



December 15, 2008

To: Dr. Josh Sharfstein
Transition Team

From: Bill Vaughan, consultant
Consumers Union

Short-term announcements/actions

To help Americans fight recession and save money:

--announce initiative to reduce generic approval backlog;

--announce commitment to resolving pathway for bio generic approvals;

To show a new tone on behalf of the public:

--immediate unraveling of previous Administration's pre-emption efforts;

--pledge to ensure safety of imported drugs (and foods)—schedule of unannounced inspections and testings funded by user fees if necessary as a condition of importation;

--call for a high level review/scientific summit on BPA and nano-technology side effects: show a willingness to look at long-term consumer health issues rather than just industry positions;

--quick action to show tougher DTC enforcement. Act on device ads which fail to warn of side-effects. For example, announce favorable action on Consumer Union's citizens petition requiring ads to warn of dangers of infection from operations (FDA docket 2007P-0479);

--most important 'tonal' change you could announce would be a re-opening of PDUFA IV (or an announcement about PDUFA V) that would adopt Rep. Maurice Hinchey's approach of keeping the user fee revenues but breaking the industry ties.

FDA should play a role in health reform—helping with comparative effectiveness and cost containment-- by proposing ASAP (or as part of PDUFA V) that

--drugs and devices will be tested not just against placebo but against best or most common practice for the condition they are to treat;



--after an appropriate time (e.g., a year) unsuccessful Phase I trials shall be made public (and successful ones reported when the drug is approved), thus expanding the base of scientific knowledge and reducing the waste in replication of unsuccessful theories

Thanks for your consideration—and best wishes.