



advocates for
informed choice

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July 14, 2010

Dr. Antonio M. Gotto, Jr.
Dean of Weill Cornell Medical College
525 East 68th Street, L-126
New York, NY 10065

Dear Dr. Gotto:

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 Dr. Harry Lander, the Associate Dean supervising Weill-Cornell's human subjects protection programs, in February of this year urging your institution to investigate the practices of your former employee, Dr. Maria New, who studied use of the steroid dexamethasone to treat pregnant women who may give birth to a child with ambiguous genitals during her tenure at Weill-Cornell Medical College and New York Presbyterian Hospital (NYPH). AIC has not yet received any response from Weill-Cornell or NYPH.

I am writing today on behalf of AIC to express our continued serious concern over reports about treatment of children with intersex conditions at your hospital. By now you must know that Weill-Cornell and NYPH have come under intense public scrutiny over the practices of both Dr. New and Dr. Dix Poppas, who performs elective genital surgery on young children with atypical genitals and follows up with questionable "clitoral sensitivity" tests.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 these Weill-Cornell/NYPH doctors' practices involved research on these children and 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 while at Weill-Cornell/NYPH.

¹ Dreger, A. (2010). Can You Hear Us Now? *Psychology Today*. Available at www.psychologytoday.com/blog/fetishes-i-dont-get/201006/can-you-hear-us-now.

Dreger, A., & Feder, E.K. (2010). Bad Vibrations. *Bioethics Forum*. Available at www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4730&blogid=140.

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.

Savage, D. (2010). Female Genital Mutilation at Cornell University. *The Stranger*. Available at <http://slog.thestranger.com/slog/archives/2010/06/16/female-genital-mutilation-at-cornell-university>.

² Tamar-Mattis, A. (2010, February 10). *Letter of Concern to FDA 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.

Tamar-Mattis, A. (2010, June 25). *Letter of Concern to OHRP from Advocates for Informed Choice*. Available at <http://aiclegal.files.wordpress.com/2009/12/ohrp-letter-7-10.pdf>.

AIC calls on Weill-Cornell and NYPH to investigate fully, and to provide answers to the questions we have raised. We understand that Weill-Cornell is not alone in practicing elective genital surgery on young children with DSD, or in using dexamethasone prenatally for prevention of atypical genitals. However, Weill-Cornell is currently the focus of widespread attention. The public has a right to transparency and accountability from an institution practicing controversial and elective treatments on small children, especially if those children are also being used as research subjects. This crisis also represents an opportunity for Weill-Cornell to take leadership in 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 these two doctors' research practices but also of Weill-Cornell's entire protocol for treating children with intersex conditions. We further urge you to make a public statement answering the many questions raised by these incidents:

- **Did Dr. Maria New, while working at Weill-Cornell/NYPH, have institutional review board (IRB) approval for giving dexamethasone to pregnant women** who might give birth to a child with congenital adrenal hyperplasia (CAH) with the intention of publishing research on the results?
 - 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?⁵

- **Did Dr. Dix Poppas have IRB approval for performing clitoral sensitivity tests on conscious girls ages six and up** with the intention of publishing research on the outcomes of his surgical techniques?
 - If he did, how did the IRB justify the risk of psychological harm to the children from these tests? What information was provided to parents about the risk of psychological harm resulting from these tests? What information did the girls receive about their right to refuse participation?

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*.

- **Are parents who bring their children to Weill-Cornell/NYPH for genital surgery fully informed about the risks and unknowns of these procedures?**
 - The Weill-Cornell Department of Urology website claims without qualification that: “Our approach to the clitoroplasty leaves the patient with intact clitoral sensation, painless sexual arousal, a viable and sensate glans clitoridis and appropriate erectile function during sexual arousal.”⁶ This unsubstantiated public claim leaves us concerned about what parents are told privately. Are parents informed of the lack of evidence that genital surgery benefits children with atypical genitals? Are they informed of less-invasive options, such as counseling? Are they informed of the risks of nerve damage, incontinence, urinary tract infections, inability to experience orgasm, or many other problems associated with genital surgery?⁷ Are they informed of studies indicating that one girl in 20 with CAH will ultimately identify as a male?⁸

- **Are treatment protocols at Weill-Cornell/NYPH in line with current best-practice standards?**⁹
 - If genital surgery is recommended for psychosocial reasons, as opposed to physical need, are these recommendations coming from surgeons, or from doctors with specialized training in child psychology and development? Are multi-disciplinary teams fully involved in decision-making and counseling parents? Do families have the opportunity for meaningful psychological counseling as an alternative to surgery? Are parents given sufficient time to understand their options and come to terms with their child’s condition before making irreversible decisions? Is there sufficient time for psychological evaluation to determine whether surgery is in the child’s best interest before undertaking irreversible elective surgery? Are families given the opportunity to connect with other families and adults affected by DSD? Are patient advocacy groups involved with designing and reviewing Weill-Cornell’s treatment protocols?

⁶ Weill Cornell Medical College, Department of Urology. “The Surgical Management of Congenital Adrenal Hyperplasia.” Available at www.cornellurology.com/pediatrics/genitoplasty.shtml. (last accessed June 28, 2010)

⁷ Gonzalez, R, Piaggio, LA. Ambiguous genitalia. *Current Opinion in Urology* 2006;16:273–276.

⁸ Lee, PA, Houk, C, Ahmed, SF, et al. Consensus Statement on Management of Intersex Disorders. *Arch Dis Child*. 2006;91;554-563.

⁹ DSD Consortium. “Clinical Guidelines for the Management of Disorders of Sex Development in Childhood.” (2006). Available at www.dsdguidelines.org.

Lee, PA, Houk, C, Ahmed, SF, et al. Consensus Statement on Management of Intersex Disorders. *Arch Dis Child*. 2006;91;554-563.

- **Do treatment protocols at Weill-Cornell provide for full protection of the legal rights of children with DSD?**
 - It is not clear that parental consent is sufficient to authorize elective genital restructuring.¹⁰ Are children who undergo elective genital restructuring at Weill-Cornell/NYPH given the opportunity for representation and a court hearing to protect their civil rights and to protect their families from later liability?

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 conditions and families of children with intersex conditions, several of whom have been seen at Weill-Cornell/NYPH, 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, Weill-Cornell and NYPH have 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: Dr. Harry Lander, Associate Dean for Research Administration, WCMC
David J. Skorton, President, Cornell University
Dr. Laura L. Forese, Chief Medical Officer, NYPH/Weill Cornell
Maxine Fass, Chief Legal Officer, NYPH/Weill-Cornell Department of Surgery
Dr. Joseph J. Fins, Chief of Medical Ethics

¹⁰ Tamar-Mattis, A. Exploring Gray Areas in the Law About DSD and Sterilization. *Endocrine Today*. Oct. 1, 2009. Available at www.endocrinetoday.com/view.aspx?rid=44415.
See also Carlson, DR & Dorfman, DA. (2007). Investigative Report Regarding the "Ashley Treatment." Available at www.disabilityrightswa.org/news-1/Investigative%20Report%20Regarding%20the%20Ashley%20Treatment.pdf.