KEYNOTE

BY

DR. FAYE G. ABDELLAH

DEPUTY SURGEON GENERAL

U.S. PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PRESENTED TO THE SPRING ETHICS EVENT IV

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(GREETINGS TO HOSTS, GUESTS)

I'M NOT SURE I'D BE BELIEVED, IF I SAID I WAS "DELIGHTED TO BE HERE." THAT'S A STANDARD OPENING FOR A GUEST SPEAKER, I KNOW...BUT "DELIGHTFUL" SEEMS HARDLY THE WORD TO USE IN CONNECTION WITH AN EVENT THAT FOCUSES ON THE MOST DIFFICULT QUESTIONS OF HUMAN RELATIONSHIPS.

SO LET ME SAY THAT I FEEL PRIVILEGED TO BE HERE...ALTHOUGH I'M A LITTLE UNCERTAIN ABOUT BEING HERE. BUT I KNOW, DEEP IN MY HEART, I SHOULD BE HERE BECAUSE WE'RE TALKING ABOUT MATTERS THAT GO TO THE CORE OF OUR HUMANITY.

IN THE HURLY-BURLY OF DAILY LIFE, WE DON'T OFTEN GET THE CHANCE TO THINK ABOUT SUCH MATTERS. AND MAYBE THAT'S ALL RIGHT...MAYBE IT'S OUR BEST DEFENSE AGAINST THE OVERWHELMING NATURE OF THE QUESTIONS BEFORE US.

A WHILE BACK, THE REV. HARRY EMERSON FOSDICK, THE EMINENT CLERGYMAN AN ACADEMIC, SAID, "IF A MAN IS TO HAVE REAL FAITH, HE MUST GAIN IT FROM THE VERY TRUTH OF DISMAY." CURIOUS SENTIMENT, ISN'T IT? TRUTH LIES IN "DISMAY."

BUT THAT'S PROBABLY ONE OF THE KEY IDEAS THAT'S IMPLICIT IN OUR AGENDA RIGHT HERE IN WEST CHESTER COLLEGE. THE QUESTIONS WE WANT TO ASK...AND THE DISMAY WE FEEL AT THOSE QUESTIONS...AND THE TRUTH AND THE FAITH WE CAN DRAW FROM THE EXPERIENCE...THEY ARE ALL HERE. IN THE NEXT FEW MINUTES, I WILL TRY TO DEAL WITH SOME OF THEM.

BUT FIRST, A LITTLE DISCLAIMER. I WANT TO SHARE WITH YOU WHAT WE IN THE GOVERNMENT -- MORE PRECISELY, IN THE U.S. PUBLIC HEALTH SERVICE -- ARE DOING TO ADDRESS THE SAME ISSUES THAT ARE ON YOUR AGENDA. THEREFORE, I AM HERE AS A PUBLIC SERVANT, NOT A PRIVATE CITIZEN WITH MY OWN PRIVATE UNCERTAINTIES, FEARS, AND HOPES.

I HAVE THEM, TO BE SURE, BUT I WILL TRY VERY HARD TO KEEP THEM OUT OF THE WAY SO THAT TOGETHER WE CAN ALL TAKE A HARD LOOK AT WHAT THE GOVERNMENT THINKS AND DOES AND MAYBE EVEN PASS SOME JUDGMENTS ON IT.

AS A POINT OF DEPARTURE, IT MAY BE WORTHWHILE TO PERCEIVE THE FEDERAL GOVERNMENT'S ETHICAL ISSUES AS APPEARING IN TWO GENERAL AREAS OF HEALTH CARE:

ONE AREA IS THAT IN WHICH GOVERNMENT PLAYS ITS ROLE AS A PROVIDER OF HEALTH SERVICES.

THE OTHER IS IN ITS ROLE AS SPONSOR OF BIOMEDICAL AND BEHAVIORAL RESEARCH.

THE QUESTIONS THEY POSE ARE ESSENTIALLY THE SAME...THEY HAVE TO DO WITH WHAT GUIDO CALABRESI TERMED THE "TRAGIC CHOICES" TO BE MADE IN EACH ROLE. BUT WHILE THEY MIGHT BE FUNDAMENTALLY IN THE WORLD OF THEORY, THEY ARE NOT THE SAME IN THE WORLD OF REALITY.

LET'S LOOK FIRST AT THE ROLE OF PROVIDER OF HEALTH SERVICES. HERE WE HAVE TO STRIKE SOME BALANCE BETWEEN PERCEIVED HUMAN NEEDS AND THE AVAILABILITY OF RESOURCES TO FILL THOSE NEEDS. MORE PEOPLE MAY HAVE A NEED THAN THE NUMBER THAT CAN BE SERVED. THIS IS NOT A NEW QUESTION. BUT KNOWING THAT DOESN'T BRING AN ANSWER ANY THE FASTER.

THE APPROACH OF OUR MODERN MANAGEMENT-ORIENTED SOCIETY IS TO PROVIDE A CLEARER DEFINITION OF EACH HUMAN "NEED," AND LEAVE LESS ROOM FOR CHANCE OR ARGUMENT. FOR EXAMPLE, WHO NEEDS A GOOD MEAL MORE THAN A PREGNANT WOMAN OR A MOTHER WHO IS BREAST-FEEDING HER NEW BABY? AND

ISN'T IT ETHICAL TO PROVIDE THAT WOMAN WITH FOOD...AND, IF WE CAN, SHOULDN'T WE PROVIDE FOOD FOR HER CHILDREN AS WELL? OF COURSE WE SHOULD. AND WE DO.

BUT WE CAN'T GIVE EVERY MOTHER FREE FOOD. SO WE DEFINE THE NEED MUCH MORE CAREFULLY, MAKE SOME DIFFICULT CHOICES IN THE PROCESS, PUT THESE INTO GUIDELINES, AND PUBLISH THEM IN THE FEDERAL REGISTER. THE LATEST ONES FOR THE WOMEN, INFANTS, AND CHILDREN -- OR "W.I.C." -- PROGRAM WERE PUBLISHED JUST THIS PAST JANUARY. HERE ARE SOME BRIEF HIGHLIGHTS:

§ A PREGNANT OR LACTATING WOMAN MUST MEET CERTAIN CRITERIA OF NUTRITIONAL RISK. SOMEONE KNOWLEDGABLE MUST CERTIFY THAT SHE IS ANEMIC OR DIABETIC, OR HAS ABNORMAL WEIGHT LOSS OR GAIN, OR SUFFERS FROM TOXEMIA OR A METABOLIC DISORDER, AND SO FORTH.

§ IF SHE DOES HAVE A NUTRITIONAL RISK, SHE MIGHT ALSO HAVE TO SATISFY A RESIDENCY REQUIREMENT. IN OTHER WORDS, SHE HAS TO BE A RESIDENT SOMEPLACE. THE LAW DOES NOT ALLOW STATES TO SET MINIMUM LENGTHS OF STAY FOR RESIDENCY, BUT IT DOES ALLOW A REQUIREMENT.

§ IF SHE HAS A NUTRITIONAL RISK AND IS A RESIDENT SOMEPLACE, SHE MUST ALSO MEET CERTAIN INCOME CRITERIA. SHE HAS TO BE "POOR." HER FAMILY INCOME CAN BE AS HIGH AS 185 PERCENT OF THE NATIONAL POVERTY LEVEL FOR A FAMILY THE SIZE OF HERS. THAT ALSO HAPPENS TO BE THE LEVEL AT WHICH CHILDREN ARE ELIGIBLE FOR SCHOOL LUNCHES.

GOVERNMENT HOPES THIS IS FAIR. BUT QUESTIONS ALWAYS ARISE ABOUT THE DIFFERENT CRITERIA. THE BEST WAY TO ANSWER THE ETHICAL QUESTIONS WOULD BE TO PROVIDE ALL PREGNANT AND LACTATING WOMEN AND ALL YOUNG CHILDREN WITH ALL THE FOOD THEY NEED. BUT THAT'S SIMPLY BEYOND SOCIETY'S MEANS.

AND THAT SEEMS TO BE THE PROBLEM WITH MOST ETHICAL QUESTIONS IN THE AREA OF SERVICE -- THAT IS, THE ULTIMATE ANSWERS ARE SIMPLY NOT POSSIBLE. SO WE MUST PROCEED IN THE SPIRIT OF COMPROMISE. FROM THAT POINT ON, WE FASHION THE BEST COMPROMISE WE CAN LIVE WITH.

IT'S NOT ARBITRARY AND IT'S NOT UNIMPORTANT. BUT NEITHER IS IT ABSOLUTE. SO WE CONTINUALLY SHUFFLE ABOUT, TRYING TO FEED THE MOST PEOPLE WITH LESS THAN A FULL LOAF.

BUT SOMETIMES WE ARE CONFRONTED WITH AN UNEXPECTED COMPLEXITY, WHERE ETHICAL BEHAVIOR TOWARD ONE CITIZEN IS, AT THE SAME TIME, UNETHICAL BEHAVIOR TOWARD ANOTHER...WHERE THE SERVICE PROVIDED FOR ONE IS A DISSERVICE FOR THE OTHER. WE HAVE SOMETHING OF THAT ISSUE IN THE CURRENT PUBLIC HEALTH PROBLEM CALLED "ACQUIRED IMMUNODEFICIENCY SYNDROME," OR "A.I.D.S."

BRIEFLY, THIS IS THE SITUATION. "A.I.D.S." IS A MYSTERIOUS CONDITION THAT ATTACKS THE IMMUNE SYSTEM, MAKING ITS VICTIMS SUCCUMB TO SUCH DISEASES AS KAPOSI'S SARCOMA AND OTHER CANCERS AND TO PNEUMONIA, HERPESVIRUS, AND CYTOMEGALOVIRUS. IT SEEMS TO BE TRANSMITTED BY SEXUAL CONTACT OR THROUGH BLOOD OR BLOOD PRODUCTS. SO FAR, "A.I.D.S." VICTIMS TEND TO BE HOMOSEXUAL MEN, DRUG ABUSERS WHO TAKE THEIR DRUGS INTRAVENOUSLY, HAITIANS, AND PERSONS WHO RECEIVE TRANSFUSIONS OF BLOOD CONTAINING THE "A.I.D.S." INFECTIOUS AGENT.

THE NATIONAL HEMOPHILIA FOUNDATION -- AND HEMOPHILIACS GENERALLY -- ARE PROFOUNDLY ALARMED BY THIS MYSTERIOUS DISEASE. "A.I.D.S." WAS UNKNOWN TO HEMOPHILIACS BEFORE 1982. BUT IN THAT SINGLE YEAR, 1982, "A.I.D.S." BECAME THEIR SECOND LEADING CAUSE OF DEATH.

HEMOPHILIACS SURVIVE ON TRANSFUSIONS OF GREAT AMOUNTS OF DONATED BLOOD. BUT THESE LIFE-SAVING DONATIONS MAY BE THE VERY MEANS BY WHICH A FATAL DOSE OF "A.I.D.S." IS TRANSMITTED TO A HEMOPHILIAC. THE FOUNDATION, THEREFORE, ASKED THE ORGANIZATIONS THAT COLLECT BLOOD TO SCREEN OUT DONORS FROM POPULATIONS AT RISK, PARTICULARLY SEXUALLY ACTIVE HOMOSEXUAL OR BISEXUAL MEN WITH MULTIPLE PARTNERS.

THE NATIONAL GAY TASK FORCE CALLED THAT ACTION "SCAPEGOATING." THEY SAID THAT SUCH A SCREENING PROCESS WOULD BE A CLEAR VIOLATION OF THEIR RIGHTS OF PRIVACY. IN ADDITION, THEY SAY, ALL GAY MEN WOULD BE STIGMATIZED, EVEN THOUGH ONLY A SMALL MINORITY MAY FIT THE DEFINITION OF "SEXUALLY ACTIVE WITH MULTIPLE PARTNERS."

WHAT DO WE DO? WELL, FOR ONE THING, THE PUBLIC HEALTH SERVICE HAS JUST ISSUED A SET OF "INTERIM RECOMENDATIONS" THAT MIGHT HELP THE AMERICAN PEOPLE COPE WITH THE "A.I.D.S." EPIDEMIC. THE FIRST RECOMMENDATION SUGGESTS THAT YOU AVOID SEXUAL CONTACT "WITH PERSONS KNOWN OR SUSPECTED TO HAVE 'A.I.D.S.'" IT ALSO WARNS OF THE INCREASED RISK FOR PERSONS WITH "MULTIPLE SEXUAL PARTNERS." THIS IS THE FIRST TIME IN MY MEMORY THAT THE UNITED STATES GOVERNMENT HAS BEEN THAT EXPLICIT ABOUT THE SEXUAL RELATIONSHIPS OF ITS CITIZENS.

WAS IT ETHICAL TO DO SO? WE BELIEVE IT WAS, SINCE LIVES ARE IN THE BALANCE AND ETHICAL QUESTIONS ULTIMATELY COME DOWN TO THIS: DID THE ACTION PROLONG LIFE OR HASTEN DEATH? WE THINK IT CAN PROLONG THE LIVES OF MANY OF OUR PEOPLE.

THAT BASIC QUESTION COMES FORWARD WITH GREAT POWER IN YET ANOTHER AREA OF GOVERNMENT SERVICE. IT IS ONE IN WHICH THE GOVERNMENT IS THE "SERVANT OF LAST RESORT." A GOOD EXAMPLE IS THE WAY GOVERNMENT HAS HANDLED THE SO-CALLED "ORPHAN PRODUCTS" OF MEDICINE, THOSE DRUGS AND DEVICES USED TO DIAGNOSE OR TREAT RARE DISEASES.

HERE'S JUST ONE ILLUSTRATION. ONLY ABOUT A THOUSAND PEOPLE IN THIS COUNTRY HAVE "WILSON'S DISEASE." THEY ARE UNABLE TO EXCRETE EXCESS AMOUNTS OF TRACE ELEMENT COPPER. IT'S A RARE CONDITION AND IT CAN BE FATAL. PENICILLAMINE IS THE DRUG OF CHOICE FOR PERSONS WITH WILSON'S DISEASE.

HOWEVER, ABOUT 1 IN EVERY 10 PERSONS WITH WILSON'S DISEASE CANNOT TOLERATE PENICILLAMINE. WHAT THEN? WELL, THEY NEED <u>ANOTHER</u> DRUG, TRIETHYLENE TETRAMINE DIHYDROCHLORIDE. BUT IT'S UNECONOMICAL FOR ANY

COMPANY TO MAKE THIS DRUG FOR ABOUT A HUNDRED PEOPLE. HENCE, THE GOVERNMENT HAS STEPPED IN TO PROVIDE CERTAIN SUBSIDIES AND TAX INCENTIVES FOR DRUG COMPANIES THAT "ADOPT" THESE "ORPHAN PRODUCTS." AND THE DRUG INDUSTRY HAS RESPONDED WELL.

IF OUR GOVERNMENT DID NOT ACCEPT THIS KIND OF RESPONSIBILITY, THERE WOULD BE NO HOPE AT ALL FOR PEOPLE WITH TOURETTE SYNDROME OR POST-ANOXIC MYOCLONUS OR LOU GEHRIG'S DISEASE OR HEPATIC PORPHYRIA, WHICH ARE JUST A FEW OF THE SEVERAL DOZEN "ORPHAN DISEASES" THAT CAN BE DIAGNOSED OR TREATED WITH "ORPHAN PRODUCTS."

OUR POSITION IS A GOOD ONE AND CONSISTENT WITH THE ETHICAL VALUES ON WHICH THIS COUNTRY WAS FOUNDED. IF THERE IS SOMEONE TRULY IN NEED AND NO ONE ELSE AROUND WHO CAN DO ANYTHING -- OR WHO WANTS TO DO ANYTHING -- THEN WE LOOK TO THE GOVERNMENT TO BE THE "SERVANT OF LAST RESORT."

NOW LET ME SHARE WITH YOU A MORE COMPLEX EXAMPLE OF GOVERNMENT AS THE CITIZEN'S ULTIMATE DEFENSE. THIS EXAMPLE IS ROOTED IN SECTION 504 OF THE REHABILITATION ACT OF 1973. THAT SECTION "FORBIDS RECIPIENTS OF FEDERAL FUNDS FROM WITHHOLDING FROM HANDICAPPED CITIZENS,

SIMPLY BECAUSE THEY ARE HANDICAPPED, ANY BENEFIT OR SERVICE THAT WOULD ORDINARILY BE PROVIDED TO PERSONS WITHOUT HANDICAPS." HERE, THE GOVERNMENT IS THE "PROTECTOR OF LAST RESORT," A VARIATION OF THE SERVANT'S ROLE.

SECTION 504 IS EASY TO UNDERSTAND WHEN WE THINK ABOUT PEOPLE WHO MAY BE BLIND OR DEAF, WHO ARE IN WHEELCHAIRS, OR WHO HAVE A MENTAL HANDICAP OF SOME KIND. WE PICTURE THESE PEOPLE GOING TO SCHOOL OR GOING TO WORK, TRYING -- WITH THE REST OF US -- TO OBTAIN THE BEST QUALITY THEY CAN FOR THEIR LIVES. THAT'S THE USUAL PICTURE. BUT IT'S NOT THE ONLY ONE.

LAST APRIL, IN BLOOMINGTON, INDIANA, A TINY HANDICAPPED INFANT WAS BORN WITH DOWN SYNDROME -- MENTALLY RETARDED -- AND ESOPHAGEAL ATRESIA, A CONDITION THAT PREVENTS A BABY FROM TAKING ANY NOURISHMENT BY MOUTH. IT IS USUALLY CORRECTED BY SURGERY. YOU MAY REMEMBER THAT THE CORRECTIVE SURGERY WAS NOT CARRIED OUT AND THE CHILD DIED. THE INFANT BECAME KNOWN IN THE MEDIA AS "THE BLOOMINGTON BABY" AND IN THE COURTS AS "INFANT DOE."

GOVERNMENT SAW THIS TRAGIC OUTCOME AS A CHALLENGE TO SECTION 504. HERE WAS A "CITIZEN" WHO HAD BEEN DENIED THE KIND OF TREATMENT THAT WOULD HAVE BEEN GIVEN TO ANOTHER INFANT. WHY? APPARENTLY BECAUSE THIS CHILD HAD DOWN SYNDROME, A PERMANENTLY HANDICAPPING CONDITION.

ON MAY 18 OUR DEPARTMENT OF HEALTH AND HUMAN SERVICES SENT A LETTER TO THE 6,800 HOSPITALS REIMBURSED BY MEDICAID AND MEDICARE. IN THAT LETTER WE REAFFIRMED "THE STRONG COMMITMENT OF THE AMERICAN PEOPLE AND THEIR LAWS TO THE PROTECTION OF HUMAN LIFE."

IN THE FALL, THE CONGRESS TOOK A CLOSER LOOK AT THIS SITUATION AND ASKED THE SURGEON GENERAL OF THE UNITED STATES, DR. C. EVERETT KOOP, MY BOSS, TO GIVE HIS OPINION. MANY OF YOU KNOW, I AM SURE, THAT BEFORE BECOMING SURGEON GENERAL, DR. KOOP HAD BEEN THE CHIEF OF SURGERY AT THE CHILDREN'S HOSPITAL OF PHILADELPHIA. IN A CAREER SPANNING 35 YEARS, HE AND HIS COLLEAGUES PERFORMED SOME 475 OPERATIONS ON CHILDREN WITH ESOPHAGEAL ATRESIA. "AFTER RECOVERY," HE TOLD THE CONGRESSIONAL COMMITTEE, "THESE BABIES WERE ALL ABLE TO TAKE NOURISHMENT BY MOUTH."

DR. KOOP SAID THE VAST MAJORITY OF DISABLED INFANTS ARE WITHIN THE REALM OF TREATMENT. "MOREOVER," HE SAID, "I BELIEVE THERE IS A 'BOTTOM LINE' IN ALL THESE CASES AND IT IS THAT YOU FEED THE PATIENT -- EITHER

ORALLY OR INTRAVENOUSLY. INDEED, IN THE CASE OF INFANT DOE, THE FACT THAT NOURISHMENT WAS WITHHELD PROBABLY DID MORE THAN ANY OTHER SINGLE FACT TO SHOCK THE MEDICAL PROFESSION AND THE PUBLIC."

IN FOUR DAYS, ON MARCH 22, A FINAL INTERIM RULE ON "INFANT DOE" CASES WILL GO INTO EFFECT. THE DEPARTMENT IS TAKING PUBLIC COMMENT ON THE RULE UNTIL MAY 6. ESSENTIALLY THE RULE SAYS THAT RECIPIENTS OF PUBLIC FUNDS CANNOT WITHHOLD NOURISHMENT OR MEDICAL TREATMENT TO SUSTAIN THE LIFE OF AN INFANT MERELY BECAUSE THE INFANT HAS A HANDICAP, ASSUMING, OF COURSE, THAT SUCH TREATMENT IS NOT MEDICALLY CONTRAINDICATED.

THAT IS THE STATEMENT OF ONE SET OF ETHICS, REAFFIRMED IN THE LAW, THAT EVERY LIFE IS PRECIOUS AND OUGHT TO BE SAVED. IT CLASHED WITH THE NOTION THAT SAYS, "IF A LIFE IS NOT WORTH LIVING, LET IT END." AND BOTH FACED THE MEDICAL ETHIC, EXPRESSED BY HIPPOCRATES ABOUT 2,400 YEARS AGO: A PHYSICIAN IS PROFESSIONALLY BOUND TO "HELP THE SICK ACCORDING TO MY ABILITY AND JUDGMENT, BUT NEVER WITH A VIEW TO INJURY AND WRONGDOING."

EVEN THOUGH THE HIPPCRATIC OATH HINTS AT JUST SUCH SITUATIONS AS "BABY DOE," WE ARE JUST THIS YEAR GETTING OUR ETHICAL HOUSE IN ORDER SO THAT WE MAY DEAL WITH THEM. AS THE YEARS GO BY, THERE IS NEVER A LACK OF WORK FOR MEDICAL ETHICISTS.

AT THIS POINT I WANT TO TURN TO GOVERNMENT'S OTHER MAJOR ROLE IN THE FIELD OF HEALTH CARE AND MEDICINE -- THAT OF SPONSOR OF BIOMEDICAL AND BEHAVIORAL RESEARCH. THE ETHICAL QUESTIONS RELATED TO THE RESEARCH ROLE ARE NO LESS DIFFICULT THAN THOSE RELATED TO THE SERVICE ROLE.

RESEARCH CREATES NEW KNOWLEDGE. BUT THAT'S ONLY PART OF IT. AS THE MEDICAL ETHICIST, BENTLEY GLASS, HAS WRITTEN, "KNOWLEDGE CREATES RESPONSIBILITY." AND THAT'S THE TRIANGLE: RESEARCH -- KNOWLEDGE -- RESPONSIBILITY. YOU CAN PAIR OFF ANY TWO SIDES.

THERE ARE FEW AREAS IN RESEARCH IN WHICH THE THREE SIDES ARE JOINED MORE CLOSELY THAN THEY ARE WHEN HUMAN SUBJECTS ARE INVOLVED. SO IN THE NEXT FEW MOMENTS, I WOULD LIKE TO CONCENTRATE ON SOME OF THE ETHICAL ISSUES SURROUNDING RESEARCH THAT INVOLVES HUMAN SUBJECTS.

IN THE SCHEME OF THINGS, LOOKING BACK ON FIVE OR SIX THOUSAND YEARS OF RECORDED HUMAN HISTORY, CONCERN ABOUT EXPERIMENTATION INVOLVING HUMANS IS FAIRLY RECENT. WHEN THE FULL STORY OF THE NAZI HORROR CAME OUT AT THE NUREMBERG WAR CRIMES TRIALS, WE GOT A SHOCKING, DOCUMENTED REPORT OF THE LENGTHS TO WHICH ONE HUMAN BEING WOULD GO TO DESTROY ANOTHER IN THE NAME OF "SCIENCE."

IN 1947 THE NUREMBERG CODE WAS PROMULGATED AS A RESULT OF THESE TRIALS. THE KEY FEATURE OF THE CODE IS THE REQUIREMENT FOR OBTAINING THE VOLUNTARY INFORMED CONSENT OF THE PERSON WHO WILL BE THE SUBJECT OF AN EXPERIMENT. THIS WAS NUMBER 1 OF THE CODE'S 10 PRINCIPLES. IT SAID...

> "THE VOLUNTARY CONSENT OF THE HUMAN SUBJECTS IS ABSOLUTELY ESSENTIAL." THE NEXT PARAGRAPH EXPLAINS THIS IN SOME DETAIL, ADDING THAT "THE PERSON...SHOULD HAVE SUFFICIENT KNOWLEDGE AND COMPREHENSION OF THE ELEMENTS OF THE SUBJECT MATTER INVOLVED AS TO ENABLE HIM TO MAKE AN UNDERSTANDING AND ENLIGHTENED DECISION."

USING THE NUREMBERG CODE AS A BASE, THE CIVILIZED W
ADOPTED THE "HELSINKI DECLARATION" IN 1964. THIS STATE
ETHICS GOVERNING MEDICAL EXPERIMENTATION WAS NEXT REVIS... ... TOKYO IN
1975. THAT VERSION SPOKE TO THE NEED FOR REVIEW COMMITTEES TO INSURE ETHICAL BEHAVIOR WHEREVER HUMAN EXPERIMENTATION WAS TAKING PLACE.

SINCE 1971 OUR DEPARTMENT HAS BEEN PUBLISHING AND REVISING ITS RESEARCH GUIDELINES AND REGULATIONS. WE HAVE HAD THE ASSISTANCE OF A "NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH," SET UP BY THE CONGRESS IN 1974. BEFORE THE COMMISSION CLOSED ITS DOORS IN 1978, IT PUBLISHED WHAT WAS TO BECOME THE GOVERNMENT'S FRAMEWORK FOR JUDGING ETHICAL RESEARCH BEHAVIOR, PARTICULARLY WHEN THAT RESEARCH INVOLVES PERSONS FROM VULNERABLE POPULATION GROUPS. THE COMMISSION ALSO PROPOSED THAT ANY INSTITUTION RECEIVING FEDERAL RESEARCH FUNDS OUGHT TO HAVE AN "INSTITUTIONAL REVIEW BOARD" -- OR "I.R.B." -- TO OVERSEE THE CONDUCT OF ITS LOCAL RESEARCHERS, A PROPOSAL THAT ECHOED THE REVISED "HELSINKI DECLARATION."

TWO YEARS LATER, IN 1980, CONGRESS ESTABLISHED THE PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND

BIOMEDICAL AND BEHAVIORAL RESEARCH, OF WHICH DR. RENEE FOX HAS BEEN AN OUTSTANDING MEMBER. ON THE 31ST OF THIS MONTH, THE PRESIDENT'S COMMISSION WILL CLOSE ITS DOORS, ALSO.

BUT TWO POINTS NEED TO BE EMPHASIZED AT THE VERY OUTSET:

FIRST, OUR DEPARTMENT'S REGULATIONS GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS WERE ARRIVED AT WITH THE FULL COOPERATION AND INVOLVEMENT OF THE GREATER RESEARCH COMMUNITY. IN FACT, IT WOULD BE ACCURATE TO SAY THAT THE NON-GOVERNMENTAL RESEARCH COMMUNITY HAD A GREAT DEAL MORE INFLUENCE ON THE SHAPE OF THE CURRENT REGULATIONS THAN THE FEDERAL PERSONNEL CHARGED WITH DRAWING THEM UP. IN ADDITION, THE GUIDELINES AND REGULATIONS ARE PART OF AN EVOLUTIONARY PROCESS -- IT'S STILL GOING ON -- IN WHICH THE ENTIRE SCIENTIFIC COMMUNITY PARTICIPATES IN ONE WAY OR ANOTHER.

SECOND, AND FOLLOWING NATURALLY UPON THE FIRST, THE GUIDELINES AND REGULATIONS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES HAVE BEEN ADOPTED VIRTUALLY UNCHANGED BY MOST OF THE COUNTRY'S MAJOR RESEARCH INSTITUTIONS. IN OTHER WORDS, RESEARCHERS GENERALLY -- NOT JUST THE GOVERNMENT -- HAVE A SENSE OF PROPRIETORSHIP ABOUT THE ETHICAL RULES GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS.

THE SCIENTIFIC AND MEDICAL PRESS HAS BEEN VERY GOOD IN FOLLOWING THE DEVELOPMENT OF THESE RULES. EVEN THOUGH THE RULES ARE FAIRLY RECENT -- THE FIRST FULL VERSION WAS ONLY PUBLISHED IN JANUARY 1981 -- THEY ALREADY BOAST A LARGE BODY OF MATERIAL IN THE PROFESSIONAL LITERATURE. MANY OF THE DISCUSSIONS HAVE DEALT WITH NUANCES AND WITH ADMINISTRATIVE PROBLEMS. I'LL PASS THEM BY. BUT OTHER DISCUSSIONS HAVE DEALT WITH THE ETHICAL ISSUES ADDRESSED BY THE RULES. I WANT TO TOUCH ON THOSE.

AS I INDICATED EARLIER, THE NUREMBERG CODE SPELLED OUT FOR THE FIRST TIME THE MODERN CONCEPT OF "INFORMED CONSENT." BUT IT WENT FURTHER. THE CODE ALSO MAKES US MORE SENSITIVE TO THE CONCEPT OF "RISK." THE CODE SAYS THAT A PERSON WHO IS ABOUT TO BE INVOLVED IN AN EXPERIMENT SHOULD BE TOLD "ALL INCONVENIENCES AND HAZARDS <u>REASONABLY TO BE EXPECTED</u>; AND THE EFFECTS UPON HIS HEALTH OR PERSON WHICH <u>MAY POSSIBLY COME FROM</u> HIS PARTICIPATION IN THE EXPERIMENT."

TODAY, I THINK WE UNDERSTAND THIS PROBLEM A LITTLE BETTER. WE HAVE BEEN ABLE TO FOCUS DOWN ON THE SPECIFIC ISSUE OF "RISK ASSESSMENT." WE ASK, FOR EXAMPLE, "IS THE PROPOSED PROCEDURE LIFE-THREATEN-

ING IN ANY WAY? WHAT ARE THE SAFEGUARDS FOR LIFE AND HEALTH? HAVE THOSE BEEN TESTED BEFORE? HOW LONG MIGHT A PERSON BE NEEDED FOR THIS RESEARCH? WOULD HE OR SHE HAVE AN "ESCAPE CLAUSE?"

A REPORT RELEASED ON THE FIRST OF THIS MONTH BY THE NATIONAL ACADEMY OF SCIENCES IS THE LATEST ON WHAT WILL CERTAINLY BE A LONG LIST OF PUBLICATIONS ON RISK ASSESSMENT. THE REPORT DEALS PRIMARILY WITH QUESTIONS ABOUT THE GOVERNMENT'S ABILITY TO MANAGE THE RISK ASSESSMENT PROCESS. BUT ONE OF ITS CONCLUSIONS DOES HAVE MUCH WIDER IMPLICATIONS. IT SAYS, IN PART, THAT...

> "RISK ASSESSMENT IS AN ANALYTIC PROCESS THAT IS FIRMLY BASED ON SCIENTIFIC CONSIDERATIONS, BUT IT ALSO REQUIRES JUDGMENTS TO BE MADE WHEN THE AVAILABLE INFORMATION IS INCOMPLETE..."

SO, EVEN WITH GOOD TRAINING AND COMPUTER MODELS AND SO ON, WE CAN STILL FIND OURSELVES CAUGHT IN THAT GRAY AREA BETWEEN ART AND SCIENCE.

BUT FOR THE ETHICIST, IT WOULD SEEM THAT THE NUB OF THE PROBLEM MAY BE RISKS AS THEY ARE PERCEIVED. A RESEARCHER PERCEIVES A RISK IN A WAY

THAT IS DIFFERENT FROM THE WAY IT IS PERCEIVED BY A SUBJECT. AND THE REWARDS ARE DIFFERENT, SO THE VALUE PUT ON THE REWARD, RELATIVE TO THE PERCEIVED RISK, IS WEIGHTED DIFFERENTLY BY EACH.

IN THE NORMAL COURSE OF EVENTS, THIS TENSION BETWEEN THE RESEARCHER AND THE SUBJECT IS UNDERSTANDABLE AND IT CAN BE ARBITRATED, IF NEED BE, BY THE INSTITUTIONAL REVIEW BOARD. BUT SOME GROUPS OF SUBJECTS CANNOT PERCEIVE THE RISKS...CAN'T MAKE A REASONABLE ASSESSMENT OF THEM...OR, TO PHRASE IT ANOTHER WAY, NEITHER THE RESEARCHER NOR THE PUBLIC CAN RELY ON THEIR ASSESSMENT OF THE RISKS. FOUR SUCH GROUPS ARE...

- PRISONERS
- CHILDREN
- INSTITUTIONALIZED PERSONS WHO ARE MENTALLY DISABLED, AND
- FETUSES, PREGNANT WOMEN, AND HUMAN IN VITRO FERTILIZATION.

IS IT ETHICAL, THEREFORE, TO CARRY OUT RESEARCH INVOLVING MEMBERS OF ANY OF THESE GROUPS? IF THE ANSWER IS "YES," THEN WHAT ARE THE CONDITIONS?

OUR DEPARTMENT'S REGULATIONS COVERING THE PROTECTION OF PRISONERS BEGINS BY ACKNOWLEDGING THAT "PRISONERS MAY BE UNDER CONSTRAINTS BECAUSE OF THEIR INCARCERATION, WHICH COULD AFFECT THEIR ABILITY TO MAKE A TRULY VOLUNTARY AND UNCOERCED DECISION WHETHER OR NOT TO PARTICIPATE AS SUBJECTS IN RESEARCH." THE SOURCE OF THAT QUOTATION IS SURELY THE RECORD OF THE NUREMBERG WAR CRIMES TRIALS, WHICH REVEALED HOW PRISONERS OF CONCENTRATION CAMPS WERE USED BY THEIR NAZI CAPTORS.

THIS PART OF THE REGULATION IS FAIRLY EXTENSIVE...SO MUCH SO THAT NO RESEARCH PROJECTS USING PRISONERS AS HUMAN SUBJECTS ARE CURRENTLY FUNDED BY THE NATIONAL INSTITUTES OF HEALTH.

BUT WE'VE ALREADY COME UPON A SITUATION WITH THESE PRISONER REGULATIONS THAT IS SOMEWHAT ANALOGOUS TO THE ONE INVOLVING THE "A.I.D.S." RECOMMENDATIONS THAT I MENTIONED A FEW MOMENTS AGO. IN MAY 1980 THE FOOD AND DRUG ADMINISTRATION CAME OUT WITH ITS OWN REGULATIONS REGARDING THE USE OF PRISONERS IN DRUG OR DEVICE RESEARCH AND PRETTY MUCH FOLLOWED THE DEPARTMENT'S LANGUAGE. THIS BROUGHT AN UNUSUAL RESPONSE TWO MONTHS LATER FROM FOUR INMATES AT THE JACKSON STATE PENITENTIARY IN JACKSON, MICHIGAN.

THESE FOUR PRISONERS HAD BEEN INVOLVED IN DRUG STUDIES SPONSORED BY THE UPJOHN COMPANY, WHICH HAS A RESEARCH FACILITY INSIDE THE PRISON. IN JULY 1980 THEY SUED THE F.D.A., SAYING THAT THE REGULATION HAD THE EFFECT OF DEPRIVING THEM OF THEIR CONSTITUTIONAL RIGHT TO PARTICIPATE IN RESEARCH IF THEY WANTED TO. UPJOHN JOINED THEM IN THEIR SUIT. THE F.D.A. HAS SINCE REVISED ITS REGULATIONS AND THE PRISONERS' LAWSUIT WAS DISMISSED. WHETHER OR NOT THEY WILL SUE AGAIN ON THE NEW REGULATIONS REMAINS TO BE SEEN.

JUST LAST WEEK, ON TUESDAY, MARCH 8, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLISHED THE FINAL VERSION OF ITS CHILDREN'S REGULATIONS. THEY TAKE EFFECT ON JUNE 6 OF THIS YEAR. ESSENTIALLY THEY INSTRUCT THE I.R.B.s TO DO SEVERAL THINGS, SUCH AS TAKING A CLOSER LOOK AT THE RISKS INVOLVED AND SEEING TO WHAT EXTENT THE RESEARCH MIGHT POSSIBLY BENEFIT THE CHILDREN WHO ARE SUBJECTS. THE REGULATIONS ALSO TRY TO ENSURE THAT RESEARCHERS TAKE EXTRA PAINS "FOR SOLICITING THE ASSENT OF THE CHILDREN, WHEN IN THE JUDGMENT OF THE I.R.B. THE CHILDREN ARE CAPABLE OF PROVIDING ASSENT."

FINAL REGULATIONS SPECIFIC TO MENTALLY DISABLED PERSONS IN INSTITUTIONS ARE STILL BEING WORKED ON. HOWEVER, IN THE ORIGINAL, BASIC SET OF THE DEPARTMENT'S REGULATIONS THERE IS A CLEAR STATEMENT THAT

"ADDITIONAL SAFEGUARDS" MUST BE INCLUDED IN RESEARCH TO PROTECT THE RIGHTS AND WELFARE OF SUBJECTS WHO ARE "LIKELY TO BE VULNERABLE TO COERCION OR UNDUE INFLUENCE, SUCH AS PERSONS WITH ACUTE OR SEVERE PHYSICAL OR MENTAL ILLNESS..."

THE REGULATIONS GOVERNING RESEARCH INVOLVING FETUSES AND PREGNANT WOMEN AND HUMAN IN VITRO FERTILIZATION STUDIES ARE ALSO RATHER EXTENSIVE, WITH THE EMPHASIS VERY CLEARLY ON THE CONCEPT OF "MINIMAL RISK." THIS MEANS THAT THE RISK IS "NOT GREATER, CONSIDERING PROBABILITY AND MAGNITUDE, THAN THOSE ORDINARILY ENCOUNTERED IN DAILY LIFE."

I APOLOGIZE FOR RACING THROUGH THESE LIKE THIS. I KNOW THIS IS A LOT OF INFORMATION TO ABSORB. IT MAY MAKE IT A BIT EASIER IF WE JUST REMEMBER THAT GOVERNMENT'S ANSWERS TO THE ETHICAL ISSUES RAISED BY THE USE OF HUMAN SUBJECTS IN RESEARCH IS SLOWLY EVOLVING. HOWEVER, THE FOUNDATION FOR THOSE ANSWERS IS STILL FIRMLY WITHIN SUCH DOCUMENTS AS THE NUREMBERG CODE, THE HELSINKI DECLARATION, AND THE NATIONAL COMMISSION'S FINAL REPORT. IN THAT RESPECT, THE GOVERNMENT REMAINS QUITE MINDFUL OF THESE THREE CONSIDERATIONS:

* FUNDAMENTAL TO THE ETHICAL STRUCTURE IS THE CONCEPT OF INFORMED CONSENT. IF IT IS TO BE QUALIFIED IN ANY WAY, IT WOULD BE TOWARD MORE RIGOROUS REQUIREMENTS FOR OBTAINING AND ASSURING THE CONSENT OF HUMAN SUBJECTS IN RESEARCH.

* NEXT, WHILE ALL SUBJECTS REQUIRE PROTECTION, SPECIAL SAFEGUARDS MUST BE ESTABLISHED TO PROTECT SUBJECTS DRAWN FROM VULNERABLE POPULATIONS. THE MOST VULNERABLE PERSONS ARE USUALLY THE EASIEST FOR A RESEARCHER TO IDENTIFY AND CONTROL. WE HAVE HAD OUR SHARE OF CASES IN WHICH THE RESEARCHER'S PURPOSE OVER-RODE THE WELFARE OF THE SUBJECTS -- THE SYPHILIS PROJECT INVOLVING SOUTHERN NEGRO MEN, FOR EXAMPLE -- AND WE MUST BE VIGILANT THAT SUCH CASES NEVER OCCUR.

* AND FINALLY, THE RESEARCH COMMUNITY NEEDS TO BECOME MORE SKILLED AT ASSESSING AND EVALUATING THE RISKS TO HUMAN SUBJECTS AND CONVEYING THAT INFORMATION TO THEM. THIS KIND OF ACTIVITY NOT ONLY MAKES INFORMED CONSENT POSSIBLE, BUT IT IS A DISCIPLINE FOR THE RESEARCHER AS WELL.

THIS SURELY IS NOT ALL OF IT. THERE IS MUCH TO DISCUSS HERE... "MUCH MEAT FOR GOOD ARGUMENT," AS SHAKESPEARE SAYS...BUT WE MUST NOT BE FOOLED INTO PLAYING AT THIS AS AN INTELLECTUAL EXERCISE. IT ISN'T. MOREOVER, FOR EACH OF US, THERE MAY BE A MORE PROFOUND LEVEL OF UNDERSTANDING THAT WE NEED TO REACH. THE GREAT AMERICAN PHILOSOPHER, DOCTOR, AND HIMSELF A RESEARCHER IN THE FIELD OF PSYCHOLOGY -- WILLIAM JAMES -- PUT THE MATTER QUITE SIMPLY, WHEN HE WROTE...

> "IF YOUR HEART DOES NOT <u>WANT</u> A WORLD OF MORAL REALITY, YOUR HEAD WILL ASSUREDLY NEVER MAKE YOU BELIEVE IN ONE."

IN THE WORLD OF ETHICS, LET US ALL HOPE THAT BOTH OUR HEARTS AND OUR HEADS ARE IN THE RIGHT PLACE.

THANK YOU.

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