OUTSIDE LEVERAGING CASE STUDY: Making Stone Soup*

Case Study Abstract

Outside Leveraging is a concept that enables government agencies to optimize their limited resources by working collaboratively with those with whom they share responsibility for the desired end results/outcomes. It is a recognition of the partnership between the government and the governed to attain shared goals. FDA has a responsibility to protect the public health but it cannot do this important mission alone. FDA cannot personally supervise/inspect the design, testing, production or use of every medical device, drug, food or cosmetic product. FDA must work effectively with academia, health care professionals, consumers, manufacturers, professional organizations and others as partners to achieve the important outcome of protecting the public health.

FDA continues to be a regulatory agency. This reality requires special care be taken to ensure that no conflict of interest or appearance of that violates the trust of the American people. FDA knows, from its study of other regulatory federal agencies, that it is both possible and desirable to achieve core mission objectives with the help of outside resources that expand both the quality and effectiveness of important decisions. This case study tells the story of how one office in FDA began to think differently, from concept initiation to initial implementation. The appendices provide copies of all relevant documents to enable you to replicate the process within your own organization if you choose to do so. We obtained help from many disparate sources along the way. Those sources are referenced to assist you in your process. We share our experience with you in the hopes it may help you in your own outside leveraging journey.

*The Stone Soup metaphor (see Appendix 1) refers to the extraordinary and sometimes surprising outcomes which can be achieved by people with a shared interest pooling their diverse talents and resources to achieve results better than any of them could have accomplished alone.

Outside Leveraging Case Study: Making Stone Soup

Table of Contents

Boxes to Accompany the Case Study

Outside Leveraging Case Study: Making Stone Soup

The Kickoff

Larry Kessler looked out over the crowded conference room and quoted Archimedes, “Give me a place to stand and rest my lever on, and I can move the earth.” Thus began the Office of Surveillance and Biometrics (OSB) Outside Leveraging Seminar on October 28, 1998. The next eight hours were packed with discoveries, challenges to old ways of thinking and imagined possibilities. Outside leveraging is an underutilized government strategy of accomplishing vital work through partnering with others who choose to share responsibility for achieving vital public health and safety outcomes. The FDA attendees who had successfully partnered with industry and professional associations in the past to accomplish important work, smiled in quiet satisfaction to hear their pioneering efforts so affirmed. Those who struggled with the idea of a regulatory agency sharing responsibility for public health with the very industry they regulate listened intently. Some of them were searching for logic flaws that would allow their comfort level to return. Others were trying to make peace with holding two seemingly incompatible belief systems simultaneously.

Background

The OSB Outside Leveraging Seminar was just one reinvention initiative underway at the Center for Devices and Radiological Health (CDRH). The U.S. Food and Drug Administration (FDA), like most government agencies over the last decade, was struggling to effectively accomplish an increasingly demanding and complex mission in the face of ever shrinking resources. Stakeholders wanted foods, drugs, medical devices, and cosmetics that were instantly available, absolutely safe, worked as promised, and, because of the national attention on managing the expensive health care system, cost effective as well. These idealistic expectations combined with an explosion in scientific knowledge and biotechnology and an ever shrinking budget caused FDA and CDRH to reexamine almost every aspect of their operation. The Agency was seeking new ways to accomplish its mission, streamline its processes and redefine the nature of the work.

OSB, led by Dr. Kessler, was participating in critical CDRH reinvention initiatives as well as refocusing and enhancing the capability of OSB to meet their growing postmarket surveillance mission. OSB had been created about four years previously by merging elements of the post market surveillance mission which had been located in other parts of CDRH. The push for more rapid approval of devices had heightened the need to consolidate most aspects of post market surveillance under one leader, one office.

OSB, like any newly formed organization was clarifying its mission, establishing boundaries for roles and responsibilities, merging the various histories, experiences and cultural values of its members, carving out its niche in the CDRH family and attempting to build its rather disparate parts into a smoothly functioning team. Dr. Kessler was the third leader in OSB’s short four-year existence. Faced with inadequate information management systems to

support the critical MDR network (see OSB Fact Box), unclear roles, conflict within the Office and between the Office and its Center counterparts and more demanding work than seemed possible to accomplish, he tasked an OSB team to select a strategic planning consultant to help them take a fresh look at the organization and how it was to progress into the future. The team researched the strategic planning process and interviewed a number of consultants. They selected Mary Jones to assist them in their strategic planning.

Mary gathered data from over 70 sources. Leaders, employees, stakeholders and customers, both inside and outside FDA were given the opportunity to offer their ideas, hopes, criticisms and improvement suggestions for the future of OSB. The data were compiled and provided to the strategic planning team as a springboard for their deliberations and decisions during a series of intense strategic planning meetings conducted over the spring and summer of 1997. A primary motivation for the strategic planning process was to ensure that OSB was expending its precious resources on the most important outcomes and in the most efficient manner.

During one particularly difficult discussion, the group was grappling with the reality of current workload and the demands of pursuing new initiatives. The facilitator asked,

> "Is there anything you do that you could stop doing, or give to someone else to do for you? Several of the people interviewed for the data package mentioned the idea of using industry to do some kind of trend analysis and reporting to cut down on the voluminous raw data that the MDR analysts now have to review. Is this concept expandable to other kinds of work you currently do?"

A very lively discussion ensued with a particularly vehement series of objections coming from an ex-compliance employee who took the lead in voicing his deeply held convictions that, "…. industry couldn't be trusted." While this one participant was particularly vociferous in his views, he simply said out loud the concerns that many FDA employees worried about more privately.

Embracing the idea of "partnering" with those they regulate was a frightening concept to some. Comments such as, "It's the fox guarding the henhouse!" "We're an enforcement agency…the real customer is the American public…they count on us to protect them!" revealed the strong internal conflict inherent in this concept.

Other OSB planning group members offered different perspectives. Pat Spitzig, who had joined OSB after working for the FDA Center for Food Safety and Applied Nutrition (CFSAN), shared her experience with positive and enthusiastic industry partners who had worked with the Agency to implement a quality assurance system, Hazard Analysis and Critical Control Points (HACCP) for the seafood industry. Pat spoke with passion about the potential of such partnering and proposed that the same process might play a role with the device industry.

The argument ebbed and flowed. When the group appeared to have exhausted all the relevant points of view, the issue was tabled and the group moved on to the next issue. Although this discussion was an uncomfortable one for many in the group, the strong feelings expressed served a very useful purpose. Hundreds of ideas had been proposed for consideration by the planning team, both in the data package and during the course of the group process. The emotion and energy generated by this idea insured that it wasn't lost in the winnowing out process inherent in group planning.

This concept touched deeply held beliefs. Most FDA employees are incredibly committed to their responsibility to protect public health. It is the aspect of their jobs about which they are most proud. Although almost everyone acknowledges that the truly "bad actors" of industry comprise a very small percentage, some in FDA fear that a lack of vigilance or a poor decision on their part, will allow those "bad actors" to hurt someone. Some suffer under the illusion that as long as FDA stays in control, stands firm on compliance and enforcement, remains suspicious, demands irrefutable proof in all its interactions and keeps a safe, objective "arms length" from the regulated industry, that they can stave off human injury and death in the areas FDA regulates. Confronting that often unstated but deeply held belief is difficult but potentially fertile ground.

As government regulatory agencies have come to understand…more regulations, more inspections, more distrust and conflict between the regulators and the regulated does not guarantee safe, effective, readily available, cost effective products and services. In fact, using those negative strategies exclusively virtually guarantees that no one gets the desired positive outcomes they want.

The Birth of an Idea

"We will negotiate and implement with outside groups more efficient post market surveillance activities, placing a greater responsibility on them." This was Goal 3 of the OSB Strategic Plan rolled out to the Office workforce in the Fall of 1997. It is notable that at this point in our thought process, this concept was still looked upon as a method to "offload OSB work." The idea of a shared responsibility for public health, a new mental model, was still months away.

Some OSB members volunteered to assist Goal Group 3 in the implementation of this concept. Pat led a committee comprised of Mary Beth Abt, Lily Ng, Dan McGunagle, Carol Herman and Suzanne Rich. The committee met sporadically during the Fall and Winter of 1997 without much progress. Workloads were heavy, the concept was still fuzzy and not everyone was convinced that this was an idea worth pursuing.

Mary and Pat talked periodically by phone trying to find ways to energize and clarify the concept. We discussed overcoming resistance to the idea by demonstrating that other regulatory agencies had had successful experience in similar undertakings. We were convinced that with all the NPR (National Performance Review) and Reinvention initiatives underway that we could find such evidence easily. It wasn't easy. Literature searches for "Leveraging" brought us "leveraged buy-outs"…no, that wasn't what we were searching for. "Outsourcing" gave us lots of stories about contracting out government functions and paying someone else to do it…. No, we didn't have the money to pay someone else. Partnering gave a rich listing of stories, but many of them were simply about working cooperatively on an area of shared interest…That would certainly feel good but it didn't move the mountain of work off the desk.

The literature searches and our continued discussions revealed that we needed to define exactly what we were talking about, what made it different than some of the other concepts we had explored. Pat came up with the words "Outside Leveraging" after hearing a National

Public Radio story that described that concept. That term now replaced the others we had been using imprecisely and interchangeably.

In April 1998, Pat and Dan McGunagle met with Jim Heslin, the FDA Training Officer, seeking his help in locating a consultant expert in Outside Leveraging. Since we did not yet have a definition for this concept, which we had just named, Jim was unable to give Pat a viable lead. Mary and Pat continued to talk by phone. Mary developed a proposed definition:

> **"Outside Leveraging is the creation of relationships and/or formal agreements with others outside the Center for Devices and Radiological Health (CDRH) to obtain services/support for little or no monetary exchange."**

Mary proposed finding speakers from regulatory agencies with positive OL experience and conducting a series of seminars to educate potential OSB OL participants. Pat continued to research a vast array of sources, seeking OL stories and searching for an expert OL consultant.

The Connection Breakthrough

Pat solicited help from the National Performance Review (NPR) group who graciously placed her call for information on their web site on 14 May 1997. Pat heard from a number of people and organizations offering help and ideas. A particularly helpful lead came from her conversation with Gene Reaulau, of Gene Reaulau and Associates, Lake Kiowa, Texas. Gene mentioned that an associate of his, Russ Linden, had prepared some case studies about reinvention successes at EPA, OSHA and the U.S. Customs Service that sounded like the kinds of examples she was seeking.

Pat contacted Russ and explained what OSB was attempting to accomplish. Russ, with great generosity, agreed to provide the three case studies to Pat for use within FDA for a small fraction of his normal fee. Pat received the case studies in July. They eventually led to contact with Mr. Charles Winwood, U.S. Customs Service; Mr. Bob Pitulej, OSHA and Ms. Chris Tirpak, EPA. All three agreed to be keynote speakers at the OSB Outside Leveraging Seminar scheduled for October. We now had three very appropriate and credible speakers from other regulatory agencies, ready and willing to share their OL success stories with OSB. Copies of the case studies for EPA and OSHA are attached at Appendices 2 and 3. Activities in Customs that were described in the case study have been superceded by other reinvention initiatives.

In the meantime, OSB had applied for and had been chosen as a client for a group of NTL (formerly known as the National Training Labs) Organizational Development graduate students who were conducting a practicum as part of their study program. They facilitated an assessment and feedback process in mid-July. OSB staff generated lists of hopes and fears about Outside Leveraging which was very useful in expanding our understanding about potential motivators for OL as well as staff concerns which needed to be addressed in order for OL to be more widely embraced. The NTL assessment summaries are attached at Appendix 4.

During this period Pat developed a proposed statement of work and received a small OSB budget allocation to seek some consultant assistance in designing and facilitating the OL Seminar and the subsequent OL Project Workshop. A number of consultants submitted cost proposals for the work. Some looked promising but unfortunately were priced beyond what the OSB budget could afford. OSB decided to work with Mary Jones, who although not an "expert" in Outside Leveraging, was willing to learn with Pat as the process unfolded.

The Summer of 1998 continued as a "treasure hunt". In addition to her eventual successful contact with the three outside speakers, Pat was pursuing leads about FDA employees who had reportedly conducted OL activities. While there was no central repository documenting such cases, Pat had heard stories from time to time about creative, open minded FDA staff who, faced with an important task to be done and insufficient resources, had figured out ways to accomplish seemingly impossible outcomes by forging relationships with those outside FDA.

Pat tracked down some of these OL pioneers. We interviewed each of them by phone to collect their lessons learned and invite them to be speakers in the OL Seminar. We asked them to focus their presentations to highlight the process and mechanisms they had successfully employed. These internal FDA OL success stories are particularly admirable since they were accomplished on the initiative of a few dedicated individuals, sometimes within an organizational culture that didn't necessarily support or encourage partnering or outreach with the regulated industry.

September and October of 1998 were filled with all of the myriad tasks involved in putting on a seminar (i.e., letters to speakers and invited guests, collecting documents for the participant manuals, conference design and speech writing, posters, resource materials, etc.) These activities consumed enormous amounts of time and energy and without the able assistance of a number of volunteers, particularly Midge Brier at the OHIP Staff College, could not have been accomplished.

Copies of all relevant documents leading up to and including the OL Seminar Participant Manual, which contained copies of the 14 OL success stories presented at the Seminar, are provided at Appendices 5 through 14. Approximately 60 people, the maximum capacity of the room, attended at least part of the Seminar on 28 October 1998. Special invitations were extended to the FDA Office of General Counsel and the CDRH Ethics Office, as we anticipated potential OL projects might need the support and counsel of these two areas of expertise. We wanted them to be aware of the OL philosophy so they could best advise us in the future. We also invited representatives of each CDRH office.

The day was a resounding success. The speakers were dynamic and inspiring; the attendees were enthusiastic; and the volunteers who handled the crucial support functions that make a seminar run smoothly were dedicated and effective. Initial feedback about the Seminar from Dr. Liz Jacobson, the CDRH Deputy Director for Science, is attached at Appendix 15.

The OL Workshop

The day after the OL Seminar, a smaller group of CDRH staff assembled to participate in an OL Workshop. Pat had collected a number of OSB OL project ideas over the last year. Interested OSB employees had been asked to outline a project proposal and bring it with them to the workshop. The intent of the workshop was to engage these OSB employees in further OL project concept development, feasibility analysis and action planning. A few CDRH staff members, including Pat Bianchi, the CDRH Ethics Officer, attended as well to support the OSB staff in their endeavors. Documents pertaining to the design and conduct of the workshop, as well as a list of attendees and projects considered for pursuit are provided at Appendix 16.

The workshop began on a high note. The attendees were bubbling with excitement about the OL Seminar the day before. They wanted to discuss what they'd learned and share ideas that had come to them as a result of the Seminar. The Seminar had been full of presentations with very little opportunity for the participants to process what they had learned and the implications of that learning. The group did accomplish the agreed upon workshop goals but would have liked more time for creative thinking and discussion. In an attempt to be efficient, to save time and money, we had planned the Seminar and Workshop as back-to-back events.

We realized, in retrospect, that our expectations were unrealistic. We pushed forward much too fast. The participants needed more time to absorb, share and apply the learnings of the Seminar to the OL project ideas generated prior to the Seminar. Although we had asked them to arrive with an OL proposal in hand, the speakers at the Seminar had profoundly affected their OL perspective and they needed the gift of time to rethink the proposed projects in a new way.

A better plan would have been to conduct the follow-up workshop as a two-part process. The "day after" OL Workshop should have provided an opportunity for them to process and apply the knowledge gained at the Seminar, perhaps generate some new OL project ideas and ask attendees to select one idea that they would like to further develop. Then, we could have sent them off for a couple of weeks to generate those draft proposals. When they came back together as a group we could have discussed the ideas, conducted the feasibility analysis and developed action plans for those most viable for pursuit. It was a clear case of sacrificing effectiveness for efficiency. We pushed for action at the expense of creative thinking. We may have missed some additional wonderful ideas and outside leveraging opportunities that would have come from the group had they had more time to generate them.

The workshop ended with the project teams tasked to meet and complete their proposals and submit them to Larry Kessler for review. Larry would select the projects he deemed most viable to move forward. The selected OL project teams would brief Dr. Bruce Burlington, the CDRH Center Director, to obtain his approval and support. A list of all the projects considered is provided at Appendix 17. The projects currently tabled are still in consideration and development and their team members have continued to be invited to OL team meetings to insure they stay informed.

For a variety of reasons, OSB chose to use projects initiated by employees for the first stage of their OL efforts. The U.S. Customs Service, in contrast, had chosen their OL targets after careful analysis of those problems they felt would give the greatest organizational impact if resolved. The OSHA Maine 200 Program had targeted the 200 worst companies as their first OL initiative. There are sound arguments to support either approach (e.g., top down or bottom up) in selection of initial OL projects. If we were to repeat this process, we might try a combination of those two approaches.

It is important that the OL project teams have a real commitment to the initiatives they are pursuing in order to maximize their chances for success. Most people feel more committed to tasks they choose for themselves than they do to tasks imposed upon them. Initiating an OL project takes a considerable initial outlay of time, energy and flexibility. Some might argue that the cost/benefit ratio is not sufficiently attractive unless the organization is pursuing its most important outcomes. We believe that there are intangible benefits of learning, trying out new ways of thinking about the nature of the work and how it is best accomplished and establishing sound relationships characterized by mutual trust that can be utilized in the future, that make this initial investment worthwhile.

The FDA Modernization Act (FDAMA) and the new FDA Commissioner, Dr. Henney, have made stakeholder outreach and partnering key priorities for the future success of FDA. Given this new organizational climate, we believe that outside leveraging will become a common practice. The lessons learned and relationships forged during some of these individually initiated projects can make a valuable contribution to FDA's pursuit of more challenging OL projects in the future. A copy of Commissioner Henney's note to all FDA employees encouraging leveraging is provided at Appendix 21.

Obtaining Project Approval

The conflict between "new initiatives" and "real" work became clear in the months after the Seminar and Workshop. The Office Director expressed his conviction that OL is real work. The existing reporting structure and the fact that the OL project team members were already overwhelmed with what their supervisors considered real "real" work meant the road to project initiation, much less success, was a steep hill.

The OL Project team structure was outside the normal leadership hierarchy. The OL Project team members were interested staff volunteers who reported to their supervisors for all other aspects of their jobs. Pat was the designated OL Coordinator but not in a direct reporting relationship with any of the project team members or their supervisory structure. Some of the supervisors had not attended the OL Seminar and were less enthusiastic and/or knowledgeable about the potential of Outside Leveraging. All these factors led to problems in maintaining the level of performance necessary to move the projects forward quickly.

The immediate plan called for polishing the proposed OL Project drafts, conducting a "dry run" of the presentations, and presenting a decision briefing to the Center Director, Dr. Bruce Burlington, in December. This was modified to two dry runs because the initial set of presentations needed more fine tuning of project concepts, briefing materials and presentation skills. The briefing of the Center Director was conducted on February 12th. He was pleased and supportive of the projects. Three of the projects got the "green light." Two

were put on a “back burner” because the investment in resources needed to accomplish them was judged to be too large at this time. One other project was put “on hold” because the political climate would not support our interaction with the target partner at the moment. The Device HACCP project was already approved and underway by this time so it was not part of the briefing.

Two of the projects that were approved to move forward were: the MDR Network Project, to encourage industry to increase analysis of medical device problems, and the Malfunction Reporting Project, to eliminate excess reporting of device malfunctions by further defining "likely to cause serious injury or death." These two projects were eventually folded into one. The third was the Device Use Error Reduction ("DUER") project to reduce "use error" by rewarding manufacturers who work to reduce this kind of error.

Also during this period Larry and Pat were selected for training by the Society for Organizational Learning (SOL) in Boston, MA. The group that awarded them this training opportunity was the High Performance Committee of Human Resource Development Specialists of the Department of Health and Human Services (DHHS), the Veterans Administration (VA), Office of Personnel Management (OPM) and other federal agencies. The SOL, originally out of MIT, focuses on how people and their organizations can be more effective. This training was instrumental in helping OSB embrace new ways of thinking. The OSB managers were trained first. They found the experience valuable and recommended that the entire OSB workforce receive the training as well. We anticipate that this experience will continue to help OSB with future OL initiatives.

OL Project Team Training

A one-day training and coaching workshop was conducted on March 18, 1998 to provide the project teams with an introduction to some win-win negotiation and presentation skills they might find useful in their initial meetings with industry. Larry Kessler, Pat Spitzig, Mary Jones and Pat Bianchi also met with each team individually to assist them in thinking through their initial approach and in polishing their project presentations. The teams also briefed each other to keep everyone informed and share strategies. The agenda for that meeting is provided at Appendix 18.

OL Project Initiation

The OL Project Teams made their initial approach to the stakeholder organizations during the spring of 1999. Their first forays had mixed results. One stakeholder group was immediately enthusiastic; another was unsure; a third group embraced the desired outcome but renegotiated the proposed process with the OL team.

Pat brought the OL Project Teams together in the late summer of 1999 to share their various experiences with one another. Up until this point the teams’ primary focus had been on their own project team and the stakeholder group with whom they were attempting to build a new relationship. As the stories from the various OL Project teams were shared, a rich discussion

of their various experiences ensued. The individual OL project teams came to view one another as a mutual learning support system

Largely because OSB was so strapped for time and money, very little formal support or preparation was provided to the project teams who volunteered to take on an OL project. These dedicated employees have pursued these projects as an additional duty to already heavy workloads. Because of that, progress has been slow, but very encouraging. While we don't yet have the dramatic results that characterize the case studies presented at the OL Seminar, we believe the future of our projects is very promising. Copies of the case studies for each team, which summarize their OL project progress to date, are provided at Appendices 19 and 20. Two of the original OL projects (MDR Network and Malfunction Reporting) were combined into the current Orange County Medical Device Network Project. The teams plan to provide quarterly updates on this site so that interested parties can track their progress and lessons learned. As OSB initiates new OL projects, those case studies will be added and updated quarterly on this web site.

Conclusions

Safe and effective products are a responsibility the FDA shares with many others. Leveraging with groups such as academia, industry and consumer organizations provides all involved with the opportunity to honor that shared responsibility and realize shared benefits. Over the years many creative people in FDA have "done more with less" by engaging in OL activities. Until recently, however, most people in the agency saw leveraging as an exception to the usual methods of accomplishing FDA's mission. This mental model limited most leveraging projects to perceived "low-risk" activities such as FDA encouraged/Industry initiated training course development, etc. What is unique about the work described in this case study is that we in OSB named outside leveraging, defined it, systematized it and obtained organizational sanction to do it as a legitimate way to solve identified problems and/or improve public health outcomes. We also invited others in our Center and the Agency to join with us in exploring leveraging as a viable approach. This is very much in tune with our new Commissioner who has gone on record as wanting to be truthful about what the agency can and will do and the help we need from others to accomplish FDA's vital mission. Dr. Henney wants to share information about and responsibility for public health with all our stakeholders. We believe outside leveraging will provide a welcome, effective and efficient means to accomplish the Agency's goals.

Potential Benefits of OL for Stakeholders and FDA

- Share responsibility for public health with all the players involved who attack the problems and not each other.
- Improve communications and share problem solving among regulators, users, industry and the public.
- Improve feedback loops about actual product experience. Encourage innovative approaches to maximize public health.
- Enhance the science base and intellectual capital addressing public health issues by using the talents and resources of all involved.

Success Stories

EPA's 1991 33/50 Program set a national goal of reducing the environmental release of 17 high priority toxic chemicals by 33% in 2 years and 50% in 5 years. EPA enticed 1300 firms, starting with the worst offenders, to join this voluntary program with a simple "just write us" request which put the responsibility for setting company goals, corrective strategies and verification of their accomplishment squarely on the companies themselves. The country experienced a 40% reduction of toxic waste, exceeding the 1992 goal of 33% by 100 million pounds. Participating companies reported reductions in release of chemicals at nearly 3 times the rate of non-participating companies. The program met the 50% reduction goal 1 year early (1994).

OSHA's 1992 Maine Top 200 program transformed the adversarial and costly, "OSHA inspects/Industry resists" relationship with most of Maine's largest companies, many of which had the worst records for workplace injuries and illnesses. OSHA inspectors acted as teachers, coaches, analysts and feedback providers to help the employers and employees detect and plan for workplace hazard abatement. In the first two years of the program, participating companies found and corrected 70% of workplace hazards resulting in the reduction of overall injury and illness rates in 65% of the companies and a 47.3% decrease in compensible worker compensation claims. The 70% reduction in workplace hazards is particularly impressive when one realizes that the participating employers and employees detected and voluntarily reported six times the number of hazards than OSHA inspectors had detected in the preceding 8 years of inspections at thousands of Maine companies.

The U.S. Customs Service, recognizing that it had insufficient resources to accomplish all it's mission objectives, established data driven priorities and targeted industry leveraging partners to address key issues of mutual concern. A commercial import industry invoicing system was identified as a source of costly delays for all the parties. In working group discussions with industry partners, a mutually acceptable modification of the invoice system was designed that would make the process better for all concerned. Industry gladly implemented the changes, at a cost of approximately $12 million. The cost to the U.S. Customs Service was only that of attending the meetings and engaging in the dialogue.

Quotes from OL Seminar Speakers

"Start at home. If you don't have buy-in within your family, you can't get buy-in outside your Agency."

"Law enforcement, regulatory responsibility does not get in the way of informed, educated, cooperative compliance…you cannot have one without the other…there is a multiple approach to achieving compliance…the companies came to understand this."

"Keep focused on the goal you are trying to achieve…not your argument."

"The vast majority…want to do it right…the few that do not…become targets for…more draconian methods."

Mr. Charles Winwood
US Customs Service
Department of the Treasury

"We understand that enforcement is our main hammer in our tool box…but we don't have to use a hammer in every situation."

Mr. Bob Pitulej
Occupational Safety & Health Administration

"EPA cannot protect the environment all by itself…must have partners…must get them to the table…shift from liability avoidance to environmental problem solving."

"Separate the violation from the violator…"

"Reward results not bureaucracy…the absence of a stick is not a carrot…any 'dumb bunny' knows that…"

Ms. Chris Tirpak
Environmental Protection Agency

FDA SUCCESS STORIES

The FDA Center for Devices and Radiological Health (CDRH) worked with the American National Standards Institute and the International Organization of Standards to develop a standard for contact lens products that reduced agency time spent reviewing new product applications, among many other results. Contact: Dave Whipple

The FDA's award winning, teleconferencing center, run by CDRH's Division of Communications Media has successfully used an ad hoc network of down-link sites sponsored by and paid for groups who partnered with the agency to deliver important public health messages to diverse audiences. Contact: Robert McCleary

The May '98 live, interactive, educational teleconference, *Natural Rubber Latex Allergy Recognition, Treatment and Prevention,* was the result of a precedent setting collaboration between 17 major Federal and non-Federal stakeholder organizations. They contributed funding and other support that allowed this teleconference to be developed and certified for continuing education credit within a very short timeframe. This award-winning international telecast was thought to have reached the largest audience of health care professionals ever via satellite downlink. Contact: Sharon Dillard

FDA's Center for Food Safety and Applied Nutrition (CFSAN) with the support of industry trade groups in the early 1980's launched a program of industry sponsored / FDA endorsed education that continues today. Contact: Cynthia Leggett

The FDA ensures national quality standards for mammography via a State Working Group that assists CDRH in developing Demonstration Projects and a regulatory program. Contact: Ruth Fischer

CDRH and a number of volunteer medical device firms are piloting a process quality control approach that focuses on critical control points (HACCP), that has been successfully used by the seafood industry to insure product safety. Contact: Adrianne Galdi

The FDA Center for Drug Evaluation and Research (CDER) is piloting a program where firms would provide quality assurance information to FDA and consequently undergo modified FDA inspections-- a First Party Audit Program. Contact: Russ Rutledge

In an effort to resolve outstanding issues with refurbishers of medical devices (products that are not subject to the usual level of pre-market and post-market regulatory oversight by FDA), CDRH and the affected industry met in public forums to find points of common understanding and begin a "problem solving dialogue." Contact: Cap Uldriks

To improve statistical information in pre-market applications and thus reduce review times, CDRH's Division of Biostatistics partnered with other organizations to develop outreach programs (e.g., FDLI/FDA joint teleconference on "clinical trials" and statistics: The Secrets of Success." HIMA/FDA workshop on "Bayesian Methods for Medical Device Clinical Studies").

Lessons Learned Quotes collected from OL Seminar Attendees

"Outside Speakers as well as several in house ones, make the point that the regulated industry can be dealt with with hugs rather than hammers."

"Consider all possibilities. Let them tell us what can be done and how to do it. Show good faith in discussions. Make sure there is a common language. Don't be tied to the past."

"It might be possible to deal with a problem firm using both voluntary and regulatory approaches at the same time."

"You do not have to have all the answers. The answers will arrive at the table."

"Regulators need to see themselves as resources…We have carrots. We <u>are</u> carrots!"

"Soliciting help usually works. We don't have to do it alone**."**

Sequel

One year plus after the seminar and initial workshop, we believe the seminar and follow on activities were a useful mechanism to inspire and encourage our staff and managers to better understand and consider the potential of outside leveraging. The speakers challenged our assumptions about what leveraging is possible and helped us redefine the "our" in "our work" to include the stakeholders who share responsibility with us for protecting the public health.

Since the seminar we have learned even more. We have been surprised and gratified that people in industry have shown an interest in our pilot outside leveraging proposals. Not only have they been willing to explore possibilities, they have suggested how we might better work with them and how they might better work with one another…. all with the shared goal of better protection of the public health. The best outcome so far is that industry colleagues have offered to share with each other, via an FDA web page, information we had assumed they would carefully guard from each other as well as from FDA. We are delighted that Commissioner Henney established a Task Force in 1999 to institute leveraging as a primary strategy to accomplish the Agency's mission. Dr. Henney's emphasis on leveraging as a key means of accessing the diverse talents necessary to address emerging health concerns creates a fertile ground in which leveraging initiatives will flourish.

OSB Facts

The Office of Surveillance and Biometrics (OSB) is the organization within the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration that monitors medical device performance. CDRH approves, tests and conducts surveillance and compliance activities to enforce the laws and regulations that pertain to medical devices. OSB collects data from medical professionals and institutions through its Medical Device reporting (MDR) System; analyzes it; and takes the lead in involving the rest of the Center as well as health professionals and the industry, in resolving medical device issues that threaten public health.

OSB receives 90,000 voluntary, mandatory and summary MDR reports each year. Throughout the Center, OSB provides: statistical consulting, primarily for agency pre-market review; epidemiological expertise; and organizes and manages Ad Hoc committees that resolve public health issues that cross Office lines within the Center.

It accomplishes this broad mission with a relatively small staff of 96. OSB's mission touches every American, 23,000 hospitals and treatment facilities, 680,000 health professionals and care providers, and 13,500 manufacturers. OSB is the major feedback loop in the Center connecting the agency's pre-market decision-making with actual post-market experience. It's major challenge currently is that public pressures to speed new therapies to market have been accommodated recently which has resulted in greater pressure on OSB/CDRH to identify problems and take action quickly once products are cleared for market and are in use.

Special Thanks To:

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AOL Case Study Appendices – Table of Contents