TO DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD + DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20852

7407 '99 JUL -8 P2:05

IN REGARDS TO DOCKET NO. 99D-0557

I AM CONCERNED ABOUT THE CONSIDERATION OF GENETICALLY ALTERED PIGS AS THE PRIMARY SOURCE OF XENOTRANSPLANTS. THE FDA HAS ALREADY BANNED THE USE OF NONHUMAN PRIMATE SOURCES BECAUSE OF RISKS OF SIGNIFILANT INFECTIOUS DISEASES. I WONDER HOW CAN PIGS BE ANY SAFER, ESPECIALLY IN THE LIGHT OF THE NUMEROUS DISEASES THAT ARE FOUND IN PIGS THAT CAN INFECT HUMANS. ALSO CAN WE REALLY JUSTIFY RAISING MORE PIGS FOR HUMAN USE WHILE THE ENVIORMENTAL PROTECTION AGENLY IS PLACING NEW RESTRICTIONS ON LIVESTOCK POLLUTION? WHO WILL PAY THE HIDDEN COSTS (ESPECIALLY THE ENVIORMENTAL ONES) OF BREEDING, HOUSING, FEEDING, TRANSPORTING RENDERING, AND THE DISPOSAL OF WASTE + THE REMAINS OF THE HERDS OF GENETICALLY ALTERED PIGS? THE FDA HAS VIOLAD THE NATIONAL ENVIORMENTAL POLICY ACT BY FAILING TO PERFORM AN ENVIROMENTAL IMPACT STATEMENT BEFORE ALLOWING CLINICAL XENO-TRANSPLANTATION EXPERIMENTS. ALSO THIS IS RECEIVING PUBLIC FINANCING WITHOUT ADEQUATE PUBLIC DEBATE. PERHAPS THERE ARE SAFER, MORE COST-EFFECTIVE, AND HUMANE ALTERNATIVES THAT ARE NOT BEING EXPLORED BY REGULATORY AUTHORITIES. I THINK THE MORE IMPORTANT AREA OF RESEARCH WOULD BE PREVENTIVE PROGRAMS TO REDUCE THE VERY NEED FOR THESE TYPE OF

99D-0557

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TRANSPLANTS. A CLOSE LOOK AT AMERICANS DIETS AND HOW THE OVER RELIANCE ON MEAT + DAIRY PRODUCTS + HOW THIS RELATES TO CANCER + HEART DISEASE WOULD BE VERY EFFECTIVE.

I AM ALSO CONCERNED ABOUT THE NEED FOR MONITORING OF XENOGRAFT RECIPIENTS THROUGHOUT THEIR LIVES FOR SIGNS OF INFECTION. WHAT IF THESE DISEASES DO INFECT HUMANS? ALSO IF THESE TRANSPLANTS ARE MORE COSTLY FOR THE PATIENT ~~HEALTHWISE~~ FINANCIALLY AS WELL HEATHWISE HOW WILL WE PAY FOR THESE EXPENSES WHEN SO MANY AMERICANS DO NOT HAVE ADEQUATE HEALTHCARE ALLREADY. THIS DOES NOT SEEM LIKE A WISE COURSE OF ACTION TO ME. AS A CONCERNED CITIZEN I WISH THAT MY TAX DOLLARS DO NOT SUPPORT SUCH A RISKY + COSTLY PROGRAM. I WOULD EVEN GO SO FAR AS TO SUGGEST A BAN ON ALL TRANSPLANTS FROM NON-HUMAN SPECIES.

SINCERELY

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