Using the Law of Requisite Variety (LRV) to Manage Federal Programs

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The Law of Requisite Variety and its Relevance to Federal Administrators

Federal administrators face increasingly complex challenges in meeting the public needs of U.S. citizens. They must design programs that successfully address these needs in virtually every aspect of a citizen's life – including health care, education, the environment, National security, and the Economy to name a few. Within each of these arenas the crux of this challenge is to design programs with a sufficient variety of strategies to accurately match the varied needs of those citizens that are impacted by the Federal response. Insufficient variety does not effectively meet citizens' needs while too much variety poses fundamental challenges in managing the program. Ross Ashby, a pioneer in the field of cybernetics, captured the Federal administrator's dilemma, in his 'Law of Requisite Variety' (LRV), introduced in the 1950s (Ashby, W.R. 1958, Requisite Variety and its implications for the control of complex systems, Cybernetica (Namur) Vo1 1, No 2, 1958). LRV prescribes a generic solution to program design that enables a manager to achieve a desired end state in the most cost-effective manner possible. The solution, in essence, is designing a program that is not so complex that the program itself cannot be managed, but contains sufficient variety and nuance to match the complexity of the problem being addressed. In sum, the solution cannot be overly complex or simplistic. LRV offers a generalized solution to the fundamental challenge faced by Federal program designers.

To bring this concept 'down to earth,' I explained the idea of 'requisite variety' to my son, who is an ardent backpacker and hiker. To apply the idea in his terms I offered the following scenario:

> "I am packing for a one week trip this winter on the Appalachian Trail, which extends from Georgia to Maine. My goal is to survive, and in good physical, mental and spiritual condition. My backpack should contain a sufficient variety of appropriate materials to assure that I meet my goals. If I pack inappropriately (which could mean not having the right gear or insufficient gear) I may get hungry, frozen, lost or attacked by a bear. If I pack for every possible eventuality the backpack will weigh 90 pounds and I will not be able to stand up. So I have to choose the contents of the backpack carefully."

Although correctly packing for a hike on the Appalachian Trail does not approach the complexity of public sector issues that are faced by our Federal leaders, the illustration does capture the essence of the challenges; leaders must design programs with sufficient variety to match the complexity of problems they are addressing.

In this article I will first describe three generic steps required to establish requisite variety in the design of a program or intervention in order to achieve the goals of an organization in a cost effective manner. These steps are universal and apply to any situation in which a manager is attempting to regulate or manage a condition external to the program. Next, I will identify factors that are prevalent in the public sector, and that pose unique challenges to a Federal administrator who is attempting to design effective solutions to complex public issues. I will then illustrate

how LRV is being utilized to manage a highly visible Federal Program, and one that is being closely examined by the new Administration – the U.S. Food and Drug Administration's Office of Drug review. Finally, I offer some generic recommendations that can enhance a Federal program's capacity to address complex public sector issues.

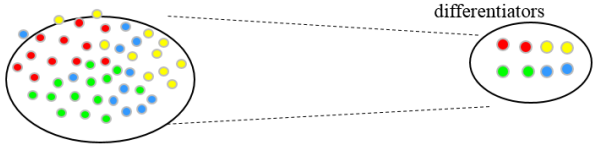
Three Key Steps in Establishing Requisite Variety - Scoping, Modeling, Strategizing

Figure One Below illustrates the three key steps involved in establishing requisite variety in the design of programs. The first step is scoping, in which a program designer identifies the stakeholder environment in all of its complexity. The scoping process can be viewed as a subjective enterprise. One's world view, and how one pays attention to his/her surroundings strongly influences the shape of the 'relevant' universe in which one engages. As Karl Weick has explained: "we act first, and then form our ideas and opinions (of the relevant universe) based on our actions (within that universe), rather than vice versa." (Karl Weick – "The Social Psychology of Organizing" December 1979).

Figure One: Three Steps in Establishing Requisite Variety

1. Scoping: Identify the stakeholder environment in all of its complexity

2. Modeling: Construct a representation of the stakeholder environment, highlighting key differentiators



3. Strategizing: Tailor strategies to address significant components of the stakeholder environment

Model Components	Strategic Approach
●	Strategy One
●	Strategy Two
●	Strategy Three
●	Strategy Four

Step two is modeling, in which the program designer constructs a representation of the stakeholder environment, highlighting features of the environment that are differentiated because they embody significantly different aspects of the problem or issue at hand. The model is a simplification of the complexities in the real world. Each different aspect of the model provides guidance to the program designer, who then must tailor strategies (step three in the requisite variety-creation process) that address each unique aspect of the problem. To illustrate, a police department constructs a model of the universe of possible crimes that may occur within its jurisdiction. Key differentiators that warrant different strategic responses in this milieu may include: personal crimes, property crimes, attempted crimes and statutory crimes. (http://www.legalmatch.com/law-library/article/what-are-the-different-types-of-crimes.html).

Step three is incorporating tailored strategies in the program design that address each key differentiator in the constructed model. To extend the police department analogy, law enforcement program designers differentiate the policies and protocols that are used to address personal crimes as opposed to property crimes, intended crimes or statutory crimes.

Factors That Complicate the Establishment of Requisite Variety in Federal Programs

Initial applications of the Law of Requisite Variety were concerned with mechanical or information systems. For example, the mapping of input bits to output bits in a piece of computer software or hardware can produce an estimate of the minimum hardware or software components necessary to produce the desired control behavior. Unlike computer systems, the design of federal programs is impacted by several factors which complicate the design process. Key factors include:

- Varying decision making models that may be encountered depending upon the specific Federal programs. These may include:
  - ✓ Centralized command and control models with a small cadre of decision makers dominating the decision-making process
  - ✓ Pluralistic models involving key internal and external stakeholders in industry, Congress and the executive branch
  - ✓ Emergent models that work through self-organization and involve vast networks with solutions evolving through creative discourse among nodes of influence that are richly connected through information channels
- Multi-level perspectives required to address problems – e.g., technical, managerial, political and cultural;
- High-velocity operating environments
- Varying degrees of 'reflexivity,' or self-reflection by actors – regardless of the LRV approach taken

Although each of the above factors, are not exclusively the province of the public sector, they nevertheless complicate the program design process.

Varying Decision Making Models – The decision making approach prevalent in Federal agencies ranges across the full spectrum from centralized command-and-control programs (usually internal programs that are isolated from stakeholder influence) to self-organizing networks surrounding programs that collectively arrive at an emergent solution (the U.S. health care challenge is an example of an issue that has been percolating for years through self-organizing networks with no emergent solution in sight). Strategies for implementing LRV must be sensitive to the relevant decision-making model

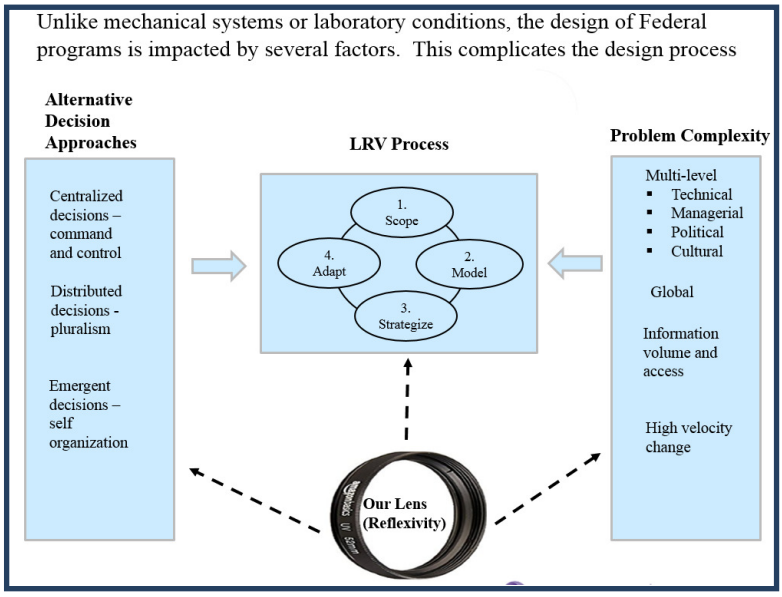
Multi-level perspectives required to address problems – Since Federal programs deal simultaneously with citizens, experts, organizations, institutions, the body politic and the larger

culture, they must be designed to address concerns at each level. Holistic solutions that integrate each of these perspectives are necessary These include technical issues that require subject matter expertise; managerial issues associated with allocating resources in the most cost effective manner possible; political issues that may vary both across the stakeholder spectrum, and through time, for example with the change in Administrations; and cultural issues which can occur within organizations or in the larger society; and which may prove the most chronic and most resistant to change.

High velocity environment –Federal programs must be sufficiently nimble to accommodate rapid changes occurring at all levels in our society. To illustrate a few: New generations of technology in the information and medical fields are succeeding each other at warp speed. The Economy is taking unexpected twists and turns – spurred on by prevailing political inclinations to embrace or refute globalization. Sustainability of the global climate is on an accelerating downward trajectory. The demographics and tastes of the U.S. population are experiencing major shifts. As a result, Federal program designs must be sufficiently flexible in order to keep pace with such environmental changes.

Reflexivity – The concept of reflexivity, or self-reflection, refers to the lens through which actors in the decision-making process view the world around them. How participating actors understand and implement the LRV process in all of its complexities is shaped by each actor's perspective. It is useful for actors to include themselves and their predispositions as an integral part of understanding the scope of problems addressed and the strategies implemented to address these problems. Recognition of one's internal stances opens the door to seeing other possible ways of viewing and addressing the situation at hand. Edmund Husserl (1931) described the processes of 'phenomenological reduction (epoche) and 'imaginative variation' as methods for breaking one's embedded frame of reference in order to see new possible solutions to problems. Phenomenological reduction involves suspending judgments, or preconceived notions, about observed phenomena. It is, in essence, attempting to start with a 'blank slate.' Once reduction is achieved the task of imaginative variation enables the observer to seek new possible meanings through the utilization of imagination, varying the frames of reference, employing polarities and reversals, and approaching the phenomenon from divergent perspectives, different positions, roles, or functions.

Figure 2 below illustrates the influences that each of the above factors exert on the fundamental LRV process:



Applying Requisite Variety to FDA's Office of Drug Review

To illustrate how requisite variety concepts are applied in the Federal environment, I have selected the FDA New Drug Review Program. I worked at FDA for 24 years in their Office of Planning and evaluation; and interacted on a regular basis with FDA's Center for Drug Evaluation and Research.

FDA's Offices of New Drug Review and Generic Drug Review

The Office of New Drugs (OND) is responsible for providing regulatory oversight for investigational studies during drug development and making decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. The Office of Generic Drugs (OGD) reviews generic drug applications (known as abbreviated new drug applications or ANDAs) to ensure patients receive safe, effective and high-quality generic drugs. Together, these offices receive around 100 to 200 new drug applications, of which 20 to 25 comprise new molecular entities; and 40 to 50 generic drug applications annually. (Source: FDA.gov website).Although safety and efficacy is FDA's mandate, the Agency is surrounded by stakeholders with varied goals and interests

FDA Scoping, Modeling and Strategizing

The scope of FDA's new drug environment has been defined in various legislative mandates, beginning with the Federal Food, Drug, and Cosmetic Act of 1938. As public and political

sensitivities to drug issues increased, the scope of FDA's responsibilities in overseeing drug safety and efficacy has also expanded through a series of legislative amendments to the original Act. Today, FDA has modeled this increasingly complex drug environment by differentiating the major kinds of drug challenges they must regulate. Separate offices have been established to address each key drug challenge. These include: investigational new drugs, new molecular entities, generic drugs, and non-prescription drugs.

FDA has tailored strategies to address each unique drug challenge. For investigational new drugs their strategic approach is to require that drug manufacturers submit an investigational application based on animal research to ensure safety prior to clinical testing on human subjects. For new molecular entities the Agency requires an exhaustive new drug application process based on clinical trials with human subjects, to ensure efficacy and a fast track for breakthroughs. For generic drugs the approach is a paper review process once patents have expired. And for non-prescription drugs we ensure that drug monographs exist to explain OTC drugs. The essence of requisite variety is embodied in the process of categorizing drug challenges based on major perceived differences in the nature of the challenge; and the subsequent design of tailored strategies to address each different challenge. If FDA attempts to adopt different regulatory approaches to match each new technology breakthrough in the drug industry, it will overwhelm the Agency's ability to manage its own regulatory programs. One result may be slower drug review times and a backlog of drug applications, thereby preventing life-enhancing or life-saving drugs from reaching the market. Over-simplifying the drug regulatory model can also present threats to the health and safety of U.S. citizens. If the Agency is not sufficiently agile in adapting the regulatory model to address emerging diseases requiring attention, they will be unresponsive to critical needs. This was illustrated during the 1980s when the AIDS epidemic was reaching its peak. At that time, FDA did not have a 'fast track' to accelerate drug review and approval for critically needed products. Activists protesting the absence of a fast track approval process, surrounded and temporarily closed the FDA building that housed the Office of New Drug Review. These protests, in part, influenced the establishment of an accelerated review process for AIDS drugs. (FDA. Pressed to Approve More AIDS Drugs – New York Times October 11, 1988).

FDA's Offices of New Drug Review and Generic Drug Review are in a continuous mode of achieving a delicate balance between simplistic and overly complicated drug review strategies. This is the heart of the requisite variety challenge. Designing programs to achieve this balance is a dynamic process; and one that is subject to ongoing scrutiny by consumers, industry, Congress and the scientific community.

Additional Challenges to Establishment of Requisite Variety and Possible Solutions – the Drug Review Example

The challenge of establishing requisite variety in the design of Drug Review strategies, is exacerbated by three additional problems: 1) the distributed nature of decision making and goal

divergence; 2) multi-level perspectives required to design effective drug review strategies; and 3) the high velocity nature of the drug review operating environment. In the sections below I provide examples of the specific problems associated with each challenge; and offer some plausible solutions – many of which have already been adopted by FDA.

1. The Prevalent Decision Making Model (Pluralism)

The challenge: FDA's drug review programs are surrounded by 360 degrees of stakeholders. Although all stakeholders have the same general aims in mind – availability of safe and effective drugs – there are sharp differences in how the Agency role is viewed, the legitimacy of scientific conclusions that underpin drug review decisions, and in the pace at which drug review should occur. Unlike a company CEO, there is a de facto distribution of power and influence, although putatively FDA makes the final decisions on whether or not to approve a drug for marketing. Differences in opinions and associated political influence concerning such drugs as the "morning after" pill have delayed decisions for years and even decades. One might make the case that the 'de facto' approach to making drug decisions is gravitating toward the 'self-organizing' emergent model. The advent of medical information websites (webMd to name a predominant one) and online social networking are two drivers that are accelerating the distribution of information about drugs, their benefits and side effects. A consumer is the ultimate 'decider' in whether or not to resort to a cholesterol reducing drug. FDA may have made the decision on approving five different statins that are safe and effective; but the self-organizing online social networks and medical information websites may have a stronger influence on the emergence of a 'statin solution' for consumer X.

Plausible solutions: Collaboration among stakeholders in arriving at solutions is essential. FDA drug reviewers must serve as "coaches" as well as "referees" in reviewing industry drug applications. Prior to submission of investigational or new drug applications, FDA officials consult with the industry early in the drug development process to recommend research protocols that are acceptable to the Agency. In other cases, the Agency partners with industry to solve immediate crises that cannot be addressed by either party alone. In 1982, several deaths occurred in Chicago as a result of cyanide being injected into Tylenol capsules. Johnson & Johnson, the manufacturer of Tylenol worked with FDA officials to introduce a new tamper-proof packaging, which included features that signaled to a consumer if tampering was evident. These packaging protections soon became the industry standard for all over-the-counter medications. ("How the Tylenol murders of 1982 changed the way we consume medication" – Dr. Howard Markell, PBS News – September 19, 2014).

2. Multi-level perspectives required to design effective drug review strategies

The challenge - Drug approval decisions are a composite of multi-level perspectives. An effective decision must be considered from technical/scientific, medical, legal, managerial, political and cultural standpoints. At the technical/scientific level, risk assessment is necessary

to determine the nature, incidence and distribution of risk. Decisions on acceptable levels of risks associated with new drugs must also be considered within the existing regulatory framework. Management must determine the risk-benefit tradeoff, and allocate resources appropriately to address the highest priority risks. At the political level, views on the role of FDA vary, dependent upon the Administration in power. Cultural factors at both the agency and societal level must also be considered in making final drug review decisions. To illustrate at the organizational level, FDA lawyers and scientists operate from within different paradigms. Essentially, scientific conclusions are probabilistic in nature. By contrast, legal decisions are binary – the agency approves or disapproves of a drug being marketed commercially. At the societal level, drug approval decisions may be strongly influenced by the prevailing cultural values – e.g., views on birth control.

Plausible Solutions - Several mechanisms have been established to facilitate drug review decisions by mediating among these different perspectives. Although FDA has maintained a stance of political neutrality in light of competing interests, the following mechanisms institutionalize a balanced approach:

- FDA advisory committees have been established to provide a neutral perspective in drug review decisions. In general, each committee includes a chairperson, a consumer representative, an industry representative, and often a patient representative. Additional experts may be added for specific meetings, as needed. Committee membership typically includes ethnic, gender, and geographic diversity. Members have recognized expertise and judgment in a specific field. (Source: FDA Consumer Updates – December 9, 2010)

- User fees paid by the regulated industry for drug reviews drive accountability by establishing performance metrics that monitor the timeliness of drug review decisions. Such accountability necessitates the galvanizing of different perspectives in order to meet review commitments

- Standard protocols have been established that define specific roles for scientists, managers and lawyers in the drug review process. Although scientists 'weigh in' with risk assessments, their role is proscribed. Managers and lawyers also maintain their fundamental roles within their own spheres.

- FDA has established a structured framework for evaluating risks vs. benefits associated with new drugs. The framework operates at the intersection of science, medical, policy, legal and managerial judgment; and forms the backdrop for drug review decisions. The benefit-cost framework was authorized by The Food and Drug Administration Safety and Innovation Act (FDASIA) of July 9, 2012. The Act required FDA to *"implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decision-making, and the communication of the benefits and risks of new drugs."* (Source: U.S. Food

and Drug Administration: "Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision Making" – Prescription Drug User Fee Act Implementation Plan - February 2013)

3. <u>High velocity operating environment.</u>

The challenge: FDA operates in an environment characterized by continuous science and technology advances. The emerging world of new drug development bears little resemblance to the drug development world of even 20 years ago. Innovative breakthroughs include: the use of precision medicines to tailor drug treatments to a patient's genetic make-up; health sensors that can monitor key indicators via devices such as smart phones; 3D printing of drugs that can more accurately construct appropriate dosages; nanotechnology that enables microscopic particles to be introduced into the human body for both diagnosis and treatment; and computers with learning capabilities such as IBM's Watson, that can assimilate and understand millions of pages of scientific research in order to accelerate and focus new drug developments. (Source: ProClinical Life Sciences – December 8, 2015).

These new developments pose a regulatory challenge for both FDA and the pharmaceutical industry. From both a resource and talent perspective it is increasingly difficult for Agency drug reviewers to keep pace with continuous changes in the technologies driving new development. When new drugs arrive at FDA's doorstep the reviewers must be in a position to make approval decisions based on an understanding of the emerging technologies that is sufficient to guide research protocols and review criteria. In the absence of sufficient understanding, the reviewer's only realistic alternative is to defer decisions until the appropriate review protocols can be established. For example, evaluative tools to test the chemical, physiological and medical integrity of the new drug may not yet be in place. This delays the entry of needed medicines into the marketplace. The drug industry is also handicapped because new drugs will not be allowed on the market until a regulatory framework and appropriate evaluation tools are in place. This also becomes an investment challenge for the industry; the regulatory uncertainty surrounding the new technologies provides little guidance to the drug firm on where to focus research efforts.

Plausible Solutions - Steps can be taken that would enable FDA's Drug Review Program to keep pace with new innovations in the industry. The Agency could invest resources in forecasting emerging trends in new drug developments well before they arrive in the form of a drug application awaiting review. A concerted forecasting effort can provide FDA with signals about the technical, economic and societal feasibility of these new developments; and a prediction about when they will emerge. Advanced notice of the more realistic developments will enable the Agency to be better positioned to make drug review decisions. This will be possible by: 1) focusing recruitment and training of chemists, physicians and pharmacologists on the more promising trends in new drug development; and 2) developing the testing protocols that are necessary to evaluate products that emerge from the new technologies.

Other strategies to keep pace include: consultation with and guidance to drug manufacturers early in the drug R&D process to ensure quality applications; online reviews of drug applications to accelerate drug review process; and computer simulations to test impact of new molecular entities on the human body, which reduces the need for time consuming tests using animals.

4. Reflexivity

The Challenge: If you ask any professional working at FDA about the fundamental mission of the Agency, all will agree that it is to ensure the safety and efficacy of the Nation's foods, drugs, biologicals and medical devices. This is not just a slogan to them. They 'live' the mission on a day-in and day-out basis. FDA subcultures, however, tend to have different worldviews when it comes to approaches for how to accomplish the mission. Two of the primary subcultures are the Agency's scientists and its' lawyers. Scientists tend to view all health and safety risks as probabilistic in nature. Every drug, for example, is not entirely risk-free. There are always side effects – which is the reason for the labels that accompany the sales of these products. Scientists virtually never see hazards in black and white, 100% or 0% terms. This is because science results are not completely predictive. Lawyers, on the other hand, must establish regulations that clearly establish 'yes' or 'no' constraints. You are either in compliance with regulations or you are not. Clearly, scientists and lawyers must work together to arrive at safety and efficacy decisions that will protect the U.S. citizen; but the challenge is in finding common ground between two different world views

Plausible Solutions: The establishment of multi-disciplinary advisory groups within the Agency and advisory committees external to the Agency both serve as forums that, at least in theory, enable the two subcultures to view safety and efficacy challenges from each other's perspective. Based on such exchanges, compromises in decisions concerning drug safety and efficacy are arrived at.

Remedies to Enhance Federal Agencies' Capacity to Absorb Variety

Federal program managers can resort to a range of variety-enhancing strategies that will increase their capacity to address complex public sector issues. Although the illustrations below apply to FDA, they are generic in nature, and potentially applicable to any Federal program. One caveat is that these strategies should be carefully evaluated and selected to match the specific characteristics of the Program's operating environment.

- Form partnerships with other stakeholders who have a vested interest in the Program's mission, and whose capabilities complement those inherent in the Federal Program. The result can be synergistic and create a "2+2=5" effect. FDA's collaboration with Johnson and Johnson to develop tamper-proof packaging is an illustration of this synergy.

Johnson and Johnson provided the packaging expertise and FDA contextualized realistic packaging solutions within a realistic regulatory framework.

- Achieve economies of scale by joining with other stakeholders to maximize utilization of available capacity. FDA has established a Food Emergency Response Laboratory Network (FERN). FERN cooperative agreements target state, local and Tribal laboratories to provide increased sample analyses in the event of food outbreaks or other large-scale food emergency events requiring surge capacity testing of implicated food samples. Such a strategy leverages limited resources and spreads fixed costs while expanding overall capacity to deal with a wide variety of food safety threats. (Source: https://www.fernlab.org/)

- Transfer core competencies. This is a strategy for expanding limited available expertise throughout a larger network of multiple stakeholders who have a common vested interest in addressing a public sector challenge. When FDA provides guidance to drug manufacturers early in the drug R&D process to ensure quality applications, they are transferring core competence, and as a result, expanding the capacity of the pharmaceutical industry to provide needed medicines on a timely basis.

- Prioritize risks. This variety-reducing strategy would seem self-evident. However, institutional resistance, often embedded in statute or cultural precedent, poses formidable obstacles to implementing a risk-based strategy. In FDA, there is a statutory requirement to inspect all drug firms at least once every two years. This statue runs counter to a risk-based strategy. It potentially diverts limited resources from focusing on the highest risk firms in favor of inspecting all firms at the required two year intervals.

- Capitalize on information technology to enhance variety absorption. Virtually every Federal program has at least potentially increased its capacity to absorb variety in addressing public sector issues. At FDA the drug review process can potentially be accelerated by allowing drug firms to submit online drug applications. However, having more rapid access to information may also expand a program's reach rather than its grasp.

- Improve process design**.** Business process reengineering can be a powerful tool in accelerating the throughput of a process such as drug review. The Drug Review program has designed its review process so that steps that were once carried out in sequence, can now be performed in parallel operations.

Summary

Federal managers instinctively employ the Law of Requisite Variety in managing complex public sector problems, although they may not be familiar with the theoretical construct. Nevertheless, they 'model,' or build a representation of, their universe of issues in order to simplify a very complex situation. The process of modeling is an exercise in interpreting the most critical differentiators. Even when an Agency's mission is anchored in statute, interpretation of the law is part of the modeling process. The manager's challenge is achieving a delicate balance between simplistic and overly-complex management approaches. Unlike closed mechanical systems, the LRV approach encounters extenuating circumstances when applied in the dynamic open system environment of a federal program. Strategies are available to assist in reducing complexity and enabling successful problem management…if not resolution. FDA's Offices of New Drug Evaluation and Generic Drug Evaluation have done a commendable job of establishing requisite variety in their program design. Because of the open system nature of these programs, the offices are kept in check by their many stakeholders if they err in oversimplifying or over-complicating the programs.

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