

Q1 2004 Alliance Advisory Interview

[Alliance Sciences](#), a global leader in organizational partnering consulting, interviewed the US FDA's Peter Pitts, Associate Commissioner External Relations, for their [Q1 2004 Alliance Advisory](#) newsletter. Peter discussed the difficulties associated with cross industry collaboration and shared case studies and management processes that are critical to the FDA's success in partnering.



Peter Pitts

Peter Pitts is one of the country's most respected writers and councilors in the arena of strategic leadership communication. His advice is sought by leading corporate and political leaders around the world.

His most recent book, *Become Strategic or Die*, is widely recognized as a cutting edge study of how leadership, in order to be successful over the long term, must be combined with strategic vision and ethical practice.

Mr. Pitts writes a regularly syndicated national column for United Press International on topics related to successful leadership practices. He is frequently interviewed by the business press and has recently published a well-regarded article on communications theory in *The Strategist* and on crisis communications in the wake of the recent StarLink/biotechnology crisis in *PR Tactics*.

Mr. Pitts is FDA's Associate Commissioner for External Relations. As FDA's "Chief Messaging Officer," Mr. Pitts challenge is to clearly define FDA's brand image and to communicate the agency's main themes to its many constituencies. He sees FDA's mission within the acronym of "SELF," – Sound science, Ensuring safety, Lowering costs, and Fostering innovation. Read the [full bio here](#)

PP: Let me just start by mentioning that the FDA has been around almost 100 years. For our first hundred years our mission was protecting America's health and our mission for the second hundred years is protecting and advancing America's health. That's appropriate for Partnerships because protecting is adversarial in a sense because you "protect from" whereas for advancing you "advance with" – it needs to be collaborative and that is in many respects a new mindset for folks at the FDA. In many instances we have to both regulate AND partner with facilities and that's going to be an interesting duality. We're going to have to learn how to have both those relationships simultaneously.

AS: Why does the FDA incorporate Alliances, or leveraging, as a part of its strategy? Can you speak to the importance of leveraging as a part of the 2004 Performance Plan? See <http://www.fda.gov/ope/fy04plan/2004pp-appendixd.html>

PP: The important thing to understand is for us to succeed in our mission we need resources both and academic. We need the best minds & the best resources to work with those minds. We have finite resources both from a budget standpoint and a human resources standpoint. So, to assume we can do it all with what we've got is not the best way to go. We want to reach out to people, we want people to share what they're thinking and from an outreach standpoint...

AS: With whom does the FDA collaborate?



See <http://www.fda.gov/ope/fy04plan/2004pp-appendixd.html>

PP: It really covers the water front, we have such a broad number of constituency group among the food and drug continuum – it really is anybody and everybody we deal with on a regular basis – also including consumer groups. I'll give you an example, hormone replacement therapies – we recently concluded a study that showed there were issues with that. We partnered with pharmaceutical companies, we partnered with women's groups and we partnered with consumer advocates and we partnered with retail pharmacies to get this message out as to the appropriate way to get this message out. What we have that no one else has is the bully pulpit to get people excited and magnetized around a given issue – whether it's importation of drugs, dietary supplements, safety in food or safety in drugs. We can act as the catalyst or change agent around whom these folks can focus their efforts and be sure that they're all on point and sharing the same message.

AS: Can you cite a particularly successful collaboration as an example?

See <http://www.fda.gov/oc/leveraging/activities.html>

PP: Yes. As demographics of the country change and the Hispanic population becomes a leading minority group, we have a much greater need to reach out to that population in Spanish on public health issues. And the question becomes can we hire a parallel staff to communicate with these constituents in Spanish, and the answer of course is no. So what can we do? So what we did is we reached out and found the leading Hispanic health care organization called the National Alliance for Hispanic Health. We crafted and negotiated an MOU with them where we work with them to get out all our public health messages in Spanish to that constituency, but simultaneously we also hear from them what are the special interests and concerns are of that community. We are contracting it out, we're simply partnering because we both have an interest in accomplishing the same thing. It isn't a vendor or provider/payer relationship, it's a partnership of two healthcare organizations that have a common need, but both have differing areas of expertise and resources.

AS: In what cases will you partner with public sector organizations (federal and state agencies), non-profit (academic institutions, for instance) and private sector (pharmaceuticals companies) organizations?

PP: Let's take food companies for example. We regulate food companies, largely. We would never contract with a company who we regulate. But we meet with them and talk about our concerns and, from our position as bully pulpit speaker, ask them how they can help us help the public. And one area I think of great success in recent memory is the issue of trans fats, wherein the FDA identified trans fats as a major contributor relative to the issue of growing obesity in this country. And we raised the issue and we talked about it with food organizations and food companies and we got them the right things and also supported them with what we wanted to have happen with trans fats... which is basically to minimize its introduction to the American diet. So we could have just regulated it, which we did ultimately, but we went into it with the full support of the food community. It's a lot easier to move forward with that than fight against it. It isn't a question of those we regulated being bad people with only profit in mind, they wanted to



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do the right thing as well, and we recognize that. We want to help them do it and we recognize when they do the right thing as well.

AS: That's a great example from the private sector, how about the public sector or higher education?

PP: Well, that's more common. We started a new department about 8 months called the Department of Intellectual & Academic Partnerships where we are actively reaching out to the academic community to find out how we can help them and what resources they have that can help us as well. Again, we don't exist in a vacuum and we need to know what other people are doing. And I think the bottom line is it's foolish of us to try and re-invent the wheel every time we want to do something.

AS: And what's the primary benefit of those institutions that may want to collaborate with you?

PP: They learn what we know. Again, they get a broad access to the regulatory process and learn what we know. The FDA is a tremendous resource and compendium of information on a wide range of issues.

AS: What makes public-private partnering (P3) particularly demanding or challenging?

PP: Significantly different cultures. Significantly different agenda. What we need to do is ultimately find the concentric aspects of the circle, focus on those. In other words, take pharmaceutical companies for example. Pharmaceutical companies have as part of their core mission public health. Those also have as part of their mission making money. We need to focus on the part of their mission that jives with our mission which is public health. Similarly with food companies, food companies understand that nutritional benefits can be a very powerful marketing proposition. We feel that the more people are educated on better nutrition, the more they can use food as a potent tool to improve their own health... and that's a concentric circle. By understanding where the mutual benefit is, that gives you your leverage point.

AS: How do you manage intellectual property transfer with your Partners? Is this an area of focus? <http://www.fda.gov/oc/ofacs/partnership/techtran/1stpg.htm>

PP: By law, let's take drug applications for example, that information is strictly proprietary. The FDA learns so much, the question becomes how can we – with the understanding that intellectual property rights are present and need to be understood – how can we take what we've learned to help others get to where they need to be faster. In other words, we know so much that could help people improve the public health quicker, how can we use that information to speed along the process with greater safety and greater efficacy and lower costs. Ultimately, if our goal is to bring new safe and effective therapies to market, and we can help to make that happen quicker, that will allow people to be healthier and that saves money too. Milton Friedman, the Nobel Prize winning economist, was quoted in the conference yesterday as saying that FDA is one of the major cost factors for drug development because of our obsession with safety... and that's true. And we accept that, but the question becomes how can we maintain our obsession with



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safety and give that with our desire to improve the public health by expediting better and newer therapies to market.

AS: Dr. McClellan's (FDA Commissioner) economic background is a tremendous asset as the leader of a high profile public sector organization. Can you speak to the performance or management metrics the FDA seeks as a return from partnership efforts?

PP: Apropos of partnerships, metrics are going to be different depending on what you're setting out to accomplish. The metrics are always going to be different, but you need to have them. I think what's important in that respect is when you sit down to create a partnership you need to say how are we going to measure whether this is successful. So I think the answer to your question isn't so much what the metrics are so much as we absolutely as part of the negotiation process put metrics in place. As they say, "if you can't measure it, it doesn't count".

AS: What are the most common mistakes made in Alliances in the public sector?

PP: That a lot of effort is put forth in getting them together, but then they assume that once you have the paper signed, that's the end of the drill. That's really just the very beginning of the drill. A lot of people think that the deliverable is the contract, or the MOU or the Agreement, but that's actually when the work starts.

AS: Is there anything else you'd like to cover? For those who want to learn more about FDA Alliances, where should we direct them? <http://www.fda.gov/oc/leveraging/levcontacts.htm>

PP: We are open to partnering and we mean it. We approach people, but we also need to be approached. Don't hesitate to make contact. As an old boss of mine use to say, "If you don't ask, you don't get it". *Email can be sent to Vicky Kao at vkao@fda.gov.*