



TO: FDA Transition Team

FR: Peter Pitts

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RE: **Areas of Opportunity**

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### **1. A Strong, Science-Based FDA**

Everybody benefits from an FDA that leads. This means the agency has to be out in front of every issue for which it is responsible. Every specific action the agency takes is an opportunity to speak to a larger public health issue. Vioxx, for example, was a missed occasion for the FDA to seize the day on the issue of drug safety. When the FDA confidently leads, other stakeholders follow with their expertise, resources and sense of duty. This is not a people-intensive proposition. But it does require the commitment and the skill to do it – and do it right and regularly.

### **2. The Reagan/Udall Foundation: A Partnership of Unequals**

The FDA must be both regulator in protecting the public health and colleague in helping to advance it. This is a delicate balance and in the current political climate the agency gets no merit points for being seen as collaborating with those it regulates. The best way to do this is via the Reagan/Udall Foundation. Now that the election is over an immediate first step should be for the new FDA Commissioner to meet with Representative DeLauro and issue a joint announcement on moving forward with the work of the agency's Critical Path program to develop the tools necessary for 21<sup>st</sup> Century pharmaceutical and medical device development and regulation. But FDA must be seen as leading rather than simply participating in the process.

### **3. Clarity vs. Ambiguity**

Regulators often love ambiguity – because ambiguity is power. The problem is that such a philosophy can lead to regulatory dissonance – ranging from completed Phase III trials supported by the agency at advisory committee meetings and then derided by a division afterwards, to warning letters sent to companies over marketing materials that have been “pre-cleared” by DDMAC. If people want the various industries regulated by the FDA to follow the rules, there need to be as many bright lines as possible – and they need to apply to everyone equally. While a high degree of pragmatism will always be required, this is not an excuse for “I know it when I see it” regulation.

### **4. Information Management**

The FDA's information management system is dysfunctional. The FDA sits at the crossroads of vast amounts of information that is of vital use to both protecting and advancing the public health. –yet most of it is unusable. The new Commissioner should immediately appoint an IT Czar who, as her first order of business, should audit existing systems and draw up an information technology roadmap for the agency. A solid “taskforce of talent” is needed to address this tremendous opportunity. Solid information management systems will allow the agency to do its job better, faster, and less expensively. A solid public health triple play.



## 5. Food Safety and Security

The agency's programs on food safety and security are failing. Resources at CFSAN (the Center for Food Safety and Applied Nutrition) are stretched drum tight. More money is certainly needed – but there is also a crisis in confidence that the agency knows what its doing – or that it cares. The issue of BPA (bisphenol A) is a good example. The FDA was purely reactive in its call for a review by its panel of experts. As a result, the agency was destined to have its judgment called into question whatever the decision. And this is precisely what happened. This further cements the general perception that the FDA doesn't care and/or is beholden to the industries it regulates. The BPA issue was out there for a long time in a visible way. And the agency didn't do anything. It didn't lead, it followed. And the consequences shouldn't have surprised anyone. A similar situation is brewing with melamine in baby formula. Further, there is a growing sense that CFSAN should be moved to the USDA. Perhaps. But for this to proceed, serious thinking needs to go into two issues: (1) DSHEA and the regulation of dietary supplements as foods, and (2) the increasingly important issue of nutraceuticals and qualified health claims. Both are clearly FDA issues and should remain so.

## 6. Risk Communications

Rather than assuming the mantle of responsibility and proactively stepping forward with more regular and transparent risk communications programs, the FDA was driven by the winds of crisis. Today the agency has implemented certain programs (some required by FDAAA) that provide risk information – but without any context, rhyme or reason. The result is confusion among patients and physicians and a field day for the media. The unintended consequences have swamped the public health benefit. Senior agency leadership knows it – but what are they doing to address it? The answer is not clear. A good beginning would be for the FDA's Risk Communications Advisory to look into the matter. This problem needs to be fixed as no one (not industry, not doctors, not patients,) are happy with the current state of affairs.

## 7. The Drug Label and the “Safe Use” of Drugs

The drug label is the single most important piece of communications material the agency issues – and it isn't working as well as it should. The New Physician Labeling Rule (January 2006) has had minimal impact for three main reasons: (1) It has not been widely adopted for products licensed prior to the rule (not a requirement, but an option), (2) There has been little agency outreach to physicians and, (3) There has been no broader agency program on the issue of “safe use.” This last point will change in January when the FDA (via CDER – the Center for Drug Evaluation and Research) launches a more comprehensive “safe use” initiative. The agency must consider not just safety, efficacy and quality – but safe use as well. Not just drug safety, but patient safety. This makes perfect sense and gives the FDA the opportunity to speak not only to physicians, but to consumers as well. The program should be expanded to also include medical devices. It is a timely, important, and urgent opportunity and must be done with determination, creativity, and relentless passion. It must be the FDA *on the offense* for the public health. And the offense must never stop.

**There are more many issues (a more thoughtful position on expanded access, US/EU regulatory harmonization, etc.), and I look forward to working with the transition team to ensure that the new Commissioner can hit the ground running – in the right direction – with some early and important wins that will set the tone for a newly confident FDA.**