this. Either we do not have enough knowledge to detect and correct the cause of your infertility. Or, simply by chance, you have not yet become pregnant—but in time, you will. Realize that even after successful therapy, you should not expect success for at least six to twelve months. [28]

#### OTHER PROCEDURES AND TREATMENTS

##### Vaginal Ultrasound

Vaginal ultrasound is a new, high technology advance in the field of infertility which is also proving of extreme value throughout the field of gynecology as well as early pregnancy evaluation. There are many who liken vaginal ultrasound to “having an eye on the tip of one’s finger.”

Unlike the older methodology of abdominal ultrasound, which required two or three hours of preparation and discomfort while allowing the bladder to fill up in order to obtain the required contrast for imaging, vaginal ultrasound is performed with an empty bladder. This permits rapid and convenient testing. The image is far more accurate and sensitive than prior technology, and allows for accurate measurement of follicle size. Early pregnancies, previously visible on abdominal ultrasound at six weeks following the last period, can now be visualized up to two weeks earlier. Unfortunate ectopic pregnancies can now be detected early enough so as to virtually eliminate the need to lose the affected tube. IVF and GIFT techniques have become more successful as the result of vaginal ultrasound.

Vaginal ultrasound is also becoming more and more useful in general gynecology. Pelvic masses such as ovarian tumors and fibroids can be diagnosed with greater accuracy. Ovarian cysts can now be accurately followed and even drained through the vagina using vaginal ultrasound, thereby eliminating the need for previously required major surgery to remove ovarian cysts. Vaginal ultrasound is being used in many centers to screen for ovarian malignancies.

The Fertility Institute is proud to have been the first center in Western Massachusetts to utilize vaginal ultrasound in the diagnosis and management of infertility and gynecological related problems. It has been predicted that someday every gynecologist will employ the use of vaginal ultrasound on a routine basis.

#### Hysteroscopy

Similar in technique to the laparoscopy, the hysteroscopy allows the physician to examine the inside of the uterine cavity and the uterine canal. The procedure assists your physician to both diagnose and treat your infertility.

To perform a hysteroscopy, your doctor employs a small telescope-like instrument called a hysteroscope. After gently dilating your uterine canal with a small amount of carbon dioxide, your doctor inserts the hysteroscope into the uterus. The hysteroscope enables the doctor to evaluate certain anatomical causes of infertility—such as septa, adhesions, polyps, and fibroids. In many cases, your doctor can actually treat these conditions at the time of the hysteroscopy.

The hysteroscope may be used to make a diagnosis, in which case the procedure is called diagnostic hysteroscopy, or it may be used to perform surgery inside the uterus, in which case the procedure is called operative hysteroscopy. [29]

At the Fertility Institute, we perform the hysteroscopy in conjunction with laparoscopy, which enables us to correct abnormalities through either the hysteroscope or the laparoscope. The combined procedure is performed under general anesthesia in the same day out-patient surgery unit.

Finally, one additional exciting advance with regard to laparoscopy and hysteroscopy. These procedures are performed by viewing the pelvic structures through a video monitor, during which time the procedure is taped on a VCR. This technique, called Videoendoscopy, allows for documentation in which you can actually view your findings as well as any treatment that may have been performed. In addition, the tape provides an excellent record (which you may have copied to take with you should a "second opinion" be desirable).

### Microsurgery

A new and exciting advance in the treatment of infertility, microsurgery offers significantly improved pregnancy rates for millions of infertile women.

In microsurgery, the surgeon looks through a microscope while operating with newly developed precision instruments. These delicate instruments allow the surgeon to gently handle small structures and delicate tissue, to control bleeding during the operation, and to suture fine stitches.

For this reason, microsurgery results in significantly fewer post-operative scars. In addition, the technique enables the surgeon to take his time in the operating room. While conventional surgeons must operate as quickly as possible in order to minimize trauma and post-operative complications, microsurgeons work slowly. Thus, a 45-minute conventional procedure may take the microsurgeon three hours.

Studies are now conclusive that this slow and delicately fine microsurgical procedure, however, achieves double the success rate of the older, more conventional surgery—double the pregnancies.

The Society of Reproductive Surgeons has recently been formed to oversee the quality control of microsurgery and reproductive surgery, as well as to foster research and further success. Less than 250 fertility specialists in the United States had credentials sufficient to be accepted for membership. It is the recommendation of Fertility Institute that any patient requiring surgery to correct infertility seek only the services of a specialist certified by the Society of Reproductive Surgeons. Such a list may be obtained at the Fertility Institute, or by contacting the American Fertility Society's headquarters in Birmingham, Alabama.

The delicate procedure of microsurgery enables the microsurgeon to develop new surgical techniques and to improve older ones. Which infertility problems call for microsurgery?

Pelvic adhesions—fine scar tissue which form around the reproductive organs—account for a high percentage of infertility. Caused by prior surgery, endometriosis, or pelvic diseases, these adhesions severely limit the mobility of the organs. Microsurgery corrects these adhesions, restoring the organs to their original functionality. Endometriosis is one of the most common causes of deformities which ultimately require microsurgery for correction. [30]

Microsurgery can also clear blockages in the fallopian tubes. The prior minimal success rates of salpingostomy (opening swollen tubes) using conventional surgery has soared to almost 40 percent with microsurgery. One of the most successful areas in which microsurgery has been employed is in the situation where the tube becomes blocked in the portion where it tunnels through the uterus (the cornual portion). At this site the tube may be less than half a millimeter in diameter (less than the size of a pin). A common cause of this blockage is a disease called Salpingitis isthmica nodosa (SIN). With microsurgery, patency rates of cornual anastomosis approach 80% and success (pregnancy) rates about 60%. In the event of SIN, the success rates are lower and, unfortunately, the disease often tends to recur.

In addition, over half a million women undergo tubal ligation—"permanent" surgical sterilization—each year. Many women later regret this decision. Common reasons for wanting sterilization reversals, according to several studies, including remarriage, death or injury to a child or psychological. One interesting statistic is that most tubal ligations are performed before the age of 30. This is significant in that



these studies have clearly shown that the younger the age at the time of tubal ligation, the more likely that the patient will desire a reversal in later life. The microsurgical success rates for tubal sterilization reversal is more than double that of conventional methods.

In fact, gynecologic microsurgery not only corrects infertility problems, the technique actually prevents these problems from developing in the first place. Many women with a history of gynecologic surgery develop pelvic adhesions which damage fallopian tubes and lead to infertility. For example, 47% of women who have had surgery for appendicitis as an adolescent will have developed significant scars or adhesions. Other surgical procedures that have a high incidence of adhesion formation include pelvic surgery and gall bladder surgery. Even Cesarean sections have been associated with subsequent scars and adhesions sufficient to prevent future pregnancies. By minimizing these scars, microsurgery avoids potential infertility problems. For this reason, general gynecologists have begun to refer appropriate patients to surgeons with microsurgical training. Even better, many general gynecologists have begun to attend courses sponsored by the Society of Reproduction Surgeons, and have begun to apply the principles of microsurgery to their general gynecological surgery.

One additional note about microsurgery. As microsurgical technique has improved, so has our ability to operate through the laparoscope. Currently, as much as 70% of abnormalities which previously required major surgery—microsurgery—can now be performed through the laparoscope using the newer modalities of laser, heat, electrocautery and pelviscopy. Of course, certain procedures still require meticulous microsurgery. As a renowned microsurgeon, Dr. John Rock of Johns Hopkins has stated, "One should avoid trying to do through a keyhole what is difficult enough to do through an open door."

Your infertility evaluation and diagnostic laparoscopy will indicate whether microsurgery would prove beneficial for treating your infertility. Should you require microsurgery, Fertility Institute will provide you with more detailed information and counseling.

#### Laser Surgery

A "space-age" product, the laser beam plays an increasingly important role in infertility treatment. Coupled with microsurgery or laparoscopy, the laser dramatically increases the chances of pregnancy. [31]

Laser is a form of high energy light concentrated into a fine cutting beam—much the way we can focus the sun's rays through a magnifying glass. Used through the operating microscope during microsurgery, the laser offers shorter operating time, reduced tissue destruction, improved control of bleeding, and greater precision. In addition, infertility experts find that laser techniques present minimal side effects and more rapid healing.

Because it seals small blood vessels as it cuts, the laser discourages the formation of adhesions. Your microsurgeon can also use the laser to vaporize endometriosis implants associated with infertility. Microsurgeons with experience in laser techniques call this "the gentle touch."

One of the most important advances in laser surgery involves the use of the laser beam during laparoscopy. For example, using laser through the laparoscope, the

microsurgeon can treat endometriosis and pelvic adhesions. Thus, laser laparoscopy replaces conventional surgical procedures involving a large abdominal incision and a lengthy hospital stay.

The use of laser, a complex and precise technique, requires lengthy training on the part of the microsurgeon. For infertility patients, it offers the promise of increasingly successful treatments as new applications and new technology develop.

#### Operative Laparoscopy (Pelviscopy)

The term pelviscopy, coined by Dr. Kurt Semms of Kiel, Germany, implies the ability to perform extensive surgery that used to require an exploratory laparotomy and extended in-patient hospital stay, through the laparoscope. A simple term for this is operative laparoscopy. Although the laser through the laparoscope was the first major innovation permitting extensive surgery through the laparoscope (and still, incidentally, remains the most important modality), an impressive array of additional instrumentation and techniques, involving electrocautery (surgery using specially processed electricity to dissect diseased tissue) or heat instrumentation (unique instruments developed which can use the characteristics of heat coagulation to remove abnormal tissue) has been developed which further enhance the ability of the fertility specialist to perform all necessary surgery through the laparoscope. All of these various techniques are utilized by the Fertility Institute at Mercy Hospital in Springfield or at the University Hospital in Worcester.

In an impressive article which appeared in the scientific publication *Fertility and Sterility*, entitled, romantically, "The Leader of the Band is Tired", Dr. Alan DeCherney, of the Department of Reproductive Medicine at Yale, wrote that almost 70% of pelvic infertility surgery that used to require exploratory laparotomy can now be performed on an outpatient basis through the laparoscope. We, at the Fertility Institute, agree with Dr. DeCherney's assessment.

#### Videoendoscopy

The term videoendoscopy refers to the technique whereby laparoscopy or hysteroscopy is connected, by means of a "high tech" camera chip to a television monitor and recorded on a VCR. This "state of the art" technique has advantages for both the patient and the physician. For the specialist, videoendoscopy allows him to operate more comfortably while looking at a television monitor. The technique is physically more comfortable, allowing the specialist to do a better job. For the patient, videoendoscopy [32] provides a permanent VCR recording which allows the physician to review the procedure in an understandable manner with the patient. Although an "operative report", a dictated transcription of any surgical procedure, is always available, the availability of a VCR recording of an operative or diagnostic laparoscopy or hysteroscopy is far superior should you wish a "second opinion".

#### Artificial Insemination Using Donor Semen (AID)

The problems of male infertility, and the decreasing number of babies available for adoption, have contributed to a burgeoning interest in artificial insemination with donor semen. Although we do not know the exact figures, we do know that thousands of babies are born each year as a result of AID.

When the fertility evaluation indicates that the husband is sterile or subfertile, and

the sperm do not respond satisfactorily to in-vitro washing and capacitation, we may recommend artificial insemination using donor semen.

In addition, we advise couples to consider AID when the husband is a carrier or victim of a serious inheritable disease. We also suggest AID to couples whose pregnancies have failed because of erythroblastosis fetalis—an allergic reaction in which an rh negative mother develops antibodies in-utero to a child conceived with an rh positive father.

To rule out any complicating factors, we advise a diagnostic laparoscopy prior to artificial insemination. In this way, you will not undergo the emotional stress and expense of six months of artificial insemination, only to discover that the failure was due to pelvic scars, or endometriosis. Instead, we can uncover and correct these conditions by microsurgery or laser laparoscopy before beginning artificial insemination.

The reported success rate for AID—when all the female factors prove normal or corrected—averages between 70 and 80 percent. We try to match donors to the husband's physical characteristics—race, eye color, complexion, hair color. (Of course, if the wife has an rh negative blood type, we use semen from an rh negative donor.) Couples are often pleasantly surprised by how “like the father” children conceived through AID appear.

The majority of women who conceive with artificial insemination do so within three cycles—and 90 percent within six cycles. Because of this, we ask you to commit yourself to at least six cycles before beginning a course of AID. Usually, we perform two inseminations during each ovulation period.

Interestingly enough, 60 percent of couples impregnated with donor sperm give birth to baby boys.

As you may well imagine, AID has many legal and psychological ramifications. For this reason, we will employ it after an honest and serious discussion with both husband and wife. In addition, you will never learn the donor's identity, nor will he ever learn yours. We keep no records connecting the donor with the recipient.

One unfortunate aspect of AID is the recent importance attached to AIDS (acquired immuno-deficiency syndrome). As of the writing of this manual, there has not been one single documented case of AIDS transmission through clinical donor insemination. Nevertheless, the theoretical possibility of transmitting AIDS through artificial insemination [33] is indeed frightening and should be avoided at all costs. Such a program, of course, increases the cost of AID. All donors are screened by history. Only married, heterosexual individuals with proven fertility and a written denial of homosexuality are used. In addition to the routine screening, initially, for venereal diseases, all donors are screened every three months for the presence of AIDS antibodies. Any individual with a positive AIDS antibody is not eligible to serve as a donor. In addition, all potential patients, both male and female, who would be candidates to receive donor insemination must be screened for the presence of the AIDS antibody prior to receiving any inseminations.

In keeping with the recent recommendation of the American Fertility Society, The Fertility Institute uses only frozen donor sperm. This sperm is used after a six month freezing incubation period and after the donor remains AIDS negative six months following donation. As the six month incubation period significantly exceeds the incubation period of the AIDS virus, this eliminates the chance of transmitting AIDS

through donor insemination. To be sure, these recently introduced precautions significantly increase the cost of artificial donor insemination.

During your infertility evaluation and treatment at Fertility Institute, we will not bring up the subject of artificial insemination using donor sperm. Should your evaluation disclose male sterility as the major cause of your infertility, and should you wish to investigate the option of AID, it will be your responsibility to raise the issue of artificial insemination.

#### Artificial Insemination Using Homologous (Husband) Semen (AIH)

In certain cases, artificial insemination using the husband's own sperm proves an effective means of conception. We essentially limit the use of AIH to when the husband is fertile but impotent. In addition, the procedure works well when the husband has an extremely high sperm count—a factor, strangely enough, also associated with infertility.

While artificial insemination using husband's semen does not present couples with the obstacles associated with AID, AIH has not proven highly successful (this does not refer to the newer procedure of IUI with enhanced sperm, which is a different type of AIH). The few but precious pregnancies with AIH occur most often when the problem is impotence, premature ejaculation, or some other difficulty related to intercourse.

#### Intrauterine Insemination with Enhanced Sperm

A recent advance—intrauterine insemination using washed, enhanced, capacitated sperm—promises to significantly increase the success rates for artificial insemination using husband's sperm.

Fertility Institute and the Reproductive Diagnostic Center for Research and Testing has developed a particularly effective technique which actually improves (enhances) and concentrates the husband's sperm, then injects the sperm directly into the uterine cavity.

This new technique currently offers an overall success rate of 35 percent—with almost all of the successes within the first four treatment cycles. [34]

#### The GIFT Program

The newest—and most successful “high tech” treatment for infertility, is GIFT, which is an acronym that stands for Gamete Intra-Fallopian Tube Transfer. The Fertility Institute is proud to have been the first to achieve a reported successful live birth GIFT pregnancy in a Catholic hospital in the United States. As of 1988, the success rate for GIFT procedures performed by the Fertility Institute was 35%.

GIFT was pioneered by Drs. Ettore Cittidini of Italy and Richardo Asch, at the Department of Gynecology at the Baylor College of Medicine in Texas. Three of the first ten patients achieved a live birth pregnancy! Mercy Hospital, in cooperation with the Fertility Institute of Western Mass, was one of the first hospitals on the East Coast to implement a GIFT program.

How does the GIFT procedure work? First, the female is stimulated with pergonal or a clomiphene/pergonal combination. Then when the eggs have become perfectly ripe, as in the process of *in vitro* fertilization (IVF), we surgically remove the developed eggs from the woman's body during laparoscopy. The eggs are then placed into a catheter along with washed, capacitated sperm. An “air space” is left between the eggs and the sperm so that fertilization does not occur in the catheter. During the

same laparoscopic procedure, the egg/sperm loaded catheter is threaded into the fallopian tube and the contents injected directly into the fallopian tube. Ideally, three eggs are placed into each fallopian tube. Unlike *in vitro* fertilization, GIFT permits fertilization to occur in the fallopian tube, as it would normally, rather than outside the body in a test tube. Incidentally, it is this absence of extra-corporeal (outside the body) development that makes GIFT more philosophically acceptable to numerous religions.

Simply put, in IVF the laboratory serves as a "surrogate" fallopian tube for approximately two days until the fertilized egg is mature enough to be placed into the female uterus. With GIFT, the unfertilized egg and the capacitated sperm are deposited directly into the fallopian tube where fertilization occurs, natural nutrition and nourishment occurs, and the fertilized egg makes its own way into the uterus at the appropriate time.

Thus newly developed technique enables us to conclude the entire procedure at the time of the laparoscopy. In addition, GIFT significantly reduces expenses, because the need for a costly microbiology laboratory to sustain extra-corporeal (outside the body) growth is eliminated.

How successful is the GIFT procedure? According to the most recent International Multicenter Study Group report, GIFT offers an overall 35% success rate! This compares quite favorably with the lower overall success rate of 10-15% of IVF.

First, any patient considering one of the high tech reproductive technologies must understand how various published reports or claims by fertility clinics define "success". Initially, when IVF was in its early "research" phase, "success" meant the ability to fertilize an egg in a test tube or petrie dish. This led to claims of 80-90% success rates. Later, some clinics began to define "success" as a positive pregnancy test following the procedure. This led to a "success" rate of about 40%. Many of these "pregnancies" miscarried. Today, in order to avoid confusion, and in order to maintain standards, "success" should be defined only in terms of take home live babies. Defined in this way, that is, the number of patients entering the program divided by the number of patients taking home a baby, the finest IVF centers report about 10-15% success, while GIFT yields an enviable 35% success rate. [35]

Why is GIFT more successful than IVF? Most experts believe it is because GIFT eliminates the delicate step in the process of *in vitro* fertilization—placing the developing embryo into the uterus at the appropriate time. Moreover, the artificial nutrients in which the fertilized egg must grow during the two days of development outside the body, prior to being placed into the uterus, may be lacking. Simply put, the laboratory cannot match the natural environment of the fallopian tube. Finally, in IVF, there is the imperfect surgical procedure of placing the delicate, fertilized preembryo into the uterus following the two day period of extra-corporeal growth.

Who is a candidate for the GIFT procedure? About 10-15% of patients with longstanding infertility are candidates for GIFT. The minimal requirement is that the patient must have at least one normal, open fallopian tube. The following chart indicates the various reasons for performing GIFT.

GIFT: INTERNATIONAL COOPERATIVE STUDY  
THE FIRST 800 CASES

## Results by etiology

	<u>Cases</u>	<u>Clinical Pregnancies</u>	
		<u>No.</u>	<u>%</u>
Unexplained Infertility	499	175	35
Endometriosis	91	35	38
Male Factor	84	15	18
Failed AID	65	35	54
Periadnexal Adhesions	32	9	28
Cervical Factor	27	4	15
Oocyte Donation	<u>2</u>	<u>2</u>	<u>100</u>
Total	800	275	34.4

October, 1986)

An additional, important indication for performing GIFT, in view of its high success rate, is in the patient with long standing infertility who requires a laparoscopy. In this instance, not only can the underlying problem be diagnosed and, possibly, treated with laser, cautery or heat, but, with a simultaneous GIFT procedure, there is a 35% chance of achieving a pregnancy at the same time! In the event you are going to have a laparoscopy, the advisability of performing a GIFT procedure at the same time will be discussed with you.

#### In Vitro Fertilization

In the process of in vitro fertilization, we surgically remove an egg from the woman's body, fertilize it with sperm outside the body and then return the fertilized egg to the woman's uterus. The egg implants in the uterus and continues to develop there as a viable pregnancy which the woman carries to term. [36]

The first in vitro (literally, in glass) or "test tube" baby, Louise Brown, was born in England in 1978. The first American "test tube" baby was born in 1981.

While we no longer regard in vitro fertilization as an experimental procedure, it is far from routine. Although widely covered by the news media, the technique—available only in a few large centers—remains exceedingly expensive and carries a low success rate.

Most of these centers have expanded the criteria for in vitro candidates to:

- Blocked fallopian tubes following failed microsurgery.
- Blocked fallopian tubes in patients who are not candidates for microsurgery.
- Intractable mucopurulent cervical mucus.
- Unexplained infertility following a comprehensive evaluation.
- Male oligospermia (low sperm count) or asthenospermia (excessively slow sperm velocity)

In vitro fertilization involves the uses of powerful drugs such as Pergonal to induce multiple ovulation. In addition, the procedure employs a series of ultrasounds to pinpoint the exact day of ovulation, and monthly laparoscopies to retrieve the eggs from the ovary before ovulation. Each treatment cycle averages at least \$5,000—a fee usually not covered by insurance. Moreover, the success rate is less than 20 percent and requires a commitment to at least six treatment cycles. Thus, a procedure

offering less than a one-in-four chance for success, entails a financial liability of between \$30,000 and \$50,000.

Despite all the publicity, in vitro fertilization is not for every infertile couple, although numerous couples have achieved pregnancies with this innovative method.

There are currently three centers on the east coast performing IVF/ET with success rates that allow us to recommend them. Should you be a candidate for the technique, Fertility Institute will be pleased to provide collaborative referral services to the appropriate center of your choice.

#### Non-Surgical Embryo Transplant

A recent alternative for the infertile couple, non-surgical embryo transplant involves a surrogate—or volunteer—mother in a manner analogous to artificial insemination with donor sperm.

While still considered an experimental technique, the procedure holds promise for an infertile woman whose ovaries have been surgically removed but whose uterus remains intact.

The technique relies on impregnating the surrogate mother with the sperm of the infertile woman's husband using artificial insemination. Several days after conception, the fertilized embryo is removed from the surrogate mother's uterus and transferred by a non-surgical method to the recipient mother's uterus.

Because she lacks ovaries, the recipient mother initially will not produce the hormones necessary to support the pregnancy. For this reason, her physician administers hormones—orally or with injections—until the fourteenth week of pregnancy. At this point, the embryo and placenta begin to produce progesterone, so the pregnancy provides its own hormonal support. [37]

Only a few centers in California currently perform non-surgical embryo transplants.

#### Surrogate Parenting

In surrogate parenting, a fertile woman agrees to become impregnated via artificial insemination, using the sperm of the infertile patient's husband.

Unlike with the technique of non-surgical embryo transplant, the surrogate—or volunteer—mother carries the pregnancy through to term. The surrogate mother agrees to give the baby up for adoption by the infertile couple.

By law, babies cannot be sold. The infertile "parents-to-be" pay the surrogate mother for her time, as well as her "pain and suffering." The couple also pay all medical, legal, and agency expenses.

As in all adoptive processes, should the surrogate mother change her mind at the very last minute, the couple has no legal recourse. Although surrogate centers try to minimize this risk by requiring that all surrogate mothers be married with at least two children, it is important to realize that the surrogate mother is legally capable of changing her mind, even after the baby has been placed in the so called "adoptive" parents' home. Although only a few surrogate mothers have actually reneged on the surrogate agreement, such instances can prove financially and emotionally exhaustive!

Surrogate parenting is an option for infertile women whose reproductive organs have been removed surgically—married to fertile men.

Surrogate parenting shortens considerably the lengthy delay involved in conven-

tional adoption. In addition, the baby born under surrogate parenting is genetically related to the adoptive father.

Should you wish to consider surrogate parenting as a solution to your infertility, Fertility Institute will be pleased to offer you collaborative referral services.

#### Gender Preselection

Although not a treatment for infertility, the Fertility Institute does offer the Ericsson method for gender preselection. This is a process whereby parents who already have one or more children of one sex, can opt for a child of the opposite gender. In use for over ten years, the process offers an 80% chance for a male preselected gender and a 77% chance for a female preselected gender.

The technique, based on the observation that Y sperm swim faster than X sperm, involves processing the male sperm in such a way that the faster Y bearing sperm are selected out and then inseminated into the female at the appropriate time of her cycle by intrauterine insemination. As the process involves the loss of 80-90% of the male sperm, its use is limited to couples in whom the male has at least normal and preferably above normal sperm function and count.

The Fertility Institute is the first center in Massachusetts to be licensed to utilize the Ericsson gender preselection technique. As such, we join numerous other university and private fertility centers around the world utilizing this advanced methodology. [38]

#### INFERTILITY SERVICES AND COSTS

One of the more valuable outcomes of the 1988 Office of Technology Assessment study was the determination of the range of costs associated with varying levels of infertility services. One chapter of the study deals with the current state of infertility-related services from the perspectives of costs, affordability and insurance coverage. Such services studied included infertility treatment "including medical and surgical diagnostics and treatments that attempt to directly overcome diseases and disorders that cause infertility as well as technological procedures and practices that attempt to circumvent infertility conditions."

In most cases, infertile couples first seek medical assistance so that they can have a baby genetically related to both of them. Should these attempts fail, they may consider methods by which they can have a baby that is the genetic product of at least one member of the couple (*i.e.*, artificial insemination by donor, embryo donation, ovum donation, or surrogate motherhood), or they may consider adoption. In comparing the costs and availability of assistance for infertile couples, it is important to keep in mind the widening range of alternatives that infertile couples face.

This discussion focuses on infertile married couples, primarily on the women. Although men and women are equally likely to be infertile, male infertility, despite significant strides made within the past several years, does not account for an equal proportion of the costs spent on infertility because there are relatively fewer diagnostic and treatment services for men.

In treating infertility, the more tailored the protocol is to the patient, the more likely the chance of success. Some specialists, for example, treat endometriosis with surgery, with drugs, or with both; the choice of therapy, the length of time, and the drug dosage prescribed depends on the woman's history and reactions as well as on the severity of the disease. Many patient-specific decisions may be made over the



course of treatment; the results of each test and the success of each treatment indicate the next steps to be taken. Because of the varieties of sources and types of infertility, it is often difficult to determine whether standard treatment protocols exist, how much such treatment costs, and what the effectiveness is expected to be.

In addition, as in any advancing medical arena, infertility specialists disagree as to the proper course of action in many cases. Some physicians investigate mechanical problems such as blocked or scarred fallopian tubes as part of the routine workup; others wait until ovulatory problems are cleared up before determining the status of the tubes.

Finally, there are trade-offs to be made in cost, convenience, and surgical invasiveness. For example, most infertility workups do not routinely include a sperm penetration (hamster-oocyte) test because of its \$300 price tag and the uncertainty of its importance. Nevertheless, hindsight can sometimes show that the test would have been appropriate and would have saved thousands of dollars and numerous invasive procedures.

More often, cost savings can be gained by grouping procedures together. For example, if a hysteroscopy and laparoscopy are both performed together, the cost and stress to the patient will be lower than if they were performed separately. Furthermore, an early hysterosalpingogram (hsg) may indicate no need to proceed with surgical diagnostics. On the other hand, many specialists may find it advisable to repeat tests performed by general ob/gyns. An abnormal hsg performed by a specialist may actually have been normal, thereby also eliminating the need for surgical diagnostics. Practices may vary among [39] specialists. A detailed description of the types and cost of possible procedures is presented in the table entitled "Estimated Costs of Infertility Services". Please understand that this table is a compilation of a national survey of fee schedules of all physicians offering fertility services, both generalists and specialists, in communities throughout the United States.

Significant changes in the approach to infertility treatment can be expected over the next several years as technological advances occur. Some of these developments are foreseeable, and some are already being applied in a few centers but have not yet taken hold industry-wide. Embryo freezing, for example, allows IVF to be tried a second, and possibly a third, time without requiring additional ovulation induction and oocyte-retrieval. As embryo freezing develops and becomes more successful, the cost of subsequent treatment cycles could drop by half. In addition, ultrasound rather than laparoscopy is gaining wider use for oocyte retrieval, potentially cutting costs by an additional 30 percent. The diffusion of new technology will take time, however. For example, IVF centers that invested in developing skills and purchasing equipment used in laparoscopic surgery will not necessarily dispense with that procedure in favor of ultrasound retrieval of eggs.

The most significant change likely to occur may be the frequency with which tubal surgery is bypassed in favor of IVF, GIFT, or for a similar type of technology. To date, in most cases, IVF has been considered a last resort treatment, turned to after tubal surgery has been performed with unsuccessful results or for idiopathic infertility. There are, however, growing indications that both IVF and GIFT are now considered earlier on in the process—in effect collapsing Stages III and IV into a single stage. For example, should oocyte cryopreservation techniques improve, it may be routine to collect oocytes during diagnostic laparoscopies, perform GIFT during the

procedure and save the frozen eggs or embryos for IVF at a possible later time. Techniques are now being experimented with which would involve the retrieval of eggs by vaginal ultrasound, fertilization with sperm and immediate replacement into the fallopian tube by way of the cervical route, a totally outpatient office procedure. This approach further reduces both the cost of infertility treatment and the time involved, which is often of critical importance to couples nearing the end of their childbearing years. [40]

## Estimated Costs of Infertility Services

<u>Service</u>	<u>Median survey cost</u>	<u>Survey range of costs</u>
Diagnostic services		
Patient history and full physical	\$120	\$50-415
Infection screen	\$40	\$18-138
Sonography (per exam) <sup>1</sup>	\$100	\$40-286
Hormone tests (per test)	\$50	\$25-85
Pelvic exam	\$40	\$18-75
Cervical mucus:		
Postcoital test	\$40	\$25-100
Mucous penetration	\$40	\$25-200
Hysterosalpingogram	\$150	\$50-1,500
Endometrial biopsy	\$85	\$50-850
Hysteroscopy	\$400	\$130-1,100
Laparoscopy	\$800	\$400-3,500
Semen analysis		
(conventional)	\$45	\$15-108
Semen analysis (computerized)		
	\$75	\$65-195
Sperm antibody test	\$75	\$35-300
Hamster-oocyte test	\$275	\$35-390
Infertility counseling	\$75	\$38-135
Treatment Services		
Medical treatment <sup>2</sup>		
Clomiphene citrate	\$30 per month	\$16-75
HMG	\$28 per ampule	\$24-38
	\$588 per month	\$200-1500
HCG	\$20 per 5000 units	\$10-45
Danazol	\$160 per month	\$120-200
Bromocriptine	\$90 per Rx	\$30-450
Tubal reversals <sup>3</sup>	\$2,500	\$1,300-5,000
Reversal of vasectomies	\$2000	\$1000-2,500
Tubal surgery for PID	\$2000	\$750-3,800
Repair of varicocele	\$2,000	\$2,000-2,500

<sup>1</sup> Prices do not include "facility" fee, and pertain to "older" abdominal ultrasound.

<sup>2</sup> Prices include only the cost of medication.

<sup>3</sup> Prices for all surgical procedures do not include hospital or anesthesia fees.

<u>Service</u>	<u>Median survey cost</u>	<u>Survey range of costs</u>
Laser laparoscopy	\$1,200	\$485-3,000
Endometriosis-ablation	\$1200	\$400-5,000
In vitro fertilization	\$4,688	\$775-6,200
Frozen embryo transfer	\$500	\$220-1,800
Gamete Intrafallopian transfer	\$3,500	\$2,500-6,000
Artificial insemination <sup>4</sup>		
Husband's sperm		\$35-90
intracervical	\$53	\$30-105
intrauterine, washed sperm	\$85	\$40-200
Donor sperm		
fresh	\$80	\$35-150
frozen	\$100	\$40-350
donor fee		\$50-100

SOURCE: Office of Technology Assessment, 1988 [41]

INSURANCE

The dollar value of the personal, familial and societal loses caused by infertility is inestimable. According to a recent publication of the Office of Technology Assessment of the U.S. Congress, Americans spent about \$1 billion on infertility medical care in 1987. Approximately 7 percent of the total was spent on IVF.

To be sure, costs to individual couples receiving care for infertility vary dramatically, depending on the severity of their problem and their perseverance in seeking treatment. According to the same OTA publication, a complete diagnostic workup typically costs \$2,500 to \$3,000, although most couples did not require such an extensive workup. Following diagnosis, medical treatment may cost an additional \$2,000 to \$8,000. These estimates, moreover, do not take into account time away from work or expenses involving travel and away-from-home costs.

Many private health insurers do not cover infertility, per se, or provide only limited coverage; yet, in practice, a substantial portion of infertility expenditures are reportedly reimbursed. Some individual procedures may be covered if they are not identified specifically as part of an overall treatment for infertility. Many diseases, such as endometriosis, pelvic adhesions or cervical infections, for example, which would normally be covered by insurers, may be declined if identified as part of an infertility regimen, an illogical and indefensible position. Disingenuous ways may be found to invoice for infertility services, so as to obtain reimbursement from insurers. To date, only Arkansas, Hawaii, Maryland, Massachusetts and Texas have passed legislation mandating insurance coverage for infertility treatment. The Fertility Institute was instrumental in lobbying for the recently mandated fertility coverage in Massachusetts, although some insurance companies have managed to subvert this legislation or have chosen to reimburse selectively or on an inadequate level. This sad state of affairs has forced many fertility specialists to withdraw from several insurance plans or to decline to participate in various prepaid programs. To be sure, much work remains to be done in support of the consumer in this area.

Insurance companies often decline to reimburse for infertility services under several

<sup>4</sup> Prices include only cost of specimen, not insemination or handling fees.

guises which have no basis in fact and are outright myths. The following are five common reasons cited by insurance companies to justify their failure to reimburse for fertility services, along with our rebuttals.

#1. Infertility treatment is not a necessity. Curing infertility, either by achieving a biological child, adopting or deciding to live child free, is necessary for both physical and emotional well-being. The American Fertility Society considers "the right to procreate to be a fundamental human right" and believes it "has a moral obligation to provide...access to health services. Besides the serious emotional problems that couples with infertility often experience, infertile women are at a high risk for such diseases as endometriosis and, later in life, for various types of cancer such as of the breast or uterus. Infertility treatment is not a cosmetic issue or a luxury; it is a legitimate health problem.

#2. We can't pay for infertility treatment because it is still experimental. Insurance companies often tend to hide behind the ruse of labeling a procedure "experimental". The fact is that the vast majority of infertility treatment is not experimental. Many infertility therapies have decades of experience and have been approved by the Food & Drug Administration for use in the population for years. Even IVF and GIFT are "no longer considered to be experimental" according to official statements by [42] the American Fertility Society. It is important to remember that in many cases treatment is successful and results in a child.

#3. Adoption is cheaper and easier. Waiting time for a baby is often 2-6 years or longer. Couples often find that they turn 40 during the waiting period, at which age they then become ineligible for adoption! Foreign adoptions appear to be somewhat quicker, but can suddenly be blocked by changes in policy in the originating country. The red tape and bureaucratic process in agency adoptions can be stressful and humiliating. The majority of private adoptions fall through, and a couple may lose as much as \$10,000 or more with no legal recourse. The average cost of an adoption ranges from \$6,000-15,000 depending on whether it is private or agency sponsored.

#4. Infertility costs will drive insurance premiums way up. Not true! Eighty percent of all infertility treatment is currently covered. The nationwide cost of infertility therapy is but a tiny fraction of the U.S. health care budget. In Maryland, where coverage for all infertility services, including IVF, was mandated as of July 1, 1985, Blue Cross/Blue Shield paid only \$900,000 during the first 18 months. In lobbying against the bill, Blue Cross/Blue Shield had claimed the anticipated costs would run over 5 million dollars. Blue Cross/Blue Shield took the same tack in Massachusetts when lobbying against the recently passed bill mandating insurance coverage of infertility services in the Commonwealth.

#5. If insurance covers infertility services, all patients will require IVF or GIFT. Infertility therapy includes a wide variety of treatments ranging from drugs to major surgery to the more advanced technologies. Less than 5 percent of infertility patients will need or benefit from IVF or GIFT, and more than 60 percent will conceive a child through more basic, standard therapies. IVF and GIFT are only a very small, albeit important, part of the infertility issue, despite the publicity they receive.

As mentioned above, Maryland, Massachusetts, Hawaii, Texas and Arkansas already have passed bills requiring mandatory coverage for infertility treatment, and several other states have similar bills under consideration. A recent landmark decision involving a suit against the Kaiser HMO in California has set a legal precedent that it is discriminatory not to provide this type of service. Several national consumer groups

are lobbying actively for coverage and receiving both local and national media attention. Infertility is news. Patients and their physician advocates who are unwilling to accept an initial refusal of benefit coverage are finding their efforts more and more rewarded with subsequent agreement to coverage by their insurance companies.

Please bear in mind that the fee structure for fertility services provided at the Fertility Institute may vary from those schedules compiled from the national OTA averages listed above. A comparison of Fertility Institute's fee schedule with that of the national mean reveals that our fees, for the most part, fall near the median. Similarly, insurance coverage in Massachusetts may significantly deviate from the OTA national averages. We at the Fertility Institute will work with you in a creative and compassionate way so as to maximize your insurance coverage for treatment rendered.

#### SOME FINAL THOUGHTS

Success in achieving pregnancy depends greatly upon close cooperation and understanding between husband and wife, on the one hand, and the infertility specialist, on the other. As you proceed through your infertility evaluation, we ask you to keep in mind the following points: [43]

1. As many as 80 percent of infertile couples will succeed in achieving pregnancy—but only if they pursue a thorough investigation and undertake appropriate therapy for the appropriate time.

2. You must undergo a complete infertility survey. There are no shortcuts.

3. You must be patient. Certain tests may be performed only at specific times during the menstrual cycle. Tests involving treatment and re-evaluation may require several visits in successive months. Thus, it may take three or four months—sometimes even longer—to complete your infertility evaluation.

4. Be assured of the strictest confidence in all matters. Upon completion of your infertility survey, we will discuss our findings, our conclusions, and our recommendations with the two of you at a confidential conference.

5. You may require minor—or even major—surgery in order to become pregnant. Often infertility patients undergo minor surgery, such as a diagnostic laparoscopy. However, certain anatomical abnormalities, scarring, or endometriosis, may call for major microsurgery.

6. Please feel free to discuss costs and fees. We cannot easily determine in advance the exact cost of your infertility evaluation and treatment. These charges vary from patient to patient, depending on the particular studies and treatments required. When you begin your infertility evaluation, we will provide you with a rough estimate of the procedures most commonly followed. Depending upon your particular coverage, health insurance may cover various aspects of the evaluation.

7. You must make a firm decision to stick with the infertility evaluation from beginning to end. This commitment assures you of your best chance for success. Patients who complete only a part of a survey and then leave waste their money and their effort. If you have a history of unsuccessful infertility treatments, please discuss this with us before beginning the infertility evaluation.

8. In the light of recent clinical research, we can now offer many therapeutic approaches to the infertile couple—including surgery, microsurgery, laser, and other medical techniques. Once we identify your specific problem or set of problems, we can help you select the most appropriate mode of therapy.

The medical and paramedical staff of Fertility Institute will do everything possible to help you, and to inconvenience you as little as possible. Please feel free to make any suggestions, or to ask any question at any time. We hope that—like many of our former patients—you will achieve a successful pregnancy within the next few months. Upon this goal we base our medical practice, and to this goal we remain committed.

GOOD LUCK!!

#### DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Boston Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Fertility Institute of Western Massachusetts ("Fertility Institute") is a sole proprietorship, with its office and principal place of business located at 130 Maple Street, Springfield, Massachusetts.
2. Respondent Ronald K. Burke, M.D., is the sole proprietor of Fertility Institute.
3. The Federal Trade Commission has jurisdiction of the subject

matter of this proceeding and of the respondents, and the proceeding is in the public interest.

## ORDER

### I.

*It is ordered,* That respondents Fertility Institute of Western Massachusetts, a sole proprietorship, and Ronald K. Burke, M.D., individually, and respondents' officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale or offering for sale of any service in or affecting commerce, as "commerce" is defined in the FTC Act, relating to the treatment of infertility, do forthwith cease and desist from:

A. Misrepresenting, directly or by implication, in any manner the number or percentage of patients that achieve success in overcoming infertility, including but not limited to the number or percentage of patients that give birth or achieve pregnancy, or have given birth or achieved pregnancy.

B. Representing, directly or by implication, any success rate of any infertility procedure, unless at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence substantiating the representation. For any test, analysis, research, study, or other evidence to be "competent and reliable," it must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession to yield accurate and reliable results.

C. Misrepresenting, directly or by implication, the cost or expense of any infertility procedure.

### II.

*It is further ordered,* That respondents Fertility Institute of Western Massachusetts and Ronald K. Burke, and respondents' officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale, or offering for sale of any service in or affecting commerce, as "commerce" is defined in the FTC Act, relating to the treatment of infertility, do forthwith cease

and desist from misrepresenting, directly or by implication, their capacity or ability to perform any test or procedure relating to the treatment of infertility and cease and desist from misrepresenting, directly or by implication, any beneficial or therapeutic aspect of any test or procedure relating to the treatment of infertility.

### III.

*It is further ordered,* That respondents shall maintain for a period of three (3) years after the date the representation was last made and, upon request, make available to the Federal Trade Commission business records supporting all claims for any infertility treatment service.

### IV.

*It is further ordered,* That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in respondents such as dissolution, assignment or sale resulting in the emergency of a successor sole proprietorship, or any other change in respondents which may affect compliance obligations arising out of this order.

### V.

*It is further ordered,* That respondents shall, within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with all requirements of this order.

Commissioner Starek not participating.



1171

Complaint

IN THE MATTER OF

IVF AUSTRALIA, LTD., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF  
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3319. Complaint, Dec. 31, 1990—Decision, Dec. 31, 1990*

This consent order prohibits, among other things, a Connecticut based corporation and its two subsidiaries, all of whom are major providers of infertility services, especially *in vitro* fertilization, from misrepresenting in its advertising, promotion, or sale the success rate in achieving pregnancies or births.

*Appearances*

For the Commission: *Michael A. Katz* and *Michael C. McCarey*.

For the respondents: *Hope S. Foster, O'Connor & Hannan*,  
Washington, D.C.

## COMPLAINT

The Federal Trade Commission, having reason to believe that IVF Australia, Ltd., a corporation, IVF Australia (NY), Inc., a corporation, and IVF Australia (MA), Inc., a corporation, hereinafter referred to as respondents, have violated Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45(a), and that an action by it is in the public interest, issues this complaint and alleges that:

PARAGRAPH 1. Respondent IVF Australia, Ltd., is a Delaware corporation with its principal office and place of business located at 500 West Putnam Avenue, Greenwich, Connecticut.

Respondent IVF Australia (NY), Inc., d/b/a IVF Australia Program at United Hospital, is a Delaware corporation and wholly-owned subsidiary of IVF Australia, Ltd. Its principal office and place of business is located at 406 Boston Post Road, Port Chester, New York.

Respondent IVF Australia (MA), Inc., d/b/a IVF Australia-Boston, is a Delaware corporation and wholly-owned subsidiary of IVF Australia, Ltd. Its principal office and place of business is located at Waltham Weston Hospital & Medical Center, Hope Avenue, Waltham, Massachusetts.

PAR. 2. Respondents are, and have been, engaged in offering and

providing services for the treatment of infertility under the names, "IVF Australia," "IVF Australia at United Hospital," and "IVF Australia-Boston". One of respondents' methods for treating infertility is through *in vitro* fertilization ("IVF").

PAR. 3. Respondents have placed or caused to be placed, and have disseminated or caused to be disseminated, advertising and promotional materials, including, but not limited to, the advertising and promotional materials referred to herein, to promote the services they provide in treating infertility and in particular, their IVF program.

PAR. 4. The acts and practices of respondents alleged in this complaint are, and have been, in or affecting commerce, as "commerce" is defined in the FTC Act.

PAR. 5. In the course and conduct of its business, respondents have disseminated and caused the dissemination of advertisements and promotional materials relating to its IVF program, by various means, including, *inter alia*, placing advertisements in newspapers and magazines distributed through the mail and across state lines, and mailing promotional materials to prospective infertility patients, for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of respondents' infertility services.

PAR. 6. Respondents' advertisements and promotional materials relating to its IVF program contain representations as to their success in achieving live births and pregnancies for patients who purchase respondents' infertility services. Typical of respondents' representations of success in promotional materials is Exhibit A. Typical of respondents' representations of success found in advertisements, but not necessarily all-inclusive thereof, are Exhibits B and C. The aforesaid promotional materials and advertisements contain the following statements, respectively:

1. "Likely Treatment Outcomes. . . Our experience indicates that when a patient at an IVF Australia Program completes four IVF treatment cycles, the chance of giving birth is about 50%. . . . [Presented in diagram which follows] If 25 women begin a total of 100 IVF cycles . . . About 13 (or about 50%) of the women give birth to 18 babies" (emphasis in original) [Exhibit A].

2. "[M]ore than 28% of the couples who complete a cycle of treatment are becoming pregnant" [Exhibit B].

3. "[O]ne out of three couples who complete a cycle of treatment is becoming pregnant" [Exhibit C].

PAR. 7. Through the use of the statements referred to in paragraph six, respondents have represented, directly or by implication, that:

1. Women who participate in a treatment program consisting of four IVF cycles have a 50 percent chance of giving birth as a result of that treatment program.

2. Women who participate in a treatment program consisting of one IVF cycle have better than a 28 percent chance of becoming pregnant as a result of that treatment program.

3. Women who participate in a treatment program consisting of one IVF cycle have a one in three, or 33 percent, chance of becoming pregnant as a result of that treatment program.

PAR. 8. In truth and in fact, women who participate in respondents' treatment program consisting of four IVF cycles have considerably less than a 50 percent chance of giving birth, and women who participate in respondents' treatment program consisting of one IVF cycle have considerably less than a 28 to 33 percent chance of becoming pregnant. Therefore, respondents' representations as set forth in paragraph six were, and are, misleading.

PAR. 9. Through the use of the statements referred to in paragraph six, respondents have represented, directly or by implication, that a specified percentage of their patients have achieved a pregnancy or a live birth without disclosing that respondents, in calculating those percentages, have excluded patients who had begun respondents' IVF treatment programs, but were unable to become pregnant or give birth because they did not achieve an embryo transfer.

PAR. 10. The fact that respondents' success rate statistics have excluded patients who had undergone respondents' treatment programs but who were unsuccessful because they could not achieve an embryo transfer is a material fact, and the failure to disclose it renders respondents' representations of success, as set forth in paragraph six, deceptive because they are likely to mislead potential purchasers of respondents' services into believing that the chances of becoming pregnant or giving birth are greater than they actually are.

PAR. 11. The acts and practices of respondents alleged in this complaint constitute unfair and deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. 45(a).

Commissioner Starek not participating.

## EXHIBIT A

IVF AUSTRALIA PROGRAM AT UNITED HOSPITAL  
 406 Boston Post Road, Port Chester, NY 10573  
 (914) 934-7484

## APPLICATION/ACCEPTANCE PROCEDURE

Your application to seek treatment with the IVF Australia Program at United Hospital will be processed with appropriate urgency and attention to detail. Together we will need to determine whether

- in vitro fertilization is advisable for you.
- you can enter treatment in a time frame convenient for you.
- you are comfortable with signing our informed consent form.

The following outline will help you estimate the time requirements and probability that your condition makes you acceptable for treatment

STEPS	ESTIMATED TIME REQUIRED
1. You return enclosed application.	3 days
2. We receive and review your medical records.	2 to 4 weeks
3. Our medical staff discusses with you whether additional tests are indicated and how they should be conducted. (If you have been treated for infertility for more than a year, it is likely that your existing medical records are adequate.)	Within 2 weeks of receipt of existing medical records.
4. An initial consultation is arranged and you receive our second information packet which contains more detailed information and consent forms. At the consultation, you will meet as a couple with a physician, nurse, psychologist and financial counselor.	Within 2 to 4 weeks of receipt of complete medical records.
5. If treatment is advised, your first treatment cycle is scheduled.	Treatment to begin within 2 months after you are accepted for treatment, providing that a space is available within the Program's schedule.

## LIKELY TREATMENT OUTCOMES

The most meaningful way to express IVF success rates is the

chance of treatment resulting in a *live birth*. Our experience indicates that if any patient at an IVF Australia Program completes four IVF treatment cycles, the chance of giving birth is expected to be about 50%. Some women establish a successful pregnancy after one attempt, others after several tries and some do not become pregnant after repeated attempts, depending on the woman's age, the number of embryos available for transfer and to some extent, cause of infertility. Please review the diagram below to understand how success is likely to evolve from each important step in a treatment cycle.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
If <u>25</u> women begin a total of <u>100</u> IVF cycles	About <u>82</u> egg retrievals occur	About <u>76</u> embryo transfers occur	About <u>18</u> clinical pregnancies begin	About <u>13</u> (or about 50%) of the women give birth to <u>18</u> babies

Please note that embryos frozen in an IVF treatment cycle and transferred during a subsequent menstrual cycle may result in additional live births.

**COST OF TREATMENT**

While your treatment may vary depending on your individual needs, you can determine approximate costs from the following sample breakdown of costs that could be incurred during treatment. Please note that this is our current estimate of costs and may change. Costs have been grouped as:

- Basic Evaluation—the basic testing and consultation required prior to your first IVF treatment cycle.
- An IVF Treatment Cycle.
- Cryopreserved Embryo Cycle—applies when you are having embryos transferred which were frozen during one or more prior IVF treatment cycles.

We will assist you in both evaluating and obtaining insurance coverage for treatment. However, we ask that you plan to deposit with us the full cost of treatment in advance.

The following reflects a sample breakdown of fees that could be incurred during an IVF treatment cycle up to and including the first pregnancy test.

## Complaint

113 F.T.C.

SERVICES	BASIC	IVF TREATMENT	CRYOPRESERVED
	EVALUATION (1st cycle only)	CYCLE Nonsurgical (payable in advance of cycle)	EMBRYO CYCLE
Initial Consultation	200		
Comprehensive Physical & Medication Instruction	125		
Hormone Assays (if necessary)	(281)		
Endocrine Monitoring	1,295	1,425	
Ultrasound Monitoring	220		
Egg Retrieval			
—Physician's Services	1,000		
Embryology	715	640	
Embryo Transfer			
—Sounding of Uterus	100	100	
Ambulatory Surgery	1,700	675	
Anesthesiologist	300		

## NOTE:

1. If the option of cryopreservation is chosen, a \$400 embryology fee will be charged at the onset of each treatment cycle in which embryos are collected and frozen. This fee is credited to the amount charged for a cryopreservation cycle.
2. A \$300 nonrefundable administrative fee is required at the onset of each cycle.
3. If your treatment is discontinued in midcycle, your charges will reflect services incurred up to the point of cancellation.
4. Occasionally a surgical retrieval is medically necessary and an additional \$700 charge is incurred.
5. In our experience, most patients have obtained partial insurance coverage of our fees.
6. Above fees do not include cost of medication and self-administration teaching, estimated to be \$500 per cycle.
7. Fees are subject to change.

## YOUR TIME REQUIREMENTS

## Frozen Embryo Transfer Cycle

If you have had embryos from a treatment cycle frozen (cryopreservation) and stored, they can be transferred to the uterus during a subsequent menstrual cycle. Frozen embryo transfer cycles are much simpler (and also less costly) than an IVF treatment cycle in which eggs are collected. In our experience, 13% of patients who have retrievals have embryos which can be frozen after each treatment cycle.

APPROXIMATE DAY OF YOUR MENSTRUAL CYCLE	YOUR TIME REQUIRED (Excluding travel time)	NATURE OF YOUR PARTICIPATION
Day 1	10 minutes	● Telephone the Program to confirm you are beginning a frozen embryo transfer cycle.
Daily from day 8 to 14	30 minutes daily	● Have a blood sample drawn twice daily.
Day 18	2-3 hours	● Have frozen embryo(s) transferred to the uterus.
Days 28-30	15 minutes	● Have blood drawn for pregnancy test.

**TRAVEL/ACCOMMODATIONS**

United Hospital is located in Port Chester, New York, in Westchester County—at the intersection of I-287 and I-95—about 15 miles northeast of New York City.

**By Automobile**

From New York City-East Side: Take I-95 North to Exit 21, Route 1 North, Port Chester. At the end of the ramp proceed onto Route 1. At the first light turn left into the hospital parking lot.

From New York City-West Side: Take the West Side Highway to the Henry Hudson Parkway to the Saw Mill River Parkway. Take first exit after toll to Cross Country Parkway East to Hutchinson River Parkway North to 287 East (Rye). Take Exit 12, bear right on ramp. At first traffic light turn left and then right into the hospital parking lot.

From upper Westchester or Rockland: From upper Westchester take I-684 to I-287 East. From Rockland take the Tappan Zee Bridge to I-287 East. Get off at Exit 12 (Route 1, Port Chester) and bear right circling back over I-287. At the first light, turn left into the hospital parking lot.

From Connecticut: Travel south on I-95, take the exit for I-287 West and immediately follow the sign for Exit 21 (Midland Avenue, Port Chester). Turn left at the end of the ramp, then take the first right. At the next light, turn right onto Route 1 North. In about a ½ mile, turn left into the hospital parking lot.

**By Train**

Take the New Haven line from Grand Central Station in Manhattan to Rye, New York (approximately a 1/2 hour trip). Cabs are available to the hospital which is a mile from the Rye station. There is a station in Port Chester, but Rye is closer.

**By Plane**

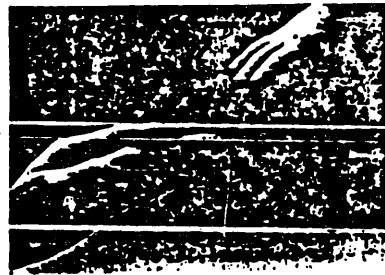
United Hospital is about 13 miles from La Guardia Airport in New York City and three miles from Westchester County Airport in White Plains, New York. The Rye Town Hilton, which is one mile from the hospital, offers limousine service from La Guardia to the hotel.

We can provide additional information on area accommodations.

## EXHIBIT B

## EXHIBIT B

# EACH MONTH WE GIVE 60 COUPLES THE CHANCE OF A LIFETIME.



For couples with infertility problems, waiting for the chance of a lifetime may seem like an eternity.

Yet, it's a reality for one out of six couples in America today.

At United Hospital, we're not simply accepting this alarming fact of life. We're doing something about it.

Which is why we're offering the IVF Australia Program, an in vitro fertilization program that utilizes advanced technology and training developed by the world-renowned physicians and scientists at Monash University, Melbourne, Australia.

As a result, more than 28% of the couples who complete a cycle of treatment are becoming pregnant. And that makes us one of the most successful in vitro fertilization programs in the world.

What's more, these couples have become pregnant without surgery, using ultrasound-guided transvaginal egg retrieval.

And our experience to date shows that our patients are receiving 80% insurance reimbursement.

Not surprisingly, the IVF Australia Program at United Hospital has become the largest in vitro fertilization program in the nation, while maintaining a commitment to patient-centered care.

For more information, please call (914) 934-7484. Or ask your physician. The IVF Australia Program at United Hospital.

It may be the chance of a lifetime.



**United Hospital**



IVF Australia Program at United Hospital, 406 Boston Post Road, Port Chester, NY 10573, (914) 934-7484.



EXHIBIT C

# EACH MONTH WE GIVE 80 COUPLES THE CHANCE OF A LIFETIME.



For couples with infertility problems, waiting for the chance of a lifetime may seem like an eternity.

Yet, it's a reality for one out of six couples in America today.

At United Hospital, we're not simply accepting this alarming fact of life. We're doing something about it.

Which is why we're offering the IVF Australia Program, an in vitro fertilization program that utilizes advanced technology and training developed by the world-renowned physicians and scientists at Monash University, Melbourne, Australia.

As a result, one out of three couples who complete a cycle of treatment is becoming pregnant. And that makes us one

of the most successful in vitro fertilization programs in the world.


What's more, these couples have become pregnant without surgery, using ultrasound-guided transvaginal egg retrieval.

And our experience to date shows that our patients are receiving 80% insurance reimbursement.

Not surprisingly, the IVF Australia Program at United Hospital has become the largest in vitro fertilization program in the nation, while maintaining a commitment to patient-centered care.

For more information, please call (914) 834-7484. Or ask your physician. The IVF Australia Program at United Hospital.

It may be the chance of a lifetime.

 **IVF Australia Program at United Hospital**

605 Beacon Plaza East, Port Chester, NY 10573. (914) 834-7484.

## DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such an agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent IVF Australia, Ltd., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 500 West Putnam Avenue, Greenwich, Connecticut.

Respondent IVF Australia (NY), Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 406 Boston Post Road, Port Chester, New York.

Respondent IVF Australia (MA), Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Waltham Weston Hospital & Medical Center, Hope Avenue, Waltham, Massachusetts.

2. The Federal Trade Commission has jurisdiction of the subject

matter of this proceeding and of the respondents, and the proceeding is in the public interest.

#### ORDER

##### I.

*It is ordered,* That respondents, IVF Australia, Ltd., a corporation, its successors and assigns, IVF Australia (NY), Inc., a corporation, its successors and assigns, and IVF Australia (MA), Inc., a corporation, its successors and assigns, and respondents' officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale or offering for sale of services relating to the treatment of infertility through *in vitro* fertilization, do forthwith cease and desist from representing, directly or by implication, that a percentage of respondents' patients have given birth or achieved pregnancy, unless:

A. The percentage represented accounts for all patients who received medication in an effort to stimulate ovulation in connection with the provision of *in vitro* fertilization services; or

B. Respondents disclose the basis used in calculating or arriving at the percentage represented. Such disclosure shall include the numerator and denominator used in calculating the percentage represented, and shall be made clearly and prominently, in close proximity to such percentage, and in a manner that can be easily understood by prospective purchasers of respondents' services.

##### II.

*It is ordered,* That respondents, IVF Australia, Ltd., a corporation, its successors and assigns, IVF Australia (NY), Inc., a corporation, its successors and assigns, and IVF Australia (MA), Inc., a corporation, its successors and assigns, and respondents' officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, sale or offering for sale of services relating to the treatment of infertility, do forthwith cease and desist from representing, directly or by implication, that a number or percentage of respondents' patients give birth or achieve pregnancy, or have given

birth or achieved pregnancies, unless such is the case, or otherwise misrepresent respondents' success rate in achieving births or pregnancies.

### III.

*It is further ordered,* That respondents shall maintain for a period of three (3) years after the date the representation was last made, and make available to the Federal Trade Commission upon request, business records supporting any claims of success in connection with their infertility treatment programs.

### IV.

*It is further ordered,* That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in respondents which may affect compliance obligations arising out of this order.

### V.

*It is further ordered,* That respondents shall, within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with all requirements of this order.

Commissioner Starek not participating.