Laurene's Commentary to the FDA

My name is Laurene McKillop, and I am the Chief Executive Officer of the Hydrocephalus Association. The goal of the Hydrocephalus Association is to eliminate the challenges of hydrocephalus by stimulating innovative research and providing support, education and advocacy for individuals, families and professionals dealing with hydrocephalus. It is estimated that close to a million people are living with hydrocephalus. On average 6,000 babies are born with the condition each year and thousands more are diagnosed later in childhood or as adults.

Hydrocephalus can strike anyone at any time and, without treatment, its consequences can be devastating, ranging from repeated hospitalizations; infection; physical, behavioral and cognitive impairment; and death. Treatment options are few; the predominant one, by far, is shunting. And yet, shunt technology is quite backward, having advanced little since the first shunt was developed in a garage by an engineer in the 1950's in a futile attempt to save his son.

Currently, one in every three shunts fails during the first year after implantation. This failure rate is among the highest of all implanted medical devices. Shunt placement remains the most common cause of brain surgery in children. After the first year, approximately 4.5 % of shunts fail each year thereafter. The total cost of shunt surgeries exceeds $2b per year, excluding the cost of any rehabilitation or educational accommodation.

While shunting has transformed hydrocephalus, in many cases, from a death sentence to a chronic condition, the need for better shunts is vast. Shunt systems have changed little relative to the advances made in other medical technologies and cause many problems for those living with hydrocephalus. Shunt complications and their management assume a major amount of a neurosurgeon's time, are hugely expensive and perhaps most costly in terms of the hydrocephalus sufferer's quality of life.

Investing in shunt improvement, and indeed, in better treatments for hydrocephalus, ought to be a priority. But sadly, it is not. To date the investment by the Federal Government in hydrocephalus falls far short of the investment made in conditions that create a similar, or indeed, smaller public health burden. Surely we can do better.

On our staff, we have a young woman - 22 years of age - who recently endured her 91st brain surgery. She wants only to live a normal, productive life. Without better shunt technology her desire is unlikely to be met. Don't we owe her more?