



Welcome!



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3rd Thursday
Lunch & Learn Series

December 15, 2016



Raise the Bar. Lead with Wisdom:

1. 3rd Thursday Lunch & Learn Series. January 19, 2017.
2. FDA/Xavier PharmaLink Conference. March 14-17, 2017.
3. FDA/Xavier MedCon Conference. May 2-5, 2017.
4. Combination Products Summit. September 12-13, 2017.

Our Distinguished Speakers



**President and Principal,
Compliance and Regulatory Affairs**

 Greenleaf Health

*Former Deputy Commissioner &
Counselor to the FDA Commissioner*



**Lead Quality System &
Compliance Consultant**

KING & SPALDING

*Former Deputy Commissioner of FDA
Office of Regulatory Affairs*



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Presidential Elections

Impact on the FDA



THE 2016 ELECTION HAS MAJOR IMPLICATIONS FOR FDA

* **Presidential Campaign – President-Elect Donald J.Trump**

- Party Platform took some positions on FDA
 - Common Themes: innovation, access, opioid epidemic
- Party Platform focused primarily on broader healthcare issues
- HHS Transition Team is in place

* **Congressional Campaigns**

- Republicans hold the Senate and the House
- Both parties have highlighted FDA issues
- 21st Century Cures Legislation provides platform for issues
- Reauthorization of user fees and more legislation
- Continuing FDA oversight



Which FDA positions are political appointments that typically change with the election of a new president?

And what Congressional hurdles need to be overcome for the appointments to be confirmed?

QUALIFICATIONS AND ATTRIBUTES FOR THE COMMISSIONER

- * **First:** Professional credentials and personal integrity are above reproach
- * **Second:** In addition to professional credentials, shown the ability to make difficult decisions
- * **Third:** Record of executive experience, leadership skills and management experience coupled with energy and stamina
- * **Fourth:** Balance the many cultures of the agency – food programs and medical product programs have distinct cultures
- * **Fifth:** Be a buffer for the civil servants – who work at the Agency from those who would try to use political or other means of influence to interfere with the objectivity and independence of their work
- * **Sixth:** Be able to speak on behalf of the Agency, have sufficient political skills to work effectively with the multiple constituencies inside and outside the administration



What FDA operations and policies are of interest to new Administrations and why?



**Does a new Administration and
new FDA leadership make
different strategic choices based
on which party or parties are in
control of Congress?**



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**Based on campaign speeches, are you
able to speculate on the impact President
Trump will have on FDA operations?**





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**How will the new election impact
the reauthorization of the four user
fee programs?**





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Thank You!!



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