

Client Alert

May 2010

In this Client Alert, we offer our views on the FDA Town Hall meeting held May 18, 2010 in Minneapolis along with a battery of resources including a video of Congressman Erik Paulsen speaking yesterday from the House Floor about the Town Hall meeting.

OBSERVATIONS

It is clear that we have a strong leader at the helm at CDRH. Dr. Jeff Shuren displayed a firm grasp on the issues and challenges and has a clear idea how to solve them. He has clarity of insight and vision. He openly, calmly and candidly addressed questions with warmth and well-placed humor. He is an effective leader and spokesman for the Agency and extremely organized and driven. These are some of our thoughts on where industry and FDA are at after the dialogue:

- We think Dr. Shuren heard from the Minneapolis Town Hall crowd that there are real concerns with his organization from the standpoint of *predictability, transparency and reasonableness*.
- He seems to have a handle on *predictability and transparency* and has ideas of how to resolve them within the Center. The problem may be that when CDRH uses the term “predictability” they may mean “predictably more” in terms of added processes (IDEs, submission reviews, handling dissent, appeals and advisory panels) which at first blush seems helpful, but actually might result in more delays. If their solutions end up streamlining these processes, then CDRH will be a success.
- In the area of *predictability*, many of the speakers and people in the Q&A session raised the issue of how FDA has plans to change guidance in various areas but begins to institute its thinking before guidance is actually published. In the meantime, a company has followed FDA’s previous position and developed its product in reliance upon it. FDA must resist the temptation to migrate to new thinking and impose it upon an applicant midstream until it is actually formulated, aired out with the public and implemented. There is no need to change course precipitously unless there is a clear and present danger to the public. FDA can wait to make these changes. FDA’s propensity for doing this is rooted in its risk averseness, discussed more below. We will never have a “flawless” regulatory framework in place (regulations, guidance documents and

unwritten policies) for a product at any given time. FDA cannot be an architect of perfection.

- We strongly believe Dr. Shuren when he says he wants the Agency to be more transparent. It already has been as evidenced by yesterday's meeting. We think this trend will continue, but delivering bad news (more requirements and expectations, review and compliance oversight) in the light of day is still bad news.
- Where we think there is still a disconnect between staff and management is in the area of *reasonableness*. After all, data requirements can be predictable and transparent, but still be unreasonable. The Center is very risk averse and still seems to struggle with balancing the risk of letting go of a device with the benefit of getting them to patients sooner. CDRH needs to come to a deep-seated understanding that not everything is or can be within their control before a device is cleared or approved. Ever-escalating the data requirements are not the answer and will certainly kill innovation and investment in this sector. An example of this is the desire to bring in clinical-trialists to assist in 510(k) IDEs. Adding the academic emphasis from a clinical-trialist for a clinical study design makes complete sense for drugs and most PMAs, but in the vast majority of cases may run counter to designing a 510(k) study that is adequate to answer any unanswered questions of safety and effectiveness. This is the most vexing problem facing industry and will be the most difficult challenge for Dr. Shuren. He actually has to impact the review culture there and that is a tall order.
- In the pursuit of "safety," the Agency must be careful not to exceed its statutory authority. Under the banner of patient safety, the Agency could justify aggressive regulatory action. Make no mistake; FDA's actions are well intended. An example of this is found in the recently published guidance on infusion pumps. CDRH continues to propose front-end loading the pre-market approval requirements as seen in the new infusion pump guidance where they are asking for risk mitigation strategies to be incorporated into future 510(k) submissions and for a pre-clearance inspection. The 510(k) statute only requires a substantial equivalence determination and specifically precludes other considerations. Let's call it for what it is; these are PMA-like requirements. This trend toward front-end loading the 510(k) is a reflection of the Agency's aversion to risk, but requirements such as these are not contemplated by or within the 510(k) statute, nor are they needed if the Agency is truly balancing pre-and post-market risk. We don't know the whole story on infusion pumps, but things happen from time to time and there are natural consequences to them—increased regulatory scrutiny, such as additional clearance requirements, inspections, adverse publicity and product liability. These events should not be a reason to allow FDA to join the development team of a medical device company and benignly dictate how they will design, test, manufacture and distribute products. There are not enough resources at FDA to do this, plus this over-reaches their authority and it is not necessary.
- We believe that the Agency needs to re-familiarize, maybe resuscitate, Least Burdensome principles and bring them back to life. The Agency's existing Least Burdensome guidance documents are very good, but have fallen into disuse. Right now they do not even seem to be on the Agency's radar screen (maybe we are wrong on this one).
- We know Dr. Shuren and his management are good listeners and they are dedicated and smart, we'll have to wait and see what they do with Minnesota's input.

TWO NOTABLE ANNOUNCEMENTS

- Ralph Hall, Distinguished Professor and Practitioner of Law University of Minnesota Law School, characterized FDA's solutions as "ready, fire, aim," because there are no data showing a problem driving these solutions. He announced that he has a grant to conduct a study of the recalls for 510(k)s and PMAs and will report on the results by the end of May.
- Erika Nelson, Senator Klobuchar's Outreach Director, read prepared remarks for the Senator, announcing that Senator Klobuchar will be holding hearings on the FDA's impact on innovation and investment.

MINNEAPOLIS FDA TOWN HALL RESOURCES

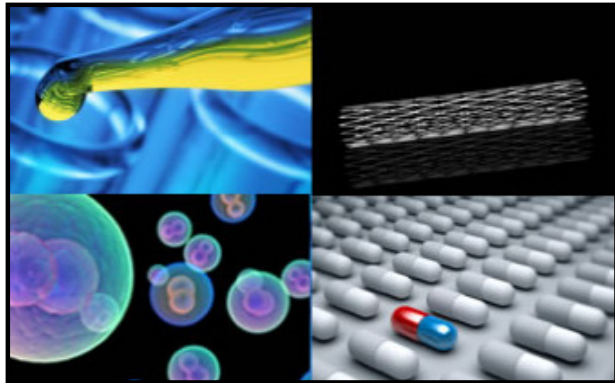
- News Links
 - Congressman Erik Paulson (discusses the Town Hall meeting on the House Floor): <http://www.youtube.com/watch?v=Gzpe2w7kvsK>
 - MPR: <http://minnesota.publicradio.org/display/web/2010/05/18/med-devices-fda/>
 - Pioneer Press: http://www.twincities.com/business/ci_15113805?nclick_check=1
 - Star Tribune: http://www.startribune.com/business/94215544.html?elr=KArks:DCiU1OiP:DiiUiD3aPc:_Yyc:aUU
 - LifeScience Alley: <http://view.exacttarget.com/?j=fe6916737265067b7515&m=ff3417707067&ls=fdef1c727362047a711d7675&l=fe9a167071620d7d75&s=fe4b1278776c0c75761d&jb=ffcf14&ju=fe21167774610079731c79>
 - WCCO (CBS): <http://wcco.com/local/FDA.medical.forum.2.1701876.html>
- Attachments (please email gardner@duvalfdalaw.com for copies)
 - Minnesota Medical Device Alliance ("MMDA") White Paper.
 - Dougherty Financial Group Town Hall overview.
- Other Contemporary News Links
 - Star Tribune (Dr. Shuren interview): http://www.startribune.com/business/93827929.html?elr=KArks:DCiU1PciUiD3aPc:_Yyc:aUU
 - Star Tribune (Gov. Arne Carlson op-ed): http://www.startribune.com/opinion/commentary/93985189.html?elr=KArksLckD8EQDUoaEyqyP4O:DW3ckUiD3aPc:_Yyc:aUUsZ

CONCLUSION

DuVal & Associates will be monitoring the upcoming Town Hall meetings in Los Angeles and Boston. We will keep you abreast of the situation. Stay tuned to www.duvalfdalaw.com for updates.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture pharmaceuticals, medical devices, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the United States' only dedicated FDA regulatory law firms our mission and absolute focus is providing our clients appropriately aggressive, yet compliant guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, legal, quality, clinical, etc. As former industry professionals in the drug and devices spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results, while practical, timely advice can help companies succeed. For more information, visit our website at www.duvalfdalaw.com or call us today for a consult.



To stop receiving CLIENT ALERTS, please reply to this email with the subject "Opt Out". To be added, please email afeldkamp@duvalfdalaw.com with your contact information.

DISCLAIMER: Material provided in *CLIENT ALERTS* belongs to DuVal & Associates and is intended for informational purposes only and does not constitute legal advice. DuVal & Associates makes no representations or warranties, express or implied, with respect to the information provided in its *CLIENT ALERTS*, including any representations or warranties as to accuracy, timeliness, or completeness. Transmission or receipt of these materials does not constitute an attorney-client relationship between the sender and receiver. Readers of this information should not act upon any information contained in *CLIENT ALERTS* or on DuVal & Associates' website without seeking professional counsel.