STEPHEN M. DOLLE
Newport Beach, California
Tel. XXXXXXXXXXX

February 25, 1999
Via FAX and U.S. Mail

Mr. Larry G. Kessler
Center for Devices and Radiological Health
1350 Piccard Drive, HFZ-500
Rockville, MD 20850 FAX No. (301) 594-2965

Re: Inquiry to STAMP Conference on Neurological Shunts.

Dear Mr. Kessler:

I am writing you as a hydrocephalus patient and conference attendee at the January 8, 1999, "Conference on Neurological Shunts." I am FAXing this letter portion today. Janine Morris, Walter Scott, and Dwight Yen each have copies of my paper.

I am requesting the Food & Drug Administration to comment in the foregoing matters in regards to three (3) ITEMS relating to the STAMP Conference. This information will improve my own health outlook, and further the required progress for individuals implanted with CNS shunts. I have listed my requests as **ITEMS 1 - 3 below**, and would ask that you reply in writing at your earliest convenience.

ITEM 1: Public Relations and Advocacy is Needed in Regards to STAMP:

I telephoned Janine Morris several weeks ago regarding obtaining more follow up information on STAMP, and if the FDA would cooperate with a news story on my efforts - and share what they hoped the conference would accomplish. I told her Dr. Burlington's presentation was not in the STAMP Catalogue, and appeared quite similar to my papers provided to the FDA. She said that she could not offer further comment, nor any public information on the conference. I also telephoned John Stigi at DSMA.

In the meantime, there was an industry news piece published January 18, 1999, in the Gray Sheet which portrayed STAMP as an intrusive, big government effort to add further scrutiny and burden to shunt technology. This does not help bring about positive change. I would ask that you seek out more favorable PR.

To date, there have been no conference related discussions among the very active shunted patient/family groups - because of a lack of press coverage. These same groups very closely followed the earlier Biomaterials Act silicone legislation, and that had much less importance to hydrocephalus care. This truly bothers me, and I believe it hurts STAMP's ability to implement progressive policies for CNS shunts.

Overall, I was pleased with the conference. There appeared to be a willingness on the part of attendees to come together on the various topics. I would have liked to give a presentation on my new DiaCeph™ Monitoring System - since shunting outcomes was a major STAMP objective. I did write a paper of recommendations, along with literature on DiaCeph™, and made that available at the conference. All 35 copies were picked up within the initial two hours of the conference.

ITEM 2: There exists an Urgent Need for Routine Home Monitoring:

In my experience as a patient, and in consideration of my understanding of CNS shunting, I ask for your cooperation regarding implementing a routine for shunt performance monitoring.

I believe home monitoring should be a requisite for independent living, working, attending school, and sustaining normal activities. There exists a fear, uncertainty, and disruption factor that plays out in the lives of those living with CNS shunts. Ideally, shunt monitoring should address shunt malfunction, sub-optimal levels of performance, help predict and compare the severity of incidents, and coordinate with other medical events whose symptoms can mimic shunt malfunction.

Home monitoring for many disorders today is a standard in chronic illnesses. And since shunt malfunction and related complaints occur intermittently and frequently, these events impact the livelihood of individuals implanted with CNS shunts.

ITEM 3: I Request the FDA's Response to my STAMP Paper and Monitoring System:

As I was invited to the conference by Jim Dillard, and submitted my "Paper Of Recommendations and DiaCeph™ Test" in consideration, I would ask you to include this as part of your conference Executive Summary. I also request this as a CNS shunt user. I believe my paper is vital to your determining an effective regulatory and scientific direction out of the STAMP Conference.

I developed the DiaCeph™ Test in response to "false negative" test findings occurring in anti-siphon devices that were well described in the literature and in my Citizen's Petition, to which the only other test course would be 24-48 hour in-hospital monitoring. DiaCeph™ data guided Dr. Michael Levy, my neurosurgeon, in successfully revising my shunt one year ago.

Attached, please find a copy of my Conference paper. I look forward to your response.

Truly,

Stephen M. Dolle
Hydrocephalus Patient & Researcher

sd/enclosures