[Slide: Overview]

Slides by Morris Bosin

Today’s presentation will cover how federal leaders design programs that successfully address the complex and varied needs of their stakeholders. We will discuss how they design a management approach with a sufficient variety of strategies to match the varied needs of the stakeholders; how insufficient variety does not effectively meet stakeholder needs while too much variety poses fundamental challenges in managing the program; we will establish that requisite variety requires achieving a delicate balance between over-complexity and over-simplification; and conclude that you need to collect the right kind of information about the environment in order to design effective strategic responses.

[Conversation with My Son – An Ardent Backpacker and Hiker]

To illustrate what the Law of Requisite Variety is I will read this conversation with my son:

* Me: Would you like to hear about a topic I'm discussing at an upcoming forum?
* Son: If you must.
* Me: It's called the Law of Requisite Variety
* Son: Explain
* Me: Blah blah blah
* Son: Let me see if I can explain it in my own terms
* I'm packing for a one week trip this January on the Appalachian Trail. If I don't pack the right stuff 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 won't be able to stand up. So I have to pack for the important stuff.

Son: Did I get it?

* Me: You got it!

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

There are three key steps in establishing requisite variety. The first step is scoping, in which you identify the stakeholder environment in all of its complexity. Step two is modeling, in which you construct a representation of the stakeholder environment highlighting its key differentiators. Step three is strategizing, in which you tailor strategies to address significant components of the stakeholder environment.

[Unlike mechanical systems or laboratory conditions…]

Unlike mechanical systems or laboratory conditions, the design of federal programs is impacted by several factors which complicate the design process. One of the factors contributing to the complication of the design process is the distributed decision making and goal divergence between the different levels and branches of government, citizens and industry. Another factor is problem solution being spread over multiple levels: technical, political, managerial and cultural. A third factor is the high velocity environment.

[Applying Requisite Variety to Two Federal Programs]

To illustrate these concepts I will apply requisite variety to two federal programs: the FDA New Drug Review and the Bureau of Indian Education.

The FDA New Drug Review is responsible for reviewing investigational, new, and generic drug applications from industry to determine their safety and efficacy. They receive around 100 to 200 new drug applications annually, and about 20-25 new molecular entities are also reviewed. Although safety and efficacy is their mandate, the FDA is surrounded by stakeholders with varied goals and interests.

The Bureau of Indian Education oversees educational standards and teaching strategies for 183 BIE-owned schools, and Tribal schools, which enroll over 41,000 students, as well as Indian colleges and universities. The Bureau must respect the sovereignty of Tribal nations and work in the best interest of students' current and future quality of life.

[FDA Drug Review Example]

In the case of the FDA when we take step one, scoping, we identify the scope of drug development efforts that must be regulated to ensure safe and effective use. In step two, modeling, we determine the key differentiators to be investigational new drugs, new molecular entities, generic drugs, and non-prescription drugs. In step three we tailor strategies to address significant components of the drug universe. For investigational new drugs our strategic approach is an investigational application to ensure safety as well as early consultation with the drug developer. For new molecular entities our approach is an exhaustive new drug application process to ensure efficacy and a fast track for breakthroughs. For generic drugs our 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.

[FDA Example – Two Extremes]

In this example there are two possible extremes: over complexity or over simplification. The symptoms of over complexity in the management model are the proliferation of drug standards to match new technology breakthroughs overwhelming the ability of the FDA to manage or industry to comply, slower drug review times, and a backlog of drug applications. The symptoms of over simplification in the management model are the FDA’s unresponsiveness to critical demands for treatment (the AIDS epidemic for example) and the utilization of traditional brick-and-mortar, paper-intensive regulatory practices in light of the online trading environment and globalization of drug industry.

[FDA Complexity Challenges and Variety Reducing Solutions]

The FDA problem has several challenges and variety reducing solutions.

One challenge is that drug approval decisions are a composite of multi-level perspectives. The technical perspective is the science that assesses the risk, the managerial perspective are the reviewers who must consider costs vs benefits in managing the risk, the political perspective is influenced by the views of the current administration and the cultural perspective is that lawyers and scientists operate from different paradigms and yet must arrive at a consensus. The impact of all this is slower drug reviews and that needed medications do not reach patients. The variety reducing solution is collaboration such that FDA advisory committees provide a neutral perspective in drug review decisions; standard protocols define specific roles for scientists, managers and lawyers in the review process; user fees for drug review and performance metrics drive accountability and help to galvanize different perspectives to support review decisions; and the FDA attempts to maintain political neutrality.

[FDA Complexity Challenges and Variety Reducing Solutions 2]

Another challenge is the high velocity technology environment making it difficult for drug reviewers to keep pace with changes and difficult for pharmaceutical firms to focus drug development efforts so that they comply with FDA research protocols. The impact of these difficulties is again that there are slower drug reviews and that needed medications do not reach patients. The variety reducing solution includes technology forecasting in which chemists, physicians and pharmacologists are recruited and trained based on forecasting emerging trends in new drug development; early consultation to provide 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.

[Indian Education Example]

Our next example is the Bureau of Indian Education. In step one we identify the scope of Indian Education challenges in Indian Country. In step two we determine the key differentiators to be tribal schools, BIA-owned schools, Indian colleges, and preschool. In step three we tailor strategies to address significant components of the Indian Education universe. For Tribal schools our strategic approach is administrative support to assist the Tribes in managing their own schools. For BIA-owned schools our goals are school modernization through construction and broadband access. For Indian colleges our approach is to enhance scholarships. And for preschool our focus is early child and family development programs.

[Indian Education Example – Two Extremes]

In this example there are two possible extremes: over complexity or over simplification. The symptom of over complexity in the management model is the proliferation of approaches to educational standards between Federal, state and Tribal entities strain school administrators' capacity to teach and test simultaneously. The symptom of over simplification in the management model is over-reliance on uniform national educational standards is unresponsive to individual needs for educational standards at the Tribal level.

[Indian Education Challenges and Variety Reducing Solutions]

The Bureau of Indian Education problem has several challenges and variety reducing solutions.

One of these challenges is conflicting federal, state and tribal standards of learning as well as the tension between goals of maintaining cultural integrity and preparing students to succeed in the larger society. The impacts of this are that testing overwhelms the teaching environment, leaving little room for learning; frustrated students who are being tested at levels beyond their capacity and students who are marginalized between cultures that detract from learning readiness. The variety-reducing solution for this challenge is collaboration among governing entities to align standards, to have minimum core competencies throughout, and to establish intergovernmental bodies, as well as establish strong leadership at the school level that can mitigate the impact of complex and competing standards. Strong leaders are great variety reducers.

[Generic Strategies to Reduce Complexity/Absorb Variety]

There are some generic strategies to reduce complexity and absorb variety.

One strategy is to form partnerships that combine complementary capabilities and create synergies, the "2+2=5" impact. An example of this is a partnership between Johnson & Johnson, the FDA, and the FBI to develop a holistic solution to Tylenol tampering.

[Stuart: for younger readers it might be wise to say briefly what “Tylenol tampering” means.]

Another strategy is economies of scale. An example of this is that FDA shares laboratory space with other Federal and state agencies to spread fixed costs. Another example is schools spread fixed costs by renting facilities for non-education purposes.

A third strategy is to transfer core competencies. In terms of the FDA example this would mean providing guidance to drug manufacturers early in the drug R&D process to ensure quality applications. Another example would be establishing teacher mentoring programs.

[Generic Strategies to Reduce Complexity/Absorb Variety 2]

Another strategy is to prioritize risks. One example of this would be to assess student risks and design tailored educational curricula for students at highest risk. In terms of the FDA example this would mean establishing a fast track reviews for most needed drugs.

A fifth strategy is to use information technology. For example, accelerate drug review by submitting online drug applications; or broaden educational opportunities through online learning.

Improving process design is another strategy. Some examples would be using parallel rather than sequential drug review steps or team teaching.

[Summary]

In summary, federal managers instinctively employ LRV in managing complex problems. Their challenge is achieving the delicate balance between over-complexity and over-simplification in the design of an effective management approach. This can be challenging because unlike closed mechanical or human 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.