

**CBER STAKEHOLDERS MEETING  
FDAMA 406(b)**

**COMMENTS PROVIDED BY**

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**IMMUNE DEFICIENCY FOUNDATION**

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My name is Miriam O'Day and I am Vice President of the Immune Deficiency Foundation. IDF endorses the general and specific recommendations the regulated industry has made to FDA today. We would encourage continued and improved communication between both parties. IDF had short notice for a public statement and will submit formal comments to the docket.

IDF is a member of the Plasma Users Coalition along with the National Hemophilia Foundation, COTT and the Alpha 1 Foundation and Alpha 1 National Organization.

Safe products in quantities that meet the needs of the affected patient populations are common goals of consumers, manufacturers and the FDA. The frequent plasma user communities require safe products, and depend on the FDA to regulate the plasma industry accordingly. However, we also note that regulatory decisions can not be made in a vacuum due to the current problems with availability of plasma derivative products that are essential and life sustaining for the patients who consume them. Addressing product shortages and availability has been difficult for patients, physicians, manufacturers and regulators. During the current and ongoing shortage of IGIV, the IDF was able to quantify the effects of the shortage from the patient and physician perspective, through a survey sent to our constituents. The FDA, industry and consumers were taken by surprise by the shortage of IGIV and had enormous difficulty quantifying the shortage. It would seem that the FDA as the regulatory agency in control of lot release, recalls and withdrawals, and enforcement of regulatory actions regarding GMP problems, would have the ability to access information to quantify and predict near term trends. It was surprising to us and others the difficulty FDA had in determining distribution and supply in the marketplace.

Has the FDA engaged in data collection concerning supply as recommended by the HHS, Advisory Committee on Blood Safety and Availability in April? Will an ongoing effort be made by the FDA to continue to consider supply while insuring that the manufacturers are in compliance with GMP?

We support the FDA instituting expedited IGIV lot release when they became aware of the shortage, however we would recommend staggered inspections and a regulatory environment that keeps an eye on supply. IDF is concerned about anecdotal reports that even today several fractionators are not releasing product or are releasing limited amounts of product due to activities related to addressing GMP issues. Are inspections phased in and can manufacturing and lot release continue while improvements are made? We recommend that the FDA remain keenly aware of the small number of manufacturers currently producing pooled plasma derivatives. And in the case of the Alpha 1 community, that they are serviced by a sole supplier.

The shortages have highlighted a need for community outreach, which is a difficult challenge. The FDA Office of Consumer Affairs could manage solutions to patient and physician outreach and coordination of information. We would like to encourage OCA to work in conjunction with CBER in the arena of plasma derivatives. The American public feels invested in blood safety, media reports are often misleading when dealing with scientific stories. Media events occur which affect the products regulated by CBER and the American public at large. As an example I would use the outbreak of stories linking mad cow disease to CJD. OCA should be positioned as the agency prepared to give public response much in the same way they handled the situation with breast implants.

Often times consumer advocacy groups reach out to Congress or the White House if they feel the governmental agency they are dealing with is unresponsive. Ultimately the original agency of complaint falls under undue scrutiny as the result of advocacy efforts rather than responding appropriately to the original concern. To address this type of issue the NIH is establishing a public liaison office to listen and respond to constituencies. This office would be a repository of information, equipped with the ability to respond to concerns with information on existing programs.

Advisory Committees with consumer representation are an essential component in the FDA regulatory process. We support continued use of consumer advisors.

We applaud the reduction of paperwork suggested in the FDAMA plan and specifically commend the institution of BLAs. We would further recommend that the FDA improve internal communication to assist companies designing clinical trial study protocols for products already in the marketplace. We have heard from biotechnology companies that established study parameters are often open-ended, and guidance from the FDA would expedite the review process.

In closing, any recommendations or complaints that consumers may have need to be placed in the context of the FDA operating with diminished resources. It is unacceptable to us that the regulatory body responsible to ensuring safety in the plasma industry should be operating without the necessary staff. Consumer groups like ours consider FDA budget constraints devastating, and will continue to urge Congress to adopt increased FDA budgets.