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*Advocating the Legal Rights of Texans with Disabilities
Implementing the Client Assistance Program for Rehabilitation Clients*
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EQUAL OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER

November 15, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Dr.; Room 1-23
Rockville, Maryland 20587

Re: Request for Advisory Opinion

Dear Sir or Madam:

The undersigned submits this request for an advisory opinion of the Commissioner of Health with respect to the apparent lack of disability antidiscrimination regulation concerning pharmacological studies. I am an attorney with a Protection and Advocacy agency in Austin, Texas and I represented a person with visual impairments who initially was refused participation in a study conducted by PPD Development, a subsidiary of PPD Inc., 706A Ben White Boulevard West, Austin, Texas 78704-7016, to test the effectiveness of a pain killing drug on those who have had their wisdom teeth removed.

PPD subsequently offered my client participation in another study and no legal action was taken. PPD also indicated that their policy was one of compliance with the standard of practice set by the Food and Drug Administration. My concern is not with the particular study, nor with this particular organization, but with the apparent lack of anti-discrimination guidelines provided to these organizations that conduct these studies.

Thank you in advance for your time and consideration on this very important issue. Please feel free to contact me if I can in any way assist your inquiry.

Very truly yours,

Stephen J. Marshall
Attorney at Law

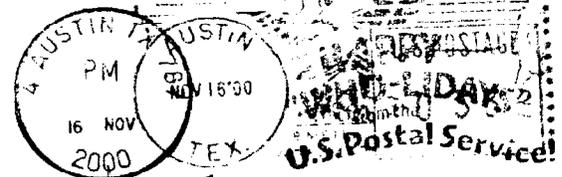
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