REMARKS OF

THE HONORABLE

HENRY A. WAXMAN,

CHAIRMAN,

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

BEFORE

THE ASSOCIATION OF FOOD AND DRUG OFFICERS

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I AM PLEASED TO BE HERE THIS MORNING TO SPEAK TO YOU ABOUT THE ISSUES WHICH WILL SURROUND THE FEDERAL FOOD SAFETY POLICY IN THE COMING DECADE. CONTROVERSIES SUCH AS SACCHARIN AND NITRITES HAVE FORESHADOWED SOME OF THE CHANGES WHICH WILL UNDOUBTEDLY BE PROPOSED AND, TO THIS EXTENT, IT IS GOOD THAT THEY WERE RAISED. THEY HAVE MADE US AWARE OF MANY OF THE STRENGTHS AND WEAKNESSES OF OUR FOOD SAFETY POLICY. THEY HAVE ALSO CONVINCED ME THAT WE CANNOT DEAL WITH THIS IMPORTANT AREA ON A PIECEMEAL BASIS. HOWEVER, BEFORE I GET INTO THE SPECIFICS OF FOOD SAFETY AND MY INTERESTS IN IT, LET ME GIVE YOU A LITTLE PRIMER ON THE COMMITTEES WITH JURISDICTION IN THIS AREA.

THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT, WHICH I CHAIR, HAS THIRTY-ONE HEALTH PROGRAMS AND THE CLEAN AIR ACT TO REVIEW AND REAUTHORIZE THIS YEAR. ADD TO THAT WHATEVER FOOD AND DRUG OR MEDICARE AND MEDICAID REFORMS WE MAY UNDERTAKE, AND YOU CAN SEE THAT IT'S GOING TO BE A VERY BUSY SEASON.

BUT BEFORE I GO FURTHER WITH PLANS AND PROGRAMS, LET ME GIVE YOU A SHORT OUTLINE OF THE CONGRESSIONAL COMMITTEES THAT DEAL WITH FOOD. I AM A MEMBER OF THE COMMITTEE ON ENERGY AND COMMERCE, FORMERLY CALLED THE INTERSTATE AND FOREIGN COMMERCE COMMITTEE. IT IS THE OLDEST OF THE HOUSE COMMITTEES AND CERTAINLY THE ONE WITH THE BROADEST JURISDICTION, INCLUDING ENERGY, COMMUNICATIONS, CONSUMER PROTECTION, HEALTH AND THE ENVIRONMENT. ALTHOUGH FEDERAL HEALTH PROGRAMS WERE SMALL UNTIL TWENTY YEARS AGO, FEDERAL REIMBURSEMENT AND GRANTS HAVE MADE THE HEALTH SUBCOMMITTEE ONE OF THE BUSIEST IN THE CONGRESS. WE HAVE MAJOR JURISDICTION OVER ALMOST ALL HEALTH MATTERS, RANGING FROM MEDICAID TO MENTAL HEALTH TO THE FOOD AND DRUG ADMINISTRATION. THE HOUSE AGRICULTURE COMMITTEE ALSO HAS JURISDICTION OVER SOME FOOD REGULATION BECAUSE OF ITS CONTROL OF MEAT AND POULTRY INSPECTION PROGRAMS, BUT ITS ROLE IS LIMITED TO THESE FUNCTIONS AND DOES NOT EXTEND TO FOOD SAFETY GENERALLY.

ON THE SENATE SIDE, THINGS ARE DIVIDED UP A BIT DIFFERENTLY. THERE ARE TWO COMMITTEES THAT DEAL WITH

HEALTH AND TWO MORE THAT DEAL WITH FOOD: THE FINANCE COMMITTEE CONTROLS MEDICARE AND MEDICAID; THE COMMITTEE ON LABOR AND HUMAN RESOURCES CONTROLS THE GRANT PROGRAMS FOR HEALTH AND MOST OF THE REGULATORY FUNCTIONS OF THE FDA; THE SENATE COMMERCE COMMITTEE CONTROLS OTHER PARTS OF THE FDA; AND THE SENATE AGRICULTURE COMMITTEE DEALS WITH USDA.

WORKING WITH SENATE LABOR AND HUMAN RESOURCES COMMITTEE, MY COMMITTEE LAST YEAR PRODUCED THE COMPREHENSIVE MENTAL HEALTH SYSTEMS ACT.

WORKING WITH THE FINANCE COMMITTEE, MY COMMITTEE DREW UP MANY OF THE REIMBURSEMENT REFORMS WHICH WERE LATER INCORPORATED INTO THE BUDGET RECONCILIATION ACT.

AND WORKING WITH BOTH THE HUMAN RESOURCES COMMITTEE AND THE COMMERCE COMMITTEE , MY COMMITTEE EXTENDED THE SACCHARIN MORATORIUM.

THERE ARE DIFFERENT CHAIRMEN AT EACH OF THE COMMITTEES NOW, SENATOR DOLE REPLACING SENATOR LONG; SENATOR HATCH REPLACING SENATOR KENNEDY; AND SENATOR PACKWOOD TAKING OVER FOR SENATOR CANNON.

BUT ALL OF THE RECENT LEGISLATION I HAVE JUST MENTIONED TO YOU HAD STRONG BIPARTISAN SUPPORT, EVEN IN THE LAST CONGRESS, AND ALTHOUGH MANY OF THE LEADERS IN THE ADMINISTRATION AND CONGRESS ARE NEWCOMERS TO THE HEALTH

FIELD, I HOPE THAT THEY WILL EVENTUALLY FIND, AS I HAVE, THAT THE ISSUES OF HEALTH AND SAFETY ARE NOT ESPECIALLY PARTISAN PROBLEMS AND THAT NONE OF THE PROBLEMS WILL BE EASILY SOLVED.

THE EFFORT TO GUARANTEE BOTH THE SAFETY AND THE AVAILABILITY OF OUR FOOD SUPPLY HAS BEEN ONE OF THE MOST DEMANDING AND IMPORTANT PROGRAMS OF THE FEDERAL GOVERNMENT IN THIS CENTURY.

WE HAVE COME A LONG WAY SINCE THE YEAR OF THE FIRST FEDERAL FOOD LAW, WHEN UPTON SINCLAIR'S NOVEL THE JUNGLE TOLD THE CONSUMER OF 1906 WHAT SOME OF THE INGREDIENTS OF THEIR DIETS REALLY WERE. NOW WE CAN DESCRIBE THESE INGREDIENTS IN PARTS PER TRILLION.

AND WE HAVE ALSO COME A LONG WAY SINCE THE DAY WHEN MOST AMERICANS ATE ONLY FRESH, UNPROCESSED FOODS. NOW OVER 1,800 CHEMICALS ARE ADDED ROUTINELY TO OUR FOOD SUPPLY.

THIS TRANSITION FROM A NATION OF FARMS AND LOCAL FOOD TO A NATION OF FACTORIES AND FOOD PROCESSING HAS, I THINK, BEEN REMARKABLY SUCCESSFUL.

AND MUCH OF THIS SUCCESS CAN BE TRACED TO THE CAUTIOUS COMMON SENSE OF THE FEDERAL FOOD AND DRUG LAW.

THE HISTORY OF THE LAW IS FAIRLY STRAIGHTFORWARD: FOOD IN AMERICA WAS ONCE A LOCAL COMMODITY -- YOU DIDN'T NEED TO HAVE IT REGISTERED AND INSPECTED BECAUSE EVERYONE

HAD SOME IDEA OF WHAT THEY WERE BUYING AND WHERE IT CAME FROM.

BUT ABOUT THE TURN OF THE CENTURY, THERE CAME NEW TRANSPORTATION THAT MADE THE WHOLE COUNTRY A SINGLE MARKET AND THEN CONSUMERS COULDN'T BE SURE WHERE THEIR FOOD WAS FROM.

AND, MORE IMPORTANT, THERE CAME PROCESSING, AND CONSUMERS COULDN'T ALWAYS BE SURE WHAT THE FOOD WAS.

SO THE FIRST FOOD LAW WAS VERY SIMPLY CONCERNED WITH "ADDED POISONS," AND IT PROMISED CONSUMERS ONLY THAT THE GOVERNMENT WOULD INTERVENE AND STOP THE DISTRIBUTION OF FOOD THAT WAS "INJURIOUS TO HEALTH."

BUT IT SOON BECAME CLEAR THAT THE 1906 LAW WAS NOT ENOUGH. UNDER THAT LAW THE FDA COULD FIND WHATEVER CONTAMINANTS AND POISONS IT COULD, BUT EACH BATCH OF FOOD HAD TO BE SEPARATELY INSPECTED AND ATTACKED: 100 CASES OF OYSTERS HERE, 20 CHICKENS THERE. IT WAS OBVIOUS THAT THE GOVERNMENT COULDN'T MOVE FAR ENOUGH FAST ENOUGH TO PROTECT PEOPLE AGAINST CONTAMINATED AND DANGEROUS FOOD.

SO IN 1938, THE FIRST COMPREHENSIVE FOOD LAW WAS PASSED. THAT LAW ALLOWED THE FDA TO BAN INGREDIENTS AS WELL AS CANS OF FOOD, AND IT SET UP A REGULATORY FRAMEWORK WHICH IS STILL IN EFFECT TODAY.

THAT FRAMEWORK WAS DEVELOPED THIRTY YEARS BEFORE MOST CONGRESSMEN HAD HEARD OF RISK/BENEFIT ANALYSIS OR REGULATORY TRANSACTION COSTS. AND IT WAS SET UP A LONG TIME BEFORE ECONOMISTS HAD BEGUN TO TALK ABOUT THE ENFORCEMENT COSTS OF FEDERAL INTERVENTION.

BUT IN MANY WAYS, THE FOOD AND DRUG ACT, AS IT WAS PASSED AND AS IT HAS BEEN AMENDED, IS ONE OF THE MOST REASLITIC ATTEMPTS EVER MADE TO REGULATE A WORKING MARKET.

I THINK THAT FOR YOUR CONCERNS AS MANUFACTURERS, THE LAW RECOGNIZES THE NEED FOR DIFFERENT REGULATIONS FOR DIFFERENT TYPES OF FOODS. FOR EXAMPLE, FOODS WHICH NATURALLY CONTAIN SUBSTANCES THAT ARE HARMFUL -- SUCH AS NITRATES IN SPINACH OR THE AFLATOXINS IN PEANUTS -- THE LAW ALLOWS THE FDA TO INTERVENE ONLY IF THE EVERY DAY CONSUMPTION IS OBVIOUSLY DANGEROUS. BUT FOR DIRECT FOOD ADDITIVES, THE LAW ESTABLISHED A STRICT STANDARD OF SAFETY AND PERMITS NO RISK OF CANCER.

THE LAW ALSO RECOGNIZES THAT SOMEWHERE BETWEEN THESE TWO CLASSES IS AN EVEN MORE DIFFICULT GROUP OF SUBSTANCES WHICH ARE NEITHER NATURAL NOR NEW -- THE ADDITIVES, INCLUDING SUGAR AND SALT, WHICH HAVE BEEN A PART OF THE AMERICAN DIET FOR SOME TIME AND ARE "GENERALLY RECOGNIZED AS SAFE," AND THE ADDITIVES WHICH HAD RECEIVED REGULATORY APPROVAL (AND INDUSTRY RELIANCE) BEFORE THE 1958 FOOD ADDITIVES AMENDMENT.

THESE ADDITIVES, BECAUSE OF THEIR TRADITIONAL USES, AND PRODUCERS' AND CONSUMERS' TRADITIONAL RELIANCE UPON THEM, HAVE A PRESUMPTION IN THEIR FAVOR: PROOF OF DANGER TO THE PUBLIC HEALTH MUST BE MADE BEFORE THEY CAN BE REGULATED, AND REMOVAL FROM THE MARKET HAS BEEN SUCCESSFUL IN ONLY A LIMITED NUMBER OF CASES.

WITH THIS FRAMEWORK, THE FDA HAS REMAINED A BUREAUCRACY WITHIN REASON AND WITH SOME FLEXIBILITY, KEEPING A SHARP WATCH ON NEW ADDITIVES TO PREVENT NEW DANGERS FROM ENTERING OUR DIETS AND MEANWHILE REFRAINING FROM INTERFERING IN THE EVERY DAY EATING OF TRADITIONALLY CONSUMED FOODS.

BUT THIS BASIC PROGRAM HAS AROUSED CONTROVERSY FROM ALL SIDES, MOSTLY IN RESPONSE TO THE FDA'S ATTEMPT TO BAN SACCHARIN AND OTHER FAMILIAR SUBSTANCES.

THE NATIONAL ACADEMY OF SCIENCES HAS DESCRIBED THE FEDERAL FOOD LAW AS "CONFUSING AND CUMBERSOME."

AND WITHIN THE PAST TWO YEARS THERE HAVE BEEN MORE THAN FORTY BILLS INTRODUCED IN THE CONGRESS TO REVISE FOOD SAFETY REGULATION.

AND I DO AGREE THAT SOME CHANGE, CAUTIOUS CHANGE, IS NEEDED. BECAUSE OF THE MANY CATEGORIES OF FOOD, REGULATION IS OFTEN INCONSISTENT. A SUBSTANCE OCCURING NATURALLY MAY BE MORE CARCINOGENIC THAN A NEW ARTIFICIAL ADDITIVE, BUT ONLY THE ADDITIVE IS PROHIBITED. A HARMFUL SUBSTANCE MAY BE PERMITTED AS AN ENVIRONMENTAL CONTAMINANT, BUT PROHIBITED AS A FOOD ADDITIVE.

BUT INCONSISTENCIES IN SAFETY STANDARDS ARE NOT INHERENTLY BAD PUBLIC POLICY. WE MUST BE OPEN TO IMPROVEMENTS IN OUR FOOD LAWS, BUT WE SHOULD CHANGE THEM IN DIRECT RESPONSE TO REAL PROBLEMS.

SEVERAL ALTERNATIVES HAVE BEEN PROPOSED. I MUST SAY THAT SOME OF THESE ALTERNATIVES SEEM LESS PRACTICAL THAN THE PRESENT SYSTEM.

LET ME DESCRIBE SOME OF THESE PROPOSALS AND MY RESPONSES TO THEM.

FIRST, AS ALWAYS, ~~THERE ARE THOSE WHO SAY THAT~~ THE FEDERAL GOVERNMENT OUGHT NOT TO REGULATE FOOD SAFETY AT ALL.

AT A TIME OF GREAT ECONOMIC STRAIN, WHEN IT HAS BEEN DEMONSTRATED THAT PREVENTIVE INTERVENTION CAN RETURN HUNDREDS OF DOLLARS FOR EACH DOLLAR INVESTED, I CAN'T SAY THAT THIS PROPOSAL SEEMS REASONABLE TO ME. THIS YEAR THE FEDERAL GOVERNMENT ALONE WILL PAY OVER $50 BILLION FOR HEALTH CARE AND THE REST OF THE NATION WILL PAY OVER $160 BILLION MORE, 9% OF THE GROSS NATIONAL PRODUCT. IF CANCER, BIRTH DEFECTS OR OTHER ILLNESS CAN BE REASONABLY AVOIDED, WE CANNOT AFFORD TO SAY "NO".

THE INSTITUTE OF MEDICINE AND THE NATIONAL ACADEMY OF SCIENCES HAS FORMALLY DISCUSSED A SECOND ALTERNATIVE: ABANDON THE MULTI-TIER SYSTEM AND REGULATE FOOD SOLELY ON THE BASIS OF RISK.

THE INSTITUTE FOUND NO SCIENTIFIC BASIS FOR TREATING A FOOD DIFFERENTLY BECAUSE OF ITS NATURAL, ADDED, HISTORIC, OR SANCTIONED STATUS. THE ACADEMY'S 1979 SACCHARIN REPORT SAYS SIMPLY, "A GIVEN SUBSTANCE IS JUST AS SAFE OR JUST AS TOXIC WHETHER IT IS A NATURAL COMPONENT OR IS SYNTHESIZED IN A LABORATORY." THE REPORT THEN GOES ON TO RECOMMEND THAT THE GOVERNMENT BEGIN A SINGLE FOOD SAFETY SYSTEM THAT REGULATES ALL SUBSTANCES ALIKE.

WHILE I WOULD BE THE FIRST TO ACKNOWLEDGE THAT THE CURRENT LAW IS COMPLICATED WITH CATEGORIES AND EXCEPTIONS AND GRANDFATHER CLAUSES, IT ALSO CONTAINS MANY SOUND PUBLIC POLICIES WHICH BALANCE THE PUBLIC'S HEALTH WITH THE NEED FOR A PLENTIFUL FOOD SUPPLY. THE ACADEMY'S REPORT DESERVES CAREFUL AND OBJECTIVE ANALYSIS OF ITS GOALS AND ITS PROPOSED METHODS; BUT SO DO EXISTING POLICIES.

SCIENCE AND TECHNOLOGY ARE SPEEDING AHEAD, BUT THE ABILITY OF REGULATORY AGENCIES TO MAKE DIFFICULT EVALUATIONS OF THE RELATIVE RISKS OF DIFFERENT FOODS HAS CHANGED ONLY SLIGHTLY.

ATTEMPTS TO TEST EACH FOOD FOR ITS RISKS--POTATOES FOR THEIR SOLANINE, SPINACH FOR ITS NITRATE--WOULD BE COMPLICATED BEYOND IMAGINATION. IF THE FDA HAS NEVER MANAGED TO PRODUCE A

DEFINITIVE LIST OF THE 600 OR SO INGREDIENTS THAT IT HAS GENERALLY RECOGNIZED AS SAFE, HOW LONG WOULD IT TAKE FOR THE AGENCY TO TEST ALL FOODS AND ASSIGN A RISK VALUE TO EACH? AND IF SUCH A CATALOGUE OF RISKS INDEED SUGGESTS THAT POTATOES AND SPINACH ARE HIGH-RISK FOODS, HOW COULD THE AGENCY BEGIN TO REGULATE THEIR CONSUMPTION?

OTHERS HAVE PROPOSED THAT THE FDA CONSIDER THE BENEFITS OF FOODS -- AS WELL AS THE RISKS -- BEFORE REJECTING OR BANNING A SUBSTANCE. THIS HAS CERTAINLY BEEN THE MOST DISCUSSED OF THE PROPOSALS.

THIS ARGUMENT HAS BEEN MADE AGAINST OTHER PUBLIC HEALTH PROGRAMS AS WELL, AND I AM SERIOUSLY CONCERNED BY THE CLAIM THAT RISK-BENEFIT -- OR COST-BENEFIT ANALYSIS IS SUFFICIENTLY ADVANCED TO DICTATE WHICH PROTECTIONS ARE WORTH HAVING AND WHICH ARE NOT.

I DON'T DISPUTE THE NEED TO EXAMINE THE BENEFITS AND RISKS A PROPOSED REGULATION CAN BRING. BUT WE CANNOT EXPECT ANALYSIS OF COSTS AND BENEFITS TO BE A NEAT CALCULUS FOR DETERMINING PUBLIC POLICY.

THE PROBLEM WITH THE INDISCRIMINATE USE OF RISK-BENEFIT ANALYSIS IS CLEAR: WE CANNOT MEASURE ACCURATELY.

WHEN DEALING WITH CANCER AND BIRTH DEFECTS, STATISTICS BEGIN TO BE CONFUSED: FOOD SAFETY LAW IS PREVENTIVE AND A RISK OR COST ANALYSIS WOULD HAVE TO BE ABLE TO LOOK THROUGH UNPREDICTABLE LEVELS OF EXPOSURE AND UNCERTAIN LATENCY PERIODS TO DETERMINE THE VALUE OF THE REGULATION. THE ANALYST WOULD ALSO, OF COURSE, HAVE TO HAVE SOME WAY OF COUNTING LIVES NOT SHORTENED OR STUNTED. AND, IF THE CALCULUS IS ECONOMIC, HOW CAN WE PLACE MONETARY VALUES ON THE LIVES LOST?

IT IS EQUALLY CONFUSING TO ASSIGN NUMBERS TO THE BENEFIT SIDE OF THE RATIO: WHAT KIND OF BENEFITS ARE RELEVENT, AND BENEFITS TO WHOM? ARE ADDITIVES OR PRESERVATIVES WHICH INCREASE THE AESTHETIC APPEAL OF FOOD BENEFICIAL TO CONSUMERS? CAN ANYONE GUESS AT THE PERCEIVED PSYCHOLOGICAL BENEFITS OF DIETERS WHO GIVE UP SUGAR? ARE PROFITS AND LABOR BENEFITS ALWAYS APPROPRIATE CONSIDERATIONS?

FINALLY, ALTHOUGH IT SOUNDS LIKE GOOD PUBLIC POLICY TO SAY LET'S EVALUATE THE RISKS AND BENEFITS OF A PARTICULAR FOOD OR SUBSTANCE, I WONDER WHO IS KNOWLEDGEABLE ENOUGH TO ACTUALLY MAKE THIS BALANCE. IS THE CONSUMER, WHO IS INFORMED ONLY BY THE SIDE OF A CAN? IS THE FDA, WHICH IS INFORMED OF EATING HABITS BY BRIEFS AND LETTERS?

I BELIEVE WE MUST PROCEED CAUTIOUSLY WHEN WE TALK OF SUCH SWEEPING CHANGES IN OUR FOOD LAWS. BUT RAPID TECHNOLOGICAL PROGRESS IN RESEARCH MUST MAKE US WONDER WHETHER THE LAW PROCEEDS TOO CAUTIOUSLY.

WHEN THE ORIGINAL FOOD LEGISLATION PASSED, ANALYSIS IN TERMS OF PARTS PER THOUSAND WAS COMMON, BUT ADVANCES IN RESEARCH TECHNOLOGY HAVE NOW MADE IT POSSIBLE TO DETECT PARTS PER BILLION. AS A RESULT, THE MIGRATION OF PACKAGING MATERIALS, GLUE, AND TRACES OF IMPURITIES INTO FOOD ARE KNOWN AND THESE SUBSTANCES ARE OFTEN DEFINED AS ADDITIVES. THE REMOVAL OF THESE SMALLER AND SMALLER QUANTITIES OF ADDITIVES COULD BECOME PROHIBITIVELY EXPENSIVE. AND IF THEY AREN'T REMOVED AND ARE CARCINOGENIC TO ANY EXTENT, THEN THE DELANEY CLAUSE WOULD REQUIRE A BAN.

AS TO WHAT THE FUTURE HOLDS FOR FOOD SAFETY LEGISLATION, THERE ARE A GREAT MANY ISSUES TO BE LOOKED AT. NO LEGISLATION DEALING WITH THE MAJOR ISSUES SURROUNDING FOOD SAFETY HAS BEEN INTRODUCED, EXCEPT THAT YESTERDAY A BILL TO EXTEND THE SACCHARIN MORATIUM FOR AN ADDITIONAL TWO YEARS WAS INTRODUCED IN THE SENATE. HOWEVER, I AM SURE MANY OF YOU HAVE SEEN A DRAFT BILL TO REVISE THE FOOD LAWS WHICH HAS BEEN PREPARED BY THE SOFT DRINK MANUFACTURERS AND THE MEAT PACKERS.

THE SUBCOMMITTEE IS COMMITTED TO A CAREFUL REVIEW OF BOTH INDUSTRY AND CONSUMER GROUPS' CONCERNS ABOUT THE STATUTE AS IT STANDS NOW. WE WILL BE BEGINNING A PROCESS OF THOROUGH CONSULTATION WILL ALL OF THE INTERESTED FOOD GROUPS SO THAT WE MAY BETTER UNDERSTAND THEIR DIFFERING VIEWS ON THE ISSUES. IN THIS REGARD, I HOPE YOU WILL CONTACT MY SUBCOMMITTEE WITH YOUR VIEWS ON THE ENTIRE FOOD SAFETY AREA AND SPECIFICALLY ON THE DRAFT INDUSTRY BILL.

OUR LEGISLATIVE CALENDAR IS CROWDED THIS SESSION. WE MUST DEAL WITH APPROXIMATELY SEVENTEEN PROGRAMS WHICH NEED TO BE REAUTHORIZED AND IN JUNE WE WILL BEGIN THE PROCESS OF RECONCILIATION. I, THEREFORE, DO NOT ANTICIPATE ANY ACTION IN THE FOOD SAFETY AREA UNTIL LATE IN THE YEAR, OR MORE LIKELY, SOMETIME DURING THE NEXT YEAR.

I WOULD BE HAPPY TO ADDRESS ANY QUESTIONS YOU MAY HAVE.