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

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 (Gamete Intrafallopian 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. Peress M.D. and embryologist Joseph E. Sokolonki, 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. 21644 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 (Gamete Intrafallopian 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. Perow M.D. and embryologist Joseph E. Sokoloski, 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, 20644 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 chorianic 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.

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

RONALD K. BURKE, M.D., FACOG
Infertility, Gynecology,
Microsurgery, and Pelvic
Laser Surgery

PAUL SHORE-SUSLOWITZ, EdD
Licensed Clinical Psychologist
Infertility and Couples Counseling,
Reproductive Psychology

EILEEN K. BURKE
Executive Director,
Case Management Coordinator

WILLIAM V. NIZINSKI
Laboratory Director
Biologist

130 Maple Street, Springfield, Massachusetts 01103
(413) 781-8220

UNDERSTANDING YOUR FERTILITY

Table of Contents

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.

Factor	%
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 interrelated 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 (varicocelectomy), 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 antisperm 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 laytex 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