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A Review of Planned Parenthood Clinical Trials

Prepared by Jim Sedlak, Vice President, American Life League



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Last year, we brought you the story of how Planned Parenthood has been getting involved in clinical trials as a way to increase its professional identity and as a way to increase its income. We have recently completed a review of the government database on clinical trials and found 33 of them that involved Planned Parenthood.

Presented below is a great deal of detail on the various trials involving Planned Parenthood. We do not expect you to be interested in all this detail, but are presenting it to you so that...

- ... You will get a sense of the scope of Planned Parenthood's involvement.
- ... You will have the data to understand that Planned Parenthood is not just another organization doing abortions and other procedures, but it is intimately involved in creating and evaluating techniques and finding ever more "efficient" ways of killing babies.
- ... You will understand how much of Planned Parenthood's efforts involve underage girls and how much its activities in this area are funded by our own government agencies.
- ... You will be able to talk to your elected officials and make them understand just how much federal agencies are involved with Planned Parenthood and how shutting off Planned Parenthood's taxpayer money is much more than stopping Title X funds.

A total of 28 Planned Parenthood affiliates were involved in these trials — many of the affiliates were involved in more than one trial.

Trials on Underage Girls

Of particular interest were the 10 trials (30 percent) that involved girls under the age of 18. Of those trials, one was on girls as young as 13; three more involved girls as young as 14; another five are on girls as young as 15; and the tenth trial involves girls as young as 16.

As you read the information below, please remember that, in most states, minor girls being involved in sexual activity is considered sexual abuse and is illegal.

The Planned Parenthood affiliates doing the clinical trials with minor children include Planned Parenthood of Georgia, Planned Parenthood Mar Monte, Planned Parenthood of Central North Carolina, Planned Parenthood League of Massachusetts, Planned Parenthood of Maryland, Planned Parenthood of Shasta-Diablo, Planned Parenthood Golden Gate, Virginia League of Planned Parenthood, Planned Parenthood of New York City, and Planned Parenthood of Houston and Southeast Texas.

These trials involve a number of different programs and products. Here are the details of the 10 trials on underage girls:

- 1. Two of the trials are specifically aimed at getting these minor girls to take their birth control more consistently by sending them text messages reminding them to take their pills.
 - a. One of those trials is sponsored by Columbia University and is aimed at New York City girls as young as 15.
 - b. The second one is sponsored by "an anonymous foundation" and has the Planned Parenthood League of Massachusetts determining whether there is increased oral contraceptive pill adherence in girls as young as 14, receiving daily text-messaging reminders to take their OCP.
- 2. Emory University is a sponsor of three of the clinical trials, all involving underage African-American girls:
 - a. Emory and pharmaceutical company Merck are conducting a trial with Planned Parenthood of Georgia to increase the use of its Gardasil shot among 13- to 17-year-old African-American girls.
 - b. Emory and the National Institutes of Health are conducting a trial with Planned Parenthood of Georgia to develop and test a culturally and gender-appropriate (African-American girls) sexual health education program designed to promote long-term maintenance of HIV preventive sexual behaviors over a long follow-up period. Girls as young as 14 are participating in this trial.
 - c. Emory and the National Institutes of Health are also conducting another trial with Planned Parenthood of Georgia to study the efficacy of a multi-session HIV prevention program (HORIZONS HIV) for African-American female teens. This completed trial accepted girls as young as 15.
- 3. Planned Parenthood Mar Monte in California and Planned Parenthood of Central North Carolina are involved in clinical trials to increase the use of emergency contraception among sexually active girls aged 14- to 24-years-old. The trials are being sponsored by the National Institute of Child Health and Human Development.
- 4. Planned Parenthood in Maryland is involved in a National Institute of Child Health and Human Development clinical trial to study the risk of chlamydia and gonorrhea in children as young as 15.
- 5. Two Planned Parenthood California affiliates (Planned Parenthood Shasta Diablo and Planned Parenthood Golden Gate) are conducting trials sponsored by the University of California at San Francisco and the National Institutes of Health. The purpose of these trials is to examine "such things as the relationship between partnerships, parental and peer influences, and contraceptive choice; factors associated with long term continuation of contraceptive methods; attributes of new hormonal contraceptive associated with user satisfaction and long-term continuation; and the extent to which high-risk women who use these methods are also condom users and determine the characteristics of these users." These trials are accepting girls as young as 15.

- 6. The Virginia League of Planned Parenthood is involved in a clinical trial to get girls as young as 15 to use a "quick start" method of using the NuvaRing in adolescents. The trial is sponsored by Bayer, the American College of Obstetricians and Gynecologists, and Virginia Commonwealth University.
- 7. Planned Parenthood of Houston, Texas, is one of 120 various locations where KV Pharmaceutical is conducting clinical trials of a new vaginal infection drug. The trial includes girls as young as 16.

Trials involving medical abortion techniques

Planned Parenthood, operator of the nation's largest abortion chain, is involved in some trials involving medical abortion techniques.

- 1. Planned Parenthood of Waco is involved in a trial, paid for by Gynuity Health Projects, on changing the way misoprostol is given to a woman after she has been given methotrexate to start a medical abortion. The FDA-approved procedure is that misoprostol should be given vaginally in the office. At Planned Parenthood today, women are routinely told to take it orally at home. This trial is to test giving it to women buccally (a drug delivery method where the drug is administered in the mouth, not by swallowing but by absorption through the skin of the cheek; often by placing between the top gum and the inside of the lip).
- 2. Planned Parenthood League of Massachusetts and Society for Family Planning are involved in a trial on the effectiveness of buccally administered misoprostol instead of a Dilapan-S rod placed three to four hours before a dilation and evacuation abortion.
- 3. Planned Parenthood of San Diego and Planned Parenthood of New York City are both involved in a trial funded by Gynuity Health Projects and the David and Lucile Packard Foundation to "investigate the possibility that medical abortion using mifepristone and misoprostol can be administered in a manner that is simpler and less costly than that routinely employed [no sonogram and only one visit] in the United States."

Trials involving birth control techniques

Planned Parenthood distributes birth control at over 800 facilities across the country. It is involved in a number of clinical trials concerning emergency contraception and the delivery of birth control shots.

- 1. Planned Parenthood in Utah is conducting a trial funded by the University of Utah and an anonymous foundation. The stated purpose of the trial is "to see if women presenting for emergency contraception are willing to accept the copper intrauterine device." This will be accomplished by offering all women who present for EC at participating Planned Parenthood Utah clinics during the study period the option of having the copper IUD or Plan B. Women who agree to the study will be followed for six months.
- 2. Planned Parenthood in Chapel Hill, North Carolina is running two trials:

- a. The first is funded by Pfizer, the University of North Carolina Chapel Hill and Planned Parenthood Federation of America. The purpose of the trial is to train women to self-administer Depo-Provera shots at home.
- b. The second is also funded by Pfizer. The purpose of this study is to see if it is feasible to have women receive their second and third birth control injection (with Depo-Provera) at a pharmacy compared with receiving it at a Planned Parenthood clinic.

Trials on Pain Reduction

It appears clear that if you are a Planned Parenthood insider and you want to send would-be trials on pain management to one of your affiliates, there is only one natural choice: Planned Parenthood of Columbia-Williamette in Portland, Oregon. This affiliate is involved in more clinical trials (six) than any other Planned Parenthood affiliate. Five of the six are about pain. The six trials are

- 1. Reducing pain during a first trimester abortion through an intrauterine lidocaine (a numbing medication) infusion. The trial was sponsored by the Oregon Health and Science University. This trial was completed in 2004.
- 2. Another clinical trial sponsored by Oregon Health and Science University examines the effect of lidocaine inside the uterus on patient pain during an early abortion, compared to the paracervical block (lidocaine injected on either side of the cervix). This began in 2007.
- 3. In 2008, a trial studied the analgesic effects of combined ketorolac and lidocaine in a paracervical block during an abortion. This trial was sponsored by Johns Hopkins. The trial is also being conducted at Planned Parenthood of Maryland's Baltimore clinic.
- 4. Another trial on the use of lidocaine to reduce pain began in 2007. This one was directed at the pain subjects experience during and after Essure transcervical tubal sterilization. Again, the sponsor of this trial was the Oregon Health and Science University.
- 5. Reducing pain of IUD insertion by using misoprostol (a medication that softens the cervix) before placing an IUD. The trial is sponsored by the Oregon Health and Science University.
- 6. To assess the safety and efficacy of a new emergency contraceptive called Ella. Ella is designed to "prevent pregnancy" when taken three to five days after unprotected sexual intercourse. The trial is sponsored by HRA Pharma and is also being done at 15 other Planned Parenthood clinics. HRA Pharma reportedly expects to launch Ella in 2009.

In addition to these trials at Planned Parenthood in Oregon,

- 1. The Planned Parenthood affiliate in San Diego completed a trial in 2008 that examined how best to control the pain of a first trimester suction curettage abortion. That trial was sponsored by the University of California at San Diego.
- 2. The Planned Parenthood League of Massachusetts conducted a clinical trial sponsored by an anonymous foundation "to determine the equivalency of oral conscious sedation and intravenous conscious sedation for first trimester surgical abortion." The clinical trial system indicates this trial was terminated prior to completion.

HIV/AIDS-related trials

In addition to the two studies mentioned above on underage African-American girls, Planned Parenthood was involved in other HIV/AIDS-related trials. While reading the descriptions below, it is important to remember that Planned Parenthood's biggest product is birth control pills. It has been known for decades that women on the pill are more susceptible to AIDS/HIV than those not on the pill. If Planned Parenthood was really interested in preventing AIDS, it would get all its customers off the pill.

- 1. Planned Parenthood of El Paso, Texas, was where to go to when you wanted to conduct research on Hispanic men and women with HIV. (The affiliate went out of business in June 2009.) This affiliate was
 - a. Conducting a trial sponsored by Boehringer Ingelheim Pharmaceuticals to give the investigational drug Tipranavir for HIV-infected adult patients with no other treatment options.
 - b. Involved with a trial sponsored by Bristol-Myers Squibb to study the treatment of HIV infections. Specifically, it sought to "find out the frequency of the I50L substitution among patients experiencing treatment failure on an atazanavir-containing regimen."
 - c. Conducting a trial sponsored by the Centers for Disease Control and Prevention on how to teach HIV prevention techniques to Hispanic men.
- 2. Planned Parenthood of New York City is participating in a trial sponsored by the New York Academy of Medicine to determine "what programmatic approaches effectively address two of the most difficult hurdles in HIV health services delivery: (1) getting people who would benefit from health care to use it and (2) getting people who do use health care to do so more consistently and effectively."

Conclusion

As Planned Parenthood continues to spread its tentacles throughout our country's health care establishment, it is imperative that they be met with resistance at every turn. We encourage everyone who lives in the areas serviced by the Planned Parenthood affiliates mentioned in this report to launch educational campaigns against Planned Parenthood.

We, at American Life League's STOPP project, stand ready to assist you in all phases of your efforts against Planned Parenthood. Feel free to contact us by mail at STOPP, P.O. Box 1350, Stafford, VA 22555; by phone at 540-659-4171 or by e-mail at stopp@all.org.