

Appendix 14

"LESSONS LEARNED"

The following are quick notes made by participants at the FDA/CDRH/OSB Outside Leveraging ("OL") Seminar on 10/28/98. At the end of the day participants were asked to note the major new concepts they understood as a result of the training. These are listed in no particular order.

Here are 5 concepts to consider in designing your CDRH voluntary OL program:

- ? COMMUNICATION =
 - 50% PERSONAL PRESENCE
 - 40% VOICE TONE
 - 10% MESSAGE
- ? CHANGE=
 - 75% LEADERSHIP
 - 25% MANAGEMENT
- ? BEHAVIOR =
 - PEOPLE BEHAVE IN WAYS THEY
 - THINK YOU EXPECT THEM TO BEHAVE,
 - USUALLY
- ? COMMON GROUND (SHARED INTERESTS)
- ? A CHAMPION IS NEEDED THE PHARMACEUTICAL SECTOR HAD THE HIGHEST PARTICIPATION % IN THE FIRST YEAR OF 33/50!

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- ? These are CREATIVE OPPORTUNITIES:
 - There are NO RIGHT/WRONG ANSWERS

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- ? MYSTERY MODULES (a training aid where the problem is embedded in a scenario and participants must find it, like a game of "Clue")

[With OL programs, Industry does] NOT FOCUS ON LIABILITY –
[Instead they] SPEND MONEY ON FIXES

- ? WE CAN HAVE COMMON GOALS WITH INDUSTRY THAT SURPRISE US
 - ? AUTO INDUSTRY CHANGED INVOICES AND HELPED GOVERNMENT
 - ? [As regulators we should] NOT JUST USE HAMMERS
 - ? WE NEED TO CONSTANTLY CHANGE AND IMPROVE
 - ? SOME OF THESE PROJECTS ARE TOO RESOURCE INTENSIVE
 - ? 30% OFF THE TOP
-

? FOR LEVERAGING TO WORK THERE MUST BE A BENEFIT TO THE ORGANIZATION WE ARE GOING TO BE WORKING WITH. WE NEED TO BE ABLE TO ACHIEVE [OUR] GOALS [S] WITH FEWER RESOURCES

? EMPHASIS ON OUTCOMES, AND NOT PROCESS, CAN LEAD TO INNOVATIVE APPROACHES TO IMPROVE OUTCOMES THAT MATTER.

? A LOT OF LEVERAGE ACTIVITIES ARE ALREADY GOING ON IN FDA

? SUCCESSFUL LEVERAGING REQUIRES DEEP UNDERSTANDING OF HUMAN AND INSTITUTIONAL BEHAVIOR.

? PEOPLE ARE WILLING TO HELP-GIVE THEM A CHANCE

? BABY BOOMERS HAVE A DIFFERENT ATTITUDE, MORE CONDUCTIVE TO COOPERATION

? COMMUNICATE, COMMUNICATE, COMMUNICATE LISTEN, LISTEN, LISTEN

? INDUSTRY KNOWS WHAT THEY NEED – LET THEM USE THEIR EXPERTISE TO DO OUR WORK – TRUST THEM AND USE THEM

? OUTSIDE LEVERAGING [PARTNERS] NEED GOOD INCENTIVES

? EVERYONE HAS SAME PROBLEM – WORKLOAD THAT FEDERAL EMPLOYEES CAN'T HANDLE - NEED SOME OTHER WAY TO GO

? CAN BE TALKING COOPERATIVELY WITH INDUSTRY AT THE SAME TIME YOU ARE PROVIDING SANCTIONS.

? CRIMINAL INVESTIGATIONS, INSPECTIONS, AND POSITIVE PARTNERSHIP ACTIVITIES CAN HAPPEN SIMULTANEOUSLY WITH INDUSTRY AND FDA

? OUTSIDE SPEAKERS, AS WELL AS SEVERAL IN-HOUSE ONES, MAKE THE POINT THAT THE REGULATED INDUSTRY CAN BE DEALT WITH [using] HUGS RATHER THAN HAMMERS.

? CAPITALIZE ON THE INFORMATION RESOURCES WE HAVE IN THE CENTER (for Devices)

? REGULATORY AGENCIES CAN BROKER COMPLIANCE
ACTIVITIES. EXAMPLES: IF YOU PARTICIPATE IN VOLUNTARY
PROGRAM WE WILL NOT INSPECT YOU
?
CARROT VS STICK

? CDRH HAS SEVERAL GOOD EXAMPLES OF OL ALREADY IN
PLACE

? THERE NEED TO BE INCENTIVES “FOR INDUSTRY TO PLAY”
WHICH ARE MEASURABLY COMMENSURATE WITH THEIR
LEVEL OF INVESTMENT

? CONSIDER ALL POSSIBILITIES
?
LET THEM (Industry) TELL US WHAT CAN BE DONE AND HOW
TO DO IT
?
SHOW GOOD FAITH [during] DISCUSSIONS
?
MAKE SURE THERE IS A COMMON LANGUAGE
?
DON'T BE TIED TO THE PAST

? THE REGULATED INDUSTRY MAY BE APPROPRIATELY
REPRIMANDED AND COMPLIMENTED/COMMENDED AT THE
SAME TIME!!! (OBVIOUSLY NOT FOR THE SAME ISSUE!)

? THINK PEOPLE IN FEDERAL AGENCIES CAN COMMUNICATE
WITH ONE ANOTHER AND ACTUALLY GET THE JOB DONE.

? HOW CAN WE OVERCOME THE INTERNAL “NAY-SAYERS”?

EPA/OSHA:

? CAN WE USE OUTSIDE (OTHER GOV'T OR CIVILIAN) ENTITIES
TO DO OUR INSPECTION PROCESS. THEY ARE ALREADY IN
THERE DOING THEIR INSPECTIONS – WHY BE REDUNDANT.
ESPECIALLY WITH HACCP & QSIT BEING IMPLEMENTED
?
ONE CAUTION NOTE – WE MUST BE VIGILANT IN OUR
ETHICS/INTEGRITY.
?
CAUTION NOT TO ALLOW UNAUTHORIZED
PROCUREMENTS [to] “SLIP IN”?

? IT MAY BE POSSIBLE TO DEAL WITH A PROBLEM FIRM USING BOTH VOLUNTARY AND REGULATORY APPROACHES AT THE SAME TIME

? “FIRST PARTY INSPECTIONS” MAY BE A USEFUL ?ALTERNATIVE. COULD IT BE COMBINED WITH HACCP OR QSIT?

? CONTINUING ASSESSMENT OF WHAT FDA ONLY MUST DO– FDA CAN PARTNER WITH OTHERS TO ACCOMPLISH

? NEED TO CONSIDER BRINGING HIGH POINTS OF THIS MEETING TO ATTENTION OF DR. HENNEY – ENTIRE AGENCY NEEDS HER ATTENTION AND TO BROADCAST ACCOMPLISHMENTS THROUGH OUTSIDE LEVERAGING!

? SUGGEST SOMETHING ON INTRANET TO ALL EMPLOYEES RE: MAJOR POINTS OF LEVERAGING – ALSO ACCOMPLISHMENTS

? SOME TASKS CAN BE SHARED WITH OTHER AGENCIES TO INCREASE EFFICIENCY (INSPECTIONS, FINES, ETC).

? GOOD IDEAS WILL GET PARTICIPATION, EVEN IF THE TRADE ORGANIZATIONS ARE NEGATIVE ON THE IDEA

? INVOLVE BAD ACTORS AS WELL AS GOOD ONES AS A WAY TO MOVE THEM TO THE GOOD END. CAN REWARD AND PUNISH AT THE SAME TIME

? CONCERNS THAT FDA MAY NOT BE DOING ITS JOB IF IT IS ENTERING “PARTNERSHIPS” (LEVERAGING) WITH INDUSTRY.

? COMMUNICATION AND NEGOTIATION ARE KEY TO MAKING LEVERAGING WORK

? OUTSIDE LEVERAGING IS NOT LIMITED TO WORKING WITH OUTSIDE PARTIES; IT CAN ALSO INVOLVE (IN THE STANDARDS EXAMPLE, PARTICULARLY) THE ADOPTION OF THE WRITTEN WORK PRODUCT OF OTHERS THAT FDA HAD LITTLE OR NO ROLE IN DEVELOPING

? CONTINUING INCREASING GAP BETWEEN RESPONSIBILITIES AND RESOURCES UNDERSCORES THE IMPORTANCE OF UTILIZING OUTSIDE LEVERAGING.

? DOES “FDA” HAVE TO DO THIS? (Implication: FDA does not need to do everything.)

? DO NOT HAVE TO HAVE ALL THE ANSWERS – THE ANSWERS WILL ARRIVE AT THE TABLE.

? THE OVERALL IMPACT AND IMPRESSION IS VERY EXCITING, HOWEVER, “THE DEVIL IS IN THE DETAILS” WHAT IS THE MOTIVATION FOR INDUSTRY TO PARTICIPATE?

? REDUCE REGULATORY CONTROL

? SAVE OR MAKE \$\$

? ORGANIZATIONAL STATURE “RECOGNITION” PROVIDE INFORMATION

? CONTRIBUTE RESOURCES TO COMMON INTERESTS; PREFER CERTAINTY FOR CONTROL VENTURES

? MIND SHIFT IN INDUSTRY AND FDA [is needed]

? TO HAVE TRUST YOU MUST BE TRUSTWORTHY

? THAT I AM ALREADY INCORPORATING OL

? IT IS ANOTHER EXAMPLE OF THINKING OUTSIDE THE “BOX”

? IT IS IMPOSSIBLE TO COMMUNICATE (WITHIN YOUR ORG. OR [with] PARTNERS) TOO OFTEN OR TOO DIRECTLY

? THE LION’S SHARE OF THE WORK IS OFTEN DOMINATED BY A FEW OF THE REGULATED ENTITIES

? “REGULATORS” NEED TO SEE THEMSELVES AS RESOURCES (WE HAVE CARROTS! WE ARE CARROTS.)

? ENSURE THAT THE ORGANIZATION (FAMILY) [members] ARE ON THE SAME PAGE

? TRYING TO FIGURE OUT HOW TO PAY FOR RUNNING A PROJECT...START UP AND ONGOING...LOOKING FOR “POOLED” RESOURCES

? MULTIPLE COMMON DYNAMICS/THEMES – BUT A BIG ONE IS DECIDING BETWEEN A “STICK” OR “CARROT” – OR SOME COMBINATION THEREOF – FOR “MOTIVATION”

? THERE MUST BE RECOGNITION FROM MANAGEMENT THAT A GREAT (DEAL) OF FRONT-END WORK MUST BE DONE. PERSONAL CONTACT AND AN ESTABLISHED RESPECTFUL RELATIONSHIP ARE REQUIRED FOR SUCCESS.

? YOU MUST IDENTIFY THE COMMON NEEDS, ISSUES/VALUES AND GOALS OF PARTICIPANTS. THEN A DIALOGUE CAN BEGIN.

? OPEN COMMUNICATION WITH THE REGULATED INDUSTRY; MEETING TO DISCUSS ISSUES; NEED FOR A COMMON GOAL
? SOLICITING HELP USUALLY WORKS. WE DON'T HAVE TO DO IT ALONE.

? OTHER CENTERS AND AGENCIES ARE DOING THINGS WE CAN USE WITHOUT HAVING TO REINVENT THE WHEEL. A LOT IS ALREADY BEING DONE
? THE BIG PROBLEM IS HOW DO WE CATALOGUE THIS INFORMATION AND GATHER IDEAS FROM WITHIN OUR CENTER. THIS WORKSHOP ONLY TOUCHED A SMALL NUMBER OF STAFF. THIS WAS AN EXCELLENT PROGRAM.

? EPA'S ABILITY TO CREATE AN AVENUE FOR [a large number of] COMPANIES TO VOLUNTARILY CUT DOWN THE POLLUTION
? THE STRUCTURED, YET SIMPLE, ACTION PLAN LENT ITSELF TO BE EASILY FOLLOWED.
? REMARKABLY ACHIEVING GOAL A YEAR AHEAD OF SCHEDULE

? INDIVIDUALS IN OTHER REGULATORY AGENCIES DESCRIBED WAYS THEY RE-ENGINEERED TO SHIFT/REDUCE THEIR BURDENS WITHOUT REDUCING OR ELIMINATING THEIR ABILITY TO REGULATE THEIR INDUSTRY TO THE SAME DEGREE (I.E., THEY DID NOT NECESSARILY DEREGULATE TO REDUCE BURDEN)

? COMMUNICATE – INTERNALLY AND EXTERNALLY

? OUTSIDE ORGANIZATIONS, INDUSTRY, ETC., ARE OFTEN EAGER TO LEND RESOURCES, TIME, ETC. TO FDA IN ORDER TO

FURTHER AN INTEREST SHARED WITH FDA – I.E. GUIDANCE,
QUALITY ASSURANCE.

- ? KNOW THE VESTED INTERESTS OF THE COMPANIES
 - ? LEARN THE VESTED INTERESTS OF PLAYERS NOT IN
MANUFACTURING IN THE MEDICAL INDUSTRY
 - ? USE THE VESTED INTERESTS INCENTIVES FOR THOSE
OUTSIDE THE AGENCY TO PROVIDE RESOURCES TO THE
AGENCY.
-

- ? BENEFITS FOR FDA EVEN WITH "NOT SO GOOD" FIRMS
 - ? COMMUNICATION IS ESSENTIAL
 - ? MONEY SAVINGS
 - ? WAYS TO MEET REGULATORY REQUIREMENTS IN REDUCING
RESOURCES
 - ? EACH PARTNER MORE RESPONSIBLE.
-

- OUTSIDE LEVERAGING IS CHALLENGING. HOWEVER, IT IS A
FEASIBLE WAY TO EXPAND OUR WORKING POWER.
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- ? OTHER REGULATORY AGENCIES AS WELL AS CDRH ARE
THINKING CREATIVELY
-

- ? “BAD PLAYERS” CAN BE BROUGHT INTO THE PROCESS
LEADING TO COMPLIANCE (VOLUNTARILY), WITH CARE
 - ? WHEN WE HAMPER THE ABILITY TO PERFORM A JOB WELL,
LOOK BOTH INSIDE AND OUTSIDE THE CENTER/THE
AGENCY/THE GOVERNMENT FOR ASSISTANCE
-

- ? FROM THE FIRST THREE SPEAKERS I LEARNED THAT
REGULATORY AGENCIES, SUCH AS FDA , FOUND DIFFERENT
WAYS TO GO OUTSIDE THE 9 DOTS AND PARTNER WITH
INDUSTRY. I NOW BELIEVE THAT FDA CAN DO THIS TO A
MUCH GREATER DEGREE.
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- ? LET FIRMS WITH LESS THAN PERFECT COMPLIANCE OR
REGULATORY STATUS PARTICIPATE IN OUTSIDE
LEVERAGING.
-

- ? NEED TO OVERCOME NAY-SAYERS WITHIN
BUREAUCRACY.
-

? CREATIVE IDEAS CAN FIND AN OUTLET IN THE FEDERAL GOVERNMENT

? OUTSIDE FOLKS TO A LARGE DEGREE ARE WILLING TO HELP, ESPECIALLY IF THEY SEE A BENEFIT FOR THEIR ORGANIZATION.

? LET THE DECISION FOR OUTSIDE LEVERAGING BE DRIVEN BY UNMET REGULATORY NEEDS. THE SOLUTION OR RESOLUTION OF THESE NEEDS PROVIDED A MEANS FOR MEASURING OL SUCCESS.

? [There are] MULTIPLE APPROACHES [to use] WITH REGULATED INDUSTRY...DON'T BE AFRAID TO FAIL.

? TELECONFERENCING: HAS MUCH [to offer].

TELECONFERENCING CAN BE USED TO EDUCATE....

? REACTIVE SOLUTIONS AND PROACTIVE SOLUTIONS- CUSTOMER SATISFACTION...
