



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 25, 2009

Danielle Brian
Executive Director
Project on Government Oversight
1100 G Street, NW
Washington, DC 20005

Dear Ms. Brian:

Thank you for your letter of June 6. I appreciate your clear perspective on the issues involved with AM2PAT, Inc., and I share your interest in protecting the public from dangerous medical devices.

In your letter, you request that FDA ask the Office of Inspector General (OIG) for the Department of Health and Human Services to investigate the agency's response to warning signals that syringes manufactured by AM2PAT, Inc., might pose a public health risk. Among the warning signals that you refer to are regulatory violations FDA identified during our inspection of AM2PAT's manufacturing facility, adverse event reports received by the agency with respect to the syringes, and an e-mail to FDA from an AM2PAT employee, who warned the agency about unsuitable conditions at the AM2PAT facility. You also ask FDA to examine the sufficiency of the process under 510(k) of the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medical devices manufactured by small firms with little to no experience in the device industry.

As you may know, the OIG is already conducting a study to evaluate FDA's adverse event reporting system for medical devices. The OIG plans to assess how FDA uses adverse event reports to identify safety risks and the agency will take the conclusions and recommendations of the study very seriously.

FDA's Center for Devices and Radiological Health (CDRH) also has a new acting director: Jeffrey Shuren, M.D., J.D. Dr. Shuren recently held an all-hands meeting with CDRH staff. During that meeting, he presented his plans for the next ninety days. Those plans include evaluating CDRH's approach to many of the issues you identify in your letter, such as the 510(k) clearance process, the effectiveness of the Center's compliance strategy, and the incorporation of postmarket information into the decision-making process. I have enclosed a copy of his remarks.

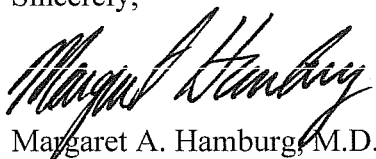
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I plan to wait for the final OIG study and the outcome of Dr. Shuren's evaluation of CDRH's approach to regulating medical devices before determining whether any additional evaluation is warranted.

The Office of the Commissioner looks forward to working with Dr. Shuren and others throughout the agency to improve all facets of the agency's regulation of medical devices.

Thank you again for your interest in these issues. If we can be of further assistance, please contact us. A similar letter was sent to Dr. Feder.

Sincerely,

A handwritten signature in black ink, appearing to read "Margaret A. Hamburg". The signature is fluid and cursive, with the first name being the most prominent.

Margaret A. Hamburg, M.D.
Commissioner for Food and Drugs

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Silver Spring, MD 20993

September 25, 2009

Ned Feder, M.D.
Staff Scientist
Project on Government Oversight
1100 G Street, NW
Washington, DC 20005

Dear Dr. Feder:

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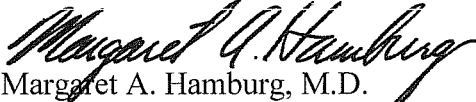
Page 2 – Ned Feder

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Sincerely,


Margaret A. Hamburg, M.D.
Commissioner for Food and Drugs

Enclosure

Center for Devices and Radiological Health All Hands Meeting
Jeff Shuren's Remarks

Good morning and thank you for joining me for my first CDRH All Hands. Although I have had the opportunity to work with some of you over the years, I have not had the chance to meet and work with most of you in this room and watching by webcast. So, I wanted to use our first opportunity to meet together as a Center to tell you a little bit about myself and what I see as the Center's priorities in the near term, as well as to answer questions you may have. Over the next few weeks, we will be developing the Center's priorities for the coming year. It is important that all managers seek the input of your staff to collect insights about the actions and issues they believe are important priorities for the Center in the coming year so we all may benefit from them. This information will help inform our 2010 goals that we will establish next month.

I appreciate that this is a time of change for CDRH. The agency has new leadership and now you have a new acting Center Director. I understand change can create concern. Having worked in the Office of the Commissioner over the course of three Administrations, I have been through numerous changes in leadership and organization. I appreciate at a personal level the uncertainty some of you may be feeling. While I do not yet know whether the Center might benefit from some organizational changes, I can tell you that I agreed to come to CDRH because I have great regard for the people and the work of the Center. You have accomplished much under Dan's leadership. I have always been impressed by the passion of the CDRH staff in carrying out the FDA's public health mission. If I didn't believe in you and this Center, I wouldn't be here.

I want you to get to know me. By way of introduction, I am a neurologist and an attorney. I spent the early part of my career in academic medicine. My specialty area is behavioral neurology, which means I worked with patients who suffered from cognitive disorders such as those that result from Alzheimer's Disease, stroke, and head trauma. My clinical research addressed several types of cognitive function, including studies on how humans reason, which I conducted while serving as a Staff Volunteer at NIH.

I first came to FDA in 1998, and other than spending a year on Capitol Hill working for Senator Kennedy and almost two years working at CMS in the Coverage and Analysis Group, I have spent the rest of my government career at this agency. Over this nearly 12 year period, I have gotten to know many of you. In the late 1990s I collaborated with CDRH and other Centers on developing policies for the regulation of promotional material on the Internet and determinations of medical necessity for medical product shortages. We have worked together to establish the general framework and principles of the Sentinel Network, developed a Pandemic Influenza Preparedness Strategic Plan, drafted a guidance on In Vitro Diagnostic Multivariate Index Assays, entered into information and expertise sharing MOUs with the VHA and the DoD, as well as implemented the Action Plan for Import Safety. For almost two years, I was your lead negotiator for MDUFMA reauthorization. In that capacity I was your advocate in negotiations with industry. In my new position I will be your advocate with all stakeholders and the general public.

Although I am the acting Center Director, my desire is to be the permanent Center Director. I tell you this so you understand the level of my commitment to the Center. I expect the search process

will be conducted over the next one to three months. During this time, I have the full support of Dr. Hamburg and Dr. Sharfstein to work with you to move the Center forward. There is too much at stake for us to be standing still.

I see six opportunities for progress over the next 90 days.

First, our public health mission is to protect and promote the public health. Devices are unique among other medical products because they are defined by innovation either through incremental evolution or radical revolution. To foster innovation we need to provide the regulated industry with predictable pathways for the approval of new products. Our challenge is that we need to respect precedent but we also need to adapt when science evolves or our understanding of a device's risk/benefit profile changes based on new data. Therefore, in the next 90 days I will establish an internal task force to review how we use new science in our regulatory decision-making and to make recommendations on how we can quickly incorporate evolving and new science into regulatory decision-making while providing sponsors with predictable regulatory pathways that foster innovation. As part of its charge, the task force will seek input from both you and our stakeholders.

Second, to succeed in our public health mission we must make decisions that are consistent with science and the legal standards under which we operate. By committing to this principle we are more credible and predictable in our decision-making. When I was in academic medicine I could make decisions about patient care solely based on the scientific data before me. At FDA, a great challenge we face is that many of our decisions, particularly those pertaining to product premarket review, are science-based but must be made within a particular legal framework.

The 510(k) program has had many successes since its inception and achieving its goals is important for public health: to make available to consumers devices that are safe and effective and to promote innovation in the medical device industry. Nevertheless, there is a growing sentiment from people both inside and outside the FDA that the 510(k) program presents challenges. Therefore, it is time that we undertake a full review of this program to determine whether or not long term changes should be made. In the next few weeks I will provide you with more details about how we will proceed in this assessment, an effort that will include feedback from our stakeholders as well as from you. At the same time, we will have an internal working group explore actions we can take in the short term to improve consistency in decision-making for 510(k) notifications.

Third, as Commissioner Hamburg has said, an effective compliance strategy depends on several key elements: FDA must be vigilant, strategic, quick, and visible. Within the next 90 days we will lay out the general framework for a CDRH compliance strategy that incorporates the Commissioner's objectives, as well as a clear articulation of what is an effective compliance program, our measures of success, and the important steps the Center should take to achieve effective compliance.

Fourth, premarket and postmarket information must be integrated in our decision-making in order for us to fulfill our public health mission successfully. This lies at the heart of a total product life cycle approach to medical devices. Much has already been accomplished in this area.

The matrix was established roughly one year ago to achieve this goal. In the next few weeks we will assess the effectiveness of the matrix so far. I congratulate CDRH for being willing to engage in this kind of internal analysis. We will act, as appropriate, based on the findings of this review to ensure we have the best mechanisms in place to achieve an optimal level of integration.

Fifth, to be effective stewards of the public health we must have the trust and confidence of the American public. You accomplish much every day, but the public will not fully understand what you do on their behalf and the challenges you face to meet our mission if we are not transparent in our decision-making. In the next few months we will seek ways to better explain our regulatory decisions to the public as a first step in providing greater Center transparency.

Sixth, I believe our ability to succeed in achieving these priorities and in accomplishing our public health mission depends to a great degree on our being able to work together as a team; having a work environment in which staff and managers can freely and openly discuss and disagree about scientific and regulatory matters without fear of retaliation. A critical step to ensuring such an environment is the establishment of and adherence to clear procedures that foster dialogue and protect against retaliation for unresolved differences of opinion. While we must be clear that our job is to reach final conclusions, it is inevitable there will be times when professionals must “agree to disagree.” I want to be sure we have procedures in place that are transparent to all as to how we will resolve differences of opinion going forward. A draft of these procedures has been circulated among the offices for review that is focused on internal scientific disagreements. Early input has suggested that we expand it to cover other types of internal disputes, and we will do so. We will also begin to update our current guidance on the available processes for external persons to resolve disagreements with the Center.

These are only some of the actions we will take in the next 90 days. Though I have not directly spoken about all the activities of the Center, please do not interpret my silence as a lack of interest or an indication that I will not actively engage with those programs both in the short term, and, hopefully, in the long term. I fully appreciate that the work all of you do every day is paramount to protecting and promoting the public health.

I already have started to meet with different offices. Over the coming weeks I plan to meet with all the offices. During those sessions I want to hear more about what you do, as well as what you view as the most important Center goals, and what challenges we face in accomplishing those goals. When things go well I want to hear it. When things don't go well I have to hear it.

This opportunity to lead CDRH is an honor and a highlight of my career. I look forward to working with all of you as we face the challenges ahead and build on this Center's tradition of excellence.

On that note, let me thank you for coming today or watching by webcast. And now I'd like to address any questions you may have.