

Up Front

Time for a New & Improved FDA Commissioner

“Due to the vital nature of the FDA’s public health oversight, identifying a strong, independent FDA Commissioner should be among the first accomplishments of the new Administration.” – Billy Tauzin, President of Pharmaceutical Research and Manufacturers of America (PhRMA)



There is no doubt that Dr. Andrew von Eschenbach, the current FDA Commissioner, will soon be leaving the FDA and will not allow the door to hit him on the ass on the way out.

Who will Obama nominate to replace von Eschenbach? There are plenty of special interest groups that would like to influence his decision.

Animal activists (eg, PETA) want president-elect Obama to nominate someone who will “mandate the use of scientifically proven nonanimal testing alternatives;” women’s rights activists want a “pro aborion” commissioner, whereas pro-lifers want the opposite; scientists and clinicians like Steve Nissen want an FDA Commissioner who places safety first; various consumer groups also want safe drugs, but also want an FDA Commissioner who will not stand in the way of the importation of cheap drugs, whereas the drug industry is vehemently opposed to re-importation even if the FDA is given new authority to inspect imports; the drug industry also wants an FDA Commissioner who will apply user fees and new authority to streamline the approval process by not placing too much emphasis on safety versus efficacy; etc., etc.

I wonder how Obama will balance all these diverse interests to pick the right person? Whoever the nominee is, the new FDA Commissioner will also need to balance competing interests.

Clearly, von Eschenbach has had problems managing competing interests even within his own organization. As evidence of this I cite the fact that FDA scientists recently wrote a letter to Congress complaining that top FDA officials engaged in “serious misconduct” by ignoring concerns of the scientists and approving for sale unsafe or ineffective medical devices. The new FDA Commissioner must have the managerial skills to resolve such disputes between factions within the FDA. “The individual ... must have strong managerial skills that are essential for directing science-based activities at an Agency that has just expanded its ranks with thousands of new employees,” says Tauzin.

Among other desired attributes most cited for the new FDA Commissioner are these:

- have a solid grasp of the pharmaceutical industry without being associated with it;
- balance the policy maker hunger for safety while assuring that the pipeline produces;
- be an incredible visionary and communicator.
- rebuild the agency’s staff of scientists. An advisory committee, for example, warned this year that the FDA lacks scientists with experience in biologics and cell-based therapies.

To be consistent with Obama’s stated preferences and desires for the FDA, the new commissioner also must be eager, willing, and able to enforce new authority given the FDA by Congress or by new executive orders issued by president Obama, including:

- authority to control tobacco and nicotine as a drug (Obama was a sponsor of legislation to give FDA this authority);
- allowing the import of drugs while bolstering inspections of imported food and drug products (Rep. John Dingell, chairman of the House Energy and Commerce Committee,

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has introduced tough legislation that would add new fees on imports to help pay for more inspections of foreign country-based plants and incoming drugs and food);

- authority to review and approve generic versions of biologic drugs;
- end FDA preemption of consumer lawsuits against drug companies following a presidential executive order

Above all, the new FDA Commissioner should ensure that the FDA makes decisions based on science and that promote the health and well being of the public. That means being independent of politics and special interest groups. Such a commissioner, for example, would not block the approval of drugs like the morning after contraceptive when the FDA staff and advisory committees recommend approval. Undoubtedly, any Obama appointee will face stiff questions from the Republican minority on abortion issues.

Who Would You Recommend as a New Commissioner?

Pharma Marketing News is currently hosting a survey of readers about who Obama should nominate as the next FDA Commissioner. Over 150 people have already taken the survey, which you can find here: <http://tinyurl.com/5rhy9o>

The survey includes a list of 10 “contenders” that were assembled from blogger posts and news stories that speculated on who Obama would nominate. Survey respondents can also write in their own candidate. The list of contenders included in the survey includes:

1. **Robert Califf**, vice chancellor for clinical research and professor of medicine in the Division of Cardiology at Duke.
2. **Dora Hughes**, Health Policy Advisor to Senator Barack Obama.
3. **David Kessler**, former FDA Commissioner.
4. **Steve Nissen**, cardiologist at Cleveland Clinic.
5. **Mary Pendergast**, industry consultant who was a former associate FDA Commissioner under David Kessler.
6. **Peter Rost**, former Pfizer VP of Marketing, now a blogger.
7. **Joshua Sharfstein**, commissioner of the Baltimore City Health Department.

8. **Mike Taylor**, former Deputy FDA Commissioner under Clinton
9. **Susan Wood**, the former head of women’s health at FDA, who resigned in protest after the delay in switching the morning-after pill over-the-counter.
10. **Janet Woodcock**, Center for Drug Evaluation & Research Director

Please take 2 minutes to cast your vote in the “Who Should Obama Nominate for FDA Commissioner?” survey. After you complete the survey, you will be able to view a summary of the results. No comments or other identifying information is included in the summary. Your comments are confidential (anonymous) unless you specifically provide your contact information at the end of the survey and allow us to attribute comments to you personally.

John Mack, Editor

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Who Should Obama Nominate for FDA Commissioner?



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