



Dear FDA: Please don't....



Dear FDA:

We know that our president called together the top executives in the pharmaceutical industry just a few weeks ago. Although it is a bit hazy what exactly was discussed,¹ a directive from our administration is that, for every new regulation passed, two should be repealed. It is not clear whether this topic was discussed at the meetings with the executives of our industry, and some have said that it may not apply to the FDA,² but...

Please, FDA, don't do this with drug safety regulations. We are glad that your strict safety regulations on drugs have been closely enforced and expanded over the years. In the '80s and '90s, drugs approved by your agency often hit the market, use of the product expanded logarithmically versus the numbers exposed in clinical trials, and products were quickly withdrawn.³ We remember Omniflox (temafloxacin) withdrawn 4 months after approval,^{3,4} Rezulin, withdrawn 3 years after approval,^{3,5} Vioxx, withdrawn 5 years after approval,^{3,6} and many others due to safety issues.

Thank you, FDA, for not complying with the “withdraw 2 regulations for every 1 new regulation” directive.

Sincerely,

Debbie Glick

Thoughts? Do we need a petition to circulate from the regulated industry as a new type of advocacy group?



Debbie Glick
Managing Partner

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1. Nocera J. Commentary: Trump had a good idea on drug costs. He ditched it after meeting with pharma execs. *The Chicago Tribune on line*. <http://www.chicagotribune.com/business/ct-trump-drug-costs-20170202-story.html>. February 2, 2017. Accessed February 26, 2017. 2. Gingery D. US FDA likely not "significant", could be mostly spared from Trump's regulation-slashing order. *The Pink Sheet*. February 10, 2017. 3. Berndt ER, Gottschalk AH, Philipson TJ, Strobeck MW. Industry funding of the FDA: effects of PDUFA on approval times and withdrawal rates. *Nat Rev Drug Discovery*. 2005;4(7):545-554. 4. Rubenstein E. History of quinolones and their side effects. *Chemotherapy* 2001;47(suppl 3):3-8. <http://www.karger.com/Article/Abstract/57838>. Accessed March 20, 2017. 5. Rezulin to be withdrawn from the market. *HHS News*. March 21, 2000. https://www.fda.gov/ohms/dockets/ac/00/backgrd/3634b1a_tab6c.htm. Accessed March 27, 2017. 6. FDA Public Health Advisory: Safety of Vioxx. September 30, 2004. FDA website. <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106274.htm>. Accessed March 20, 2017. Image courtesy of iprostocks at FreeDigitalPhotos.net



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