

## HOW (NOT) TO REGULATE ARTS: LESSONS FROM OCTOMOM

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PROFESSOR RAO:

So, the title of my talk is *How Not to Regulate ARTs, Lessons from Octomom*.

We have already heard of a lot about Nadya Suleman who on January 26, 2009 gave birth to octuplets by means of IVF.

An article in the *Medical Journal of Fertility and Sterility* characterized the birth of these octuplets as a quote, “truly transformative event, because it has served as a catalyst to examine a range of clinical and ethical decisions.”

Nadya Suleman has been widely demonized as the quote, “Octomom”, a clever juxtaposition of octuplets and mother that conjures up images of a sinister octopus-like figure with eight squirming tentacles reminiscent of the evil sea witch in Disney’s *The Little Mermaid*. You can see that I am watching cartoon and Disney movies.

I must add that I really do not like this label, Octomom, and so from now on I am going to refer to her by her real name, as Nadya Suleman, not as the Octomom.

After this event the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology were besieged by calls from reporters and the general public raising questions about the lack of regulation in this field.

The outcry of Nadya Suleman’s story appears to have altered the public attitude towards assisted reproductive technologies, and prompted a legislative backlash where several states proposed new laws to regulate ARTs in the wake of this event.

Last year both Georgia and Missouri considered, but ultimately did not enact legislation that would have limited the

number of embryos that could be implanted in a woman's womb at any one time. And in fact I think Lee was referring to the Georgia bill that I mentioned here, Georgia SB 169, The Ethical Treatment of Human Embryos Act, which was tabled, and Missouri, House Bill 810, which would have enacted ASRM embryo transfer guidelines into law, but ultimately did not pass.

While California, the California legislature, considered a law that would have placed fertility clinics under the jurisdiction of the medical board. But this law was ultimately vetoed by Governor Schwarzenegger.

I think that Nadya Suleman's case provides a paradigm, both for how to regulate and especially for how not to regulate ARTs.

Some critics of Suleman focus upon the medical procedures that gave rise to the birth of octuplets. Namely the implantation of what was then thought to be six embryos.

Just that week some of you may have heard that it actually turned out that Dr. Kamrava, her physician, implanted twelve embryos, not six, into her womb.

But other critics focus upon Nadya Suleman herself, her identity as a non-white single woman who was unemployed and had been supporting herself with Worker's Compensation and disability payments for several years, and her alleged inability to parent eight more children when she already had six children under the age of eight and was living with her parents in a three bedroom house on the verge of foreclosure. These were a lot of the facts that are talked about in that case.

I think that Suleman's case exemplifies a line, a line between status and conduct based regulation of ARTs, because it has really provoked calls for both kinds of regulation.

Status based regulation would limit ARTs to certain types of people. For example, married couples rather than single persons or heterosexuals rather than homosexuals. Status based regulations might also deny or limit access to ARTs based upon factors such as race, ethnicity, class or disability.

Conduct based regulation of ARTs on the other hand would regulate what may be done but not who may do it. For example, laws that prohibit certain technologies such as reproductive cloning or laws that limit the total number of embryos that can be implanted in a woman's womb at any one time would regulate conduct in order to prevent potential harm either to the woman or to the children born of such technologies.

But such laws would not limit the types of people who could

have access to ARTs.

I first proposed this distinction between status and conduct based regulations of ARTs in an article that I wrote called *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, which was published shortly before Suleman gave birth to octuplets.

In the article, I advocate a novel approach to constitutional analysis of assisted reproductive technologies that emphasizes reproductive equality rather than reproductive liberty. I argue that there is not really a right, a general right to use assisted reproductive technology as a matter of reproductive autonomy, but there may be a limited right, a more limited right to use ARTs as a matter of reproductive equality.

So the government could theoretically prohibit the use of a particular technology that it thinks is particularly harmful across the board for everyone, but once the state permits use in some context it should not be able to forbid use of the same technology in other contexts. Hence, all persons must possess an equal right if—even if no one has an absolute right to use ARTs.

My theory does not bar government from drawing any lines with respect to ARTs, but it circumscribes the government's regulatory power when the line between what is permitted and what is proscribed is unconstitutional. And I argue that lines that are drawn based upon the status of the people should be judged unconstitutional, whereas lines drawn to differentiate between different acts could be deemed constitutional. Hence a law that permits ARTs to be used by married people but not single people, or by heterosexuals but not homosexuals, should be judged unconstitutional. But a law that merely distinguishes between different acts, such is a law that limits the total number of embryos that could be implanted at any one time probably should be judged constitutional.

Applying this theory of equal liberty to Suleman's case, the question arises why exactly are so many people angry and upset about the birth of octuplets to Nadya Suleman? Almost everyone appears to disapprove of this event, but the reasons behind their disapproval are remarkably varied.

Many critics decry the fact that Nadya Suleman was an unemployed, non-white, single mother who was receiving government assistance in the form of disability and other kinds of payments.

From the equal liberty perspective I would argue these are

impermissible factors because they would limit access to technology based solely upon her status, but then status-based factors, some of Suleman's critics emphasize the sheer size of her brood. They find it outrageous that Suleman gave birth to octuplets when she already had six children under the age of eight, and these critics argue that both eight is enough and Suleman's desire to reproduce in such large quantities is a cause for our concern.

But what exactly is so objectionable about having eight or even fourteen children? U.S. law generally doesn't limit family size for fertile persons, so can or should we cap family size for the infertile? And if the problem is not the size of Suleman's brood, but rather the fact that she had so many children as an unemployed, non-white, single mother who is receiving disability payments, then once again where her offense seems to turn upon her status rather than her conduct.

But perhaps the problem is not that Suleman now has a total of fourteen children, but rather that she gave birth to eight children at the same time. Not eight is enough, but rather eight at one time is too much. This is because the birth of multiples, especially in such high numbers, poses a great risk of harm both to the mother and to the children born using such technologies.

And I think that laws that focus upon this type of conduct and regulated even-handedly and across the board for everyone, perhaps those should be deemed constitutional.

Still other critics focus on Suleman's conduct, and what it seems to suggest about her mental capacity. Some of these critics argue that her extraordinary desire to have so many children under such extreme circumstances itself provides evidence that she's unhinged or mentally unfit, and that is—unstable and that is unfit to be a parent. Once again U.S. law generally does not condition the ability to have children upon one's mental capacity.

So I guess the question arises can or should we demand a psychological exam as a prerequisite for infertile persons to have access to assisted reproductive technology?

Although these criticisms appear to be couched in the language of conduct, I hear they inevitably turn on status. And they lead to dangerous judgments regarding who's fit to be a parent and who is not.

For example, would we infer mental instability if the same desire to have a large number of children was manifested of a

rich and famous actress?

Right. And I think Angelia Jolie, Suleman apparently models herself on Angelia Jolie and the photos there kind of show you how similar I guess she's trying to look.

So what if Nadya Suleman were rich and famous, would the same criticisms of her mental capacity be made? And in light of the tragic history of forced sterilization in the U.S. remember *Buck v. Bell* and *Skinner against Oklahoma*. I believe that the power to choose who should reproduce and who should not is too great a power and the risk to equality is too great to place those kinds of dangerous judgments in hands of others, whether they be the government or the medical profession, and in this respect I agree with scholars who argue that infertile persons should be granted equal liberty with fertile persons, so that there should be parallel regulation of coital and non-coital reproduction and some people argue for that.

But then the question arises, what are the alternatives to direct government regulation of assisted reproduction technologies? I would argue that deregulation of ART—of ARTs is a myth because there are—there is no such thing as these lack of government regulations.

But one alternative to direct government regulation is the indirect regulation of ARTs that we already have in the form of tort liabilities and the rules of family law. The tort system provides one means to regulate the safety of ARTs by imposing tort liability upon physicians and parents who engage in negligent conduct that causes harm to offspring. And the family law system employs the allocation of parental rights and the best interests of the child standard as another mechanism to police the use of ARTs.

So I—here I agree with the critics who charge that direct government regulation of ARTs poses a risk to those who are concerned about equality. The risk being that the majority may not be willing to extend equal rights to use this kind of technology to members of unpopular minority groups.

For example, law in Italy limits the use of ARTs to married people or stable heterosexual couples who are of the childbearing age and infertile, denying use of these technologies to single persons and homosexual couples. But I would argue that there is an even greater threat to equality that is posed by these alternate forms of indirect government regulation.

Tort liability for one is a random and haphazard process that

overcompensates some, under compensates others, and costs a huge amount to administer, so that it is incredibly inefficient. But some scholars suggest that tort liability may be preferable to direct government regulation of ARTs because it avoids or at least appears to avoid the problem of government designating which controversial uses of ARTs are undesirable and cause harm to women or children.

For example, if we impose tort liability among parents who genetically select traits in their offspring that might appear preferable to government regulation, because it appears to avoid the vexing problem of eugenics by not requiring the government to determine which genetic traits are undesirable.

So a principle virtue of tort liability is that it really does not seem to be a form of government regulation at all. But tort liability does not really imply a lack of government regulations, the government hasn't withdrawn from the field, the government's still regulating by permitting the imposition of tort liability. For the government could always announce a law that expressly prevents tort liability as California did in the wake of a controversial decision, the *Perlinger* Decision, which seems to suggest that parents could be held liable for selecting genetic traits in their offspring. In the wake of that decision California enacted a law to make it clear that they could not be held liable. And government's failure to prevent the imposition of tort liability is also a form of government regulation.

More fundamentally, the tort system masks or appears to avoid the problem of direct government regulation of ARTs, only at the cost of delegating the incredibly important and dangerous power to make decisions regarding parent's freedom to use ARTs to reproduce. It delegates this power to judges or juries in individual cases.

By permitting tort liability the government is not withdrawing it is giving judges or juries, uneducated members of the general population, the discretion to decide which parental decisions inflict harm and which do not. And this greatly increases the risk of discriminatory decision-making where juries are likely to impose their own conscious or unconscious biases through this objective, invaluable vehicle of the reasonable person standard.

And moreover, the lack of transparency would make these kinds of discretionary decisions incredibly difficult to challenge, effectively insulating them from any oversight.

So, I think tort liability is very problematic.

And this has been one of the options or one of the suggestions in the Octomom—sorry, in Nadya Suleman’s case. One of the suggestions has been to hold Suleman’s physician liable in tort for quote, “gross negligence.” And he’s currently, in fact, they’re currently holding a hearing to try to determine whether Dr. Kamrava should lose his medical license because the California Medical Board filed a complaint against him alleging gross negligence. And the complaint alleges that he is guilty of gross negligence both for what he did, namely implant too many embryos at the same time, but the complaint also argues or alleges that he’s guilty of gross negligence because his—he failed to refer Nadya Suleman for a medical exam. So tort liability poses problems.

Another alternative and the same problems would be raised with family law, but I do not have time to talk about that, I want to talk about another form of regulation, namely private self-regulation.

Another alternative is this self-regulation by the medical profession. But the evidence suggests that self-regulation by the medical profession will not work because financial and other incentives bribe doctors to flout or ignore professional guidelines. Yet the medical profession lacks the power and the will to effectively enforce these guidelines.

For example, the ASRM had already established guidelines regarding the maximum number of embryos to be implanted in women at various age ranges, yet Suleman’s doctor repeatedly and flagrantly violated these guidelines. Dr. Michael Kamrava claims that he departed from the guidelines and he implanted the unprecedented huge number of twelve embryos because Nadya Suleman requested him to do so, even though he knew that this would endanger both her health and that of her potential offspring.

Concerned about backlash after the birth of Suleman’s octuplets, it appears that the medical profession is now belatedly attempting to enforce its guidelines against her physician and he—ASRM revoked his accreditation and he is now being accused, as I said of gross negligence by the California Medical Board and is currently undergoing a hearing to determine whether he should lose his license.

But the studies show that the conduct of Suleman’s physician in implanting many more embryos than was recommended under the guidelines is not an isolated departure from the guidelines,

but a relatively common occurrence.

A 2009 article published in *Fertility and Sterility* surveyed embryo transfer practices in the U.S. and found that 94 percent of the clinics surveyed reported routinely following ASRM embryo transfer guidelines, but 55 percent of these same clinics admitted that they would deviate from the guidelines based upon the patient's request. So if a patient asks for it, they will depart from the guidelines. Another 55 percent said they would deviate from the guidelines for cycles involving the transfer of frozen embryos. And 75 percent said they would deviate for patients with previously failed IVF cycles.

So the evidence suggests that self-regulation will not work because physicians fail to follow their own guidelines. The financial incentives to deviate from the guidelines are enormous as clinics implant more embryos in order to inflate their success rates and to attract patients.

Another article in *Fertility and Sterility* suggests that these incentives might be reduced by tweaking the definition of reproductive success. And so let us see here, I have got that, yes, tweaking the definition of reproductive success.

For example, are we defining the birth of triplets or higher order multiples as a failure rather than a success?

Perhaps the incentives might also be altered by requiring a higher standard of informed consent. The doctors rarely tell patients about the dangers of multiple gestations. But Dr. Kamrava said he did that with Nadya Suleman and she still begged for more embryos and said what should he have done when the patient requested it.

So but there is an even more fundamental problem and I should say that the ASRM has revised its guidelines to change them a little bit in 2009 and it also enforced them against Suleman (sic) by expelling him from the ASRM.

But the more fundamental problem with self-regulation by the medical profession is that it poses a greater threat to equality even than government regulation, because the providers are likely to regulate all the wrong ways. Some providers may decide that the lesson to be learned from the outcry over Suleman's case is not to allow ARTs to be used by the wrong people: single people, gays and lesbians, poor persons and those with disabilities.

Surveys suggest that providers may deny access to ARTs on a variety of problematic grounds that old term status of the

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participants rather than the harms posed by their actions.

And so you can see that in the screening practices of ART providers, many of them would engage in marital status discrimination. There is a gender disparity here, or sexual orientation discrimination, economic discrimination, age discrimination and race discrimination.

In some states these kinds of discriminatory denials of access to medical services by physicians may be challenged under state public accommodations law, and this has been done in California. But in other states there are none, these denials are completely immune from any oversight.

In conclusion, the birth of octuplets to Suleman was a truly transformative event. I think it completely changed the regulatory climate in the field. Prior to that no one seemed concerned about the lack of regulation, but after the birth of octuplets there has been a legislative backlash and a regulatory backlash and belated attempts to enforce professional regulations against Dr.—Suleman's physician, Dr. Kamrava.

Hence, I think it is no longer a question of whether to regulate ARTs, the only question really is how to regulate and who should do the regulating? If you are concerned about the equality as I am, then ART regulations should focus upon conduct rather than status, upon what they have done and not who was doing it.

Moreover, I prefer direct and visible regulation to indirect invisible regulation which tends to be discriminatory and privileged majoritarian values.

And finally, clearly articulated regulations that are enacted by publicly accountable bodies are preferable to ad hoc discretionary decisions rendered by the patchwork of individual decision makers, whether they be physicians, fertility clinics or even judges and juries ruling in different cases.

Thanks.