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**Comments for FDAMA Meeting April 28, 1999**

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1. *What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision making?*

\* Implement your own QA Guidelines (7-97) into labs and processes at FDA.

\* Adopt a systems approach to FDA's own quality system and operational areas, such as the ISO 9000 model, incorporating principles of continuous process improvement, tracking, trending, etc.

\* Maintain first hand scientific expertise on relevant technology and diseases, or supplement with experts/partnering from various fields to expedite evaluation of new applications of products, and requirements for donor blood testing.

\* Access scientists and medical experts; have a scientific advisory committee, not just the current BPAC, which has few scientific/blood banking and transfusion experts.

\* Perform risk-assessment based on true hazards or harmful incidents, NOT just every cGMP violation. FDA has made extra work that has nothing to do with minimizing 'harmful risks'.

\* Identify errors that present known harmful risks and require only those to be FDA-reportable, for example, true infectious disease reactive unit issued, contaminated unit issued, untested unit issued, ABO/Rh mislabeling. Minimize FDA reporting to critical issues.

\* Use scientific evidence (by expert consensus) to establish new regulations.

\* Do NOT implement 'precautionary' measures without known fact or cause/effect impact that will decrease the donor/donation rates, and by how much.

NOTE: Eliminating eligible donors on speculation or just theoretical possibilities can result in lack of an adequate blood supply. This CAN contribute to patient death, very directly.

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2. *What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?*

\* Reconsider the need to continue the requirement for submitting products for platelet QC. Are discrepancies and perceived failures in counts at CBER due to equipment differences, modes of use, etc.? Has this been scientifically investigated? If the facility has adequate data to show the required criteria have been met, why continue this requirement on only this one product? What is the real public health risk? Is there one? The requirement is costly and uses up valuable products that patients cannot receive - how meaningful is this process?

\* Establish a hotline, faxline, Internet page, etc., for regulated industries to obtain quick answers to questions, from an identified pool of FDA subject matter experts. This would enable greater collaboration with FDA in bringing new products to market to benefit patients, for example, licensed pediatric platelet dose (blood product), to streamlining submissions and clarification of new processes coming, like the BLA (Blood License Application). We need to work with the FDA on such issues as the Comparability Protocol, monographs for standardized blood products, and pilot programs for licensed blood products (like Irradiated blood pilot).

\* Establish public forums and workshops at national meetings, with scientific information presented. FDA must take quicker actions, and finalize documents more quickly. Some items (Product License Applications) are approved after the blood center has moved on to newer methodologies.

\* Do away with PLAs altogether. If one validates and meets the criteria and regulations, allow product to move in interstate commerce.

\* Finalize all the "Draft" guidelines more quickly. The "Draft" Computer Guidelines is years old.

3. *What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision making?*

\* Provide analogies of real-life risks undertaken daily - driving a car, flying in a commercial airliner, riding a bike, walking up stairs, etc. This approach may assist the public in gaining a perspective on risks related to issues that are emotionally charged.

4. *What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?*

\* Streamline product licensing for standard blood and blood products to a monograph system of basic specifications.

\* Eliminate the need to submit platelet products to be sent to CBER for QC.

\* On site inspections and overall enforcement via reporting of Errors/Accidents (E/A) and Recalls focus on minute details, not usually the overall system, or real risk to transfusion recipients. A systems approach to both would allow delineation of isolated events, from true system-wide issues that need to be addressed in a larger context.

\* Require E/A reporting and Recalls only on issues that pose real risk (by some predefined criteria) to the public. So many errors are cGMP related ONLY, and almost all donor 'accidents' from post-donation information are low risk (potential malarial exposure travel, subsequent illness). Focus on higher risk issues for biggest benefit to public. And, require reporting only if the data are used for some follow-up purpose. What is currently done with E/A data, other than generation of an internal (to FDA) quarterly summary? How is this used? Is it used?

\* Set a timetable for updating of all the blood and blood product regulations, and pull them all together into one set. Incorporate all the previous FDA Memos (that are enforced) into regulations.

\* Make the regulations in CFR available on the Internet with a search capability by topic, and cross-referencing to related topics.

\* Continue to decrease/eliminate the paperwork burden of reporting and licensing. The Annual Report is one example of additional new reporting requirements that have a significant increase in data handling and reporting to CBER. The new BLA and Form 356h will require more data and information to be submitted for product licensing than the previous process required.

4. *continued*

- \* Revise the Recall regulations to provide more specific criteria based on real risk, for required notifications and recall, and follow-up of disposition of products. This action would decrease the amount of activity now required for many low risk recalls (cGMP breach only).

- \* Plan the public meetings on new regulations, new guidance documents, new proposed programs to be bi-coastal, or via satellite downlink or audioconference. Due to distance and travel expense, we cannot send a representative to a one-day meeting in the middle of the week on the opposite coast!

- \* FDA assessments of fiscal impact and paperwork reduction impact are totally unrealistic in proposed documents, and largely unfounded.

- \* Address, up front, the reimbursement issues of blood centers and hospitals as FDA adds mandates or "recommendations" for testing, or product manufacturing, or strongly supports new research testing (HIV Ag, NAT, leukoreduction of blood products). Notify and encourage HCFA about adequately reimbursing for added costs of FDA mandates and recommendations

NOTE: Most blood centers and hospitals are "not for profit". The decisions for new requirements MUST include how they will be paid for.

- \* Eliminate unnecessary activity (Recalls) that will not provide a beneficial outcome, or prevent harm. Many Recalls and component retrievals are useless in reducing risk.

- \* Really listen to CFRR (Coalition for Regulatory Reform) input. Many blood centers forward written concerns and comments to the CFRR for presenting to CBER, but it seems to have little weight. We are told CBER wants to hear individually from centers and individuals, not the CFRR. We rely on CFRR to represent us since most of us cannot send representatives to meetings that the CFRR would attend.

5. *What actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?*

\* Written surveys to stakeholders (seeking input on topics, questions, etc.)

\* Provide feedback from surveys, meetings, etc., via Internet, written reports, etc.

\* Set up Internet page for dialogue/feedback on topics, or on defined questions that change, on some regular basis.

\* Set up mechanism to do E/A reporting via Internet (with encryption?)

\* The new FDA Annual Report notification of changes process has added pounds of paper word for Blood Centers. What good is that doing to protect the blood supply, or for the Centers? FDA inspectors can inspect for any/all changes they want during inspections--what is the value of submitting all this detail to the FDA?

\* Have inspectors review product validation when on site. Can the FDA really manage all the reports it gets? In a timely manner?

*General*

\* Give a concrete and specific answer when we ask for one, preferably in writing. Do not respond "It's under review.", or "That document will be out soon.", or "We're here to help you."

Provide an answer which we can refer to based on current regulations, and respond quickly.

\* Update all the Biologics regulations - many are archaic. Put them all in one section. Resolve discrepancies between CFR and FDA Memos and Guidelines!! "Just Do It!" based on scientific information from expert consensus. If consensus not reached, do NOT make them regulations.

\* Evaluate risk in general:

Would our tax dollars be better spent on societal risks posing greater harm??? Some examples of these are:

Smoking

Drugs

Guns

Poor Education

Lack of medical access/general care

Underage drinking

Please feel free to contact Sally Morgan-Gannon, Sallie Holliman, or me about any of the above.

Thank you for the opportunity to provide comments to the FDA. I trust those provided are helpful and constructive.

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