NATIONAL PHYSICIANS ALLIANCE

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

December 22, 2014

Dear Commissioner Hamburg:

As members of the National Physicians Alliance (NPA) FDA Task Force, we are writing to request increased opportunity for providers without financial conflicts of interest with the pharmaceutical and medical device industry to contribute to discussions regarding drug, biologics and device approval. The NPA is a multispecialty organization dedicated to advocating first and foremost on the behalf of patients; the organization is free of conflicts-of-interest. The FDA Task Force is comprised of NPA members who have chosen to focus on the FDA and offers unbiased expertise to protect the agency's mission of ensuring safe and effective treatments for our patients.

On December 4 and 5, representatives from our FDA Task Force testified before the Anti-Infective Advisory Drug Committee (AIDAC) during the Open Public Hearing session, where we were each allotted five minutes to speak. We noted that there was a session dedicated to "Professional Organizations" where speakers were given 15 minutes to speak and then additional Q&A time. All these speakers had financial conflicts of interest with industry and one organization had two representatives speak separately on their behalf. It seems as though these meetings, which should provide a variety of viewpoints for members to consider, are heavily biased towards industry.

We recognize that the FDA is under tremendous pressure from both Congress and industry to create new pathways to expedite approvals. While we too want a responsive and efficient regulatory agency, we also need an agency that maintains scientific rigor in evaluating therapeutic products. We are concerned that fast-tracking FDA approvals may mean compromising scientific evidence and risking harm to patients in a hurry to find new cures.

Recently the media and medical journals have also noted conflicts of interest within FDA advisory committees. Several of us who have testified over the past year at FDA hearings have experienced this directly and have felt frankly discouraged. Not only do advisory committees have many members working with industry, but there is little turnover of these members, even though terms of service are three years.

We feel that the voices of those without obligations to industry are not being heard. We therefore ask for consideration of the following:

1) Advisory committees should include physicians who are genuinely free of any financial conflicts of interest. They should also include primary care doctors, who so often write and

renew the majority of prescriptions. Terms should be limited or at least rotated to bring in new viewpoints.

2) At advisory committee hearings, at least one hour of formal testimony should be allotted to consumer organizations with time allotted for discussion and Q&A, in addition to the hour of short public testimony.

The National Physicians Alliance would be happy to provide new members to serve on advisory boards. (Several of us have applied but have been rejected because current members have decided to stay on.) We also would be willing to provide more expanded testimony than current time allowed.

We appreciate your listening to our concerns and would be glad to meet with you to discuss this further.

Respectfully,

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