COMPLIANCE WITH THE FDCA B WHY BOTHER?[1]

I. INTRODUCTION

CHESTER BOWLES, A REGULATOR IN ONE OF THE ROOSEVELT ADMINISTRATIONS AND A MEMBER OF THE 1941 WARTIME OFFICE OF PRICE ADMINISTRATION, OBSERVED:

> "20 % OF THE REGULATED POPULATION WILL AUTOMATICALLY COMPLY WITH ANY REGULATION, 5 % WILL ATTEMPT TO EVADE IT [NO MATTER WHAT], AND 75 % WILL COMPLY SO LONG AS THEY THINK THAT THE 5 % WILL BE CAUGHT AND PUNISHED."[2]

I DON'T KNOW WHETHER MR. BOWLES HAS THE CORRECT PERCENTAGES (I SUSPECT THE PERCENTAGES VARY WITH THE INDUSTRY, THE TIMES, AND THE PARTICULAR REGULATION AT ISSUE), BUT I BELIEVE HE HAS CORRECTLY IDENTIFIED THE MAJOR GROUPS.

THERE ARE MANY RESPONSIBLE CORPORATE EMPLOYEES AND EXECUTIVES WHO PLACE A HIGH PREMIUM ON OBEYING THE LAW, NOT ONLY BECAUSE IT IS THE ARIGHT THING@ TO DO, BUT ALSO BECAUSE IT MAKES GOOD BUSINESS SENSE.

IF YOU ARE IN MR. BOWLE'S 20% GROUP AND "DO THE RIGHT THING" ACCURATELY REFLECTS YOUR PERSONAL PHILOSOPHY AND CORPORATE CULTURE, YOU HAVE LITTLE NEED TO LISTEN TO THESE REMARKS, EXCEPT PERHAPS FOR POSITIVE REINFORCEMENT. SIMILARLY, IF YOU ARE IN THE 5% GROUP, SOMETIMES REFERRED TO AS THE "TRUE BELIEVERS," THIS TALK WILL PROBABBLY NOT BE THE BEST USE OF YOUR TIME.

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[1] Eric M. Blumberg, Deputy Chief Counsel for Litigation, FDA.

[2] Quoted in Rechtschaffen, C., "Deterrence vs. Cooperation and the Evolving Theory of Environmental Enforcement," Southern California L.R. (Sept. 1998), 15.

HOWEVER, IF YOU ARE IN THE 75 % CATEGORY AND THINK YOU MAY BE FACED WITH A DECISION WHETHER OR NOT TO COMPLY WITH LAWS THAT FDA ENFORCES, PERHAPS YOU WILL FIND MY VIEWS THOUGHT PROVOKING.

IN MY VIEW, A *RESPONSIBLE* CORPORATE EXECUTIVE MAY NOT REASONABLY CONCLUDE THAT HE OR SHE HAS A CHOICE WHETHER TO OBEY THE LAW.

I WOULD ARGUE THAT CORPORATE DECISION MAKERS AND EMPLOYEES ARE PROFESSIONALLY, LEGALLY, AND EVEN ETHICALLY OBLIGATED TO OBEY THE LAW. PROFESSIONALLY, THE LONG TERM SUCCESS OF YOUR COMPANY, YOUR PRODUCT LINES, AND YOUR EMPLOYEES AND STOCKHOLDERS, DICTATE THAT YOU MAKE AND DISTRIBUTE COMPLIANT PRODUCTS. IF YOU THINK NOT, TALK TO FOLKS AT ARTHUR ANDERSON. LEGALLY, CORPORATE EMPLOYEES WHO DECIDE NOT TO COMPLY WITH THE LAW, PLACE NOT ONLY THEIR PERSONAL AND THEIR COMPANY'S REPUTATIONS AT STAKE, BUT ALSO THEIR PERSONAL LIBERTY. IF YOU DISAGREE, ASK MARTHA STEWART AND ANDY AND LEA FASTOW. VIEWD FROM AN ETHICAL PERSPECTIVE, THE PUBLIC RELIES ON YOU TO MAKE PRODUCTS THAT ARE SAFE, EFFECTIVE, AND HONESTLY PROMOTED.

II. POTENTIAL CONSEQUENCES FOR VIOLATING THE FDCA

A. GENERAL

WHATEVER SHORT-TERM GAINS MAY BE ACHIEVED BY FAILING TO COMPLY WITH THE FDCA ARE OFFSET BY THE POTENTIAL CONSEQUENCES OF AN FDA ENFORCEMENT ACTION. IF FDA DECIDES TO PROCEED WITH AN ENFORCEMENT ACTION AGAINST YOUR COMPANY AND/OR YOU, THE GENERAL CONSEQUENCES MAY INCLUDE, TO NAME A FEW:

ADVERSE PUBLICITY, WHICH MAY RESULT IN LOSS OF CONSUMER CONFIDENCE IN YOUR COMPANY AND ITS PRODUCTS; PERSONAL STIGMA TO YOU AND YOUR FAMILY MEMBERS;

DELAYED PRODUCT APPROVALS WHEN RELEVANT SYSTEMS AND PROCESSES ARE FOUND NON-COMPLIANT;

DECLINING STOCK VALUATIONS AND STOCKHOLDER CONFIDENCE;

INTERRUPTED PRODUCTION AND DISTRIBUTION, PERHAPS WITH LOSS OF MARKET SHARE;

BUSINESS UNCERTAINTY WHILE REGULATORY ISSUES ARE BEING RESOLVED;

LEGAL FEES AND EXPERT CONSULTANT FEES;

DECREASED EMPLOYEE MORALE PERHAPS WITH EMPLOYEE TURN OVER;

INCREASED PRODUCT LIABILITY EXPOSURE;

DIFFICULTY OBTAINING CAPITAL; AND, IN SOME CASES,

PERSONAL AND CORPORATE CRIMINAL CULPABILITY AND LARGE FINES.

B. FDA INJUNCTIONS

IF FDA DECIDES TO SEEK AN INJUNCTION AGAINST YOUR COMPANY AND YOU, YOUR LAWYER MAY RECEIVE A LETTER FROM THE DEPARTMENT OF JUSTICE (DOJ) STATING THE GOVERNMENT'S INTENT TO FILE A COMPLAINT IN FEDERAL COURT UNLESS A CONSENT DECREE IS AGREED UPON WITHIN A SPECIFIC TIME FRAME.

ONCE MATTERS HAVE REACHED THIS STAGE, THERE IS NO REASONABLE PROSPECT OF AVOIDING EITHER A TRIAL OR A JUDICIAL DECREE OF PERMANENT INJUNCTION.

IN ANY INJUNCTION DECREE, FDA WILL SEEK BROAD RELIEF THAT LIKELY WILL INCLUDE THE FOLLOWING:

NAMING RESPONSIBLE CORPORATE OFFICIALS AS DEFENDANTS IN THE CAPTION OF THE CASE;

CESSATION OF MANUFACTURING AND DISTRIBUTION OF AFFECTED PRODUCTS UNLESS AND UNTIL THE VIOLATIVE CONDITIONS HAVE BEEN CORRECTED TO FDA'S SATISFACTION (REFERRED TO AS AN "UP FRONT SHUTDOWN");

A REQUIREMENT THAT YOU HIRE OUTSIDE CONSULTANTS TO EVALUATE YOUR COMPLIANCE AND REGULARLY REPORT TO CORPORATE MANAGEMENT AND FDA ON THE EFFECTIVENESS OF YOUR COMPLIANCE EFFORTS;

A POST-DECREE INSPECTION BY FDA TO EVALUATE YOUR CORRECTIVE ACTIONS AND DETERMINE WHETHER YOU MAY RESUME OPERATIONS;

DESTRUCTION OF VIOLATIVE PRODUCTS ON HAND;

WHEN APPROPRIATE, DISGORGEMENT OR RESTITUTION. (FDA HAS RECENTLY OBTAINED THESE REMEDIES IN AMOUNTS RANGING FROM 30 TO 500 MILLION DOLLARS);

A PROVISION THAT ENABLES FDA TO ORDER THE COMPANY TO HALT OPERATIONS AND TAKE OTHER ACTIONS, INCLUDING PRODUCT RECALLS, IF THERE HAS BEEN BACK-SLIDING (REFERRED TO AS "LETTER SHUT DOWN" AUTHORITY)

AN AARBITRARY AND CAPRICIOUS@ STANDARD OF JUDICIAL REVIEW OF FDA'S DECISIONS UNDER THE DECREE; AND

A REQUIREMENT THAT THE COMPANY PAY FOR FDA'S COSTS OF INSPECTIONS, SCIENTIFIC ANALYSES, AND REVIEW OF YOUR RECORDS.

DO NOT EXPECT THAT YOU WILL BE ABLE TO NEGOTIATE YOUR WAY OUT OF THESE PROVISIONS. A REVIEW OF FDA CONSENT DECREES OVER THE YEARS SHOWS ONLY VERY RARE DEPARTURES FROM THESE PROVISIONS. IN MOST SITUATIONS, BY THE TIME IT HAS BECOME NECESSARY FOR FDA TO SEEK JUDICIAL RELIEF, THE COMPANY HAS HAD MANY OPPORTUNITIES TO CORRECT VIOLATIONS. IT IS FOR THIS REASON B AND REASONS OF FAIRNESS AMONG PERSONS SIMILARLY SITUATED - THAT SUCH COMPREHENSIVE AND ENFORCEABLE MEASURES ARE NECESSARY TO ASSURE ACCOUNTABILITY AND COMPLIANCE GOING FORWARD.

WHEN THE DUST HAS SETTLED WITH FDA, YOU WILL NOT ONLY HAVE SPENT THE MONEY AND DEVOTED THE RESOURCES TO CORRECT THE INITIAL PROBLEM B MONEY THAT YOU THOUGHT YOU WERE SAVING BY POSTPONING COMPLIANCE B BUT ALSO WILL HAVE INCURRED THE ABOVE COSTS AND OBLIGATIONS AS WELL.

III. FAILURE TO COMPLY WITH THE FDCA MAY HAVE OTHER CONSEQUENCES.

EMPLOYEES, WHETHER FOR ALTRUISTIC OR OTHER, LESS NOBLE PURPOSES, MAY FILE QUI TAM SUITS UNDER THE FALSE CLAIMS ACT, 31 U.S.C. s 3729 ET SEQ. THE FINANCIAL INCENTIVES TO BRING QUI TAM CASES ARE SIGNIFICANT: DEPENDING ON SEVERAL VARIABLES, A QUI TAM RELATOR MAY RECEIVE BETWEEN 10 AND 30% OF THE PROCEEDS OF THE CLAIM;[3] (THE PERSON SITTING ACROSS THE TABLE FROM YOU WHO APPEARS TO BE CONSPIRING WITH YOU MAY BE TAKING NOTES FOR HIS OR HER QUI TAM COMPLAINT.)

[3] **31 U.S.C. 3730(d)**

EMPLOYEES MAY DISCLOSE INFORMATION ABOUT YOUR AND YOUR COMPANY'S CONDUCT TO FDA, STATE, AND OTHER REGULATORY AGENCIES;

INDIVIDUAL AND CLASS ACTION TORT SUITS RESULTING IN NINE FIGURE JUDGMENTS;

AGGRESSIVE COMPETITORS CAN BE COUNTED ON TO EXPOSE SHORT-SIGHTED COMPLIANCE DECISIONS TO DISPARAGE YOUR PRODUCTS AND COMPANY. DETAIL MEN ENGAGE OFTEN ENGAGE IN THIS CONDUCT; AND

SHAREHOLDERS MAY BRING SUITS TO CHALLENGE YOUR COMPANY'S FAILURE TO COMPLY WITH THE LAW.

IV. WHAT CAN YOU DO TO PREVENT THESE OUTCOMES?

TO STAY OUT OF FDA'S SIGHTS AND AVOID THE FOREGOING CONSEQUENCES, THE BEST STRATEGY INCLUDES THE FOLLOWING STEPS:

CREATE AND FOSTER A CORPORATE SPIRIT ("CULTURE") OF COMPLIANCE. TELL YOUR EMPLOYEES THAT COMPLYING WITH THE LAW IS A CORPORATE PRIORITY AND BACK UP THE WORDS WITH RESOURCES AND ACTION. CORPORATE CULTURES (AND REPUTATIONS) ARE CREATED BY COMPANY LEADERS. IF LEADERSHIP SETS THE TONE *AND THE EXAMPLE*, ONLY THE OBSTINATE WILL FAIL TO FOLLOW.

ESTABLISH INTERNAL SYSTEMS AND CONTROLS TO DEFINE, MEASURE, MONITOR, AND ASSURE COMPLIANCE.

HIRE AND ASSIGN *QUALIFIED* PERSONNEL TO MANAGE QUALITY ASSURANCE AND COMPLIANCE SYSTEMS AND GIVE THEM THE NECESSARY AUTHORITY AND AUTONOMY TO CARRY OUT THEIR CHARGE.

AQUALIFIED@ INCLUDES NOT ONLY SCIENTIFIC AND REGULATORY KNOW-HOW, BUT INTEGRITY, MATURE JUDGMENT, INITIATIVE, AND A GENUINE DESIRE TO KEEP THE COMPANY ON THE RIGHT TRACK.

CONDUCT PERIODIC REVIEWS WITH YOUR INTERNAL TEAMS TO ASSESS COMPLIANCE. *WHEN PROBLEMS ARE IDENTIFIED, FIND THEIR CAUSES AND FIX THEM.* REGULARLY NOTIFY SENIOR MANAGEMENT, INCLUDING THE BOARD OF DIRECTORS, OF SUCCESSES AND FAILURES.

OBTAIN QUALIFIED, EXPERIENCED, INDEPENDENT EVALUATIONS OF YOUR COMPANY'S COMPLIANCE.

REGULARLY REVIEW WITH INDEPENDENT AUDITORS AND OUTSIDE CONSULTANTS: LISTS OF OBSERVATIONS (FDA FORM 483S), FDA ESTABLISHMENT INSPECTION REPORTS (EIRS), CORRESPONDENCE TO AND FROM THE AGENCY (WARNING LETTERS, UNTITLED LETTERS), AUDITS, AND CONSUMER COMPLAINTS.

ARE THE DATA IN THOSE DOCUMENTS CONSISTENT WITH EACH OTHER? IF NOT, RESOLVE THE INCONSISTENCIES AND IDENTIFY THE REGULATORY PROBLEMS B AND PROBLEM MAKERS -- THAT NEED ATTENTION. *WHEN PROBLEMS ARE IDENTIFIED, FIND THEIR CAUSES AND FIX THEM.*

THE DEPTH OF YOUR REVIEW WILL DEPEND ON YOUR LEVEL IN THE CORPORATE HIERARCHY. YOU MAY HAVE TO RELY ON SUMMARIES, BUT THIS SHOULD BE ACCEPTABLE IF YOU CHOOSE YOUR AUDITORS AND CONSULTANTS WISELY AND HOLD THEM FULLY ACCOUNTABLE FOR THE ACCURACY AND COMPLETENESS OF THEIR REVIEWS. AS I WILL DISCUSS IN A MINUTE, HOWEVER, YOU RELY ON YOUR STAFF AT YOUR PERIL.

REGULARLY NOTIFY SENIOR MANAGEMENT, INCLUDING THE BOARD OF DIRECTORS, OF SUCCESSES AND FAILURES.

TAKE PROMPT AND COMPREHENSIVE ACTION TO CORRECT THE VIOLATIVE SITUATION.

WHEN YOU LEARN ABOUT A VIOLATIVE CONDITION OR PRODUCT, MOVE SWIFTLY, DECISIVELY, AND COMPREHENSIVELY TO IDENTIFY THE CAUSES AND CORRECT THE PROBLEM.

NOTE: A ACOMPREHENSIVE@ RESPONSE ADDRESSES NOT ONLY THE SPECIFIC OBSERVATIONS OF FDA AND YOUR AUDITORS, BUT ALSO THE BROADER IMPLICATIONS RAISED BY THOSE OBSERVATIONS. FOR EXAMPLE, IF YOU LEARN THAT A PARTICULAR SYSTEM HAS NOT BEEN PROPERLY VALIDATED, YOU SHOULD TAKE STEPS TO LEARN WHETHER ALL SYSTEMS HAVE BEEN VALIDATED.

FDA INVESTIGATORS DO NOT HAVE TIME TO EXAMINE ALL OF YOUR PROCESSES AND SYSTEMS IN ONE INSPECTION. HOWEVER, IT IS NOT UNHEARD OF FOR FDA TO LOOK AT OTHER SYSTEMS AND PROCESSES DURING LATER INSPECTIONS.

MONITOR THE CORRECTIVE ACTION TO ASSURE THE FIX WORKS IN BOTH THE SHORT TERM AND LONG TERM.

YOU MAY OR MAY NOT HAVE IDENTIFIED ALL THE ROOT CAUSES OF THE PROBLEM AND YOU MAY OR MAY NOT HAVE PRESCRIBED THE RIGHT MEDICINE

TO FIX THE PROBLEM. THE ONLY WAY TO BE SURE YOU HAVE RESOLVED THE PROBLEM IS REGULAR, CAREFUL, HONEST, AND INDEPENDENT EVALUATION.

COMMUNICATE PROMPTLY AND CONSTRUCTIVELY WITH FDA.

WHEN FDA BRINGS VIOLATIONS TO YOUR ATTENTION, FOR EXAMPLE BY AN FDA-483 OR WARNING LETTER, IMMEDIATELY NOTIFY THE AGENCY OF YOUR INTENTION TO CORRECT THE VIOLATION, AS QUICKLY AS PRACTICABLE TELL THE AGENCY HOW YOU PLAN TO FIX THE PROBLEM, AND GIVE SPECIFIC TIME FRAMES FOR EACH SPECIFIC CORRECTIVE ACTION. ALSO, PROVIDE OBJECTIVE EVIDENCE OF THE CORRECTIONS AS WELL AS THE PREVENTIVE STEPS YOU HAVE TAKEN

HAVE SYSTEMS IN PLACE TO ASSURE THAT FDA COMMUNICATIONS ARE BROUGHT PROMPTLY TO THE ATTENTION OF SENIOR MANAGEMENT.

DO NOT WAIT FOR AN FDA WARNING LETTER BEFORE YOU TAKE ACTION. IT OFTEN TAKES FDA MONTHS TO ISSUE A WARNING LETTER. THIS IS TIME YOU SHOULD NOT WASTE.

IF YOU DISAGREE WITH THE AGENCY'S FACTUAL FINDINGS OR CONCLUSIONS, RESPOND IN A CIVIL AND CONSTRUCTIVE MANNER. KEEP THE DIALOGUE OPEN.

YOUR RESPONSE SHOULD FOCUS ON THE FACTS. PERSONAL ATTACKS ON INVESTIGATORS, CLAIMS OF FDA VINDICTIVENESS, AND THREATENING SUIT AGAINST FDA ARE NOT PRODUCTIVE OR WINNING STRATEGIES. ANY ATTEMPT TO EXCUSE A VIOLATION ON FDA'S FAILURE TO DISCOVER THE PROBLEM DURING EARLIER INSPECTIONS WILL NOT BE HEARD SYMPATHETICALLY. IT IS YOUR RESPONSIBILITY TO ASSURE THE CONTINUOUS COMPLIANCE OF YOUR PROCESSES AND PRODUCTS.

COMPANIES SOMETIMES DECIDE TO DELAY SENDING ADVERSE PRODUCT EXPERIENCE REPORTS TO FDA UNTIL THEY HAVE IDENTIFIED AND FIXED THE UNDERLYING PROBLEM. THESE COMPANIES BELIEVE THAT WHEN THEY TELL THE AGENCY, THEY CAN REPORT THAT THE PROBLEM HAS BEEN RESOLVED.

THIS IS A BAD IDEA.

FIRST, IF YOUR DELAYS EXCEED REGULATORY REPORTING DEADLINES, YOU HAVE VIOLATED THE LAW. ALSO, IN SOME JURISDICTIONS, IT WILL INCREASE YOUR PRODUCT LIABILITY EXPOSURE. I RECENTLY READ ABOUT A COMPANY THAT DELAYED REPORTING ADRs TO FDA. THE JURY AWARDED THE PLAINTIFF $900 MILLION IN PUNITIVE DAMAGES.

SECOND, IT ALMOST ALWAYS TAKES LONGER TO IDENTIFY THE ROOT CAUSE(S) AND FIX THEM THAN COMPANIES PREDICT. THIS DELAY HAS AT LEAST TWO COLLATERAL CONSEQUENCES: (A) THE FDA AND THE PUBLIC HAVE NOT BEEN WARNED, PRODUCT USAGE PATTERNS CONTINUE, AND ADVERSE EFFECTS MULTIPLY; (B) YOU HAVE DUG YOUR VIOLATION HOLE DEEPER BY DELAYING COMPLIANCE BEYOND THE REPORTING TIME FRAMES. BY THE TIME YOU FIX THE PROBLEM (IF YOU EVER DO), THE TEMPTATION IS TO NOT TELL THE AGENCY AT ALL BECAUSE TO DO SO NECESSARILY POINTS OUT THAT YOU HAVE VIOLATED THE LAW.

V. STRICT LIABILITY

EARLIER, I MENTIONED THE POSSIBILITY THAT YOU COULD BE HELD PERSONALLY (NOT JUST YOUR COMPANY) AND CRIMINALLY LIABLE FOR VIOLATING THE FDCA. THE FDCA IS NOT LIKE MOST OTHER CRIMINAL LAWS.

THE FDCA IS A ASTRICT LIABILITY@ STATUTE. THIS MEANS THAT YOU MAY BE INDIVIDUALLY FOUND CRIMINAL RESPONSIBLE FOR A VIOLATION OF THE FDCA B- EVEN THOUGH YOU *DID NOT PARTICIPATE* IN THE VIOLATION, YOU WERE *NOT AWARE* OF THE VIOLATION, AND/OR YOU DID *NOT ACT WITH CRIMINAL INTENT OR EVEN NEGLIGENCE*.

TO STATE THE CASE AFFIRMATIVELY, UNDER THE FDCA, YOU MAY BE HELD CRIMINALLY ACCOUNTABLE FOR THE VIOLATIVE CONDUCT OR PRODUCT BECAUSE YOUR MANAGERIAL POSITION GIVES YOU THE AUTHORITY AND POWER TO HAVE PREVENTED THE VIOLATION BEFORE IT OCCURRED.

THE SUPREME COURT STATED IT SIMPLY:

> A***THE [FD&C] ACT IMPOSES NOT ONLY A POSITIVE DUTY TO SEEK OUT AND REMEDY VIOLATIONS WHEN THEY OCCUR, BUT ALSO, AND PRIMARILY, A DUTY TO IMPLEMENT MEASURES THAT WILL ENSURE THAT VIOLATIONS WILL NOT OCCUR.***@[4]

ALTHOUGH FDA'S *USUAL* PRACTICE IS TO GIVE COMPANIES NOTICE OF THE VIOLATIVE CONDITIONS SO THAT THEY MAY CORRECT THEM PROMPTLY WITHOUT FACING REGULATORY OR JUDICIAL ACTION, DO NOT SIT BACK AND WAIT FOR A WARNING. IN CASES OF OBVIOUS, EGREGIOUS, INTENTIONAL VIOLATIONS, OR VIOLATIONS THAT JEOPARDIZE THE PUBLIC HEALTH, FDA MAY PROCEED DIRECTLY TO COURT WITHOUT PRIOR NOTICE.

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[4] **UNITED STATES V. PARK, 421 US 658,672 (1975)**

WE COME FULL CIRCLE. BY FAR, THE BEST STRATEGY IS TO PUT YOUR COMPANY IN ORDER SO THAT YOU ARE NOT CONFRONTED WITH AN FDA REGULATORY ACTION AND ITS CONSEQUENCES.

VI. STRICT LIABILITY; A CLOSER LOOK B THE SUPREME COURT CASES

LOOK BRIEFLY AT THE TWO SUPREME COURT CASES THAT ESTABLISHED THIS DOCTRINE B *DOTTERWEICH* AND *PARK*

A. UNITED STATES v DOTTERWEICH[5]

MR. DOTTERWEICH BOUGHT DRUGS FROM A MANUFACTURER AND REPACKAGED THEM UNDER HIS OWN LABEL

NO EVIDENCE THAT HE DELIBERATELY COMMITTED THE VIOLATIONS OR THAT HE WAS EVEN AWARE OF THEM; HE MAY HAVE BEEN OUT OF FACTORY THE DAY VIOLATIONS WERE COMMITTED

JURY FOUND HIM GUILTY OF MISBRANDING DRUGS; SECOND CIRCUIT REVERSED

SUPREME COURT REVERSED THE SECOND CIRCUIT AND REINSTATED THE CONVICTION (5-4):

[5] 320 U.S. 277 (1943)

"[THIS TYPE OF] LEGISLATION DISPENSES WITH THE CONVENTIONAL REQUIREMENT FOR CRIMINAL CONDUCT -- AWARENESS OF SOME WRONGDOING. IN THE INTEREST OF THE LARGER GOOD IT PUTS THE BURDEN OF ACTING AT HAZARD UPON A PERSON OTHERWISE INNOCENT BUT STANDING IN A RESPONSIBLE RELATIONSHIP TO A PUBLIC DANGER."[6]

THE COURT CONTINUED:

THE OFFENSE IS COMMITTED ... BY ALL WHO DO HAVE ... A RESPONSIBLE SHARE IN THE FURTHERANCE OF THE TRANSACTION WHICH THE STATUTE OUTLAWS, ... HARDSHIP THERE DOUBTLESS MAY BE UNDER A STATUTE WHICH ... PENALIZES THE TRANSACTION THOUGH CONSCIOUSNESS OF WRONGDOING BE TOTALLY WANTING. BALANCING RELATIVE HARDSHIPS, CONGRESS HAS PREFERRED TO PLACE IT UPON THOSE WHO HAVE AT LEAST THE OPPORTUNITY OF INFORMING THEMSELVES OF THE EXISTENCE OF CONDITIONS IMPOSED FOR THE PROTECTION OF CONSUMERS BEFORE SHARING IN ILLICIT COMMERCE, RATHER THAN TO THROW THE HAZARD ON THE INNOCENT PUBLIC WHO ARE WHOLLY HELPLESS."[7]

B. UNITED STATES V. PARK[8]

JOHN R. PARK WAS CEO OF ACME MARKETS, A MAJOR US GROCERY STORE CHAIN

ACME HEADQUARTERS, INCLUDING PARK=S OFFICE, WAS IN PHILADELPHIA, PA.

ACME HAD 36,000 EMPLOYEES, 874 RETAIL OUTLETS, 12 GENERAL WAREHOUSES

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[6] Id. at 281.

[7] Id. AT 284-85.

[8] SEE n. 4.

1N *1970*, FDA SENT PARK A LETTER REGARDING AN INSANITARY WAREHOUSE LOCATED IN PHILADELPHIA.

IN *NOVEMBER-DECEMBER 1971*, FDA INSPECTED AN ACME WAREHOUSE IN *BALTIMORE*, MD AND FOUND SIMILAR INSANITARY CONDITIONS

FDA CONDUCTED A *SECOND INSPECTION* OF THE BALTIMORE WAREHOUSE IN *MARCH 1972* AND FOUND *IMPROVEMENT*, BUT SOME CONTINUING VIOLATIONS

FDA THEN FILED A 5 COUNT MISDEMEANOR INDICTMENT.

NOTE THAT FOUR OF THE COUNTS WERE FOR OBSERVATIONS MADE DURING THE 1971 INSPECTION; THE FIFTH COUNT CHARGED THE 1972 VIOLATIONS.

THE COMPANY PLEAD GUILTY BEFORE TRIAL; MR. PARK WENT TO TRIAL. HIS DEFENSE WAS THAT HE HAD DELEGATED THE RESPONSIBILITY FOR SANITATION TO SUBORDINATES AND HE EXPECTED THEM B *HAD BEEN ASSURED* BY THEM B THAT THE PROBLEMS WERE FIXED.

THE JURY CONVICTED. THE 4TH CIRCUIT REVERSED, AND THE CASE WENT TO THE SUPREME COURT.

THE SUPREME COURT REVERSED AND REINSTATED THE CONVICTION.

HERE IS WHAT THE COURT SAID:

> **" THUS *DOTTERWEICH* AND THE CASES WHICH HAVE FOLLOWED [HOLD THAT] THE [FOOD AND DRUGS] ACT *IMPOSES NOT ONLY A POSITIVE DUTY TO SEEK OUT AND REMEDY VIOLATIONS WHEN THEY OCCUR BUT ALSO, AND PRIMARILY, A DUTY TO IMPLEMENT MEASURES THAT WILL INSURE THAT VIOLATIONS WILL NOT OCCUR*. THE REQUIREMENTS OF FORESIGHT AND VIGILANCE IMPOSED ON RESPONSIBLE CORPORATE AGENTS *ARE BEYOND QUESTION DEMANDING, AND PERHAPS ONEROUS*, BUT THEY ARE NO MORE STRINGENT THAN THE PUBLIC HAS A RIGHT TO EXPECT OF THOSE WHO VOLUNTARILY ASSUME POSITIONS OF AUTHORITY IN BUSINESS ENTERPRISES WHOSE SERVICES AND PRODUCTS AFFECT THE HEALTH AND WELL-BEING OF THE PUBLIC THAT SUPPORTS THEM."[9]**

I WANT TO EMPHASIZE TWO POINTS ILLUSTRATED BY *DOTTERWEICH* AND *PARK*:

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[9] Id. at 672

1. IT IS NOT ENOUGH THAT YOU CORRECT VIOLATIONS AFTER FDA HAS FOUND THEM. YOUR JOB IS TO *PREVENT* THE VIOLATIONS FROM OCCURRING IN THE FIRST INSTANCE;

2. THE COURT RECOGNIZES THAT YOU HAVE A DIFFICULT JOB AND THAT THE STRICT LIABILITY STANDARD IS ONEROUS. HOWEVER, BECAUSE YOU HAVE *CHOSEN* TO WORK IN AN FDA-REGULATED BUSINESS AND THE POTENTIAL CONSEQUENCES OF YOUR FAILURE TO DO YOUR JOB IS SO GREAT, THE RISKS OF POOR PERFORMANCE SHOULD FALL ON YOU RATHER THAN ON THE PUBLIC, WHICH HAS NO OPPORTUNITY TO PROTECT ITSELF.