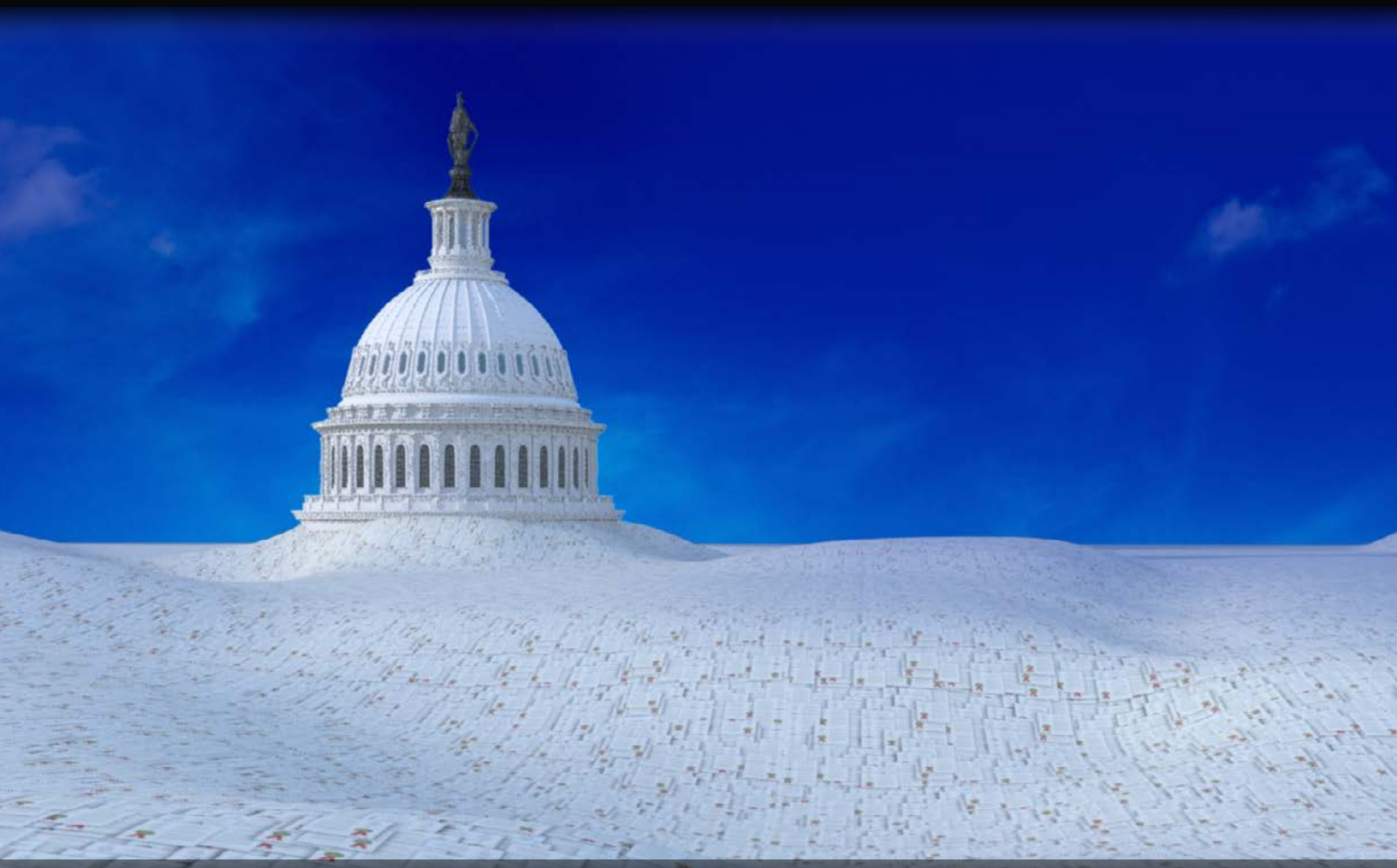
REGULATORY EFFICIENCY
IS OUR REGULATORY PROCESS WORKING?



A Seminar Hosted by the Regulatory Science & Engineering Center
at the Potomac Institute for Policy Studies

POTOMAC INSTITUTE FOR POLICY STUDIES

RSEC
REGULATORY SCIENCE AND ENGINEERING CENTER

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EXECUTIVE SUMMARY

Legislation is only as impactful as the regulations that interpret and implement its intent. Laws generally do not dictate the language of regulations; they instead grant authority to federal regulatory agencies to create the particular rules that govern society. The rules created by agencies through the rulemaking process have a more direct and tangible effect on the American people than laws passed by Congress. In order to ensure policies enacted by Congress are creating the desired benefits for society, in the least burdensome way, a method to measure the efficacy of our regulations and regulatory processes is needed.

For every law the US Government has passed since 1976, on average, it has passed nineteen final rules in comparison. In addition, the number of pages in the *Federal Register* increases by approximately 300 pages every year and the US Government spends over 4 billion hours a year on regulatory paperwork. Given such statistics, it has been argued that the current regulatory process is inefficient and excessively burdensome. However, these metrics provide no scientific validation of the efficacy of our regulatory policies and regulations. The purpose of the regulatory process is to develop regulations that generate desired societal behaviors and benefits intended from the laws from which they are derived, while minimizing negative impacts of regulation on society. Determining the efficacy of regulations requires more than quantifying compliance with regulations or the associated paperwork. The unfortunate reality is that no reliable metric exists for determining the effectiveness of our regulatory process.

The Potomac Institute for Policy Studies' Regulatory Science & Engineering Center (RSEC) serves to study and influence the regulatory process by incorporating the best available science into its policy recommendations. The primary goal of RSEC is to develop regulatory policy solutions that lead to the betterment of society. RSEC is engaged in various in-depth studies of the rulemaking process across several Federal agencies and is using the information gathered to develop a framework for understanding the "regulatory science" of how regulations are made and how we measure their effectiveness. By bringing together individuals from the regulator, regulated, and legal sides of the regulatory process, RSEC is shedding light on what regulatory science is and what the role of science in regulations should be.

RSEC hosted its first seminar in its 2015 Regulatory Science & Engineering Symposia Series on September 15th. The seminar, titled "Regulatory Efficiency: Is Our Regulatory Process Working?", featured the following distinguished panel: Mr. Michael S. Swetnam (CEO & Chairman of the Board, Potomac Institute for Policy Studies), The Honorable Dr. Lee Buchanan (President & CEO, Areté Associates), Ms. Michelle C. Jackson, Esq (Attorney, Venable LLP) and Dr. Charles Mueller (Director, RSEC, Potomac Institute for Policy Studies).

Mr. Michael Swetnam opened the discussion outlining the overarching questions we must ask ourselves when making a more effective regulatory framework:

- Do we need regulations to make our government function?
- How do we design a fair, open, transparent, balanced process for developing regulations?
- Are the regulations we make effective in achieving the intent of Congress?
- How do we prevent becoming overwhelmed by regulations while still providing the framework intended by their implementation?

Dr. Buchanan provided insight to the characteristics of metrics needed for implementing effective policy and the current roadblocks that prevent implementation of effective regulations. Ms. Michelle C. Jackson elaborated on current successes and breakdowns in the regulatory process and discussed the pitfalls of informal agency actions used to circumvent the formal rule-making procedure. Overall, all panelists agreed that the current system is failing and a new process is necessary to create effective implementation of laws. The discussion suggests that the Office of Information and Regulatory Affairs (OIRA), which is the current office tasked with oversight of regulations, has failed to fix the issues associated with the process outlined in the Administrative Procedure Act of 1946 (APA). Dr. Charles Mueller ended the seminar with the goals of RSEC to improve the regulatory process and continue evaluating methods applying science-based methods to creating a more effective, goal-driven regulatory system. These goals will be an uphill battle as self-interests of stakeholders, who know how to function within the current system at an advantage, and the unwilling nature of government to innovate and replace existing legislation, are both potential roadblocks for any meaningful change in the rulemaking process. Therefore, the necessary reform will require a high priority in the eyes of both the legislative and executive branches of the US Government and the American public.

The discussion revealed three major themes:

- **M**anagement of our regulatory process,
- **A**ccountability associated with regulatory decisions, and
- **P**erformance of both our regulations and regulatory policies based on goal-driven metrics.

Together, these themes represent a Regulatory **MAP**, which identifies the problem areas we must address to fix the regulatory process. Making a more effective and efficient regulatory process will require improvements that address inefficiencies in the current system and apply the findings, conclusions, and recommendations gleaned from this seminar.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

REGULATORY MANAGEMENT

> ***"What we need is a better system for managing the regulatory process."***
>
> *— Dr. Charles Mueller*

FINDING

- **The current regulatory system is inefficient and flawed.**
  The current process for managing the output of the Federal rulemaking process as dictated in the Administrative Procedure Act of 1946 (APA) and related Executive Order is inefficient and has created a regulatory process with many flaws. The regulatory agencies are desperately trying to remain effective and, as such, are circumventing the process through exemptions of the FAR and informal rulemaking, as examples.

CONCLUSION

- **The U.S. regulatory process is being managed inefficiently.**
  The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) is failing to properly manage the US regulatory process by allowing outdated regulations to remain active and elongating the promulgation of new rules with significant economic impact on the United States. OIRA has not been provided with a clear mission to determine the impact of new rules upon the current regulatory landscape. Poor management of the regulatory process is directly related to this lack of mission and the inability of OIRA to prevent the accumulation of outdated rules.

RECOMMENDATION

- **A new regulatory management process is needed.**
  A significant research effort needs to be conducted in order to catalog the current regulatory landscape and its impacts on society such that an institution such as OIRA or Congress can use this information to design and implement a better regulatory management process. The failures of OIRA result from the system it is functioning within rather than the personnel. Congress should endorse a new model that can be implemented by an agency like OIRA to improve the current management of the rules and regulations of the US Government.

REGULATORY ACCOUNTABILITY

> ***"…rather than issuing a proposed rule using the rule making process, the FDA went to individual companies and briefed them one-on-one that the agency had changed its position [on classification of products as personal moisturizers]. In this instance, the FDA was not following the process of rulemaking and not giving companies equal opportunity to comply with the law."***
>
> *– Ms. Michelle Jackson*

FINDING

- **Regulatory agencies are not being held accountable for effective regulations.**
  The Administrative Procedure Act of 1946 (APA) is designed to ensure accountability is tracked to compliance of bureaucrats to follow the administrative procedures of each federal agency that designs, develops, and implements regulations and regulatory policy. Regardless of the effectiveness of a rule, its implementation costs the US Government and businesses large sums of money in compliance and reporting.

CONCLUSION

- **Lack of accountability has led to a lack of innovation.**
  The existing legal framework that enables the Federal rulemaking process fails to ensure proper accountability in the processes utilized to promulgate rules and run rulemaking agencies. Rather, it enables the Federal rulemaking process to fail to ensure proper accountability to bureaucrats in leadership roles resulting in a system that rewards obedience, punishes creativity/innovation, and protects the status quo. The consequence is a stagnant system that is pervasive yet prevents US inventors and innovators from achieving their full potential.

- **The current regulatory process is incapable of adapting to new technologies.**
  In a world dominated by the impacts of new science and technology, the current Federal rulemaking process struggles to function because administrative procedures have become ossified and roles of leadership have been reduced to roles of management that ensure compliance to existing administrative procedures.

RECOMMENDATION

- **New enabling legislation is needed that is flexible and maintains accountability.**
  New enabling legislation is needed to provide bureaucratic leaders with flexibility in the processes for promulgating rules specific to their agencies' missions and ensuring this new flexibility is kept in check through appropriate accountability measures. While creating a flexible system seems impossible while retaining accountability, it is possible through careful consideration and planning.

REGULATORY PERFORMANCE

> *"If you can't measure it, it shouldn't be policy."*
>
> *– Mr. Michael Swetnam*

> *"Metrics are very hard to apply if you don't know where you are going."*
>
> *– Hon. Dr. Lee Buchanan*

FINDING

- **It is not currently possible to measure the effectiveness of the regulations produced by the rulemaking process outlined in the APA.**
  The Administrative Procedure Act of 1946 (APA) provides no incentive or mandate to measure, improve, or understand the effectiveness and impact of regulations produced through the Federal rulemaking process, resulting in a process that functions with virtually no metric to assess its success. It is no wonder that the legislative branch and the regulators center to the issue are paralyzed with indecision on how to fix such as system.

CONCLUSION

- **Tools are necessary for effective rulemaking and improving the regulatory process.**
  It is not possible to improve the Federal rulemaking process through any type of scientific approach without an appropriate set of tools or processes that can measure the effectiveness of the promulgated rules it creates or the process it uses to create them. Currently, metrics are an afterthought in the regulatory process and only used when conveniently available.

RECOMMENDATION

- **Performance of regulations must be tracked with quantitative metrics.**
  New enabling legislation is needed to ensure all new promulgated regulations are designed, implemented and managed with a metric that tracks the performance of said regulations, as well as a metric for determining if the processes used for promulgation of new rules is as effective as possible; these metrics must address a clear goal, be quantifiable, indicative and timely. Not only are metrics needed to create effective and successful regulations, but they should be a cornerstone in their development and address financial as well as other impacts of the new rule.

SEMINAR TRANSCRIPT

Mr. Mike Swetnam
Welcome everyone to the Potomac Institute for Policy Studies. I am the CEO and Chairman at the Institute. I'm glad you could all make it. This is the first in what will be a long series of seminars and discussions on regulation. The Potomac Institute is all about science and technology policy. For twenty years, we've interpreted our mission to mean that we support policy influenced by good science, technology, and rationalism, rather than by religion or feelings. Good policy should come from good science. For twenty years, we've interpreted that to mean that policy and laws of the United States should be based upon good science and technology. The Institute takes great effort in trying to help the legislatures of the United States develop policy that follows those tenets. The extent we've influenced them is very debatable, but we keep trying really hard.

About five or six years ago, Dr. Alan Moghissi convinced me that the policy of the United States was more regulatory than legislative to a large extent. Every time there was a law, there were a large number of regulations or interpretations that followed. In fact, our lives are affected by regulation at least to the same level as it is by law. We founded the Regulatory Science and Engineering Center (RSEC) at the Potomac Institute to study regulations and the science of developing regulations in the United States. Over the past year, RSEC has engaged in a scholarly investigation of how regulations are developed and the underpinning legislation that the process of developing regulations in the United States is based upon. Our research confirms the regulatory nature of policy in the United States is one of the most significant components of government that we should be concerned with; more importantly, we should be discussing how science and technology can or should influence that regulatory process. This is RSEC's first seminar in a long series focused on how the regulatory process works; whether it works well; if it doesn't work correctly, how it might be changed; and, most meaningful to our Institute, how science and technology can be brought to bear to improve the regulatory process.

Like all of the seminars that we've had in this room over the last twenty years, this is a discussion. From the panel, we will have comments and their experiences to help guide the conversation, which will help us frame the discussion, but we welcome and encourage your input. We want to hear your questions, your comments, and your thoughts about understanding the process of developing regulations and how to make them better in the United States. With that framework, I'm going to turn it over to Dr. Mueller.

Dr. Charles Mueller
I am the Director of the Regulatory Science and Engineering Center (RSEC) at the Institute. RSEC seeks to improve the United States regulatory process by incorporating the principles of regulatory science and engineering into the policy recommendations that the Institute suggests. The principles attempt to apply a science-based approach to the process of creating and implementing regulations and regulatory policy. Regulations are the interpretations and implementations of law and seek to create a behavioral change in society. Legislation grants authority to a federal agency to address a specific set of societal and/or economic issues. Ideally, the behavioral

change caused by the regulation improves the problem that initiated the original legislation. Regulatory policy is the policies, tools, and processes used during the development of regulations, and regulatory science attempts to ensure that both regulations and regulatory policy are based on rational, scientific thought. For every law the United States government has passed since 1976, on average, we have passed nineteen final rules in comparison. Every year, the number of pages in the *Federal Register* increases. At some point, we must step back and ask ourselves:

- **How do we know if the regulations we've put in place are working?**

- **What kinds of analysis are we doing to measure impacts of regulation and regulatory policy?**

Answering these kinds of questions is RSEC's mission, which we have been working on for the last year. Our effort is to study the regulatory process through the lens of regulatory science. The purpose is to develop a set of policy solutions to improve the efficiency and efficacy of the process by which the United States government develops and implements regulations. In this seminar, I hope we are able to garner some insight into whether or not our regulatory process is working, and how exactly we should go about finding the answers to similar questions. If regulations seek to improve conditions in society, then after their development and implementation conditions should improve. We need some metric in place that can help us determine whether or not our regulations work and if conditions are improving. In today's discussion, we're going to examine the impacts of regulation and information we need to properly evaluate the efficiency and efficacy of our regulations and regulatory policies. With that, I'll turn it over to Dr. Buchanan.

Dr. Lee Buchanan
I am the President and CEO of Areté. Charles and I talked earlier about various experiences I have had with the regulatory process, but I will frame a more general discussion. I have battle scars from all sides of this issue. In my experience, regulation is about control. The drafters of regulation attempt and desire to control the situation and predict what controls are needed so that the controls being put in place are not perfidious. The regulations are meant to be helpful in this situation, although unintended consequences are often to the converse. The law was put in place by well-meaning people that believe they have a mission to institute some legal permission or restriction. The regulations are there to implement that restriction, meaning regulations are always restrictive of the law they reference. Regulations never expand the law, but they can constrict it. In many cases, the regulatory process becomes decoupled from the law to which it was originally related.

I'll give you an example. Back in my youth, at a place called Defense Advanced Research Projects Agency (DARPA), we were not happy with the Federal Acquisition Regulation (FAR). The FAR restricted our ability to write contracts to people, write them quickly, and write them relevantly. The "space act", which NASA instituted but decided not to use, was a law that gave them the ability to add a new dimension to procurement. Prior to that time, procurement was limited to grants and procurement contracts. This new agreement added a new "other agreement authority". Other agreements were outside the FAR and were commercial-like in their character. They could be executed quickly without the restrictions of Truth in Negotiations Act (TINA) and

the embellishments of the FAR. Other agreements gave a whole new authority so R&D agencies could do things quickly, relevantly, and move forward. That happened about 18 years ago. In the intervening 18 years, regulations have embellished the law with restrictions so the law is currently unusable. In this case, the regulation was not meant to implement the law, but rather to destroy it. The law is still in the books, but it can't be used with all the restrictions. This is a major result of regulations accumulating over time. Unfortunately, this is not an isolated circumstance. I see this tactic used in many cases. The major objective is to keep the regulations from offending the law.

The second topic I will discuss is more current. I run a company that does a lot of classified work. As a result, there's an overhead in the people we hire, in the processes we use, and in the type of real estate we can purchase. Recently, a set of regulations were put into place by the Department of Commerce in the area of information sharing. Everybody in this audience is worried about their privacy, worried about their accounts, worried about their email, and the use of the Internet. On the surface, these regulations made a lot of sense. Unfortunately, when the regulations were put into place, nobody considered who was going to pay for the overhead to implement these protections. Companies are in a situation where we have to hire a new set of people to carry out a new set of actions, and the new employees are very expensive. My customers won't allow me to charge them for this new expense because they didn't put the regulations into place. My company is stuck paying for this new regulaiton. I have to hire these people because of one regulation, but I'm prohibited to charge the cost of hiring them to my customers because of a separate regulation. The impact of these two regulations puts people in a restrictive situation, albeit unintended. The second suggestion I would offer is a method for coordination that won't allow regulations to counteract other regulations.

Ms. Michelle Jackson
I am a food and drug attorney at Venable, LLP. I work with companies who have products regulated by the FDA. As contrasted with Dr. Buchanan, I'm on the ground level dealing with day-to-day effects these regulations have on companies' every day business. I have my own "war stories" and can provide many examples of ways in which regulations are and are not working.

I would offer another example. Sometimes agencies don't follow the regulatory process correctly, which can cause severe problems. Recently, we tracked an instance where the FDA decided internally it was going to change the regulatory classification of a category of products – personal moisturizers. The agency made this determination internally but rather than issuing a proposed rule (using the rule making process) to inform industry, the FDA reached out to individual companies (via a letter), notifying them that the agency had changed its position. Instead of regulating personal moisturizers as cosmetics, which have a lower regulatory burden and threshold, the FDA was going to regulate them as medical devices, which need to be cleared by the agency first. The agency approached the larger players first, giving them significant advanced notice compared to the smaller companies in the industry. With the advanced notice, the larger players were able to compile their materials and prepare their submissions for FDA clearance before the smaller players heard of the position changes of the agency. The larger players were able to approach retail stores and say, "The FDA has changed its position, so these products are now medical devices and need to have clearance. These smaller companies don't have clearance,

but we do! You should sell our products and take all these other companies' products off the shelf." Meanwhile, these smaller companies had still not been informed of the changes to the classification from FDA, and, as far as they knew, their products were fine and being regulated as cosmetics.

It was a mess to say the least. We had to approach the agency to straighten out the issue. We urged the FDA to permit these products to remain on the shelf while the smaller companies compiled their applications and submitted them for clearance. However, it caused great financial harm to a lot of these companies since a lot of major retailers didn't want to take the risk. The stores that carry these products would say, "We'll see a risk by selling these products that haven't been FDA cleared, so why would I keep them on my shelf? Why don't I just take the product that's already been cleared?" It took a lot of behind-the-scenes effort on our part to convince the agency to allow some of these products to remain on the market. Quite frankly, we had to raise our concerns above the level of the Center [for Devices and Radiological Health] and reach out to the Ombudsmen's office to intervene. The FDA was not following the process of rulemaking and not giving companies equal opportunity to comply with the law.

If the FDA had used the regulatory process correctly as it was intended, it would have provided a level playing field for all of the regulated industry. This is important because you have small players who don't have the same resources as large companies. If the small players are unaware of the regulatory change and there is no notice in the *Federal Register*, it can cause significant harm to the smaller companies, which don't have as much leeway in their profit margin as some of the larger companies. Some larger companies may have a large variety of products, so one change in a classification of a product may not impact them. However, the smaller companies have devoted a large portion of their business to this class of product and a small change could put them out of business.

The use of guidance documents instead of the notice-and-comment rulemaking process is another example where the FDA tends to not use the regulatory process as it was intended. Using proposed rules gives industry the chance to comment before the agency comes forth with a new policy. However, frequently you'll see very long guidance documents used to essentially make a new rule. For example, there was a guidance document drafted for dietary supplements, in a category for an ingredient called a new dietary ingredient. When the printed guidance document was released for dietary supplements, it was 30 pages or so in length with small print. Typically, a guidance document is supposed to provide more insight into the regulation and help industry comply with the regulations. However, the agency is using guidance documents as a way to make rules instead of using notice-and-comment rulemaking and soliciting comments from the public. I would keep in mind that there are significant benefits to the regulatory process, even though I can give you many examples of how the process has not worked or can be slow. Generally, the notice-and-comment rulemaking process does have importance to industry in terms of providing a regulated, fair playing field. It provides industry a chance to comment before the agency takes a strong position.

Mr. Mike Swetnam
I'll help us frame the question now that we've had a few comments from our panel. I like to stand 100,000 miles back and see the issue regardless of whether it's obscured by something. The first question about regulations is, "Do I need regulations?" The Constitution does not dictate that the Federal Government must create regulations. The Constitution says the legislature is going to make laws and the president is going to implement those laws. At some level, I can ask really important questions, "Do we need regulations? What is the constitutional-level authority for implementing regulations?" Those questions are worth a scholarly, philosophical discussion regardless of whether it has practical outcomes.

If you bring your objective down to the 10,000-foot level, there are practical reasons for having regulations. Congress doesn't write very precise, directive laws. Every so often, Congress will write a 3,000-page or 30,000-page healthcare law, but most of the time Congress writes 3-page laws that says "go do something good". There is a need to take that 3-page law a step further. At the 10,000-foot level you can say, "I need a regulatory process." My next question is, "How do I design a process for developing regulations, which is faithful to the Constitution and to what the framers had in mind?" In other words, a process that is fair, open, transparent, and balanced. Based on the 1946 law, does that law and the current process answer that question? If we need to have regulations, do we have the right process for developing them?

Down to the 1,000-foot level, we have regulations that haven't been posing the right question. We have a process, and are developing lots of regulations. Are those regulations working? Am I getting out of the system what I think I should be getting out of the system? I think more often than not, the answer is no. What happens when you have a bad regulation? What happens when you have an inadequate regulation? What happens when you have a regulation that people aren't happy with? Then we develop another regulation! We put a new one next to the current one. This is the same reason the tax code has risen year after year. This is why the FAR rose every year. The answer in our current system to an ineffective regulation is to add to it and make it more detailed rather than disposing of it. The question at the 1,000-foot level is not only "Are the regulations working?" but "What do I do about the regulations that aren't working?"

All the way down at the 1-foot level, it's a very different question. At the 1-foot level, you look up and there's a mountain of regulations on top of you. Literally, you're under a mountain and the only questions you can ask at the 1-foot level are, "How can I get anything done at all? Whether you're a businessman or a federal contractor, why would any system exist in this country? How can I get anything done with a mountain on top of me?" I would pose those four questions as the framework for our discussion.

- **"Should I have regulations?"**
- **"If I have regulations, what is my processes for developing them?"**
- **"When I develop them, how do I measure if they're working?"**
- **"At what point do I need to move a mountain?"**

Dr. Charles Mueller

I've become passionate about regulation in the last year. I am trying to learn everything I can about the regulatory process. I've studied what other people are looking at when trying answer the 1,000-foot level question, "Is the regulatory process working?" When we try to answer these questions as scientists, we start by looking for information, data, and evidence. Where is evidence that our regulations are working? One of RSEC's major findings in our study of the regulatory process is that we can't find satisfactory information, data, or evidence to support this question either way. The biggest problem I've had is answering this exact question and is the reason we are here in this seminar. The Office of Information and Regulatory Affairs (OIRA) is supposed to be managing the system and answering some of these questions. The fact that OIRA is not providing sufficient answers demonstrates that we have a poor system in place for determining the efficacy of regulations. No one is having the conversation about what the metrics look like. What does the data look like? How do we create an institution that can gather information and analyze it to create an output that shows clear evidence of this regulation causing a behavioral change intended by the law? As Lee said, the intent of all regulation is control. As Mike pointed out, we have regulations that keep accumulating and no system of fixing this build up. We have a desired outcome, we write a regulation to create behavioral change, but then we focus on one issue and ignore all the other outcomes that happen as a consequence of the regulation. To fix all the other undesired outcomes, we put another regulation in place. It introduces another set of outcomes and at no point are we looking back and measuring whether the regulations are working or why we are getting undesired outcomes. Not knowing what the data or metrics look like is the root of the problem. That's a conversation I think we should be having. What does it mean to have a regulation work? What do you do to gather the information to answer that question?

Dr. Lee Buchanan

If I'm going to put a policy in to place at a company, which is the equivalent of regulations in government, the first thing I'm going to ask is, "What am I going to do? What is the desired outcome? What is the result I'm looking for?" From there, I'm going to come up with metrics based on that desired outcome that have at least three attributes. First, they have to be measurable. I have to be able to quantify something. Second, they have to be indicative. They have to relate back to my goal. Third, they have to be timely. If it's not timely, I can't take any action based on the failure of any of those previous two metrics. That process and those actions have to be done in the beginning, immediately after you figure out what you're trying to do, and before you issue any regulation. If it's not done before you put the policy in place, it doesn't make any sense to do it afterwards. What's the problem in getting regulators to follow that process? The problem is that they don't know what sort of control they want to execute down the line in the beginning. To have those metrics set upfront is going to restrict their ability to revise history when things are down the road and Congress changes. There's a piece of human nature that's going to work against the sort of derivative approach you have, Charles. I don't know how to solve that except by instituting a regulation czar that makes sure that for each proposed regulation, there is an associated metric and goal and then a routine revisiting of that metric, similar to a program manager, but that proposal is never going to fly.

Mr. Mike Swetnam
You don't think the concept of redoing the Administrative Procedure Act (APA) of 1946 and adding to it that requirement would solve the issue?

Dr. Lee Buchanan
Perhaps a revision to the APA could solve the issue, provided you have someone with the authority to accomplish that task. The problem I talked about in the beginning was that a regulation from one part of the executive branch conflicted with another part of the executive branch. A regulation czar can't be at the agency or even department level, but it's got to be above that, which puts it at the White House. That gets very political so implementation becomes an issue. I'm not sure anybody's willing to let go of the power they have as a regulator.

Mike, you made a very interesting observation earlier. There's a problem with the security classification system. Information get classified as confidential, secret, and top secret according to these various criteria as well as clearances above that, and there is an ornate process. At various parts of my government career, I had the ability to classify things based on a classification guide. I never had, nor do I know anyone that ever had, the ability to de-classify things. I'm sure there's somebody somewhere that had that authority, but I didn't. That's why nobody can de-regulate anything, except by an act of Congress.

Mr. Mike Swetnam
But there is a way to de-classify information. It is worth noting the classification system was changed under President Clinton to have drop-dead times. Now you classify something and within 30 years it's got a date where it becomes declassified or reduced in classification. That was at least an attempt of a sunset account.

Ms. Michelle Jackson
I think revising the APA to require or develop these metrics before they implement or propose rules is a good idea. It doesn't help with coordination between different agencies, but it's not something appearing in the FDA's proposed rules from what I currently observe. I do agree that it's a significant problem to try and come up with a metric after the fact to measure how well a regulation is working. Presumably, the agency has something in mind when it's creating regulations. For example, presumably the agency's goal is safer dietary supplements and quality control for dietary supplements when it promulgated the Good Manufacturing Practices for dietary supplements. Presumably, that's what the FDA had in mind when it was drafting and proposing these rules. I don't know if the agency has even contemplated how you measure those items on the back end without looking at the metrics ahead of time, other than looking at how many companies are complying and how many aren't complying during the agency's inspections. However, that doesn't get to the safety question. It intrigues me, and I think it would be useful to have agencies draft metrics before proposing regulations.

Dr. Lee Buchanan
It could be a sort of an environmental impact statement for regulation from the agency.

Ms. Michelle Jackson
Exactly.

Dr. Charles Mueller
Agencies have to submit a regulatory impact analysis that is required for significant rules with impacts of $100 million or more. Those rules get analyzed by the Office of Information and Regulatory Affairs (OIRA), where the literature says the regulations often go to die. That is partially because the process is supposed to be coordinated amongst all impacted agencies. OIRA is supposed to look at all the different agencies that have a stake in this rule, get all their input, and then come up with the best possible frame or language that the regulation should have. It appears that despite the good intentions, this process just ends up stalling the process a lot. What we need is a better system for managing the regulatory process.

Mr. Mike Swetnam
I have a fatal problem with this whole thing because the whole process is cumulative. You can claim that the APA process is relatively thoughtful as it takes about 18-24 months to put something in place. No matter how thoughtful and deliberative you are in making a regulation, the regulations still build up. There is no sunset principle. Charles, you're a scientist. You can start drawing a chart of the number of rules published per year and you can visualize when things start going non-linear; there's a point at which there are more rules than any human organization is capable of handling. In your timeframe, Lee, there was the Undersecretary of Defense who drew this wonderful chart that said, "Our airplanes keep getting more expensive and our budget gets more limited. At some point, we'll have just enough money to build one airplane."

Dr. Lee Buchanan
That was Norm Augustine – one airplane in 2047.

Mr. Mike Swetnam
You can layer requirements on in a cumulative process such that the weight is so much pressure that nothing will happen. That is the mountain at the one-foot level, I contend that in some regimes it's already happening. The Federal Acquisition Regulation (FAR) at the Department of Defense (DoD) or the Defense Federal Acquisition Regulation (DFAR) for defense make for examples. The FAR is so big, covers so much, and is so overlapping that anybody in the department who wants to say "No," can find justification. The result is that every time DoD really needs to do something, they make an exemption to the FAR. This happens because they can't actually execute any realistic program under the full weight of the FAR in any meaningful timeframe at all. Big programs that are really important that need to get done in two years, are exempt from the FAR. This process of exemptions and circumventing the process is happening in a lot of regimes from drug regulations to medical device regulations. What we're saying is, "I really need it and it's really important, but I've created too much regulation to do what's in the system, so I need an exemption." We've already created a mountain too big for us to actually be able to operate under its force. At what point do you say, "The only way to get something done is to give exemptions for the system." How many exemptions does it take before you throw the system out and start over?

Dr. Lee Buchanan
There's a second way of getting around the FAR and it's been discovered in the last 5 or 10 years. If a FAR won't let you do it and the lawyers won't let you do it, then you make it black (highly classified and on a need to know basis) and you go do it. And nobody knows what you can do so it works out fine.

Dr. Charles Mueller
As Michelle alluded to, in the FDA we see this predicament play out with their use of guidance documents. Because the process takes so long, and the field moves really fast, in order to create the effect of rules, they use guidance documents as incentives. If you follow these documents, things will happen easier for you. This is happening because nothing goes away and it keeps building. Agencies are getting creative in the way they enforce behavior.

Dr. Lee Buchanan
The dark side of this is concerning to me. Yes, the process is clogged. Yes, it is slow. Yes, it is ineffective. The lobbyists and the corporations in this town have learned how to use that to their advantage. In many cases, regulations are not sourced by people in the government, they're sourced by people in companies. The companies want to have a competitive advantage over someone else or they want to compete in a certain area to avoid obsolescence or something. I see that happening more and more often not as a way to regulate, implement, or to accelerate the use of any law, but to impede the competition and that's a bad thing.

Mr. Mike Swetnam
Smart people are going to game any system. What's the answer?

Dr. Jennifer Buss [from the audience]
There are the laws written by Congress and the regulations that implement those laws, but there is also the enforcement of the regulations. Even if you have 15+ regulations that go with a law, the enforcement is ultimately what matters in the end. I'm not saying that these other topics aren't important to discuss, but we also need to think about enforcement in the beginning as well, as part of the metrics. "If it will cost me this much and I want this eventual outcome, what are the processes I need to make that happen? What are the steps we have to go through?" It's not an answer to the question, but it's something else to consider.

Mr. Mike Swetnam
Charlie was talking about this and it starts with Congress. Congress doesn't put in the intent along with the law and that would be helpful when developing a metric. We keep talking about the Department of Defense because it's the big orange elephant in the room that's easy to identify. It's the Donald Trump of procurement. Take DoD as an example. Congress says, "We catch contractors ripping off the government. DoD, you put in place regulation that audits and manages those contractors. You ought to pay closer attention to make sure you're not getting ripped off." That's generally how it started. Now we have a DoD system that does entirely too much auditing – I know this for a fact because we're under DoD accounting at the Potomac Institute. It costs about 14% more overhead in the Potomac Institute to do government contracting than

it would to do commercial contracting. That's because we're very lean. Some companies will tell you that they spend 20% more by doing government business, and that's all because of the auditing requirements, and the oversight, and the certifications within government. You have to have that much more overhead to answer all that stuff. We cost 14-15% more because we're obeying all of these regulations that were put in place to prevent contractors from ripping off the government. Real numbers! You can go back and look at history. Government fraud or contractors ripping off the government has never been more than 3.5% of the budget. We're making companies overspend 14-15% of their budgets on compliance to avoid 3% fraud in the government's budget. This is a bad deal.

Dr. Robert Hummel [from the audience]
Absolutely, but when I went through management control training at DARPA, the consultant was very insistent that the original law instituting required management control, which was all about WFA (Waste, Fraud, and Abuse), said that you are not allowed to spend more on management control than you would be saving by suppressing WFA.

Mr. Mike Swetnam
Right, Bob. DoD cannot spend more than that mythical 3-4%. They don't spend more, but they put requirements and regulations on the contractors that cause the contractors to spend more. It's not obvious that they made everything cost more.

Dr. Robert Hummel
That's precisely what Lee was saying about the information assurance situation. My question is on the info assurance. Did they go through the sorts of processes that Michelle talked about? Was there a comment period? Did somebody complain and say that this was going to cost more, and who was going to pay for this?

Dr. Lee Buchanan
Not to my knowledge. This was passed two years ago. It was brought to our attention as contractors last November.

The problem is that there was no one qualified to be hired to do this. The first thing that had to happen was we require these information assurance specialists, of which there were none, with a specific training set that was unspecified, that had various other parameters tacked onto it. There's a small community of them that are in great demand because you have to have them, and as a result their salaries are out of sight. To my knowledge, there was never any comment period, because the Department of Commerce put the rule into place. They wouldn't think to request input from the DoD about potential consequences. By that metric, how do you measure the consequences of not doing it? Information assurance is sort of difficult to quantify. It's a liability.

Dr. Robert Hummel
What's the hypothetical cost associated with this?

Dr. Lee Buchanan
I know what it costs, but I don't know what the benefit is. How do I calculate the benefit?

Dr. Charles Mueller
There's an interesting case of that dilemma. It's a vulgar case, but it had to do with establishing rules and regulations to deal with prison rape. They attempted and could not quantify what the benefit of preventing prison rape was going to be. The could not determine what the cost of that emotional impact was going to be on those prisoners and the cost of reintroducing them into society. It's almost impossible and it's amazing we are just starting to seriously ask these types of questions after 70 years with the APA. To me, all these problems eventually point to the process. When do you need a regulation? What should be the criteria for regulation? How to evaluate it after the fact? There's a whole process here, and it is tied to the APA. No matter what regulation, be it an acquisition regulation, a contract regulation, an environmental regulation, all of them have to use the same process.

Dr. Lee Buchanan
Would there be merit to a suggestion that says, "If you have a proposed regulation for which you are unable to specify metrics – measured, indicative, and timely – you can't pass a regulation."

Dr. Charles Mueller
That is the exact opposite of what they're told to do at the Office of Information and Regulatory Affairs. They are supposed to think deeply about quantifying the unquantifiable costs and benefits of the proposed rule. However, inability to find a metric is insufficient grounds to not make a rule. I'm pretty sure there is an Executive Order to do this.

Ms. Michelle Jackson
To some extent, there's also a risk in that every law is different. In some instances, if Congress is mandating that the agency do something, if the agency were to say, "We don't have any metrics to measure this, so we don't know if we can do this," then the agency could be in violation of statute by not taking a certain action. You have that problem as well.

Dr. Jennifer Buss
Right now, the only metric I see being measured on regulations is cost. If I'm going to put this in the FAR, one thing that they're asking is, "How much is it going to cost the government to put in this regulation?"

Dr. Lee Buchanan
It's really tough to measure a cost-benefit ratio when you cannot measure the benefits.

Dr. Jennifer Buss
An impossible equation, but it goes to the point. If I know my end goal, which of those types of regulations do I need to put in place to get there? Do I really just need to get the guidance

document to help people to better understand what the agency meant by the first one? Or do I really need an entire new regulation sorted into the FAR, that has to go up to the board, that has to be approved, and they decide? They don't even tell us their metrics about whether this is a better plan or something else.

Dr. Paul Syers [from the audience]
We're talking a lot about how to change the regulatory process moving forward, but we've also heard horror stories of regulations that are currently in place that no longer work. What is the likelihood of being able to put something through that is essentially a reset button on some of these mountains of regulations, and a completely revised FAR?

Dr. Lee Buchanan
Detonation would be good, and we tried. What happens is the antibodies come out and restore. The House Governmental Affairs Committee is there to preserve the status quo. You'd have to remove that Committee, and move everybody out. There's a whole set of private industrial interests set up to take advantage of the regulations as they sit. You're removing all of their advantages, too.

Mr. Mike Swetnam
I'll give you two war stories to answer your question. Professor Buchanan and I have a shared experience over the last couple of decades. The first one is the intelligence community, which is 17 agencies, all in different departments, in a list configuration, and they used to be aligned under something called the Director of Central Intelligence (DCI). For about 50 years, people said the system didn't work very well. It worked well when you had a strong leader, and it worked poorly when you had a mediocre leader, and it was dangerous when you had a poor leader. Dr. Buchanan, myself, and those of us who grew up in that world, we used to joke about how it would be impossible to ever change that structure. It wasn't just 17 agencies. It was 17 agencies in 14 departments spread out across the whole government. You're talking about everybody having a piece of the pie, and nobody's going to let you change it. Then we had the tragedy of 9/11, which caused a paradigm shift. Low and behold, four years later, they did change that structure and they made it marginally better.

Dr. Lee Buchanan
Emphasis on marginal.

Mr. Mike Swetnam
Because of a tragic event, something that was probably politically impossible became possible and there was a marginal shift. You can call that first story where we saw change happen. The second story was less successful. For more than 20 years, Dr. Buchanan and I worked on procurement in the DoD, which in Washington is jokingly called trying to boil the ocean. It's called acquisition reform. We tried to reform the FAR into something that's more useful. Lots of people, not just the Potomac Institute, have been throwing rocks at it for decades. This past year, we had two chairmen, the Chairman of the House Armed Services Committee and the Chairman of the Senate Armed Services Committee, actually in agreement to go do something. We at the Potomac

Institute ghostwrote most of what went into the House bill. Between the House and the Senate, they were at such loggerheads over their two different forms of acquisition reform, that there will probably not be a defense authorization bill this year. That one, boiling that ocean, is probably impossible in the current political climate. I don't know what kind of crisis we would need to fix it.

Dr. Lee Buchanan
In the smaller world of the FDA, what would it take to make a major change? Presumably, that's one or two magnitudes less onerous than the ocean we're trying to boil.

Ms. Michelle Jackson
FDA is very focused on safety, so I think that it would take a large public safety crisis or emergency to really get the agency to consider discarding current regulations and moving forward. You learn this very early on in law classes, many years ago there was an issue with botulism in canned food. That was considered such a public safety crisis that it really triggered many changes, and so I think that something on that level is what it would really take for FDA to really consider discarding a regulation that wasn't working. I don't think anything cost-related is going to make a difference.

Dr. Lee Buchanan
The only way we do any changing of any of this is via disaster? Is that what we are?

Mr. Mike Swetnam
That sounds awful! That's very fatalistic.

Dr. Michael Fritze [from the audience]
Always take good advantage of a crisis, Lee. I can speak from that in the microelectronics area. We're making changes in trust and security of microelectronics because of the crisis of the sale of IBM, right? Anyway, I had a separate comment. I wanted to go back to the metrics discussion that both Charles and Lee brought up. I applaud that. I think that regulation should come with metrics. I was also lucky enough to work for Tony Tether at DARPA, and he was very big on metrics. The only thing I've learned is that metrics are hard. We couldn't do a program unless we had quantifiable metrics to measure the success. We were not given any money. Do you know the hardest thing about developing that program? It wasn't the concept, but it was the pitch. What are the metrics? Because you have to understand the field deeply, and work very hard. I applaud having metrics, but it's hard. The people are not going to want to do it. How do you respond to the reluctance of people being required to do hard work?

Dr. Lee Buchanan
Metrics are hard. No question about it. The corollary to that which is even harder in my experience is, "What leads to the metrics? What are you trying to do? What is the outcome you want?" stated in a way which metrics can be applied. If you're going to cure cancer or solve world hunger, these are not measureable things. Yet those are the goals that many of these programs have. I remember some of the programs I looked at while at DARPA. These program managers would come up and say, "We're going to write a better compiler?" What does better mean? "Well, it means better than we currently have.

How will I know the regulation is working? I'll know it when I see it! That's the mentality that a lot of regulations run around, and it's never conducive. "I'm going to give foreign aid." Who's going to give foreign aid? How much? To which countries? When? "We'll play it by ear." That's not a good regulation. Metrics are very hard to apply if you don't know where you're going.

Dr. Rebecca McCauley Rench [from the audience]
You make these really great points, but part of me thinks that if you make a law with intent behind it, then your metric is right there. You measure the current status quo of whatever it is you're trying to change. At least on the short term, let's say you're expecting change in the course of 5 years, you should be able to measure that same thing after you've put the regulation in place to see if it has improved or gotten worse in the way that you've expected. It seems like if you make a law with intent behind it, the metric almost falls into place.

Dr. Lee Buchanan
No, no, no. I'll give you an example in the Small Business Innovative Research program (SBIR), which is pervasive in this town. It now accounts for 2.75% of all the R&D funds. Billions of dollars! No metrics. None. Zero. Zilch. What are you trying to accomplish? Get money to small businesses. Just write them a check. There are no metrics, and no guiding set of principles. There are a lot of regulations and rules and formats, but nobody has a metric. Nobody knows if that program works or doesn't. Or whether it's good to have great diversity. Is it better to have more companies involved? Is more intellectual properly created by SBIR? No metrics, but lots of regulation.

Dr. Paul Syers
In your opinion does it work?

Dr. Lee Buchanan
If you had asked me five years ago, I would've said no. I was the greatest opponent of the SBIR program in this town. However, two pieces of the law changed. One was that if you have an SBIR that you be the basis for a sole source agreement going downstream, and second of all, that sole source agreement would be able to be transferred in case a company is merged or acquired. It has nothing to do with the program, except that I get to buy myself into a competitive advantage in a mergers and acquisition sense because of a change in the law. Now I'm all for it.

Mr. Mike Swetnam
There's another answer to what you just asked. Do you think it's better or do you think it accomplishes the goal? We are a science and technology policy place. We believe that policy should not be based on what somebody thinks or feels. Policy should be based upon science. By definition, the Potomac Institute is for metrics and measurements. If you can't measure it, it shouldn't be policy.

Dr. Paul Syers
Given the difficulty of coming up with a regulation that would include measurable, quantifiable, analyzable metrics, would it be feasible to have a sort of compromise in that it at least requires every regulation to have a well-defined goal? Would that be something that could be accomplished?

Because it sounds like, from comments by many people here, that requiring that every regulation has measureable, produced, quantifiable metrics would be something that might hover near impossibility, whereas at least we could get a step toward that.

Dr. Lee Buchanan
This brings me back to the regulation czar proposal. The notion that programs have goals is a good thing to say. Who gets to say whether it's a good goal, or bad goal, or no goal at all? Somebody standing from the outside with no interest in the regulation itself has to be able to judge these things in a way that is equitable and coordinated across all agencies. I don't know anybody that is able to do that currently, which is why we perhaps need a regulation czar.

Dr. Charles Mueller
I've spent of a lot of time thinking about this. If you are going to go after the Administrative Procedure Act or require metrics determined before regulations are put in place, you're affecting every agency that's out there. It is difficult to put in words what a blanket metric would be, right? An agency like the FDA, which relies on a lot of science and the regulations, makes decisions based off clinical trials and actual scientific experiments. In the case of the FDA, it is possible to have actual data to determine efficacy. However, what decisions are made and which regulations are put in place ends up coming down to determining if something is safe. This is easiest if you have well defined end points, but even with the FDA this is not always clear. In contrast, for an agency like the FCC, it's different, as the requirements and goals are different. Accountability is needed in the whole system. If you're going to have a regulation czar or put people in place to make decisions on the the impact of a regulation, they should be experts. Having an expert opinion is the whole point of the bureaucratic system since the experts should know the answer to what the goal is and whether it is working. Experts should be in charge and they should be held accountable to that process.

Mr. Mike Swetnam
I have a problem with the whole description of government we are putting forth here. I know there is the practicality of actually doing something and running a government, but if you're a purist, the Constitution calls for three branches of government. Congress write the laws, the administration enforce the laws, and the judicial branch gets to interpret them. All of a sudden you are creating a regulation czar inside the enforcement part, but they can interpret and maybe re-write Congressional laws. This puts interpretation, which is a judicial thing, under the guise of an enforcer. It gets to the point where you say, "Why did I have a piece of paper called the Constitution to begin with?" I get the practicality of having to do stuff, but can't we have a regulatory process that in some way really reflects the intent of the base document?

Mrs. Kathryn Schiller Wurster [from the audience]
Each agency right now is responsible for understanding the impact of regulation within their own domain, right?

Dr. Lee Buchanan
They're not responsible for it and that's the problem. There's no person in any agency that can look at a proposal and say, "Aside from the content of this regulation, the way it will interact with other regulations makes it ill-conceived." There are no goals. There are no metrics.

Audience Member
Isn't there a period of public comment where you send your regulations out and the public comments? I used to work for the EPA, and I actually wrote regulation. As lengthy as the process was, there were steps of accountability. I'm not saying it worked in the end, but at least there were steps of accountability. There were periods of public comment and Congress could respond. Loopholes were slowly ended.

Ms. Michelle Jackson
Yes, and I think that was to my point earlier. I think that in the FDA, that process works and it is beneficial. That's the one way stakeholders get to provide their comment in terms of, "FDA, you haven't considered this and its practical effect on my company. Let's think through what this will mean for me monetarily in my day-to-day business. You haven't considered that and you really need to focus on this and revisit another aspect of the regulation." This is helpful and what's missing from the guidance documents. When the agency comes out with a guidance document, they say, "Here's our thoughts. Here you go." Although the agency does ask for comments on a guidance document, it's very different from the formal notice-and-comment rulemaking process. I do find significant benefit to the public notice and comment and allowing the businesses and the stakeholders to make the agency consider aspects perhaps the agency hadn't considered.

Dr. Lee Buchanan
Even in the instance where you have something that's out for public comment, what obligation does any agency have to actually take those comments and fold them in to the regulation once they receive them?

Audience Member
They have to fold the comments in to the regulation.

Admiral Jamie Barnett [from the audience]
Only to the degree that the regulation can be challenged in court.

Dr. Michael Fritze
We are back to accountability. At least you can be held accountable for making a really bad decision.

Audience Member
They have to incorporate the comments. However, what concerns me is Dr. Buchanan's comment. After the regulation is in place, you don't have a way of deregulating it if it was a bad regulation or if there was an issue.

Dr. Lee Buchanan
Or if it was a good regulation that's now bad.

Audience Member
Right. That really concerns me more so than the process of writing it.

Mr. Mike Swetnam
At the accountability level, it's all over the map. Today, we have a set of laws that say, "This is the way you'll handle your immigration problem." We have a set of policy in the administration that says, "Nope, I'm going to do something else in regards to immigration." What's the challenge? It's got to go to court.

Dr. Lee Buchanan
Even more perfidious was one of the earliest examples I mentioned. Here's a law that unambiguously expressed clearly the intent of regulation to do other transactions aside from the FAR. Through a set of regulatory actions that over a period of 8-10 years through the Executive branch, it denuded the law. Now the DoD has taken a law and invalidated it through regulation.

Dr. Michael Fritze
Can you sue? Can you go to the courts?

Mr. Mike Swetnam
If you have enough money you can sue over anything. It doesn't mean you are going to win.

Dr. Michael Fritze
But if you negate a law, isn't that the grounds for judicial action?

Dr. Charles Mueller
Why doesn't Michelle tell us.

Ms. Michelle Jackson
Yes, you can sue the government. Do most companies have the stomach to do so? No. It's a long, tedious process, but it does happen. I know more about the FDA because that's what I do every day. There have been instances where companies have sued the FDA over the agency's regulations governing health claims. FDA basically invalidated the statute. The statute was written to allow companies to make certain types of claims. The FDA was sued and lost. FDA appealed and lost on appeal. The case didn't go to the Supreme Court. The law was changed that way. I will say that it takes a certain mindset of a certain company who is really willing to challenge the government, and who isn't afraid. A lot of companies are afraid that, "If I challenge the government, am I going to have an FDA inspector at my door tomorrow looking at me very, very closely?"

Dr. Lee Buchanan
Does the plaintiff ever get another contract? No!

Ms. Michelle Jackson
It takes a certain mindset that is very willing to challenge. But it can happen. It's not fast.

Dr. Michael Fritze
That doesn't sound like a practical option.

Ms. Michelle Jackson
No.

Mr. Mike Swetnam
I consider myself a Washington D.C. guy. For a lot of things, the Washington guys will tell you that for most things, it's easier to change the law then to sue.

Admiral Jamie Barnett
I'm an admitted recovering regulator having spent some time with the FCC. Sometimes these issues are agency specific. For the Federal Communications Commission, it's a field dominated by large companies, such as AT&T, Verizon, Comcast, ABC, NBC Universal, and they will take you to court. Therefore, the FCC actually becomes risk averse and will draw out their rulemakings or pullback on their rulemakings to change them. Consequently, you do see case names that are Verizon v. FCC or Comcast v. FCC that make precedent. Therefore, it probably depends on the field and the wherewithal of the companies to actually take on the government.

Mr. Mike Swetnam
That's a good point.

Dr. Charles Mueller
Is that unique to the FCC? They're an independent regulatory agency so they don't necessarily have the same oversight of the Office of Management and Budget and OIRA, right?

Admiral Jamie Barnett
Actually, this is what Lee was talking about just a minute ago. What you've asked are two different questions? At least since the Obama administration, there is a requirement now that OMB review the cost benefit analysis. The regulatory agency has to come forward with something for the OMB to review. Where is the bar on that review? Sometimes these reports do include metrics. For the FCC, if you are trying to determine the accuracy of a cellphone being located for a 9-1-1 call, it can be easy to get great metrics, such as within 50 meters 67% of the time. You can test those numbers in a test bed or in the field. However, if your goal is, "We're going to promote competition," that's a little bit harder. The agency is going to be all over the place. Who wins? Who loses? It gets very difficult with competing economists. OMB is not really going to wade in on that very far.

Dr. Charles Mueller
It sounds like if the existing statute were more clear and less ambiguous, it leaves less room for the regulator to make judgement calls.

Mr. Mike Swetnam
You're asking for Congress to do a better job. We're in trouble.

Dr. Jennifer Buss
It sounds like all we're asking for is to know the intent up front. If we always know the intent, we can describe those metrics. If we're asking Congress to put the intent in, then that's never going to happen.

Dr. Lee Buchanan
That's right. Furthermore, it's often in their interest to have little clarity because it allows for great latitude in interpretation of the law.

Mr. Mike Swetnam
Correct.

Dr. Lee Buchanan
That's the way the system works.

Mr. Richard Pera [from the audience]
I think that's true. I have a different question. In Canada, in the last several years, there have been so many regulations that it's really hurt independent business. They have a National Federation of Independent Business (NFIB) equivalent in Canada that really pushed for a law that went through the House of Commons and ended up being signed into law. It's a 1-for-1 provision. Every time a law is passed, another law must be appealed because there are just too many. It was very popular. It passed the House of Commons with only one vote against. Could something like that be pursued in our Congress? Could an equivalent of that be done in the legislative arena?

Mr. Mike Swetnam
Congress is not that disciplined. We keep coming up with these things meant to restrain Congress, such as Budget Control Acts. Congress doesn't have the discipline. Even if you had a Constitutional amendment that said that Congress must repeal a regulation for every new regulation, Congress would find a way around it. We just found a way around a Constitutional requirement that treaties needed to be approved by 3/4 of the Senate. Congress will avoid any discipline that you try and layer on them. There are other forms of government that have less of a regulatory problem than the United States. For example, true parliamentary systems don't have quite this problem and my theory is it because the legislature and executive are always of the same party. When they pass a law, the branch implementing it does so with the same intent. The regulations follow the law in a closer way. When you have a divided government, like we often have in the United States, the intent of Congress is often not the intent of the executive implementing it and you're going to end up with different interpretations.

Dr. Lee Buchanan
I'd be interested in knowing in Canada who gets to pick the law to be repealed. When I pass a law, Thursday's national popcorn day and I'm going to repeal Obamacare.

Mr. Richard Pera
From my understanding, the actual person who introduces the legislation gets to choose and that can change. There's a conference procedure. It's the individual legislator and, obviously, that takes some political handsmanship.

Audience Member
How much of the issue with regulation is really structural? The fact that you have Congress making laws and they have their idea of what the goal should be. Then you have the executive branch – a totally different branch – having to interpret "Did the Congress really want this? Do I even care what Congress really wanted when I'm deciding what regulation I'm going to make?" As well as just the pressure for the executive that they have to enforce the law. There might not be time after the law is passed to say, "What am I really going to do here and what kind of metrics can we look at?" I don't know enough about how regulation is made but there is a time pressure as well that we have to start enforcing things. How much is just built into the way our system of government is?

Mr. Mike Swetnam
That problem of our structure probably accounts for half of or more of the overall problem with the regulatory process. It would be wonderful to say this is all bureaucratic. It's all just good people trying to do the right thing and it's led to a system that needs to be fixed. No. There's an awful lot of this, "Yeah, they handed me that law and I'm going to enforce it," and "I don't agree and I'm going to find a way to make it not work." You should expect that.

Dr. Charles Mueller
The fact that we operate as a democracy definitely complicates making rules in society. Everyone is going to have a point of view. No one is going to agree on things. Tying the bureaucracy into the Congressional and governmental side of things is one of the problems. We don't have a good process or structure. The APA was supposed to help with the structure, but it clearly isn't working as well as we need it to.

Mr. Mike Swetnam
There's a really important thing that happens on January 21st after every presidential election when we change parties. A lot of people don't pay attention. Probably the biggest spike in change in US law and policy happens the day after a president is sworn in. Every new president issues about 50 executive orders on his first day and most of them are repealing policies of their predecessor. All that happens on his or her first day in office. It's missed by a lot of people. As much of our policy is from legislature, we have at least the same amount from the executive in regulatory action that is repealed every time we elect a new president. Maybe if we had more presidential elections and elected more people it would repeal more of the regulations we don't like.

Dr. Charles Mueller
I would like to ask Michelle a question. We had talked a lot about regulations that don't work and how policy is broken. If we want to figure out what we should be doing, we should talk about maybe a couple examples of regulation doing what it's supposed to do.

Ms. Michelle Jackson

I have a mixed example. It relates to the over the counter (OTC) drug review process of the FDA. It's a way for drugs not to have to go through FDA approval with an application for certain over the counter drugs that are commonly available in the marketplace. FDA started the process of the OTC drug review back in 1972, and we're not done yet. That gives you an idea of how long this process takes. While there are currently some examples of the process not working, there are some that certainly do work. Some of the drugs went very quickly through the review process. FDA established a monograph telling companies, "If you have these ingredients at this percentage, if you make only these label claims, and you use only these indications for use, you can go to market with your product without us having to review the individual product." That worked for a large category of the OTC drugs for which the FDA required reviews. Even in terms of change, I've seen regulations work. For example, one category of drugs is skin bleaching drug products. FDA published a tentative final monograph, but they hadn't finalized it yet. It had been in place for many years, perhaps since 1982 or so. FDA published the tentative final monograph and the industry had been following this tentative final monograph for releasing these products on market. In 2011 or 2012, the agency decided that it had more information, these drugs were no longer safe, and they needed to be taken off the market. It published an interim final rule, effective immediately, "We don't consider these drugs safe anymore and we're going to take them off the market." What we immediately saw was the industry came forward and say, "No, no, no. The science you're relying on is faulty. It's only a certain category of products. There's a whole set of data out here showing that these products are safe and effective. FDA, you're making a mistake." The industry rallied and gave all this data to the FDA. The FDA took a look at it and a couple months later said, "We think you're right," and they didn't drop the interim final rule but effectively hit the pause button and said, "We're not going to take any action right now." It's allowed these companies to continue marketing. FDA effectively, without saying "we were wrong," admitted they hadn't seen all the data and allowed products to continue to be marketed. There are other examples of drugs where the agency has gone through the process, but hasn't gotten to the point of a final monograph, where it allowed these companies a significant benefit in terms of going to market. Many companies can't afford the drug application process, and I see rulemaking working in this context. There are also some examples in the OTC monograph drug review process where it's not working, but I can get into that later. I want to give you an example where we see it working and it worked well and I think the industry is largely happy with it.

Dr. Charles Mueller

My question is how do you know it's working?

Ms. Michelle Jackson

When industry is quiet, it is a good thing. When you see a regulation that I would consider bad or not helping, you hear a lot of industry grumbling or you will hear a lot of consumer complaints to FDA. When we don't hear that, I think you can largely presume that things seem to be going well and the industry seems to be happy with it. You can also see the benefit at the level of the company, in terms of allowing smaller companies to get into the marketplace when they couldn't afford a new drug application. They can come to market with their topical pain reliever for arthritis

that you rub on your hands. Companies can have these types of products without having to pay the $300,000 to submit a new drug application.

Dr. Lee Buchanan
But the no scream metric can work both ways. It either says the regulation is working fine and it's delivering benefit; or it's doing nothing at all and nothing has changed and so no one cares.

Dr. Charles Mueller
None of this gets at the, "Is the regulation doing what it's supposed to do." Right? It's not Congress that's looking back saying, "Yeah, the law is being interpreted just as we wanted it to and that's the regulation we intended." It's the regulated community saying, "We're okay with that."

Admiral Jamie Barnett
What if you have both of those metrics? Speed to market: the company that wants to put this on the market in a short amount of time. Second, taking the percentage of consumer complaints. Then the company has passed through the regulatory gauntlet in a modicum of time and apparently the consumer is satisfied and this is not a complaint. There seems to be a basis for a metric in that particular example, anyway.

Dr. Charles Mueller
I remember hearing an example of the FDA using Google searches to determine if people were complaining about side effects of different drugs and using that metric to determine if consumers were reaching out or if they were upset about it. The FDA does a decent job I think of at least trying to assess consumer complaints. My goal is to get the regulatory process to a point where we're measuring the impact of regulations we need and determining whether they are working. Who are we looking to give us that answer?

Dr. Lee Buchanan
Do we put the drug preliminary process in the hands of people?

Ms. Michelle Jackson
I think the purpose of the OTC drug review is speed to market and accessibility because smaller companies don't have the financial wherewithal to speed things along.

Mr. Mike Swetnam
What we're lacking is the discipline and structure we're talking about. I think you could find Congress has written the authorization for the FDA in last three or four years with the intent for speed to market and lower level of entry for lots of drugs like this. The intent is there. Clearly people aren't grabbing. All we're lacking here is the discipline to actually measure the metric. "Did the speed to market get reduced or not?" and actually compare that against the intent of Congress and say there's your measure.

Mrs. Kathryn Schiller Wurster
I don't think the person doing that measuring necessarily has to be the agency itself. It doesn't have to be the regulator.

Dr. Lee Buchanan
As a matter of fact, it shouldn't be the agencies.

Ms. Kathryn Schiller Wurster
It can be a neutral third party observer that then goes back to Congress and says they haven't been implementing the legislation in the way that you intended or there's too much regulation.

Mr. Mike Swetnam
Perhaps doing this as a public service?

Dr. Charles Mueller
I'm pretty sure the UK has a program in place where they are actually analyzing, using a science-based approach, if the laws that are being passed are creating the behaviors that were intended. They throw money not only at developing regulation but also studying regulation and its impact.

Ms. Kathryn Schiller Wurster
To go back to the concept of having a metric in place if you want to pass this regulation at all, that seems like opening a window to shutting every regulatory process down.

Dr. Lee Buchanan
Would that be a bad thing?

Ms. Kathryn Schiller Wurster
In the case of public safety and health, I don't think you want to give an out to say if you can't prove the benefit or the risk then you just can't do anything about it.

Dr. Lee Buchanan
No, that just sends it back to the legislative process.

Mr. Mike Swetnam
I don't know. I think that's arguable.

Ms. Kathryn Schiller Wurster
There are some things we regulate that are public benefits that are difficult to measure, such as environmental issues.

Dr. Lee Buchanan
Is the seatbelt requirement a regulation or a law?

Mr. Mike Swetnam
I think it's both.

Dr. Charles Mueller
I think it's a regulation.

Dr. Lee Buchanan
That would be an example of a public benefit from regulation, if it is indeed a regulation. I don't know.

Mr. Mike Swetnam
The impact of that is very measureable. So much so that insurance companies use it as a metric.

Dr. Lee Buchanan
The seatbelt law, the airbag law, those all have measurable consequences. I don't know if those are laws or regulations.

Dr. Rebecca McCauley Rench
But the seatbelt laws also vary state by state. Not all states have the same laws.

Mr. Mike Swetnam
That's the use of seat belts. Installation is a regulation. The requirement to have them in cars is a federal regulation. Some things are hard to measure, like research and development. But some things that at first people think aren't measurable are measurable. I think an awful lot of clean water and air and environmental regulations are very measurable.

Dr. Lee Buchanan
There's going to be the natural reluctance of anybody, including the regulator, to put metrics in place that the person does not believe are going to be met. They'll make the metrics as loose as they can and there's no natural tension to the drawing back the other way. That's when the introduction of a third party is valuable.

Dr. Charles Mueller
In regards to the FDA, the 21st Century Cures Act being desbated in Congress has the goal of a way to fast track the drug approval process. Part of that is to change the metric for efficacy from an actual health endpoint like death or survival to some surrogate endpoint like tumor shrinkage. This speaks to your point, Lee.

Mr. Mike Swetnam
Those ideas should come from Congress. The more I think about it, the intent of Congress on these types of things is pretty clear. Every bill starts with, "This piece of legislation is being written because we're mad at this." It's almost always pretty clearly stated in the bill. There's your intent.

Audience Member
By the time Congress's intent gets implemented, it's pretty convoluted.

Mr. Mike Swetnam
I had a comment earlier about this whole thing. Congress says something and then the administration or the executive branch goes to interpret it and figure out what the regulation is. This is the truest example in the world of that old saying, "The devil is in the details."

Dr. Robert Hummel:
Let me posit why I think that the details are important when discussing the International Traffic in Arms Regulations (ITAR). If you look at the original Export Control Act, it would seem that the intent is to prevent the export of military items abroad. Very quickly that became, "Let's not teach people how to build military equipment abroad." My interpretation of the true intent is to maintain US dominance in military equipment.

Mr. Mike Swetnam
It says that in the first two paragraphs of the Export Control Act from 1976.

Dr. Lee Buchanan
The Export Control Act was written at a time when there was something to protect.

Dr. Robert Hummel
Exactly. The most obvious metric would be how much equipment is moving overseas. A more proper metric would be the US dominance in military technology. It's a confused situation and getting the right goal at the start might not be easy.

Dr. Lee Buchanan
This is an ideal illustration of where a regulation made sense at the time, but we've progressed out from under it and now it doesn't, but it persists nonetheless.

Dr. Jennifer Buss
In order for us to fix it, we have to add more regulations rather than deregulate.

Mr. Mike Swetnam
No, you can kill a law.

Dr. Jennifer Buss
It's a law, so it's different.

Dr. Charles Mueller
In order to fix a regulator's problem, you need to be able to remove an ineffective regulation.

Mr. Mike Swetnam
I'd like to go back to what I was saying a minute ago, which is the mountain of regulations are on top of me and I'm at the one-foot level perspective. There are only two answers to moving the mountain. Either change the law, or get a President to write an Executive Order that rescinds it. You can't ask the regulatory process to undo itself.

Mr. Richard Pera
You mentioned before, in the case of the FDA, it took a major public health crisis to change the way that it operated. With DNI, it took 9/11 to bring it about. For APA, the whole history was a Great Depression and the New Deal and then political negotiations that ended up bringing it to

life. What would it take to have a major APA reform like that today? If it took a Great Depression and all that history that lead to 1946, what does it take now?

Mr. Mike Swetnam
It would take the election of a libertarian to President.

Mr. Richard Pera
Reasonably, how could the APA possibly change?

Dr. Charles Mueller
What does a regulatory crisis look like?

Dr. Lee Buchanan
There was a financial crisis in 2008 that was supposed to be the precipitating event around changing a lot of federal financial policy, but it did nothing. That crisis brought us right to the brink of disaster. I am loath to think of what beyond that it would take to change anything.

Dr. Charles Mueller
Didn't the Dodd-Frank Act apparently require the implementation of approximately 10,000 new regulations? If you keep using the same process, at some point you're going to go crazy because it's not working.

Mr. Mike Swetnam
We started on this subject because one of our guys, Tevi Troy from HHS, wrote a book about the healthcare system, *U.S. Health Policy: An Insider's Perspective*. I recommend the book to you all. I started with his book and then went to two or three other people's books analyzing the impact of the Affordable Care Act (ACA). As an example, at the Potomac Institute, health insurance has gone up 20% this year, on top of 20% the year before, on top of 20% the year before that. That's not a 60% increase, but rather compounded. It's about 100% increase in our healthcare costs in three years. Where did that extra money go? A lot of these books, including Tevi Troy's, are looking closely at where the money went when we re-did the healthcare system and re-shuffled the money. There are 6 million more Americans covered by health insurance than there were before. Did that 100% increase in my healthcare costs go to 6 million Americans insured under the new healthcare? Did our 100% increase at the Potomac Institute cover 6 million more Americans? Guess where most of the money went. It went to answering the new bureaucracy and requirements of the Federal Government. In one book, the author says 65% of the increase in healthcare costs was due to the increased administration of healthcare, the insurances, regulations, and reporting. That is a 60% increase in our overhead for healthcare.

Dr. Robert Hummel
We call that compliance overhead.

Mr. Mike Swetnam
Increasing the overhead of healthcare wasn't the intent of Congress.

Dr. Alan Moghissi [from the audience]
Rules covering acquisition regulations is not my area of competency. However, about three or four years ago, an associate of mine evaluated the number of regulations that are being published in the *Federal Register* per agency. The number one conclusion was that the EPA had almost as many regulations as all other agencies combined.

Mr. Mike Swetnam
That doesn't surprise me. I think I have a reason for that number at the EPA. I think the metric you're citing is probably correct, and I think it makes sense to me.

Dr. Alan Moghissi
I have followed the evolution of regulations and their scientific foundation. The reason is that the EPA comes up with metrics. The EPA says, "If you reduce exposure to ozone from so many ppms to so many ppms, then so many lives are saved." However, the problem is the science used to do the computations is based on so many assumptions and judgments. In the majority of cases, depending on what science you use, the number is zero. The point is that the assumptions, judgments, opinions, and very often political visions included in an agency's decision are a huge part of the metrics used. I'm excluding purchasing because that's the part I know nothing about.

The idea of converting the prescriptive-based regulations to performance-based regulations would provide some metrics. Hopefully, that would be the methodology that, once the system is established, would be very useful. Needless to say, I'm very pleased that the Potomac Institute now has a Regulatory Science and Engineering Center. This is in addition to the Institute of Regulatory Science, which I am the head. Regulatory science is a lot more than regulatory pharmacology. It includes regulatory ecology, regulatory atmospheric sciences, regulatory whatever-you-want. I am very pleased that Potomac Institute has a RSEC.

Mr. Mike Swetnam
Bob Hummel, our chief scientist, has a wonderful saying, "All these titles that have 'science' in them generally don't really have science, like political science." I'm with you 100%. Whether there is anything today that can be properly put in a bucket and called *regulatory science*, we certainly need to be studying and developing it and figuring out what a rigorous science for the development of regulations would be. That's your goal, Charlie.

Dr. Charles Mueller
Yes, that is the goal.

Mr. Mike Swetnam
This is a good opportunity to start winding this seminar down. As I said at the beginning, this is the first of a number of seminars. This one will be written up and start to populate our website and publications. The hope is that, more than just understanding it and developing some thoughts and ideas around it, eventually we get to the point that we have some hard recommendations and policy to advocate on the Hill and in the Administration. Those recommendations will hopefully

change things for the better. We will not add to the mountain, but will figure out how to make the mountain a little more mobile so its not crushing all of us.

Dr. Lee Buchanan
I would like to suggest when you go through your analysis and look at your recommendations, please keep in mind the dominant factor of human self-interest that is driving the regulatory process and how you can take that out. I don't know how to do that. We can rationalize. We can put down metrics. We can regulate the regulatory process, but the human-interest piece of this dominates all.

Dr. Charles Mueller
I fully agree. When I talk about regulatory science, I end up talking about it more as the science of the actors involved because without taking them into consideration, nothing happens. That is the hardest part of regulatory science – the social or behavioral side. The criteria, which Dr. Moghissi was eluding to, is how do you make sure you're incorporating the best available science to inform your decision to make a regulation and to determine whether it's working. That last part is what we've hit on all day, the structural element of that 1000-foot view of, "What's the process?" There must be a better way to do this and that's going to take a lot of thinking. That's what is really important about having these seminars and drawing the awareness now because, as we keep doing these events, the questions will become more focused and, hopefully, we will come up with some real answers. Maybe that takes the form of trying to write a law that exempts a particular agency from having to deal with the APA, or that completely rewrites the APA itself.

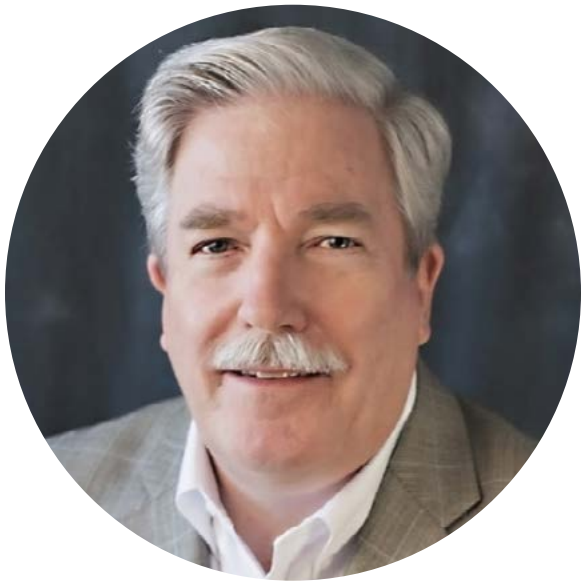
The Honorable Dr. Lee Buchanan

President and CEO, Areté

Dr. Lee Buchanan joined Areté as President and CEO in January 2014. He has over 35 years' experience in technology development, transition, and the acquisition of advanced technology systems in the Department of Defense and the Private Sector. Most recently, he was a Venture Partner with Paladin Capital Group in Washington, DC. Prior to Paladin Dr. Buchanan was Vice President, Advanced Concepts, EDO Corporation, a $1B producer of Intelligence, Electronic Warfare, sonar, and weapons systems for the US military; Executive Vice President of Perceptis, a holding company for producers of wireless data collection and intelligence systems; and President and CEO of QualStream.

Dr. Buchanan has also had a significant career with the US Government serving as Assistant Secretary of the Navy (Research, Development, and Acquisition), the most senior executive for research, development, and acquisition for the US Navy and the US Marine Corps; Deputy Director and Acting Director of the Defense Advanced Research Projects Agency; Division Manager for Titan Corporation; Senior Research Physicist at the Lawrence Livermore National Laboratory; and Naval Aviator.

Dr. Buchanan is also a Director of Tektronix, Lucent-Alcatel Government Solutions, TestMart, Corp., and the Robotics Technology Consortium.



Mr. Michael S. Swetnam

CEO and President, Potomac Institute for Policy Studies

Mr. Michael S. Swetnam assisted in founding the Potomac Institute for Policy Studies in 1994. Since its inception, he has served as Chairman of the Board and currently serves as the Institute's Chief Executive Officer.

He has authored and edited several books and articles including *Al-Qa'ida: Ten Years After 9/11 and Beyond*, co-authored with Yonah Alexander; *Cyber Terrorism and Information Warfare*, a four volume set he co-edited; *Usama bin Laden's al-Qaida: Profile of a Terrorist Network*, co-authored with Yonah Alexander; *ETA: Profile of a Terrorist Group* co-authored with Yonah Alexander and Herbert M. Levine; and *Best Available Science: Its Evolution, Taxonomy, and Application*, co-authored with Dennis K. McBride, A. Alan Moghissi, Betty R. Love and Sorin R. Straja.

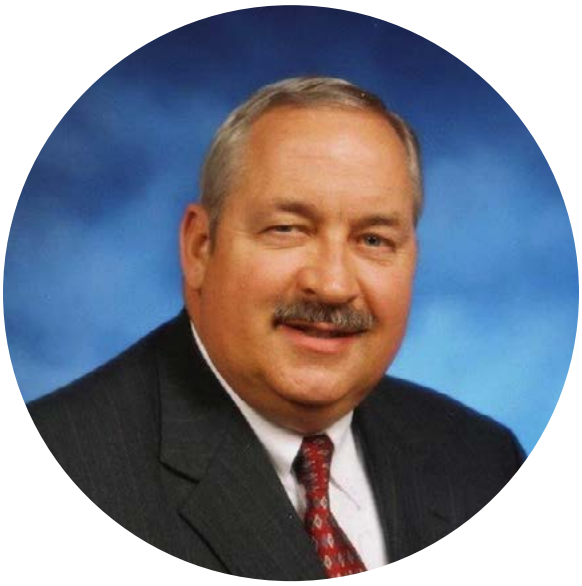
Mr. Swetnam is currently a member of the Technical Advisory Group to the United States Senate Select Committee on Intelligence. In this capacity, he provides expert advice to the US Senate on the R&D investment strategy of the US Intelligence Community. He also served on the Defense Science Board (DSB) Task Force on Counterterrorism and the Task Force on Intelligence Support to the War on Terrorism.

From 1990 to 1992, Mr. Swetnam served as a Special Consultant to President Bush's Foreign Intelligence Advisory Board (PFIAB) where he provided expert advice on Intelligence Community issues including budget, community architecture, and major programs. He also assisted in authoring the Board's assessment of Intelligence Community support to Desert Storm/Shield.

Prior to forming the Potomac Institute for Policy Studies, Mr. Swetnam worked in private industry as a Vice President of Engineering at the Pacific-Sierra Research Corporation, Director of Information Processing Systems at GTE, and Manager of Strategic Planning for GTE Government Systems.

Prior to joining GTE, he worked for the Director of Central Intelligence as a Program Monitor on the Intelligence Community Staff (1986-1990). He was responsible for the development and presentation to Congress of the budget of the National Security Agency, and helped develop, monitor and present to Congress the DOE Intelligence Budget. Mr. Swetnam was also assigned as the IC Staff representative to intergovernmental groups that developed the INF and START treaties. He assisted in presenting these treaties to Congress for ratification. Collateral duties included serving as the host to the DCI's Nuclear Intelligence Panel and Co-Chairman of the S&T Requirements Analysis Working Group.

Mr. Swetnam served in the US Navy for 24 years as an active duty and reserve officer, Special Duty Cryptology. He has served in several public and community positions including Northern United Kingdom Scout Master (1984-85); Chairman, Term limits Referendum Committee (1992-93); President (1993) of the Montgomery County Corporate Volunteer Council, Montgomery County Corporate Partnership for Managerial Excellence (1993); and the Maryland Business Roundtable (1993). He is also on the Board of Directors of Space and Defense Systems Inc., Dragon Hawk Entertainment Inc., and the Governing Board of The Potomac Institute of New Zealand.



Ms. Michelle Jackson

Attorney, Venable LLP

Ms. Michelle C. Jackson, Esq. is an attorney at the American Law 100 law firm Venable LLP. Venable has over 600 attorneys in 9 offices around the country and has a proven track record in all areas of corporate and business law, complex litigation, intellectual property, and regulatory and government affairs. Ms. Jackson has had over a decade of experience working with the complex regulatory matters of agencies like the USDA, FTC, and FDA. She was recently named one of the Washington Super Lawyer Rising Stars for Food and Drugs in 2014.

Ms. Jackson's practice is focused on regulatory counseling concerning the development, formulation, manufacture, distribution, and promotion of foods, dietary supplements, drugs, medical devices, and cosmetics. She handles matters involving regulation and enforcement by federal and state agencies, including the US Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the United States Department of Agriculture (USDA), and the Consumer Product Safety Commission (CPSC). She also regularly handles matters involving self-regulatory bodies such as the National Advertising Division of the Council of Better Business Bureaus (NAD) and the National Advertising Review Council's Electronic Retailing Self-Regulation Program (ERSP). In addition, Ms. Jackson provides valuable assistance to clients in litigation and settlement negotiations.

Ms. Jackson represents numerous clients, helping them to navigate the complex regulations governing foods, food contact substances, dietary supplements, animal supplements, medical foods, over-the-counter (OTC) drugs, homeopathic drugs, medical devices, cosmetics, and consumer products in various stages of the product lifecycle. Ms. Jackson assists clients from the beginning stages of product development, advising on product formulation and design. She also assists clients in obtaining product clearance, approval, or permits, such as 510(k) clearance for medical devices or USDA import permits for animal-derived products. She likewise assists clients in submitting required notifications, such as new dietary ingredient (NDI) or GRAS notifications. With regard to product manufacture and distribution, Ms. Jackson advises clients on FDA's good manufacturing practice (GMP) requirements and the CPSC's requirements with regard to child-resistant packaging and certification for consumer products. She also assists with product and facility registration and listing.

With regard to product promotion, Ms. Jackson has a strong understanding of both labeling and marketing requirements. She routinely advises clients on all aspects of product labeling, with particular experience in the labeling of OTC drugs, foods, and dietary supplements. She is extremely familiar with the types of claims permitted for dietary supplements, including health claims, qualified health claims, structure/function claims, and nutrient content claims. She also advises clients concerning the use of the term "organic" on product labeling. Of particular importance, Ms. Jackson understands the expectations of regulators and self-regulatory bodies

with regard to claim substantiation. She regularly advises clients on the FTC regulation of product advertising via the Internet, television, print media, and radio. Ms. Jackson has assisted with the successful defense of advertising claims before the NAD and ERSP, as well as successful challenges of competitor advertising.

With regard to agency enforcement, Ms. Jackson advises clients concerning FDA inspections and helps clients respond to inspectional observations (form 483). Likewise, she has significant experience helping clients respond to Warning Letters from the FDA, civil investigative demands (CIDs) from the FTC, and subpoenas from the FTC or State Attorneys General. Ms. Jackson also helps clients with product recalls and with issues relating to the importation or exportation of FDA-regulated goods, such as import detentions and export certificates.

Ms. Jackson has also been involved in litigation concerning constitutional and administrative law issues before the FDA, the FTC, and the federal courts.

Dr. Charles W. Mueller

Director, Regulatory Science & Engineering Center Potomac Institute for Policy Studies

Dr. Mueller is Director of the Potomac Institute's Regulatory Science & Engineering Center. He works on identifying important S&T regulatory issues and developing rational policy solutions through an approach based in the best available science. Additionally, Dr. Mueller is the lead on a contract the Potomac Institute has with the Office of Corrosion Policy and Oversight within the Department of Defense (DoD) that is attempting to optimize the DoD's current Corrosion Prevention and Control strategies by applying regulatory science & engineering principles.

Prior to joining the Potomac Institute, Dr. Mueller obtained his doctorate in biochemistry from the University of Maryland's Chemistry and Biochemistry Department in 2014. His dissertation involved the characterization of two putative DNA metabolizing enzymes in the bacterium *Deinococcus radiodurans* and required a combination of molecular biology, cell biology, microscopy, and biochemical analyses. Before obtaining his doctorate he obtained a B.A. in Chemistry from Elon University and then worked at the National Cancer Institute at the National Institutes of Health studying the effects of selenium on cancer using both live mouse models and tissue cultures.

Dr. Mueller is a member of the American Association for the Advancement of Science (AAAS).

REGULATORY EFFICIENCY
IS OUR REGULATORY PROCESS WORKING?

RSEC hosted this seminar as the first of its 2015 Regulatory Science & Engineering Symposia Series on September 15, 2015. An initiative of the Potomac Institute's Regulatory Science & Engineering Center, the seminar was intended to provide a forum to discuss the United States Federal rulemaking process. The goal was to develop a clearer understanding for how it works, the assessment criteria used during it, the impact it has on society, and importantly its effectiveness at changing society's behavior for the better. This seminar focused on discussing the effectiveness of our current Federal rulemaking process and the necessary steps needed to be taken in order to develop a quantitative, reliable metric for measuring regulatory efficiency. The seminar featured a distinguished panel that included Mr. Michael S. Swetnam (CEO & Chairman of the Board, Potomac Institute), The Honorable Dr. Lee Buchanan (President & CEO, Areté Associates), Ms. Michelle C. Jackson, Esq (Attorney, Venable LLP) and Dr. Charles Mueller (Director, RSEC).The distinguished panelists discussed their experiences with the Federal regulatory process and offered insight into what a metric for evaluating regulatory efficiency might look like.

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The Potomac Institute for Policy Studies is an independent, 501(c)(3), not-for-profit public policy research institute. The Institute identifies and aggressively shepherds discussion on key science, technology, and national security issues facing our society. The Institute hosts academic centers to study related policy issues through research, discussions, and forums. From these discussions and forums, we develop meaningful policy options and ensure their implementation at the intersection of business and government. The Institute remains fiercely objective, owning no special allegiance to any single political party or private concern. With over nearly two decades of work on science and technology policy issues, the Potomac Institute has remained a leader in providing meaningful policy options for science and technology, national security, defense initiatives, and S&T forecasting.

The Regulatory Science and Engineering Center (RSEC) at the Potomac Institute for Policy Studies is a definitive source of information on developing and implementing regulatory policy based on science and technology. RSEC builds and maintains a comprehensive library of knowledge regarding the science behind making regulatory policy and the history that created the foundations of our current regulatory practices. Additionally, RSEC serves as a resource center for all individuals or organizations that attempt to practice regulatory science by establishing various tools and processes that can assist in the practice of using science and technology in developing regulations and regulatory policies. Taken together, the basic mission of RSEC is to communicate best practices of regulatory science and engineering for the development of regulation and regulatory policy to government agencies, academia and industry, and develop new tools, standards and approaches to designing, implementing, and managing regulations and regulatory policy.