

TO: The Health Care Committee

RE: IVF Regulation

From: Lynne Millican

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If anyone had ever told me my quest for a child would have led me to the House of Representatives - I wouldn't have known what to say. But because of my journey through this medical maze, I now have a lot to say. Unfortunately this forum will only allow me to highlight these issues, but for that I am very appreciative; as these areas most definitely need to be addressed.

To quote Robin Cook, the author of the bestseller "Vital Signs" ... "the whole infertility industry is totally unregulated and unsupervised. It's grown up in a no-man's land between medicine and business. And the government has just looked the other way". While this book is fiction, these are facts which have been echoed repeatedly by Congressman Wyden and distinguished speakers at initial Congressional hearings on this subject.

I am not speaking here today simply because my IVF cycles have not resulted in a baby. There are many positive IVF cycles that result in children, and there are many positive IVF cycles that do not result in children - and these are the stories we have become familiar with.

I am here today because there are many negative experiences that have occurred and will continue to occur - and these stories are NOT publicized ... but the darker side of this industry needs perhaps more attention than the lighter side.

The segment of disgruntled I\ /F consumers includes not only those who remain without children, but also consists of women who have had successful IVF births. These women are indeed pleased with this achievement, but are also concerned and disturbed about the mismanagement and questionable treatment that they received. In fact, I am speaking on their behalf today, as they are fearful of retaliation by the industry and would not risk exposing their identity.

Because my negative experiences were nothing short of a nightmare, I voiced my concerns and complaints - not only to those involved in my care, or lack of care, but also to state agencies. However, since there is no regulation within this relatively new field of medicine, there is no accountability for any actions or inactions - and therefore no recourse.

The Board of Registration in Medicine, "dismissed my complaint after careful investigation", yet failed to investigate my complaint. The Division of Insurance, while stating it recognized the seriousness of my situation could not pursue the matter as they are "unable to get involved in anything beyond

financial solvency". The Department of Public Health "has no jurisdiction since the clinics do not require a license to operate".

The fact that there is no accountability for these physicians or insurance companies is unacceptable. These doctors who are entrusted with your reproductive health, heart and soul - because of non-regulation, can change criteria, rules and policies to suit their whims ... and are accountable to no one. This factor alone creates a run away system without any reins.

While I am neither a doctor nor a fertility specialist, I have been a registered nurse for 15 years. In addition, because of my health problems, I have been a patient for just as long. And as a professional, I have regrettably seen a lot of mistakes and mispractice in the field of medicine - my own disease was misdiagnosed for a solid decade and resulted in my infertility. But these events occurred without intent or malice, and I truly understand that even the most cautious of humans can make a mistake.

However, as a patient within this field of IVF, I have experienced frightening carelessness, poor management, deliberate and malicious mistreatment, misrepresentation of facts, multiple patients' rights violations, alteration of medical records, several breaches of confidentiality, collusion amongst those involved to commit fraud and coverup, an expressed refusal to provide care on the basis of "hard feelings" and "not having the time to waste to pour over my medical records" - to mention just the highlights.

In the interim, I have spent four years attempting to obtain just one fair, optimal cycle. Instead I have had 3 useless and wasted cycles because of oversights, was pumped full of massive amounts of hormones, was kept on an experimental drug longer than the established safety cut-off point, and required additional surgery as a direct result of their inactions, have run the known risk of my disease invading other non-reproductive organs, spent an enormous amount of my time in a systematic manner trying to rectify these wrongs - all the while generating thousands and thousands and thousands of dollars in profit for the industry ... yet still await just one fair cycle of IVF.

It is acknowledged that there is a lot of "stress" associated with an IVF cycle. Yet, the stresses that I encountered were directly caused by those administering or failing to administer my care, not from the process itself.

As a result of my outspokenness, I have already experienced retaliation ... and so I have nothing to lose in airing my views. But please bear in mind there are many IVF patients who, as yet, cannot speak.

With the utmost of convictions, I believe there can be no question regarding the regulation of this field. It is extremely difficult to prioritize the problem areas, as they all are priorities - but with regulation some of these issues would resolve themselves.

There is something fundamentally wrong when Massachusetts and every other state in the union requires a license for a beauty parlor and realtor , but no such licensing is required for an IVF clinic or embryo lab. The recent attention to the breast implant story, the mammography machine situation, and the case of Dr. Cecil Jacobson are clear examples of the harm that misinformation, non-regulation, exploitation and cover-up can produce.

These examples parallel the IVF Industry. Women, by nature of a medical need, have placed trust in modern medicine and technology ... and have been exploited, victimized, and abused - yet while the perpetrators have known about the problems in their areas; they have lied, covered up, and profited.

To grasp the extent of profit to be made in the IVF Industry, I would like to read an additional quote from Robin Cook's 'Vital Signs': "This is about profit, pure and simple. I'm talking big money. The number of couples in the U.S. that fertility specialists estimate need IVF if they want to have a child that is genetically theirs is 600,000. If we multiple that by \$50,000 (for a total of 6 cycles) we get 30 billion dollars. That's billion. Not 30 million, 30 billion. And that's just in the U.S. IVF could rival the world's illegal drug industry as a money maker".

I suspect that the figure of 600,000 couples is not accurate, but it is well known that this is a lucrative field, and as Congressman Wyden has stated "practitioners are not tripping over themselves to get into this field for nothing" . In fact NO ONE knows exactly how many people are having this done. There is no formal, mandatory, verifiable means of obtaining this and other relevant type of information.

You do not know how many clinics are open right now in this state or in this country, and you do not know how many closed yesterday, or how many will open tomorrow. You do not know the qualifications, training or past experience of the medical and laboratory personnel, and you do not know the standards, if any, for the embryo lab as it is self monitored. You cannot trust the success rates any given clinic may provide - as these figures are voluntary, non-standardized and non-verifiable, and there is a built-in arena of competition.

What we do know is that there are inferior clinics which claim otherwise, thereby instilling hope where there may be none. We know that some fertility "specialists" can obtain this mark of "specialty" by attending either a weekend or two week crash course and proclaim themselves as expert. The first year or so of this "specialist's" practice is just that ... practice; and in the interim hundreds of infertile patients have believed they've paid thousands of dollars for expert infertility care.

We know there is no uniform definition of a cycle - does a cycle begin with the first hormonal injection, or does it start with egg retrieval or perhaps egg transfer? And we know, from much debate, that there is no uniform definition of a success - are chemical or clinical pregnancies a statistical success or is it the take home baby figures?

We also know from leading IVF experts that there is "no set recipe" for IVF, and we know that there is no real data tracking ... and it appears to me that these two positions are diametrically opposed. How can the right formula become established without data collection, followed by scientific analysis? There are many more known and unknown facts - but one thing is certain ... we know that this must stop, and to this end we need your help.

The following are just three illustrations of the need for regulation:

The first is a couple I know who had yet to achieve fertilization and had a diagnosis of male factor. When fertilization was achieved, the embryologist was asked how much higher the sperm count was - and he replied that there was no change in the count, but that a different culture medium had been used. When asked what medium had been used in past cycles, this scientist replied he did not know because they don't keep that kind of data.

Secondly, I was personally told by a clinic they had a 16% rate of success with IVF and "don't worry, we'll get you pregnant". Much later I had the chance to view this clinic's voluntary report on their statistics, and they state that out of 333 IVF attempts in that year, they had 3 live births ... my calculations show that to be .09%, not 16%.

And thirdly, a fertility doctor in Connecticut maintaining his own sperm

bank was eventually found to be inseminating women with their partners dead sperm. Since there is no means to provide for external quality control, his faulty equipment was neither detected nor corrected, and so countless women went through repeated attempts to conceive, doomed to failure at the outset.

I also know of women who have been married two, three, four years who are diagnosed with unexplained infertility, undergo infertility treatment and have babies. Were these women truly infertile to begin with? Some of these women later go on to conceive without assisted reproductive technologies - and this should lead to questions about the validity of their initial IVF success. And what about clinics that accept only "easy cases" - this does not seem to reflect a true interest or dedication to treating the infertile.

While the Bill of Fertility Rights does not make mention of the drugs used in an IVF cycle, I believe the requirement to take these drugs, the cost of the drugs, and the drugs themselves beg further exploration.

A standard in IVF drug therapy is Pergonal. In 1980 the demand and consumption of this drug was far less than it is now, and at the time cost \$20 an ampule - yet today with increased demand it costs roughly \$63 per ampule? As Rep. Sullivan has stated "this carries an air of obscene profiteering". In my own cycles, I have used in excess of 100 ampules of Pergonal, costing nearly \$700 per day.

Louise Brown, the very first IVF baby, was born from a natural cycle - meaning one egg was produced by Mrs. Brown through her natural hormonal rhythm without introducing chemical stimulation. Why this option is not available for women who do not medically require chemical stimulation remains obscure. Granted, it would entail that a clinic and its physicians be available 24 hours per day year round to monitor the woman closely . . . but if this less costly and more harmonious approach is the woman's wish - why is this choice not readily available?

Not only is the availability of natural cycles virtually nonexistent, but now nearly every IVF clinic has mandated that women take Lupron - or they will not be allowed to cycle. Women are repeatedly told that Lupron is NOT an experimental drug, and yet it IS experimental. The use of this drug has become pervasive over a very short period of time, without informed consent in many, many cases, and with little, if any, clinical trials being performed. Of note when using Lupron is the coincidental requirement to use as much as three times the normal amount of Pergonal.

Women who have never cycled before as well as women who have had previous IVF babies without Lupron are told that if they desire to enter into an IVF cycle, they must take Lupron or they will not be allowed in the program. Women are told that Lupron results in better quality and better quantity of eggs; yet there is negligible research being done - so how can any assessments be made if there is no data to assess? Lupron is a potent, powerful experimental drug that has severe side effects and I speak from personal experience and this is an opinion that is shared by countless others. This drug should not be used exclusively, especially if a woman has already had success with the more established, previously used protocol.

And I question the wisdom in clinics refusing to proceed forward with egg retrieval if the woman has not been able to produce the clinic's minimum requirement of 3 eggs. A woman can go through two weeks of major doses of hormones, and may be able to only produce one or two eggs. If this is the case, and if that is all she may be able to yield - why will the clinic not attempt to retrieve what she is able to provide. Their answer to that question is that statistically you have a reduced chance of success with less than 3 eggs, therefore that's the minimum that they will attempt to

retrieve.

However, as we've seen - we are as yet unable to collect comprehensive figures and the ones we do have are skewed, at best. And besides, the woman with one or two eggs is not interested in statistics - she is interested in a baby ... and all you really need is that one! Are we seeking and paying for these services to meet their criteria or whim, which changes frequently - or are they in business to serve our best interests? This question is crucial.

On another point, insurance companies are limiting the number of cycles one is eligible for despite the fact the insurance mandate specifies this criteria cannot be used to deny coverage. Inherent to this discussion is the fact that there is no established definition of and for a cycle. For example - under my present Insurance plan I am allowed 3 IVF attempts. With this company I have had 2 bogus stimulation cycles which should not be counted at all . . . yet present insurance practice qualifies these 2 events as actual IVF cycles.

On a final Issue I would like to address the denial of infertility treatment that single women encounter. It is well known that infertility (and often its causative disease) results in marital discord and frequently divorce. What then are these infertile women to do with their desire to have children?

Despite the fact that GIFT and IVF are medical treatments for medical conditions, the majority of clinics in this state and country refuse to perform infertility procedures on single women - this judgment based on their reasoning that this would be performing a social function rather than a medical need.

However, there exists a paradox when clinics refuse to assist an infertile single woman to conceive based solely upon these social factors - yet, these same clinics provide fertile single women the medical technology to conceive ... for example, artificial insemination is provided for both the heterosexual and lesbian fertile single woman. In providing this assisted reproductive technology (which was designed for the infertile), the medical society is in effect creating the very same social posture which it uses as an argument against providing medical technologies to the infertile.

This is clearly a denial of health care based upon an individual's medical condition. In addition, there exists no state or federal law prohibiting discrimination on the basis of marital status within the health care system ... thereby eliminating any recourse.

In closing, I would like to say that in vitro fertilization is a worthy, admirable technological accomplishment, yet it is no different than anything else in this world ... if it is executed haphazardly it can become a very bad thing. But with proper regulation, safeguards will make certain that it becomes everything it should be.