

Review Draft

Vision and FDA Reform

**A Report
from the Workshop
of August 21, 1995**

December 1995

Institute for Alternative Futures

TABLE OF CONTENTS

TABLE OF CONTENTS	2
EXECUTIVE SUMMARY	3
FORWARD	6
INTRODUCTION	9
DIVERSE STAKEHOLDERS SHARE ASPIRATIONS THAT ALIGN WITH THE FDA VISION	13
DYSFUNCTIONAL RELATIONSHIPS CREATE BARRIERS TO CHANGE	19
LEGISLATED REFORM CAN ADDRESS PROBLEMS IN THE SYSTEM, BUT WILL IGNORE OR EVEN EXACERBATE CURRENTLY DYSFUNCTIONAL RELATIONSHIPS IN THE PROCESS.	22
A BASIS FOR AN ALTERNATIVE REFORM PROCESS EXISTS	24
APPENDIX A: FDA’S PUBLISHED MISSION AND VISION	29
APPENDIX B: LIST OF PARTICIPATING ORGANIZATIONS	33
APPENDIX C: WORKSHOP AGENDA AND EXERCISE INSTRUCTIONS	36
APPENDIX D: A MODEL FOR DESIGNING SYSTEMS AND RELATIONSHIPS	40

EXECUTIVE SUMMARY

IAF convened a 70-person workshop on August 21, 1995, to develop a vision for FDA reform. Workshop participants from the FDA, Congress, industry, professional and patient groups articulated a deep desire for a system of relationships that can accelerate improvements in public health. Participants also demonstrated the terribly dysfunctional nature of relationships in the current system. The workshop provided valuable insights for those who want to ensure that FDA-reform legislation achieves true progress toward a healthier nation.

Four primary conclusions arose from the workshop:

1. Diverse stakeholders share aspirations that align remarkably well with the FDA vision. The desire to ensure that medical innovation makes its greatest contribution to health is shared throughout the system.
2. Current relationships among the FDA and its stakeholders are dysfunctional and likely to distort the reform process. Mistrust, conflict and disrespect abound, marking the system with a primarily negative orientation.
3. Legislated reform can address problems in the system, but will ignore or even exacerbate currently dysfunctional relationships in the process.
4. A foundation for ensuring a more systematic and effective reform process exists.

The Workshop discussion helped clarify principles that should characterize FDA-reform dialogues. The principles that both the FDA and its stakeholders need to honor include:

1. Acknowledge the existence of a system of relationships and adopt a 'systems view' that encompasses all parties able to work with the FDA to achieve better public health;
2. Examine and understand the system and the dynamic nature of the relationships that define the system's behavior;
3. Recognize that the quality of relationships is as important as the substance;
4. Share responsibility for the quality and substance of the relationships and the behavior of the system;
5. Participate in dialogues to develop a shared vision for the FDA and its role in improved public and individual health;
6. Commit the necessary resources to participate and to align the mission of diverse organizations with a vision for improved public health; And
7. Evaluate the behavior of the system and its diverse participants to support continuous improvement.

These findings and principles can be the basis for vision-based change; a change process with four significant advantages compared to the business-as-usual reform process, which barter interests and power:

First, the process of developing a consensus vision acknowledges that the FDA is part of a large, legitimate system of stakeholder relationships. Therefore, vision-based reform will be grounded upon a deep understanding of stakeholders and their relationships.

Secondly, a vision process requires that all stakeholders be consulted and an ongoing dialogue maintained to strengthen the commitment to serving the system's highest common interest - improved public health. If a true transformation is to be accomplished, all stakeholders must participate and co-generate the change. The relationships among the stakeholders are at least as important as the role and actions performed by each stakeholder, including the FDA itself.

Thirdly, both subjective and objective dimensions of the system need to be considered. Subjective dimensions address how stakeholders feel about the system and include such issues as trust and commitment. Objective dimensions reflect how people think about

and behave toward the system and its network of relationships. It is important to note that legislated reform deals explicitly with objective dimensions of the system, and largely ignores subjective factors .

A vision-based process not only encompasses the subjective as well as objective dimensions, vision also necessarily focuses on the future. This is particularly important for the FDA, since many of the agency's greatest challenges are likely to stem from scientific discoveries, emerging technologies and unanticipated threats to human and animal health. These challenges may be greater in the future and require the collective energy of all system participants to respond. The process IAF advocates will keep all stakeholders engaged during and after the process of legislating reform.

The FDA's large role in American life and the nation's economy makes reform a vital, ongoing process. All stakeholders share a responsibility to assure that the process advances public health. The need to foster scientific innovation in the service of health may be greater than the perceived need to solve specific problems and redress grievances through legislation. This is an opportunity to design strategies for change that will propel the nation into a healthier 21st century.

FORWARD

The Institute for Alternative Futures (IAF) has worked for more than a decade with the various stakeholders and interest groups shaping the Food and Drug Administration (FDA) and related government policies. Prior to 1995, the opportunity to create a shared vision for reform appeared remote. Now FDA-reform holds this promise.

Throughout the 1980s, numerous IAF Foresight Seminars forecasted changes in the system that regulates medicines and medical devices.¹ These forecasts became more compelling by the end of the decade as a result of an extensive project on the future of regulation.² By 1990, growing problems had come into focus, but comprehensive solutions had not. Then the FDA invited IAF to help develop the Agency's vision, and in late 1994 the Agency published its new vision. Remarkably, industry, patient groups and many in Congress, who believe the Agency can better help promote public health, are now aligning themselves with the FDA's new vision. What might this mean? The convergence on the FDA vision and Congress' interest in reform convinces IAF that a new collaboration can contribute to a healthy, vision-based reform process.

Subsequent to an IAF Foresight Seminar, *The Development and Regulation of Pharmaceuticals* (April 1995), IAF has reviewed several FDA reform proposals at the request of Congressional staff. This review reveals that the legislative proposals focus on the FDA's mission and specific responsibilities where problems do exist. However, these legislative proposals are unable to address key areas that are fundamental to successful change. What the legislative process has lacked to date are a compelling and widely shared vision and a 'systems view.'

¹Jonathan Peck and Kenneth Rabin. *Regulating Change: The Regulation of Foods, Drugs, Medical Devices and Cosmetics in the 1990s*. Food and Drug Law Institute; Washington, DC. 1990.

² Institute for Alternative Futures *Foresight Seminars on Pharmaceutical R&D* have included more than 25 Foresight Seminars dealing with the future of the Food and Drug Administration, regulation and clinical trials, along with the videotape, *Pharmaceuticals for the Future*. Copies are available from IAF, Alexandria, Va.

Vision, systems-thinking and even incremental reform can be difficult, challenging and possibly threatening prescriptions for organizations and individuals. IAF experience, however, also shows that vision can provide a remarkably powerful force for creating positive change in complex human systems. IAF is committed to contributing to FDA reform and recognizes that facilitating a vision process can effectively:

- Help stakeholders examine and understand the system and its relationships;
- Encourage stakeholders to take responsibility for current circumstances and commit to changing behavior toward shared aspirations; And
- Generate a new dialogue among stakeholders to design a 'network' of relationships that focus on the health improvements for individuals and populations.

More specifically, IAF intends to:

1. Prepare and circulate the Workshop's findings, accepting comment to create a feedback mechanism for diverse stakeholders;
2. Make itself available to the FDA and its stakeholders as a resource for their own examination of roles and behaviors; And
3. Advance ongoing dialogues. If interest exists, IAF will convene a discussion among stakeholders to design a network of relationships centered on improving health.

In the coming months, IAF will be distributing this report, contacting FDA stakeholders and supporting additional informal and formal discussion about vision and FDA reform.

ACKNOWLEDGMENTS

This report is a product of the Institute for Alternative Futures, a non-profit research and education organization based in Alexandria, Virginia. The following opinions and representations are those of IAF and do not necessarily represent those of Workshop participants, the sponsors of the IAF's Foresight Seminars on Pharmaceutical Research and Development or those consulted in the preparation of this report.

The Institute for Alternative Futures gratefully acknowledges the participants of the Vision and FDA Reform Workshop for their time and candor. A listing of the organizations present at the workshop is located in Appendix B.

The Workshop and this report would not have been possible without the extraordinary leadership of facilitator Roger Fritz of Leadership By Design, Inc., of St. Louis, Missouri.

Draft of this report were reviewed and edited by staff of IAF and Stuart Robinson. The Institute, its Seminars and the Workshop are grateful for the dedication of the IAF staff, particularly Michelle Bowman, Atul Dighe, Gio Gutierrez, Erica Mayer, Kathy Scott and Sandy Tinter.

The 1995 Foresight Seminars on Pharmaceutical Research and Development are underwritten by grants from the Bayer Corporation, Ciba Pharmaceuticals, Glaxo-Wellcome, Hoechst Marion Roussel, Ortho-McNeil Pharmaceuticals, Pharmacia & Upjohn, Inc., Sandoz Pharmaceuticals Corporation, SmithKline Beecham and Zeneca Pharmaceuticals Company.

INTRODUCTION

The US Food and Drug Administration (FDA) regulates over \$1 trillion of consumer products and its actions affect each American every day. Looking toward a future when scientific revolutions could improve the health of people everywhere, the Institute for Alternative Futures (IAF) joins other FDA stakeholders interested in reforming, reinventing and renewing the Agency.

For the past 17 years, IAF has organized its Foresight Seminars on Pharmaceutical Research and Development, bringing both content knowledge and process experience to the effort. The Foresight Seminar series, currently sponsored by nine pharmaceutical companies, provides a forum for Congressional and other policymakers to examine issues from a long-term, strategic perspective. IAF seeks to develop governmental foresight, including the ability to:

- **See the big picture:** Relate specific policy choices to larger contexts of cultural forces, social and economic trends, and scientific and medical discoveries;
- **Identify emerging issues:** Illuminate opportunities and risks that have yet to become policy concerns, but likely will in the years ahead; And
- **Reveal unintended consequences:** Explore the potential for long-term and unexpected side-effects of policies and activities, that could overwhelm or sabotage policymakers' goals.

A variety of Foresight Seminars have discussed FDA roles that take on particular importance in the context of governmental foresight. The **big picture**, described by last year's Foresight Seminar participants, showed dramatic innovation coming "upstream"

and “downstream” of the Agency.³ The human genome project, for example, will lead to new pharmaceuticals and biologics, but also combinations of diagnostic devices and therapeutics.⁴ The combination of products is simply one of many challenges scientific innovation will create on the 'upstream' side, as growing 'pharmaco-genetic' knowledge creates the possibility for far greater customization of products than the current regulatory system can recognize.

Along with the strain of adapting to such upstream scientific innovation, the FDA also faces enormous downstream innovation in the marketplace. Managed care is evolving new forms of decision-making as pharmacy benefit management firms (PBMs) and disease-management systems reshape the market and place new demands for cost and outcomes information. Unfortunately, the FDA has sought to regulate these new demands by applying rules, regulations and paradigms from previous decades that may not suffice any longer. The downstream demand for customized and expanded clinical information will only grow as PBMs evolve further into “health benefit management firms” (HBMs).⁵

What does a **big picture** that shows major innovation surrounding the FDA mean? It clearly means that innovation *within* the Agency is vital. In one 1994 Foresight Seminar, a noted business-school professor (Steven Wheelwright, Harvard School of Business), who has studied innovation across numerous industries and organizations, made this point: The innovation of the health care system requires policymakers to develop a ‘systems view.’ This view shows that innovation is *most* in need in the regulatory system evaluating medical innovation.⁶

Foresight Seminars have identified a number of emerging issues that pose difficult questions for the FDA, while creating potential opportunities for learning how to best facilitate innovation. Emerging computer networks, for example, have the potential to systematically collect longitudinal data for outcomes research. Practices and conclusions that go unquestioned by current regulatory schemes may soon be

³ See the 1994 Foresight Seminars, *Health Care Reform and the Future of Innovation, The Future of Disease Management and The Human Genome Project and the Future of Biotechnology*. Institute for Alternative Futures, 1994, Alexandria, Va.

⁴ Ibid.

⁵ Leslie Epstein of Advanced Paradigm, Inc., coined this term at an IAF Foresight Seminar: *The Pharmaceutical Marketplace*, September 28, 1995. Also, for a discussion of strategies for the evolution of PBMs, see the 1995 report, *Health System Designs*, available from IAF.

⁶ Transcript of the IAF Foresight Seminar: *Health Reform and the Future of Innovation*, June 9, 1994.

challenged by integrated systems that provide knowledge about optimal use of medicines, which may not be evaluable by today's standard clinical trials. Previous Foresight Seminars and current discussions of FDA policies show how difficult it is for the Agency to adapt regulatory models to new knowledge.⁷ This difficulty makes a legislative "quick fix" tempting, but will it work?

Looking at the big picture and the many emerging issues, IAF anticipates that the **unintended consequences** of FDA-reform legislation may well overwhelm the many positive changes being sought. An approach to legislation that begins with problems and then negotiates between competing interests will guarantee 'compromised' rather than 'designed' solutions. In order to design improvements, a 'systems approach' is needed to look more broadly at the roles and behaviors of the many parties who affect and are affected by the FDA.

Legislative proposals have focused on the FDA's mission and responsibilities, but neglected its vision and the responsibilities of various stakeholders. Discussions between Congressional staff and stakeholder organizations to date have showed little or no acknowledgment of the FDA's own recently published vision and mission (see Appendix A). By following the process of hearings and public discussions of various proposals, IAF recognized that there has been a general absence of an explicit vision for the reform process. Thus IAF sought to make a unique contribution to the FDA-reform debate by facilitating a discussion about vision for reform.

On August 21, 1995, IAF convened a workshop of nearly 70 representatives from the FDA and various stakeholder groups to explore aspirations for reforming the Agency. During the four-hour workshop, participants were asked to see the system of relationships among stakeholders and the FDA. As participants discussed this system, they reflected on the improvements they would prefer to see and shared views on the relationships that can best promote and protect the public's health. See Appendix C for a complete discussion of the workshop's methodology.

IAF took extensive notes at the workshop and have informally engaged many participants and other interested parties in discussions about the Workshop's results. A draft report was prepared and circulated for comment. Four primary conclusions emerged from this work:

⁷ Transcript of the IAF Foresight Seminar: *Safety, Efficacy and Cost Effectiveness--The Future of Regulation*. February 1994.

1. Diverse stakeholders share aspirations that align remarkably well with the FDA vision. The desire to ensure that medical innovation makes its greatest contribution to health is shared throughout the system.
2. Current relationships among the FDA and its stakeholders are dysfunctional and likely to distort the reform process. Mistrust, conflict and disrespect abound, marking the system with a primarily negative orientation.
3. Legislated reform can address problems in the system, but will ignore or even exacerbate currently dysfunctional relationships in the process.
4. A foundation for ensuring a more systematic and effective reform process exists.

Each of these conclusions are discussed below including IAF's proposals for possible next action steps.

DIVERSE STAKEHOLDERS SHARE ASPIRATIONS THAT ALIGN WITH THE FDA VISION

Workshop participants described the preferred relationships that could form among the FDA and various constituents to best serve public health. The substance and quality of the relationships that are being sought align with the FDA's own stated vision to be a "trusted ... enabling ... collaborative ... high-performance" Agency.⁸

Roger Fritz, the Workshop facilitator, explained a model for seeing how human systems work and how aligning aspirations and behavior can create a powerful force for change. Appendix D contains a discussion of this 'ABC' model.⁹ He explained that healthy systems and relationships consist of three elements:

- Shared **Aspirations** for system participants and their relationships;
- Identified **Behaviors** necessary to achieve the shared aspirations; And
- Recognized **Circumstances** that present opportunities or barriers to achieving the shared aspirations or behaving in appropriate manners;

IAF has recognized two additional elements that can be added to the model:

- **Develop** strategies to overcome the barriers of recognized circumstances; And
- Periodically **Evaluate** feedback to monitor progress towards the aspirations and behavior that honors those aspirations.

⁸ US Food and Drug Administration, Department of Health and Human Services. *FDA 2000 - Building For The Future, Food and Drug Administration*. FDA; Washington, DC. March, 1995.

⁹ Roger Fritz. *The Aspiring Organization*. St. Louis, Missouri: Leadership by Design. 1995.

Once these elements were explained, participants worked in small groups to describe both current and preferred relationships that could best support public health. The tables below characterize the relationships according to quality and substance.

Table 1.

SUMMARY: Quality of Relationship

FROM	TO
Hierarchical, paternalistic and patronizing	Including all stakeholders
Fearful, suspicious and hostile	Trustful collegial partnerships
Disrespectful, polarized, threatening, erratic, controlling and distrusting	Recognizing stakeholders and FDA as legitimate contributors to the process of scientific and medical discovery, development, review, marketing and patient care.
Play-making, jockeying and seeking advantage and 'wins'	Building teams for exploring issues, developing alternatives and making decisions
Comfortable with conflict and adversarial sclerosis: Accepting quality and substance of current relationship and reluctant to risk change.	Becoming creative allies in promoting and protecting the public's health
Blind	Visionary

Table 2.

SUMMARY: Substance of Relationship

FROM	TO
One-size-fits-all regulation	Regulatory innovation and entrepreneurship with a goal of seeking separate solutions for separate problems and challenges
Role confusion: FDA as role-model, gate-keeper, detective, prosecutor, judge and executioner	FDA as facilitator and moderator
Institutional value vertigo: FDA and stakeholders having and acting on inconsistent values and motives	Established, specific and focused missions for each stakeholder based upon shared aspirations for the system of relationships
Focus on protecting the public's health via product regulation	Patient-centered and disease-centered focus
Concerned with scientific 'objectivity' of compound or device evaluations	Concerned about successful risk communication to providers, patients and the public about well characterized compounds and devices.
Focus on rigidly meeting legislative and regulatory process requirements	Focus on flexibly achieving shared aspirations and vision for network
Seeking to avoid repeating historic crises	Focus on pro-active, preemptive and anticipatory problem solving
Strategic capture of relationships that 'push-out' small and entrepreneurial firms	Sustained and systematic communication among stakeholders to promote appropriate risk taking, sustain a level and rising playing field and encourage entrepreneurship

IAF COMMENTARY ON WORKSHOP RESULTS

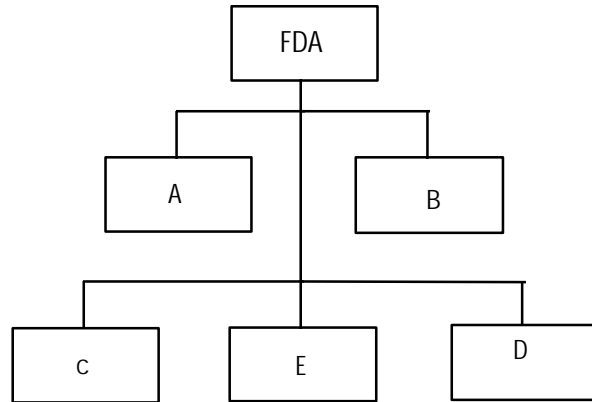
The diversity of the workshop participants makes it all the more impressive that there are such strong common elements in the relationships people would prefer to see develop around the FDA. If the FDA commits itself to a vision that aligns with those preferences, then there is an opportunity for diverse stakeholders to help the Agency move toward that vision. In truth, the quality and substance of the relationships that are generally preferred only can develop from the shared commitment of different stakeholders.

The IAF workshop did not attempt to create a shared vision for FDA and its stakeholders. However, IAF believes that the creation of *health* can be the highest aspiration for the system. This is a vision that can be honored by the FDA, industry, providers, patients, consumers and Congress.

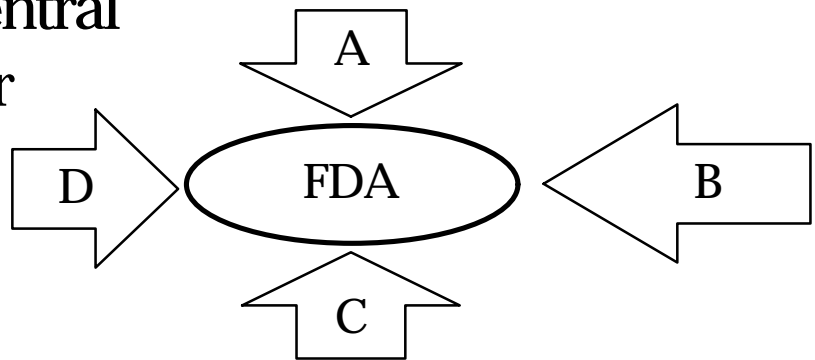
The workshop encouraged a shift in point of view - one that the workshop results suggest must go farther. The workshop helped many participants shift away from what is a hierarchical view of reform (see Graphic A). This view places FDA at the pinnacle and assumes that reform will trickle down through the system.

Models of FDA and Stakeholder Relationships

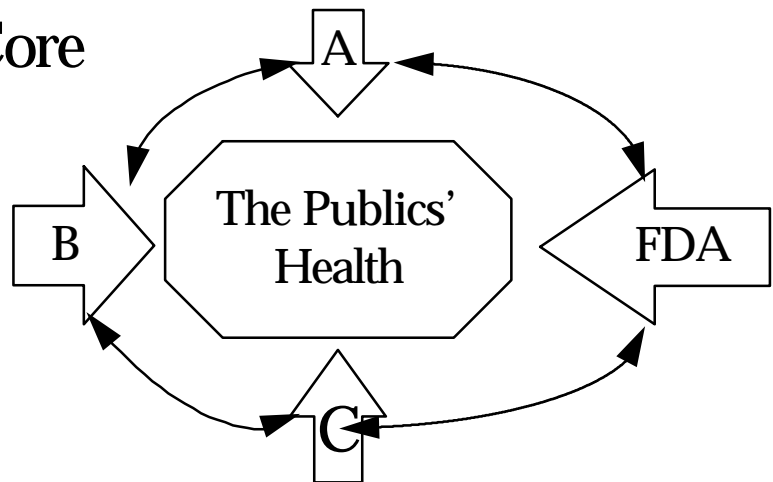
A: Hierarchical



B: FDA as Central Stakeholder



C: The Public's Health As System Core



In contrast, the Workshop exercises encouraged many participants to see how relationships between the FDA and different stakeholders define the system. This view makes the behavior of all parties the focus of reform. The resulting insight is that all parties must own their behavior and take a share of responsibility for reform. This model places the FDA at the center of all relationships (see Graphic B).

This model ignores the truth that reform must help create changes in behavior among the many diverse stakeholder relationships. The FDA may not be central to many of those relationships.

How can such an expanded agenda of reform be accomplished? The answer is as deceptively simple as “ABC” (see the discussion of the ABC model in Appendix D). To reform a system, shared aspirations must motivate changes in behavior and provide all stakeholders with the opportunity to generate positive feedback and show progress. The creation of public health may serve as the highest aspiration common to all the individuals and organizations that relate to the FDA. If such a vision becomes widely shared, then all participants in the system will have to see the behaviors in each relationship that support the vision and those that do not.

This model, shown in Graphic C, makes all the relationships and behaviors in the system important, and creates the most powerful basis to adopt change strategies that advance public health. This is the model for a vision-led system that encourages commitments and behavior throughout the system to move progressively toward greater health. This is the model that IAF advocates as the best hope to drive out the fear and mistrust that now dominate the system.

DYSFUNCTIONAL RELATIONSHIPS CREATE BARRIERS TO CHANGE

The IAF workshop showed that current relationships create barriers to optimizing the public's health. IAF's review of the meeting broke-down the participants' comments into two categories: Quality and substance. The quality of relationships refers to stakeholders' subjective experiences with the relationships. Relationship quality, based upon history, current dynamics and the attitudes/positions of organizations and individual participants, sets the tone for current and future relationships. The substance of relationships is a more objective characteristic focused on the actions, behaviors or obligations of the stakeholders and the Agency. The substance of relationships provide a structural view of processes in the system.

When asked to characterize the current quality of relationships, people from the FDA, Congress, industry, professional and patient groups emphasized 'mistrust' and 'fear.' A terribly negative tone pervaded the descriptions, making a compelling case for change in both quality and substance of the relationships. The current quality of relationships shows the need for restoring trust, while the substance of relationship shows the need for restructuring. The different roles that the FDA has been given or assumed create confusion. This confusion includes incompatibilities and conflicts built into the design of the Agency's functions. This confusion breeds mistrust, which hinders the functioning of all parties and establishes a feedback loop that undermines efforts for continuous improvement.

IAF COMMENTARY ON WORKSHOP RESULTS

The need to redesign the FDA is apparent in the enormous gap between the relationships that exist and the relationships that could move all participants to advance public health. However, if the redesign process encourages the type of behavior that has created the dysfunctional relationships shown by the workshop, there is little likelihood that the system will improve. The process of reform, therefore, should help diverse stakeholders understand that relationships are not one-sided and that all parties must commit to change.

Yet to date, FDA reform has led diverse stakeholders to acknowledge only the need for change **within** the agency. This approach ignores the reality of mixed messages, perverse incentives and convoluted practices that belong to all parties. Congress, for example, has sent mixed messages to the FDA, creating mandates in legislation without appropriating funds to carry out the mandates. Congressional oversight also has played a damaging role, creating incentives within the agency to avoid risks and depriving the public of benefits. Hearings often promote fear, blame and mistrust rather than behaviors that advance health.

Of course, neither Congress nor the FDA has a monopoly on practices that distort the system. Industry, professional providers and patients all behave in ways that create barriers toward a better system for innovation and health. Rather than confront these behaviors in the reform process, there is a tendency to blame the FDA for the system's failings. This tendency amplifies the system's dysfunctionality, creating a negative feedback loop that slows innovation.¹⁰

Dysfunctional relationships often devolve into a blame-game, with neither party willing to take responsibility for the breakdown or invest in the future of the relationship. Many parties are too invested in the problems to share in creative solutions. The result is an unhealthy co-dependency on self-defeating behaviors to which nobody admits. There are haunting similarities between the way people describe relationships between Congress and the FDA, or industry and the FDA, and the picture of dysfunctional families caught in such a dynamic of co-dependencies.

¹⁰ For a discussion of negative and positive feedback in dynamic systems, see *Health Systems Designs* (Op. Cit.).

The FDA's myriad roles create a complex web of relationships, some of which are healthy while others are not. Absent vision, the Agency and its stakeholders have no effective way to align the different behaviors. The effect was described in the workshop as 'value vertigo.' The FDA and other stakeholders are not clear and consistent about the values they uphold and how people work to support those values. This failure to clarify values and provide a coherent orientation creates an inability in the system to assess and change behavior or to see the connection between values and behavior.

**LEGISLATED REFORM CAN ADDRESS PROBLEMS IN THE
SYSTEM, BUT WILL IGNORE OR EVEN EXACERBATE
CURRENTLY DYSFUNCTIONAL RELATIONSHIPS IN THE
PROCESS.**

A review of FDA-reform proposals shows many good ideas that are both well-intended and practical. Insights from the workshop, however, reveal that it would be naive to assume that even well-intended legislation will increase the system's capacity to deliver innovation that improves public health. Legislation, if passed, only will restructure part of the system. And in so doing, the legislative process may inadvertently reinforce some of the very same behaviors that have created the dysfunctional circumstances identified in the workshop. If that occurs, legislation may worsen the quality of relationships.

The focus on the FDA rather than on the system results from a piecemeal problem-solving approach. A process of compromise among competing stakeholders, each advancing narrow self-interests and sharing only the information that makes their case, is unlikely to yield designs for a better system. Congressional staff working under heavy time pressure and a barrage of conflicting proposals and information are placed in a difficult position. Is this the best process for designing true reform of the system? Can this type of reform address all parties in the system whose behavior can advance the creation of health? Probably not. A good design process seeks the most elegant solutions that integrate the needs of the system as a whole.

Legislation that addresses the FDA mission demonstrate what legislation can and cannot achieve. A good mission delineates behavior and guides organizations in setting goals and objectives. A number of legislative proposals will reinforce the FDA's own mission statement "to protect and promote public health," with one striking difference. These proposals reverse the order to have the FDA "promote and protect public health," which

would signal a change in Agency priorities. Some worthwhile mechanisms that could help shift these priorities are included in many reform proposals.

What is not addressed, of course, are the missions of stakeholders who work with the FDA. From a systems perspective, the optimum way to advance health would be to have coordinated missions that serve a common aspiration. But reform legislation only can address one part of the system.

So while legislation can address some structural changes, more than structure has to change. Behavior must change. Yet the behavior of stakeholders in the legislative process shows few signs of this change. What changes are needed? First, behaviors must build trust by showing commitment to agreed-upon aspirations. Legislated FDA reform, however, only acknowledges problems with FDA behavior, creating an atmosphere of blame rather than trust. Since legislation does not touch on the behavior of Congress itself (which has been inconsistent and sometimes destructive) or that of other stakeholders, it may actually undermine trust.

An honest assessment of behavior would acknowledge that the problems with the system do not reside in the Agency alone. In contrast, the legislative process of reform implicitly assumes that only the FDA is responsible, and this likely will create unwanted side-effects. Legislation that emerges from a process skewed by blame could supplant trust and cooperation with an increased level of fear. Those who feel they have been blamed unfairly and dealt with dishonestly will want to retaliate rather than cooperate. At its worst, the system will oscillate between forms of blame, with over regulation blamed first, then de-regulation blamed when problems occur. The system would veer back and forth but never progress. These are dangers that, while unintended, may follow legislated FDA reform if no effort is made to improve the quality as well as the substance of relationships.

A BASIS FOR AN ALTERNATIVE REFORM PROCESS EXISTS

The IAF workshop showed that there is a foundation for initiating an alternative reform process. The foundation is a common desire for a better system upon which further efforts can build. The workshop was just a beginning. IAF will continue to hold discussions about shared aspirations and the alignment of missions and behaviors among stakeholders.

In an exercise that was but an insufficient beginning, workshop participants put forward a number of strategies for change. Table 3 presents several change strategies that were proposed. IAF separated these strategies into two categories: Those that need legislation and those that only need the stakeholders to take action.

Table 3.

Summary: Strategies for Change

Can be done without legislation	Legislation would be needed
Develop new clinical research strategies	FDA to certify and use outside clinical trial review organizations
Reward stakeholders that actively seek to achieve the shared vision	Tort reform
Develop and use process-productivity measures for the FDA	Make scientific advisory boards' decisions binding
Empower Agency reviewers to use more judgment	Increase flow of verified risk and benefit information to consumers about medical products
Increase informal discussions prior to executing clinical research	

Several participants also recommended that Congress and the FDA consider more flexible organizational designs, possibly eliminating the distinctions about what is regulated and focusing solely on levels of potential risk. Such an approach could help the FDA meet new challenges as medicinal foods, combinations of diagnostics and therapeutics and an increasing interest in alternative delivery forms.

IAF concluded the workshop recognizing that the discussions were only a starting point for further work on designing new options, learning about the system of relationships and sharing aspirations for the future. IAF promised to honor the request that this report circulate both among participants and others identified by participants.

IAF COMMENTARY ON WORKSHOP RESULTS

IAF was founded upon a commitment to develop anticipatory democracy, which promises an alternative to the cycle of blame and the proliferation of problems that might be the

unwanted legacy of FDA reform.¹¹ IAF recognizes that the foundation for a process that complements legislation must rest upon two cornerstones. One is the ability to share aspirations among stakeholders and the other is an understanding of dynamic systems.

The most important finding of the Workshop was that a relatively high level of alignment does exist among the various stakeholders who expressed aspirations for relationships with the Agency. The Agency's recently published vision could, therefore, create a good 'jumping-off' point for further dialogue. Clearly this dialogue needs to occur.

The discovery of shared aspirations among the FDA, Congress, industry, provider, consumer and patient groups can create the beginning upon which to build trust and the recognition of mutual purpose. But, there are many issues that need to be settled, including some raised by the FDA vision itself. First, is it the right vision? Then, how do the missions and behaviors of the FDA and the other stakeholders honor and support the vision? These will not be easy questions to answer and may be impossible to address honestly without an increase in the level of trust.

More than good will is needed before all parties move to advance health. This raises the need for the second cornerstone: learning about systems dynamics. Some of those dynamics come from the psychological diversity of participants in the system, while others can be seen in the interplay among industries, technologies and institutional arrangements. To advance health, learning about systems must support continued evolution, adding intelligence to the existing relationships that affect each American every day. IAF is committed to this learning and to sharing the discoveries with others who seek to advance the system.

IAF has identified the following seven principles for breaking dysfunctional relationships and moving toward a productive system:

1. Acknowledge the existence of a system of relationships and adopt a 'systems view' that encompasses all parties able to work with the FDA to achieve better public health;
2. Examine and understand the system and the dynamic nature of the relationships that define the system's behavior;

¹¹ Anticipatory Democracy. People in the Politics of the Future. Clement Bezold, editor. Vantage Books; New York. 1978.

3. Recognize that the quality of relationships is as important as the substance;
4. Share responsibility for the quality and substance of the relationships and the behavior of the system;
5. Participate in dialogues to develop a shared vision for the FDA and its role in improved public and individual health;
6. Commit the necessary resources to participate and to align the mission of diverse organizations with a vision for improved public health; And
7. Evaluate the behavior of the system and its diverse participants to support continuous improvement.

IAF's ongoing FDA-reform work will have three components to create a preferred future for reform and support healthy innovation. IAF will be available to:

- Help stakeholders examine and understand the system and its relationships;
- Encourage them to take responsibility for current circumstances and commit to changing behavior toward shared aspirations; And
- Generate a new dialogue among stakeholders to design a 'network' of relationships that focus on the health improvements for individuals and populations.

More specifically, IAF intends to:

1. Prepare and circulate the Workshop's findings, accepting comment to create a feedback mechanism for diverse stakeholders;
2. Make itself available to the FDA and its stakeholders as a resource for their own examination of roles and behaviors; And
3. Advance ongoing dialogues. If interest exists, IAF will convene a discussion among stakeholders to design a network of relationships centered on improving health.

Readers are invited to send comments and suggestions back to IAF. In part, this report simply provides feedback from the process, reflecting what was said in the exercises conducted during the Workshop. This report also reflects what IAF learned through subsequent discussions about the Workshop. IAF invites those who learned something different to share their insights. Those who see that shared aspirations are worthy of further commitment are invited to join the Institute in taking future steps.

APPENDIX A: FDA'S PUBLISHED MISSION AND VISION

Reprinted from
The FDA Almanac
Fiscal Year 1994

Office of Public Affairs
Food and Drug Administration
Public Health Service
Department of Health & Human Services
5600 Fishers Lane (HFI-40)
Rockville, MD 20857
November 1994

FDA's Mission

The Food and Drug Administration is a team of dedicated professionals working to protect, promote and enhance the health of the American people. The FDA is responsible for ensuring that:

- Foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.
- Regulated products are honestly, accurately and informatively represented.
- These products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

We strive to:

- Enforce FDA laws and regulations, using all appropriate legal means.
- Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct and apply excellent science and research.
- Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.
- Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.
- Identify and effectively address critical public health problems arising from use of FDA-regulated products.
- Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign and international agencies; industry; and academia.
- Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.
- Work consistently toward effective and efficient application of resources to our responsibilities.
- Provide superior public service by developing, maintaining and supporting a high-quality, diverse work force.
- Be honest, fair and accountable in all of our actions and decisions.

FDA's Vision

FDA in the year 2000 will be ...

- A strong science-based agency—to accurately detect and assess health risks, and to set appropriate standards.
- A trusted agency—to enforce the Food, Drug, and Cosmetic Act fairly, uphold safety standards, and protect consumers.
- An enabling agency—to steward needed products and to promote public health.
- A collaborative agency—to strengthen ties to scientific, health provider, and regulatory communities both domestically and internationally.
- A high-performance agency—to capitalize on state-of-the-art information and communication technologies and management systems to enhance performance.
- An employee-valued agency—to recruit, develop and advance employees equitably, and to position the agency to meet the changing work force needs of the 21st century.

FDA principally serves the general public in its health and safety mission. FDA also recognizes its responsibilities to the industries that it regulates and will work with them in shepherding new technologies to the marketplace. Thus it strives to maximize public health protection while minimizing regulatory burden.

APPENDIX B: LIST OF PARTICIPATING ORGANIZATIONS

This alphabetical list is of organizations that participated in the workshop. Participation in the workshop or reviewing this document does not imply endorsement, support or non-support of the workshop, this report or related findings.

American Association of Blood Banks
American Association Pharmaceutical Scientists
American College of Cardiology
American Red Cross
American Society of Hospital Pharmacists
Biotechnology Industry Organization
BPN Software
Ciba Pharmaceuticals
Congressional Research Service
Degge Group
Eli Lilly
Food & Drug Chemical Services
Food and Drug Law Institute
Glaxo Wellcome
Health Care Financing Administration
Health Industry Manufacturers Association
Hoechst Marion Roussel
Institute for Alternative Futures
Johnson and Johnson
Library of Congress
Mallinckrodt Group Inc.
National Association for the Specialty Food Trade
National Association of Community Drug Stores
National Council on Inpatient Information and Education
National Health Council
National Institutes of Health
National Organization for Rare Disorders
National Pharmaceutical Council
Nutrition Week
Office of Senator Kassebaum
Office of Senator Kennedy
Office of Technology Assessment

Parenteral Drug Association
Pharmaceutical Research Manufacturers Association
U.S. Department of Health and Human Services-Public Health Service
U.S. Food and Drug Administration-Center for Drug Evaluation and Research
U.S. Food and Drug Administration-Office of the Administrator
United States Pharmacopeia
Wyeth-Ayerst Research
Zeneca

**APPENDIX C: WORKSHOP AGENDA AND EXERCISE
INSTRUCTIONS**

AGENDA

VISION AND FDA REFORM

Monday, August 21, 1995

- 10:00 AM** Welcome - Jonathan C. Peck
Objectives for Workshop - Jonathan C. Peck
- 10:10** Model for Aspirations - Roger Fritz
Discussion
Vision and Mission Distinction
- 11:00** Exploring Current Working Relationships Between FDA and Key Stakeholders
- 11:30** Designing Preferred Relationships Between FDA and Stakeholders
(A Working Lunch Buffet will be served)
- 12:30** Sharing Vision and Change Strategies for FDA Reform
- 1:30** Concluding Discussion
- 2:00** Adjourn

Exercise 1: Exploring Current Working Relationships Between FDA and Key Stakeholders (30 minutes)

Each round table is to develop and share statements that describe the working relationship between the FDA and the table's designated stakeholder in terms of levels of trust, understanding, confidence and commitment, as well as in terms of the mechanics of the relationship (roles, responsibilities, authorities and processes).

Begin with each participant taking two minutes to identify the most important aspects of the working relationship between the FDA and the designated stakeholder and creating a list that describes the current circumstances.

A volunteer from each table is to write down the statements on a flip chart as each participant reads it aloud. Participants at each round table are invited to compare the statements and develop a realistic description of the current working relationship on flip charts labeled **"FROM"**.

Exercise 2: Designing Preferred Relationships Between FDA and Stakeholders (1 hour)

Each table is to develop a full description of the preferred, future working relationship between the FDA and the designated stakeholder. Each participant begins by considering personal aspirations and beliefs about the potential contribution the FDA and stakeholders can make to public health. From that consideration, each person writes a description of the preferred, working relationship that could and should form between the FDA and the designated stakeholder, including such aspects as levels of trust, understanding, confidence and commitment, along with descriptors of the mechanics of the relationship, including roles, responsibilities, authorities and processes.
(10 minutes)

In pairs at the table, participants share their descriptions of the preferred working relationship. As one person describes the relationship, the other listens, taking note of the values represented in the preferred relationship. Then participants reverse roles so that each person makes one presentation (5 minutes) and listens to one presentation (5 minutes).

Each table is to develop a list of common descriptions of the preferred relationship that were found in the statements shared by people in pairs. A volunteer is to write down these descriptive statements on a flip chart labeled **"TO"**. (10 minutes)

We will conduct a facilitated discussion between the tables to find common statements that can be used to create a vision for how the FDA can best serve public health in the future.

Exercise 3: Sharing Vision and Change Strategies for FDA Reform (30 minutes)

Each table is to use the statements developed in Exercise #2 to create a list of change strategies. The list is to focus on any changes in mission that would help align the FDA and other stakeholders with the vision. (Copies of existing and proposed mission language will be available.)

**APPENDIX D: A MODEL FOR DESIGNING SYSTEMS AND
RELATIONSHIPS**

A Model for Designing Systems and Relationships

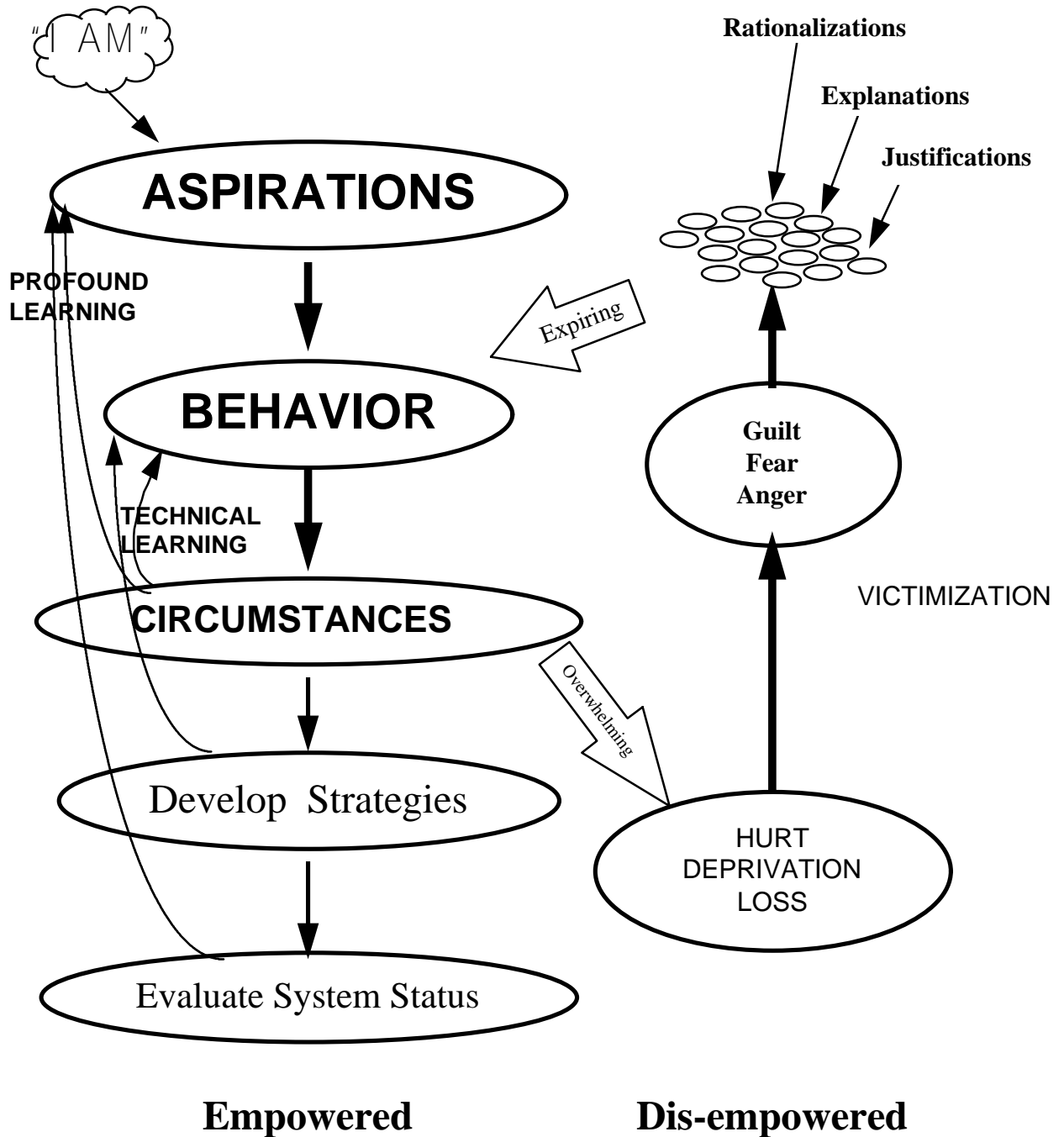
Roger Fritz presented his model for designing systems and relationships, which he developed after thousands of hours of one-on-one sessions counseling individuals on career changes. The model can be used for organizational and institutional change processes as well, but Mr. Fritz encouraged participants to begin by considering the model from a personal perspective.

The model begins with a person's aspirations, which are intimately connected to their values. Each person has a sense of self that may not be known by others, but that is in a deep sense "who I am." People who are looking at their careers will often see how their aspirations become clear when they ask: "Who am I really? Why am I here?" Once those aspirations are articulated and clarified, another conversation opens up: a conversation about behavior.

Behavior refers to mental as well as physical behavior, encompassing what you think, feel, say and do. The conversation about behavior is first a discussion of *alignment* with aspirations. We look for alignment with aspirations as evidence of integrity. Rather than focusing on the moral connotation of integrity, Mr. Fritz emphasizes the meaning of structural integrity. If you think one way, for example, but feel another way, the lack of alignment will be experienced as stress. If your different forms of behavior do not align with each other and your aspirations, you will likely experience stress and begin to question your integrity. If you can see your aspirations, you can then look at your behavior to see if it honors those aspirations.

THE ASPIRATIONS MODEL

Adopted with permission



Leadership BY DESIGN

Another view of your life looks at circumstances. If you sort through the various circumstances of your life, you may find there have been certain times or conditions, where you see your underlying aspirations in your life. These are the shining moments that, if you reflect on them, seem to matter more than the others. Often these are recognizably the times when you honored your aspirations. Upon reflection, you can see your own self-concept in your experience.

When you are clear about your aspirations and you see them reflected in your life circumstances, you have a positive feedback that lets you know who you are and what you are trying to create with your life. Yet we have to acknowledge that many aspects of life do not work this way.

Instead it is often the force of circumstances that trigger our behaviors, and we see the arrows running in the opposite direction. If the circumstances are overwhelming--causing hurt, loss or deprivation -- we become "victims of circumstances." This can be a chronic condition for some people that becomes visible in their behavior. The evidence of victimization appears as a kind of cloud over these people's heads. The cloud is a form of exhaust that appears in their conversations as explanations, rationalizations, justifications and strong opinions, wrapped up in an "attitude."

What is true of individuals is also true for organizations. Aspiring organizations have a vision that helps each individual to align behavior. The organization then monitors changes in circumstances that show how behaviors move the organization toward its vision. Leadership encourages the aspirations of individuals and helps create alignment between the values and vision of the organization and its members. For clarity, IAF has added a 'D and E' to Mr. Fritz's model:

- **Develop** strategies to take the opportunities or overcome the barriers of the recognized circumstances; And
- Periodically **Evaluate** the system and its status using feedback and monitoring systems.

Aspiring organizations are only part of the model, however; there are also "expiring" organizations. These are the organizations that pump rationalizations, explanations and justifications through the system, creating behaviors driven by circumstances rather than

aspirations. These organizations become caught in a negative feedback loop, where the memos, meetings and E-mails become the primary behavior that feeds the very circumstances that victimize the organization. Such behavior moves on the downward spiral of an expiring organization.

This simple “ABC” model of aspirations, behavior and circumstances fits individuals and organizations, and the model may prove valuable for understanding systems as well. Participants in the workshop had this model explained prior to the small group exercises that were designed to explore current behavior as well as aspirations in the system of relationships shaping the FDA.