

SENATOR BOB DOLE
FOOD SAFETY COUNCIL
DECEMBER 11, 1980
WASHINGTON, DC

I AM PLEASED TO HAVE THIS OPPORTUNITY TO SPEAK WITH ~~THE~~ ^{MEMBERS} FOOD SAFETY COUNCIL CONCERNING THE DIRECTIONS OF FOOD SAFETY REGULATIONS.

THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION, IN A SPEECH ON JUNE 11, 1980, SAID THAT OUR FOOD LAWS ARE, " OBSOLETE, CONFUSING, AND ALMOST IMPOSSIBLE TO ADMINISTER IN A CONSISTENT MANNER. INDEED, THERE MAY BE ONLY A DOZEN PEOPLE IN THIS COUNTRY WHO FULLY UNDERSTAND THE FOOD PROVISIONS OF THE FOOD, DRUG, AND COSMETIC ACT, AND I AM TOLD THAT EVEN THEY DISAGREE."

EVALUATION OF CURRENT SITUATION

THE QUESTION THAT MUST BE ASKED IS HOW DID THIS NATION, WHICH HAS THE WORLD'S MOST ABUNDANT AND WHOLESOME FOOD SUPPLY, BECOME ENTANGLED IN SUCH A MESS?

OBVIOUSLY, IT IS HARD TO LAY THE BLAME FOR SUCH AN AMORPHOUS MALADY SOLELY AND DIRECTLY AT THE DOORSTEP OF THE FEDERAL ADMINISTRATIVE AGENCIES. EVEN IF FEDERAL AGENCIES ARE THE MOST IMMEDIATE INSTRUMENTS OF OUR DISCOMFORT, THEY ARE THE INEXORABLE, AND PERHAPS INTENDED, RESULTS OF A COURSE ON WHICH WE AS A NATION EMBARKED AS LONG AGO AS ~~THE~~ NEW DEAL.

REGULATORY HISTORY

ALTHOUGH THE CONSTITUTION PROVIDES THE AUTHORITY FOR THE REGULATION OF INTERSTATE COMMERCE, CONGRESS RESISTED THIS TEMPTATION FOR NEARLY A HUNDRED YEARS UNTIL ~~IT~~ ESTABLISHED THE INTERSTATE COMMERCE COMMISSION IN 1887.

AT THAT TIME, THERE ALREADY EXISTED WIDE-SPREAD CONCERN ABOUT FOOD SAFETY, ALONG WITH GENERAL AGREEMENT THAT WE NEEDED TO ENSURE A SAFE AND WHOLESOME FOOD SUPPLY. HOWEVER, IT TOOK NEARLY TWENTY YEARS FOR THIS CONCERN TO BE TRANSLATED INTO LEGISLATION IN THE FORM OF THE FOOD AND DRUG ACT OF 1906 AND THE MEAT INSPECTION ACT THAT SAME YEAR.

-3-

INHERENTLY, AMERICANS HAVE DEMONSTRATED A RELUCTANCE TO INTERFERE WITH INDIVIDUAL FREEDOMS AND STATES RIGHTS. DESPITE THESE PREVALENT ATTITUDES, FEDERAL REGULATIONS OF FOOD SAFETY WERE PUT INTO EFFECT, AND, CONTRARY TO FEARS ON THE PART OF VARIOUS INDUSTRY GROUPS, THE EARLY REGULATORS FREQUENTLY BENEFITED THE INDUSTRY, AS WELL AS CONSUMERS. THIS OCCURRED BECAUSE THE HISTORICAL CONCEPT OF REGULATION IN THE UNITED STATES WAS THAT IT HAD A ROLE TO PROTECT AND PROMOTE THE INDUSTRY THAT WAS REGULATED. BACK IN THOSE DAYS, THERE WAS A COOPERATIVE RELATIONSHIP ON THE PART OF GOVERNMENT THAT WORKED TO PROMOTE THE REGULATED INDUSTRY IN THE BEST INTEREST OF THE NATION.

UNFORTUNATELY, AS TIME PROGRESSED INTO THE 60'S, THIS RELATIONSHIP BEGAN TO ERODE. WHILE OUR NATIONAL ATTENTION SWITCHED FROM PRODUCTION ISSUES TO QUALITY-OF-LIFE ISSUES, THERE WAS A REVERSAL IN ATTITUDES CONCERNING REGULATION. MISTRUST FINALLY UNDERMINED THE PREVIOUS COOPERATIVE SPIRIT AND ADVERSARIAL ATTITUDES BECAME DOMINANT IN THE REGULATORY AGENCIES. WE ALSO WITNESSED A DRAMATIC INCREASE IN GOVERNMENT INVOLVEMENT AND A RADICAL CHANGE IN THE ATTITUDE OF GOVERNMENT. ALMOST OVERNIGHT, REGULATORY AGENCIES SHIFTED FROM BEING RELATIVELY PASSIVE ADVOCATES TO ACTIVE AGENTS FOR SOCIAL AND ECONOMIC CHANGE.

-4-

TODAY, THERE IS GREAT PUBLIC CONCERN, EVEN ANGER, AT THE AMOUNT OF OVERREGULATION AND THE COST IMPACT IN COMPLYING WITH THE PROLIFIC RULES THAT EMANATE FROM THE FEDERAL GOVERNMENT AT A STEADY PACE. THIS SENTIMENT HAS FOUND MUCH EXPRESSION IN LEGISLATION OF THE 96TH CONGRESS. OVER 100 BILLS IN BOTH HOUSES DEAL WITH THE SUBJECT OF REGULATORY REFORM IN ONE FASHION OR ANOTHER. THIS FLURRY OF ACTIVITY ON CAPITOL HILL IS PERHAPS A RESPONSE TO THE INARTICULABLE FRUSTRATION OF THE CITIZENS OF THIS COUNTRY WITH THEIR GOVERNMENT.

A VERY REVEALING INDICATOR OF THE EXTENT TO WHICH THE REGULATORY TREND HAS MULTIPLIED IS THE SIZE OF THE CONSOLIDATED CODE OF FEDERAL REGULATIONS TODAY. WE HAVE SEEN $7\frac{1}{2}$ TIMES MORE NEW REGULATIONS IN THE PAST TWENTY YEARS THAN WERE WRITTEN IN THE FIRST 180 YEARS OF OUR NATION! TODAY, THE GOVERNMENT APPEARS TO BE CONSPIRING TO STRANGLE OUR ORDERLY PURSUIT OF INDIVIDUAL AND COLLECTIVE HAPPINESS.

TRENDS DURING THE SIXTIES

IF I WERE PARTISAN, I MIGHT SUGGEST THAT THE CHANGE IN THE 60'S OCCURRED BECAUSE THE DEMOCRATS WERE IN POWER. WHILE THIS MAY BE TRUE, MANY OF THE LAWS THAT PROVOKED THE FLOOD OF REGULATIONS HAD BEEN INSPIRED BY LOFTY GOALS, SUCH AS CLEAN AIR AND WATER, WORKER SAFETY, UNIVERSAL HEALTH AND WELFARE, AND EQUAL EMPLOYMENT OPPORTUNITY.

-5-

A COMPLACENCY WITH OUR RELATIVE ECONOMIC HEALTH OF THE 50's AND 60's BROUGHT FORTH THESE AMBITIOUS GOALS. UNFORTUNATELY, NO ONE ANTICIPATED THE FULL COST OF THESE ACTIONS OR THE PERVASIVENESS OF THE REGULATIONS WHICH RESULTED.

RESULTS OF OVER-REGULATION

TODAY, WE ARE SEEING THE RESULTS OF THE TREND TOWARD OVERREGULATION. ABOUT THE ONLY THING GROWING MORE RAPIDLY THAN REGULATION ITSELF IS THE COST OF REGULATIONS. DEPENDING ON WHO MAKES THE ESTIMATE, THE TOTAL COST IS SOMEWHERE BETWEEN \$130 AND \$200 BILLION A YEAR. THESE COSTS RESULT FROM DIRECT COMPLIANCE COSTS, LOSSES IN PRODUCTIVITY, UNEMPLOYMENT, AND INCREASINGLY, LOSSES OF MARKETS TO OTHER NATIONS.

BARRY BOSWORTH, WHILE AT THE COUNCIL ON WAGES AND PRICES, ESTIMATED THAT REGULATIONS WERE ADDING THREE-QUARTERS OF A PERCENT ANNUALLY TO THE CONSUMER PRICE INDEX. HE MAY HAVE BEEN A BIT CONSERVATIVE.

CONSUMER ATTITUDES

THE PEOPLE IN THIS COUNTRY ARE NO LONGER COMPLACENT ABOUT THESE COSTS. THE NUMBER ONE ISSUE ON THE MINDS OF MOST AMERICANS IS INFLATION. PEOPLE ARE ANGERED BY THE HIGH COST OF GOVERNMENT. THEY ARE ALSO GETTING ANGRY ABOUT EXCESSIVE GOVERNMENTAL INTERVENTION IN THEIR LIVES.

THIS CAN CLEARLY BE SEEN IF YOU COMPARE CONSUMERS' ATTITUDES. TAKE THE FDA. IN A POLL TAKEN JUST AFTER THE CRANBERRY SCARE IN 1959, THERE WAS ALMOST UNANIMOUS SUPPORT OF THE FDA'S ACTION AGAINST CRANBERRIES. HOWEVER, WHEN THE FDA PROPOSED TO BAN SACCHARIN, THERE WAS A PUBLIC OUTCRY -- MANY CONSUMERS BEGAN HOARDING THIS SUBSTANCE. IN FACT, THE MOST WIDELY HELD ATTITUDE COMMUNICATED TO ME WAS THAT CONSUMERS DESIRED TO BE PROTECTED FROM THE FDA -- AND NOT FROM SACCHARIN.

COST-BENEFIT IMPLICATIONS

HAVE WE AS A NATION, THROUGH OUR REPRESENTATIVES IN THE EXECUTIVE AND LEGISLATIVE BRANCHES OF GOVERNMENT, CHOSEN TO GIVE GOVERNMENT AN EVER INCREASING ROLE IN OUR NATIONAL LIFE? I THINK NOT.

WHEN MANY OF THE CURRENT REGULATORY ACTS WERE PASSED, ECONOMIC CONSIDERATIONS WERE RELEGATED TO A SECONDARY ROLE. INDEED, AT PRESENT, THERE IS NO LEGAL MECHANISM WHICH REQUIRES, OR EVEN ENCOURAGES, ADMINISTRATIVE AGENCIES TO TRULY EVALUATE THE BENEFITS AND COSTS OF THEIR ACTIONS. PRESENTLY, UNDER A PROGRAM INITIATED UNDER THE FORD ADMINISTRATION, CERTAIN AGENCIES ARE REQUIRED TO PERFORM A MINIMAL "REGULATORY ANALYSIS" OF CERTAIN TYPES OF RULES. YET AGENCIES HAVE STRUGGLED TO AVOID THE REQUIREMENTS OF EVEN THIS COMPARATIVELY TEPID PROGRAM.

AS A NATION, BILLIONS OF DOLLARS OF PRIVATE SPENDING ARE REQUIRED TO COMPLY WITH LITERALLY THOUSANDS OF DETAILED REGULATIONS. THE 1978 FEDERAL REGISTER, THROUGH WHICH THESE REGULATIONS ARE PUBLISHED, CONTAINED A TOTAL OF ABOUT 61,000 PAGES, PUBLISHING ABOUT 7,000 RULES AND OTHER GOVERNMENT DOCUMENTS.

-8-

JUST IN THIS DECADE, CONGRESS HAS CREATED SEVEN NEW REGULATORY AGENCIES, INCLUDING EPA AND OSHA, AND HAS ENACTED TWENTY-NINE NEW MAJOR REGULATORY STATUTES. ACCORDING TO A STUDY BY THE JOINT ECONOMIC COMMITTEE OF THE CONGRESS, DIRECT FEDERAL REGULATORY AGENCY EXPENDITURES ROSE FROM \$2.2 BILLION IN 1974 TO \$4.8 BILLION IN 1979, A 115 PERCENT INCREASE IN AGENCY OPERATING EXPENSES ALONE. YET, THE COSTS OF COMPLYING WITH FEDERAL REGULATIONS ARE NEVER REFLECTED IN ANY AGENCY BUDGET. COMPLIANCE WITH GOVERNMENT REGULATIONS IMPOSES A SIZEABLE BURDEN ON BUSINESS, YET, THIS TAX NEVER BENEFITS THE TREASURY OF THE UNITED STATES, AND OFTEN HINDERS NATIONAL PRODUCTIVITY.

COSTS TO CONSUMERS

A STUDY DONE BY THE TAX FOUNDATION CONCLUDED THAT THE COSTS TO THE CONSUMER OF COMPLYING WITH FEDERAL REGULATIONS IN 1976 WAS \$62.9 BILLION. THAT AMOUNTED TO MORE THAN \$300 FOR EVERY MAN, WOMAN, AND CHILD LIVING IN THE UNITED STATES, TWENTY TIMES THE \$3.1 BILLION SPENT TO OPERATE THE AGENCIES THAT YEAR. FOR 1979, IT IS ESTIMATED THAT \$102.7 BILLION WILL BE THE COST TO THE CONSUMER OF COMPLYING WITH FEDERAL REGULATIONS OR ABOUT \$400 PER PERSON.

-9-

IT DOES NOT REQUIRE TOO MUCH MEDITATION ON THE ECONOMIC FACTS OF LIFE TO REALIZE THAT THIS SORT OF FEDERAL REGULATION AGGRAVATES AN ALREADY EXTREME RATE OF INFLATION BY IMPOSING COSTS ON THE PRIVATE SECTOR WHICH RAISE PRICES WITHOUT A CORRESPONDING RISE IN PRODUCTIVITY. INDEED, AS DR. JAMES MILLER OF THE AMERICAN ENTERPRISE INSTITUTE HAS NOTED, "REGULATION OFTEN HAS A GREATER EFFECT UPON CONSUMER WELFARE THAN OTHER INFLATIONARY FACTORS, BECAUSE IT OPERATES DIRECTLY UPON THE REAL SUPPLY OF GOODS AND SERVICES."

EXECUTIVE TURNED LEGISLATIVE BRANCH

THE RESPONSIBILITIES THOUGHT IN ANOTHER DAY TO BE EXCLUSIVELY THOSE OF CONGRESS HAVE DEVOLVED UPON THESE UNELECTED BUREAUCRACIES IN THE FORM OF ADMINISTRATIVE AGENCIES. THROUGH THEIR ACTIVITIES, TECHNICALLY CALLED "RULE MAKING," THESE AGENCIES LEGISLATE TO STRUCTURE AND SHAPE OUR LIVES TO AN UNPRECEDENTED DEGREE. WHILE OUR ANCESTORS MIGHT HAVE RALLIED TO THE CRY, "NO TAXATION WITHOUT REPRESENTATION," WE, THE SONS OF THE SONS OF LIBERTY REMAIN PASSIVE AS UNELECTED GOVERNMENT AGENTS IMPOSE LAWS ON US WITH ONLY THE SLIGHTEST PRETENSE OF DIRECT PUBLIC INVOLVEMENT.

PERHAPS, THE CONGRESS HAS ABDICATED TOO MUCH OF ITS LEGISLATIVE RESPONSIBILITIES TO FEDERAL AGENCIES.

SINCE ADMINISTRATIVE AGENCIES REGULATE AN INCREDIBLE RANGE OF PRIVATE ACTIVITIES, THEY OFTEN FIND THEMSELVES AUTHORIZED TO PROMULGATE REGULATIONS WHICH WILL MOVE THE NATION TOWARDS GOALS WHICH, IF NOT MUTUALLY EXCLUSIVE, ARE OFTEN IN LARGE MEASURE INCONSISTENT. ONE CANNOT NECESSARILY HAVE ABSOLUTELY CLEAN AIR, ABSOLUTELY CLEAN WATER, ABSOLUTELY SAFE MINES, AND YET PROVIDE JOB OPPORTUNITIES FOR ALL AND ADEQUATELY HEAT THE HOMES OF ALL CITIZENS IN THE WINTER. HOW TRADE-OFFS ARE TO BE MADE BETWEEN COMPETING BENEFITS, OR INDEED, IN THE FIRST INSTANCE, BETWEEN BASIC BENEFITS AND COSTS OF A REGULATION, IS THE TRUE ABDICATION OF DISCRETION BY CONGRESS TO ADMINISTRATIVE AGENCIES.

IT IS UNDENIABLE THAT THE DRAFTING AND ADMINISTRATION OF REGULATIONS TENDS TO REFLECT THE ATTITUDES AND INTERESTS OF THE REGULATORY AGENCY, AND THESE MAY NOT BE IN FULL AGREEMENT WITH THE INTENT OF CONGRESS AS EXPRESSED IN THE ENABLING LEGISLATION. WHILE ALL REGULATORY AGENCIES HAVE AN INTERNAL APPEALS SYSTEM, THIS, TOO, CAN BE INFLUENCED BY THE ATTITUDES HELD WITHIN THE AGENCY. IN SHORT, REGULATORY AGENCIES TEND TO BE JUDGE, JURY AND EXECUTIONER, A SITUATION TOTALLY OUT OF STEP WITH OUR BASIC BELIEFS AND GOVERNMENTAL ORGANIZATION.

-11-

FUTURE TRENDS

THROUGHOUT ALL OF THIS DISCUSSION, WE MUST REMEMBER THAT CONGRESS DELEGATED AUTHORITY TO THE VARIOUS REGULATORY AGENCIES -- WE DIDN'T ABDICATE OUR RESPONSIBILITY. HOWEVER, THERE HAS BEEN A STRENGTHENING OF RESOLVE IN THE CONGRESS IN BRINGING OVERZEALOUS REGULATION UNDER CONTROL. THIS CAN BE SEEN IN THE INCREASED CONGRESSIONAL OVERSIGHT AND MANDATED REVIEWS OF FOOD SAFETY REGULATORY ACTIONS, SUCH AS THE NAS SACCHARIN STUDY AND THE REVIEW OF NITRITE. THERE HAS ALSO BEEN EXPANDING LEGISLATIVE INTEREST IN DEREGULATION, AND I THINK IT IS FAIR TO SAY THAT THE PACE OF THIS EFFORT WILL BE PICKING UP -- ESPECIALLY IN THE SENATE.

THE REPUBLICAN NATIONAL PLATFORM CALLS FOR LEGISLATIVE EFFORTS TO REVISE OUR FOOD SAFETY LAWS TO PROVIDE GUIDELINES FOR RISK ASSESSMENT, BENEFIT ASSESSMENT, PEER REVIEW AND REGULATORY FLEXIBILITY, WHICH ARE CONSISTENT WITH OUR HEALTH AND SAFETY POLICIES. THIS FITS RIGHT IN WITH THE CONGRESSIONAL TREND I'VE MENTIONED, AS WELL AS WITH THE RECOMMENDATIONS OF THE NATIONAL ACADEMY OF SCIENCES IN THEIR SACCHARIN STUDY.

I WOULD ADD THAT THIS IS IN PERFECT AGREEMENT WITH THE OBJECTIVES OF THE FOOD SAFETY COUNCIL REPORTS. I THINK YOUR REPORT "PROPOSED SYSTEM FOR FOOD SAFETY ASSESSMENT" IS GOING TO BE A VALUABLE TOOL IN MAKING MORE INFORMED SCIENTIFIC JUDGMENTS ON RISK. THIS WILL IN TURN ALLOW FEDERAL AGENCIES TO MAKE MORE REASONABLE DECISIONS THAN OCCURRED WITH NITRITE.

ONE OF THE MOST IMPORTANT FACTORS IN ESTABLISHING^A HEALTHY REGULATORY SYSTEM IS PLACING COMPETENT PEOPLE TO ADMINISTER THEM. I THINK WE CAN COUNT ON PRESIDENT REAGAN TO APPOINT TALENTED INDIVIDUALS TO KEY POSITIONS.

WHATEVER CHANGES MAY OCCUR UNDER A NEW ADMINISTRATION, IT IS ESSENTIAL TO RECOGNIZE THE LEGITIMATE AND NECESSARY ROLE FOR CONSTRUCTIVE FOOD SAFETY REGULATIONS. THE IMPORTANCE OF THIS AREA HAS BEEN RECOGNIZED FOR SEVENTY-FIVE YEARS AND THE REPUBLICAN PLATFORM ENDORSES THIS COMMITMENT. I BELIEVE THAT WE ARE GOING TO HAVE BETTER AND MORE BALANCED REGULATION IN THE FUTURE, BUT THE SUCCESS OF THIS EFFORT DEPENDS UPON YOU AS WELL AS THE PRESIDENT AND THE CONGRESS. SOLUTIONS TO FOOD SAFETY PROBLEMS WILL ONLY COME ABOUT AS A RESULT OF A LONG, PATIENT DIALOGUE AMONG ALL AFFECTED PARTIES. I AM LOOKING FORWARD TO WORKING WITH YOU IN CONSTRUCTING FUTURE POLICIES IN THE FOOD SAFETY AREA.