

July 20, 2010

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Chair of the Transparency Task Force

Re: FDA-2009-N-0247; FDA Transparency Initiative

Dear Commissioner Sharfstein,

On behalf of the C3: Colorectal Cancer Coalition (Colorectal Cancer Coalition), I am pleased to submit these comments in response to the FDA's draft report on the agency's public disclosure policies. The Colorectal Cancer Coalition is a nonprofit, nonpartisan advocacy organization seeking to eliminate suffering and death due to colorectal cancer. We push for research to improve screening, diagnosis and treatment of colorectal cancer; advocate for policy decisions that make the most effective colorectal cancer prevention and treatment available to all; and work to increase awareness that colorectal cancer is preventable, treatable and beatable. We commend the FDA for the work done to-date in the Transparency Initiative, which provides clarification to patients and consumers regarding the work of the FDA.

As you move forward with increasing transparency at the FDA, we strongly recommend that you move forward first with implementing changes that will have a high impact for consumers while at the same time pose relatively few implementation challenges. The second tier of proposals that we recommend you move forward with are those proposals that while high-impact, pose implementation challenges. We also identified a third tier of proposals that we do not recommend making an implementation priority given the low impact the proposals will have for patients and consumers.

Tier One Proposals

In reviewing the draft report, we identified a number of proposals that will make a significant difference for patients while at the same time should be relatively easy to implement. We strongly recommend that implementing these first tier proposals should be an agency priority. Specifically, we believe the following proposals will make a significant difference for patients and should be implemented by the FDA:

- ***Docket Management Process Proposal 3.*** Disclosing when the Department of Justice files an enforcement action on behalf of the FDA in the FDA's weekly Enforcement Report publication is an easy change to implement that will have a high-impact on increasing agency transparency for patients and consumers. We strongly recommend that the FDA move forward with implementing this proposal.
- ***Inspections Proposal 6.*** Disclosing basic inspection information will help consumers better understand the FDA's regulatory role while at the same time being a relatively easy change to implement. We strongly recommend that the FDA move forward with implementing this proposal.
- ***Product Applications Proposal 8.*** Disclosing the existence (or non-existence) of investigational applications should not only be a relatively easy proposal to implement, but it

is a change that will have a high-impact for patients and we strongly recommend that the FDA move forward with this proposal.

- **Product Applications Proposal 9.** Disclosing the status if investigational new drug applications (IND) and investigational device exemption (IDE) is a small change that will dramatically increasing regulatory transparency at the FDA. Implementing this disclosure proposal will have a high-impact on increasing agency transparency for patients and consumers. We strongly recommend that the FDA move forward with implementing this proposal.
- **Product Applications Proposal 10.** We were very pleased to see this proposal, and strongly recommend that its implementation be an agency priority. Disclosing (at the time submitted) that the FDA received an NDA, NADA, ANDA, ANADA, BLA, PMA, or 501(k) application will help patients and consumers gain a better understanding of the drug and device approval process and the drugs/devices that are in the regulatory pipeline. We strongly recommend that the FDA move forward with implementing this proposal that will have a high-impact on increasing agency transparency for patients and consumers.
- **Product Applications Proposal 11.** We were very pleased to see this proposal, and strongly recommend that its implementation be an agency priority. Disclosing that an unapproved NDA, NADA, ANDA, ANADA, BLA, PMA, or 501(k) application has been withdrawn is another proposal that should be relatively easy to implement while at the same time having a high-impact on improving transparency for patients and consumers. We strongly recommend that the FDA move forward with implementing this proposal.
- **Product Applications Proposal 13.** Disclosing that the FDA has issued a refuse-to-file or complete response letter is a small change that will dramatically increasing regulatory transparency at the FDA. Implementing this disclosure proposal will have a high-impact on increasing agency transparency for patients and consumers. We strongly recommend that the FDA move forward with implementing this proposal.

Tier Two Proposals

In reviewing the draft report, we identified a number of proposals that while they will make a significant difference for patients and consumers, do pose a number of implementation challenges. However, because they are all high-impact, we strongly recommend that implementing this second tier of proposals should be an agency priority. Specifically, we believe the following proposals will make a significant difference for patients and should be implemented by the FDA:

- **Inspections Proposal 7.** Making information obtained during FDA inspections publically available will have a high impact for patients while at the same time posing numerous challenges because of the potential for disclosing trade secrets. While recognizing the challenges posed by this particular proposal, because of the high impact for patients and consumers, we strongly recommend that the FDA move forward with implementation of this proposal.
- **Product Applications Proposal 16.** Disclosing relevant summary safety and effectiveness information from an investigational application or from a pending marketing application will have a high impact for patients while at the same time posing numerous challenges because of the intricacies of gathering and analyzing appropriate data. While recognizing the

challenges posed by this particular proposal, because of the high impact for patients and consumers, we strongly recommend that the FDA move forward with implementation of this proposal.

- ***Product Applications Proposal 17.*** Convening both internal and external stakeholders to discuss possible uses of non-summary safety and effectiveness data from product applications is another challenging proposal to implement, but one that because of the potential for being high impact we strongly recommend that the FDA move forward with implementing. Human data belongs in the human domain where it can improve outcomes for all; we believe that this proposal and Proposal 16 are good steps in that direction.

Tier Three Proposals

The third tier of proposals we identified are proposals that we believe will only minimally (if at all) make a difference for patients. Specifically, we believe that while the following proposals will increase transparency at the FDA, their impact will be low and therefore the implementation of these specific proposals should not be a priority.

- ***Docket Management Process Proposal 2.*** Making individual consumer comments available on the FDA's website is an easy change to implement, although it will have low-impact, and while we recommend that the FDA move forward with implementing this proposal we do not recommend making the implementation of this proposal a priority.

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We encourage the agency to move forward with increasing transparency at the agency, and commend you for the steps taken to-date that benefit patients, consumers, and stakeholders. We appreciate the efforts by the FDA to address public disclosure policies and provide better information to patients, consumers, and stakeholders that will enable them to understand how the agency operates and makes decisions while will maintaining the confidentiality of identifiable patient information as well as trade secrets. Overall, we commend the draft proposal and encourage you to contact Catherine Knowles, Colorectal Cancer Coalition's Director of Policy (Catherine.Knowles@FightCRC.org or 202-276-5682) if you have any questions or would like to discuss these comments in greater detail.

Thank you for your consideration,

Carlea Bauman

Carlea Bauman
President