



Regulation of ART in the US

1 Introduction

A recent article in *Fertility and Sterility* observed that it is widely perceived that assisted reproductive technology (ART) is not regulated in the United States.¹ The author proceeded to argue that ART in the US is “far from laissez faire” and calls for “perspective”, followed by a detailed listing of all the regulatory mechanisms that relate to ART.

He explains that the perception of poor regulation is fuelled by highly publicised incidents of irresponsible, unethical and illegal behaviour, by rapidly-developed techniques being used without confirmation of safety and efficacy, and by the lack of a statutory national body to oversee ART programs.

2 How ART is regulated in the US

As for all medical, scientific and commercial practice in the US, there is a range of mandatory regulations which applies. These apply to, for example, laboratory standards, licensing of medical practitioners, insurance requirements, occupational health and safety, research involving human subjects, and truth in advertising and marketing.

In general, ART-specific mandatory regulation involves annual reporting of clinic practices and results, a form of consumer protection. Cloning is in legislative limbo at the national level, and while some states (e.g. California) have legislated to allow it, the federal government may still legislate against. The Food and Drug Administration (FDA) has not approved cloning but this does not affect private entities. Extensive recommendations exist with regards to genetic testing, but few are binding.

Professional guidelines and standards have been developed by the two main relevant bodies, the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART).

Consumer advocacy groups play an important role. RESOLVE, the national consumer organisation, is dedicated to education, advocacy and support of infertile people. Its main area of concern is equal access to treatment. It is committed to evidence-based decision making, but is also concerned with “protecting the patients from further expensive regulatory mechanisms”.

The ‘big picture’ of ART regulation in the US was considered at a 1998 conference. It was decided that while the current regulatory approach is inadequate, no

¹ Adamson D. “Regulation of assisted reproductive technologies in the United States” *Fertility and Sterility* 78(5): 932-942, November 2002



international models are adaptable to the unique US situation. It was also felt that “legislation should be avoided when possible because of its tendency to restrict future choice”.

As a concept, the author writes that ‘oversight’ (rather than regulation) has many promising features, but also many disadvantages “as have been clearly recognized by practitioners from other countries, such as United Kingdom, France, Australia and Canada”. Mentioned here are some legal aspects of oversight, and serious concern that oversight could interfere in medical practice and with patients’ rights. In conclusion, he says that “oversight can discriminate against some patients, increase costs to all patients, and politicize medical and personal issues”.

3 ART progress in the US

Another article in the same issue of *Fertility and Sterility* describes US trends in ART over the past 20 years.² The author of this article gives a glowing report of improvements in ART, such as reductions in multiple pregnancies, reductions in invasive therapies, increases in efficacy and pregnancy rates. He notes that “this has occurred owing to the dedication and ingenuity of practitioners, and, notably, without federal regulation of clinical practice”.

4 Another perspective on regulation

A recent article revealed that the main source of regulation of ART, the Center for Disease Control and Prevention (CDC), has come under heavy criticism for failing to question the reliability of the evidence presented, as well as for being ineffectual.³ An immediate concern is the complete lack of on-site visits this year for verification of self-reporting (which in past years only occurred for selected clinics).

A broader concern is that it is too easy for practitioners and clinics to distort the statistics which they supply to the CDC. To maintain acceptable success rates for reporting, some clinics won’t accept difficult cases. Those clinics which do not comply with reporting requirements are not punished, but simply listed as non-reporters.

5 Ethical analysis

Fertility and Sterility has published these two articles to defend ART practices against the charge of being unregulated. To be ‘unregulated’ seems to be a bad thing – it conjures up images of mad scientists, unscrupulous doctors, and big profits. But the

² Toner JP, “Progress we can be proud of: U.S. trends in assisted reproduction over the first 20 years” *Fertility and Sterility* 78(5): 943-950, November 2002

³ Marcus AD. “Key CDC report on fertility clinics is under fire” *Dow Jones Newswires* Wednesday 11th December 2002.



term ‘regulation’ says nothing about qualitative characteristics of oversight mechanisms. Regulation is not a good in itself. It must be done for the right reasons, and in the right way.

Adamson writes that the ultimate priority is to “ensure the maximum rewards to those most affected by infertility and other reproductive issues”. It makes sense, then, that in the US ‘regulation’ consists mainly of a series of bodies intended to protect consumers (infertile people), allay public fears, and facilitate an expanding and essentially free market of infertility treatments. The tendency to resist legislation and any form of regulatory “interference” is clear. So too is the underlying belief in the concept of reproductive choice.

Hence, the current state of regulation in the US could be described as lots of bark and very little bite. Private businesses are, to a great extent, autonomous. Cloning is not banned, and has already carried out by private institutions. Professional guidelines and recommendations are not enforced and in any case tend to be highly permissive, simply reflecting a superficial account of community attitudes. As such they are not based on any expressed fundamental values and are therefore fluid.

Interestingly Adamson is critical of some aspects of regulation which can “politicize medical and personal issues”. This statement reflects the commonly-held assumption that medicine and personal life can and should be free from state interest and intervention.

Professionals involved in reproductive medicine are perhaps inspired by a utopian notion of a competitive market of high-quality infertility treatments, accessed by a population of individuals who will act on their own ethical values and standards. In this utopia, those who oppose artificial reproduction will simply not utilise such services. The infertile who accept ART will make informed decisions, with unquestioning faith in a ‘regulated’ system of providers. Self-imposed regulation and professional guidelines will suffice because practitioners are primarily interested in helping infertile people have families and will always behave ethically to this end.

But three fundamental errors exist in this picture. First, there is an inadequate portrayal of the main players in the field. The unborn play the part of ‘products’, the parents ‘consumers’ and the professional ‘providers’. The safety and rights of the products are always subordinated to the wishes of the consumer. And professionals wrongly exclude others from the debate – the fertile, laypeople, and those interested in human rights. This translates into the exclusion of those who disagree with the status quo.

Second, the educative nature of legislation means that, for many people, whatever is allowed by law must be ethical, or at worst neutral. To suppose that the state can be morally impartial, allowing citizens to decide for themselves, is a fiction. For example, if pre-implantation selection for sex is not prohibited, it is effectively permitted. If the state fails to act on the issue of cloning, it will be accepted and practiced.



Third, the ART market generates vast amounts of money. Self-regulation in this environment cannot escape the conflict of interest generated by self-interest. And who will regulate the regulators?

The perception of an absence of regulation in the US may reflect a difference in opinion of what 'regulation' should mean. Failing to establish fundamental values on which to base regulatory mechanisms results in, essentially, no regulation at all. The ART community in the US has no real reason to restrict any of its practices, so this particular breed of regulation will serve only to encourage the proliferation of infertility therapy and the great loss of embryonic human life which accompanies it.