September 6, 2016

Center of Excellence for Fetal Diagnosis and Therapy Subcommittee
Department of State Health and Human Services
Austin, Texas

RE: Considerations for your Subcommittee Duties

To: Distinguished Members of the Center of Excellence for Fetal Diagnosis and Therapy (HB2131) Subcommittee

First, thank you for your time and sacrifice and your willingness to serve on this very important Subcommittee. We know that you are extremely busy in your regular jobs, and so we thank you, your healthcare institutions and employers, and mostly your colleagues and patients for allowing you to provide your expertise for this important issue.

I am sure that Dr. Cho and others will provide you with the background for this important duty. As you study the issues, I would ask that you remember the following considerations:

1) Each of you were carefully chosen for this task, through a rigorous application process. Each of you has unique experiences, background, perspectives, and expertise.

2) Your subcommittee works best if each committee member has an equal and independent voice. This means that some of the members who are accustomed to be in charge, and are national or even international experts in the field, may need to listen more and speak less; some of you who may be a little more quiet, or may even not have dealt in the area of advanced fetal diagnosis and therapy – you will need to speak out and give your view point, don't be afraid to be the only dissenting voice, and don't be intimidated. You are representing our patients.

3) There has been a lot of discussion and stakeholder concern about the Centers of Excellence for Fetal Diagnosis and Therapy Designation legislation. You will or perhaps already have been provided a document from our Perinatal Advisory Council that collated concerns brought to us. I will highlight a few of those areas:
    a. HB2131 is bill that has gone through the legislative process approved during this past 84th Regular Legislative Session; very few bills that are filed actually become law. Thus, we should give this bill the proper respect of having gone through the rigorous committee and floor processes in carrying out the bill's stipulations.

    b. We need to recognize that HB2131 was voted on as a bill described as affecting only a few institutions in the state, and the legislative intent, testimony in committee, bill description, and stakeholder position and feedback were based on that narrow intent. The field of advanced fetal therapy is an exciting area of medicine, offering for instance in utero surgery for a fetus with a meningomyelocele, resulting in improved function and outcome for the affected child. Promoting high standards and careful informed consent for patients are noble and important goals.

    c. We must be cognizant that no other state has instituted a government process for fetal diagnosis/therapy designation, and there is currently no national standard. Thus, any such process may or may not achieve the desired outcomes, and more importantly may have unintended consequences. Indeed, many well meaning governmental interventions in fact have caused unintentional harm. Accordingly, you need to be cognizant of these potential harms, and careful in your recommendations.

d. In general, government oversight of clinical medicine should be used sparingly and judiciously, and if the same goal can be achieved by professional organizations or accreditation, it is far preferable. This is because governmental oversight inevitably adds regulation, cost, administrative overhead, and possible intrusion into the relationship between the healthcare provider/entity and the patient. The designation procedure is a lengthy and bureaucratic process, and regulations once approved are not easily changed even if problematic.

e. The proposed scope of HB2131 is narrow and only affects a very few number of patients with appropriately chosen treatable fetal anomalies; however, a designation process that is not carefully crafted may unintentionally cause harm. One such effect could be to drive a large number of pregnant patients toward tertiary care centers or high risk diagnostic centers due to marketing, or physician fear of missing a fetal diagnosis (which is common since even in the best centers, half or more of fetal anomalies are missed on antenatal ultrasound); this may greatly increase the cost of healthcare and increase anxiety of physicians and patients without improving outcome, or cause providers or facilities in smaller communities to forego obstetrics due to the perception of unreasonable pressures. Because we are the first, we would not have the luxury of learning from another state's implementation of designation to avoid their mistakes.

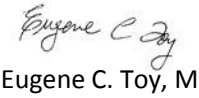
f. There have been concerns voiced among non-academic centers that this designation process may have the effect of providing an unfair advantage to academic or large medical centers.

4) Each of you Subcommittee members must put aside your own personal professional affiliation, your reputation, your financial or employment relationships, and instead, first and foremost represent the best interest of Texas and its citizens when considering your work on this subcommittee. For quite a few of you on the Subcommittee, you are very involved in the area of advanced fetal diagnosis and therapy, and we are fortunate to have you with us. Your expertise will help create recommendations based on the best clinical and scientific evidence. However, on behalf of our Texas citizens, I would ask you to reflect on the adage, "To a hammer, everything is a nail"; so although, your world is seen through the eyes of a fetal interventionist, please look at this designation process from many different viewpoints, and consider the possible ramifications of any recommendations in the immediate, moderate, and long term future, and in many different settings such as medium sized cities, smaller towns, and our rural communities.

5) I want to applaud the State for assembling such a talented, bright, and diverse group of men and women, and on behalf of the state Perinatal Advisory Council, I want to offer our resources and encouragement to you. Our Council will look forward to supporting your Subcommittee in any way. We are proud that our state has been blessed with such excellent and dedicated people, and we look forward to receiving your recommendations.

Lastly, I want to thank Dr. Frank Cho for his willingness to chair this important subcommittee, and I don't know of anyone with the combination of leadership ability, patience, listening skills, and common sense to lead your Subcommittee to success. I thank each of you for your sacrifice in participating on this important work.

Sincerely,



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