



**advocates for
informed choice**

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Kenneth L. Davis, M.D., President
The Mount Sinai Medical Center
One Gustave L. Levy Place
New York, NY 10029-6574

Dear Dr. Davis:

I am the Executive Director of Advocates for Informed Choice (AIC), a non-profit organization that advocates for the legal and human rights of children born with intersex conditions or differences of sex development (DSD) and their families. I wrote to your Institutional Review Board in February on behalf of AIC to express serious concern over reports about treatment of such children at Mt. Sinai School of Medicine. By now you must know that Mt. Sinai has come under serious public scrutiny over the practices of your employee Dr. Maria New, who is treating pregnant women who may give birth to a child with congenital adrenal hyperplasia (CAH) with the steroid dexamethasone in an effort to prevent atypical genitals, “masculinized” behavior traits, and lesbianism.¹ In addition to the ethical and medical controversies surrounding these treatment practices, concerned citizens and advocacy groups (including AIC and a coalition of bioethicists) have raised questions about whether this Mt. Sinai doctor’s practices involved research on these pregnant women in violation of federal laws protecting human research subjects.² We are also aware that both the FDA and the federal Office of Human Research Protections have opened investigations into Dr. New’s practices. Thus far, we have received no response from Mt. Sinai.

AIC calls on Mt. Sinai to investigate fully, and to provide answers to the questions we have raised. We understand that Mt. Sinai is not alone in using dexamethasone prenatally for prevention of atypical genitals. However, Mt. Sinai is currently a focus of widespread attention because of Dr. New, who has been one of the leading proponents of this treatment as “safe and effective.” The public has a right to transparency and accountability from an institution practicing controversial and elective treatments on pregnant women and fetuses, especially if those women are also being used as research subjects. This crisis also represents an opportunity for Mt. Sinai to take leadership in

¹ Elton, C. (2010, June 18). A Prenatal Treatment Raises Questions of Medical Ethics. *Time*. Available at www.time.com/time/health/article/0,8599,1996453,00.html.

Dreger, A., Feder, E.K., & Tamar-Mattis, A. (2010). Preventing Homosexuality (and Uppity Women) in the Womb? *Bioethics Forum*. Available at www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4754&blogid=140.

Begley, S. (2010, July 10). The Anti-Lesbian Drug. *Newsweek*. Available at <http://www.newsweek.com/2010/07/02/the-anti-lesbian-drug.html>.

² Tamar-Mattis, A. (2010, February 10). *Letter of Concern from Advocates for Informed Choice*. Available at www.fetaldex.org/letter_AIC.html.

Letter of Concern from Bioethicists. Available at http://fetaldex.org/letter_bioethics.html.

providing a new model of progressive, patient-centered care for children with intersex conditions: one that takes seriously the significant ethical and legal questions involved, that fosters instead of silencing public discussion, and that is built around compassion for the parents and respect for the legal and human rights of the children.

Children with DSD have long been treated as exceptions to the usual rules of ethics in medicine.³ This kind of thinking is unacceptable, and clearly the tide of public opinion is starting to reject it. We urge you to launch a vigorous investigation, not just of Dr. New's research practices but also of Mt. Sinai's entire protocol for treating children with intersex conditions and conducting research on pregnant women. We further urge you to make a public statement answering the many questions raised by these incidents:

- **Did Dr. Maria New, while working at Mt. Sinai, have institutional review board (IRB) approval for giving dexamethasone to pregnant women** who might give birth to a child with CAH with the intention of publishing research on the results of that treatment?
- If she did, **how did the IRB justify the risk of harm to the fetus**, given the fact that atypical genitals have not been shown to present any risk of harm?
- How did it justify the **risk of harm to the 7 out of 8 fetuses who did not stand to benefit** in any way from the treatment?
- Did it improperly consider **reduction of "tomboyish" behaviors or lesbianism** to be a potential benefit of treatment?⁴
- **What information was provided to the pregnant women** about the risks of this experimental treatment?
- If Dr. New did not have IRB approval for conducting research, how does Mt. Sinai plan to adjust its practices, given the **recent expert consensus statement reiterating that this use of prenatal dexamethasone should *only* happen via IRB-approved clinical trials.**⁵

AIC is pleased to offer our assistance if there is any way we can help with your investigation. We regularly consult with individual providers, medical schools, and DSD treatment teams at leading hospitals, and provide training on legal and ethical issues related to treatment of DSD. We also have contact with many adults with intersex

³ Tamar-Mattis, A. Exceptions to the Rule: Curing the Law's Failure to Protect Intersex Infants. *Berkeley Journal of Gender, Law & Justice*. 2006:21;59-110.

⁴ Dreger, A., Feder, E.K., & Tamar-Mattis, A. (2010). Preventing Homosexuality (and Uppity Women) in the Womb? *Bioethics Forum*. Available at www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4754&blogid=140.

⁵ Draft CAH guideline revealed Monday. (2010, June 19-22). *Endo Daily*.

conditions and families of children with intersex conditions who might be willing to offer their input on improving protocols for patient-centered care.

One of the best things to come from the recent public attention is the emerging open dialogue on a subject that has been shrouded in secrecy for too long. Now that the questions are out in the open, Mt. Sinai has both the opportunity and the obligation to be transparent. Parents of children with DSD have the right to full information as they make decisions about their child's future. Pregnant women and children who are used as research subjects have the right to protection and oversight. And the public has a right to know how vulnerable children and research subjects are treated in their hospitals and medical schools.

We look forward to your reply.

Sincerely,

Anne Tamar-Mattis, J.D.
Executive Director

cc: Lori Jennex, Associate Director, Program for the Protection of Human Subjects
Ian Michaels, Press Secretary
Michael MacDonald, General Counsel