

## 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. Solotolski, 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 33426 - 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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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

