

Anatomical Board of the State of Texas

John Hubbard, PhD, PT Chairman PO Box 195895 Dallas, TX 75219

September 21, 2020

The Honorable John Cyrier, Chair Texas Sunset Advisory Commission PO Box 2910 Austin, TX 78768

The Honorable Dawn Buckingham, M.D., Vice-Chair Texas Sunset Advisory Commission PO Box 12068 Austin, TX 78711

Re: Agency Response to Sunset Staff Report

Dear Chairman Cyrier and Vice-Chair Buckingham:

Thank you for the opportunity to provide comments on the Sunset Advisory Commission Staff Report that was provided to the Anatomical Board of the State of Texas (SAB) on. I wish to express our collective appreciation for the courtesies and professionalism the staff assigned to review our agency extended to us during their review of our operations. We recognize and appreciate the many hours of hard work the staff members put into obtaining an understanding of the operations and responsibilities of the SAB. We recognize the value of several of their findings and will make every effort to implement their recommendations as quickly as possible.

The SAB is aware of the outdated legislative statute under which it is operates. The last revisions of the Texas Health and Safety Code (THSC) Chapters 691 and 692A were made in 1985, and many things have changed in the past 35 years. The SAB is supportive of updating the prevailing statutes including reorganization of the board and granting the board defined enforcement authority of the regulations within the legislative statute.

The SAB, however, takes exception to the recommendations to "Abolish the SAB" and to "Authorize colleges and universities with WBPs to form a consortium, and direct them to consider adopting best practices to maintain effective and ethical WBPs in Texas", and requests that these recommendations be reconsidered. We respectfully submit the following response in the interest of improving the performance of the responsibilities assigned to the SAB to ensure that the SAB is able to continue to provide the highest level of service to the citizens of the State of Texas.

Sunset Staff Issue and Recommendations

Issue 1 - Texas' Higher Education Institutions Could Continue to Effectively Operate Willed Body Programs Without the State Anatomical Board.

Key Recommendations

- Abolish the Anatomical Board of the State of Texas.
- Authorize colleges and universities with WBPs to form a consortium, and direct them to consider adopting best practices to maintain effective and ethical WBPs in Texas.

The Anatomical Board of the State of Texas disagrees with the Sunset Review Team's recommendation to abolish the SAB as it is the only agency in the State of Texas focused on the regulation and stewardship of whole, human body donations through the Willed Body Programs (WBP). These programs exist to legally and ethically provide human cadavers and anatomical specimens for the purpose of health sciences education, research, health-care and first-responder personnel skill training, and forensic science and search-and-rescue training facilities in the State of Texas that are accredited by recognized accrediting bodies.

In addition to the WPB's operated by institutions of higher education, there are currently non-educational commercial entities wishing to establish and run WPB's within the State of Texas. Abolishing the SAB, without elsewhere assigning and strengthening the responsibilities it currently holds, will lead to no regulation over any of the WPB's, whether they are housed within educational institutions, or within private commercial entities. The result of abolishment of the SAB will be that the State of Texas will have no regulatory control over the procurement, transfer, use, and disposition of human bodies within this state. This deregulation may lead to the following adverse results:

- 1. Decrease in availability of donor bodies to institutions of higher education Donation of cadavers to educational institutions may decrease because unregulated commercial entities with large budgetary reserves to work with have ample staff and resources dedicated to acquiring cadavers. Without regulatory oversight from a state agency, their commercial interests may supersede ethical and legal guidelines resulting in paying individuals or families for their bodies. These commercial entities if left unregulated, will also be able to send those donor bodies to unregulated and uninspected facilities, or even out of the country. These are unwholesome events that do not benefit the donors, their families, nor the citizens of the State of Texas, and may bring a risk of unwanted adverse publicity to this state.
- 2. Increased costs of health-related education Abolition of the SAB will lead to no regulation over either educational institution or commercial willed body donation organizations within the State of Texas. This may ultimately decrease the number of direct donations to academic institutions and dramatically increase the cost of obtaining cadavers for use in education, research, and clinical training. These increased costs will

most likely be passed on to the universities (State and Private) and ultimately on to the students. If these institutions cannot or will not be able to afford the increased costs of obtaining cadavers, the result may be to decrease the number of students who are able to utilize human cadavers in their medical and health-related career training.

- 3. Increased costs of health-related research and skill training programs Abolition of the SAB may also lead to increased costs for biomedical research and product development and skill training courses for licensed health care practitioners. These entities currently rely on our educational based WPB's to acquire the cadavers and anatomical specimens necessary for their services. As the number of available human bodies decreases from our educational based WPB's these entities will have an increased need to reach out to the commercial WPB's to acquire the cadavers or anatomical specimens necessary to perform their research or training activities. These will come at a higher cost as these unregulated commercial WPB's would be able to charge a "market rate" for providing these donated human bodies to the research and training facilities.
- 4. Abuse of donor bodies Lack of state regulation may lead to higher incidences of abuse of donated human bodies. Without a state regulatory agency, donated human bodies may be dismembered and sold for profit without oversight as to where these bodies go to or how much these entities eventually charge for them. Additionally, these donated bodies that are dispersed will not be tracked or returned, and there would be no state regulatory enforcement over their final disposition. Abolition of the SAB will also result in the elimination of the direct cost recovery method currently used in our health-care institutions which has proven efficient and successful, and is deemed an appropriate method by legislative statute (THSC 692A.016).

The SAB also believes that the logic behind abolishing the SAB is flawed. The main reasons cited by the Sunset Review team for closing the SAB include:

 Inappropriate makeup of the SAB – The Team cites bias, a lack of fairness, an even number of board members, and potential conflict-of-interest in the current make-up of the board.

The facts are that there is no history of any complaint directed towards the SAB for a lack of fairness, or any real or perceived conflict of interest in any of its regulatory or inspection activities. The report itself does not acknowledge that any of these activities has ever occurred, but states that it can "create the appearance of potential conflicts of interest." The report also does not acknowledge the provision stated in Title 25 of the Texas Administrative Code (TAC) Section 479.2 that prohibits any board member from inspecting their own facilities or any facility to which they provide Willed Body Program specimens.

The current composition of the board is set by legislative statute (THSC Chapter 691.002), and any issues related to the composition of the board should be mitigated with appropriate legislative adjustments to this statute. Adjustments may possibly include representation from facilities with an established WPB, educational institutions without WBP's, private research or training facilities, or public members. The SAB itself recommended examining and potentially changing the makeup of the SAB to the Review Team and would be happy to participate in this revision.

2. **Regulatory power** – The Team cites the lack of any legislative appropriation; unclear requirements for certification; and a lack of closure or reprimand activity.

Many of these issues are currently governed by outdated existing statutes, revision of which was also advocated to the Review Team by the SAB in our first initial meeting with them. The SAB agrees that the outdated existing statutes need to be revised, and these prevailing statutes should be changed to articulate clear guidelines for the SAB to operate under, along with prescribed authority to enforce those guidelines.

The fact that the SAB operates without any state appropriations seems to be viewed as a negative, when in these challenging times, it should be viewed as a positive. The SAB has been, and continues to be self-sufficient. The SAB is also prepared to revise its fee structure for registrations, transfers, and inspections to allow the board to continue to support many of its functions without any state appropriations. The SAB feels that the current statute should be amended to allow this agency to hire sufficient support staff to assist the board in performing its duties with or without state appropriations. However, an appropriation from the legislature in the next budget cycle for the SAB would be beneficial to support the essential staffing recommended to provide additional regulatory orversight that the SAB has been tasked with providing; the centralized State repository for documentation of cadavers and their usage; timely and uniform inspection of all facilities by trained inspectors; and regulatory enforcement of the standards for certification.

The report stated that certification and approval standards for facilities did not exist. The standards for certification of approved facilities are clearly set out in Title 25 of the TAC, Sections 479.2 and 3, and are applied uniformily to all facilities. These standards are sent to all facilities requesting inspection by the SAB, and all facilities are subject to the same standards. The report also criticizes the SAB for a lack of closure or reprimand activity, yet they faulted the SAB for issuing reprimands to facilities deemed to not be in compliance with standards or regulations.

3. Universities can manage their own Willed Body Programs – The universities that house WBP's currently manage them under the regulatory authority of the SAB. The SAB was criticized for not having a central repository or donation facility. A facility such as this would cost the State of Texas several million dollars, and would replicate the facilities that are already in place. While cadavers donated to these individual WPB's go directly

to the programs they are donated to, they are in fact the custody of the State of Texas. The SAB can and does ensure that any inspected and approved facility needing cadavers or anatomical specimens are able to receive them from the individual WPB's. The SAB is the only agency registering, tracking, and regulating the use of cadavers within the state.

One of the primary puposes for the establishment of the SAB in 1907 was to ensure the provision of cadavers for education and training, and to limit unethical means of obtaining them. Removal of the SAB will place the responsibilities on individual universities to manage their own WBP without any regulatory oversight. This includes inspecting their own facilities, as well as any outside facilities that they provide cadavers or anatomical specimens to. Along with the obvious conflicts of interest this will create, it will add additional personnel and expense to each of these educational institutions, the cost of which will be passed on to the students of these institutions and the citizens of this state.

It is our understanding that none of the existing educational institutions with an active WBP wish to operate their programs without oversight from a recognized state agency. The SAB is able to provide clear guidance on what the uniform standards are, the opportunity to suspend WPB's who fall out of compliance, or revoke priviledges for provision of cadavers to any facility in the case where a facility is not treating these bodies appropriately. Removing the only regulatory agency for the use of cadavers in Texas is not in the best interest of the citizens of this state, and will open the doors to development of documented and publicized issues that have occurred in Arizona, Colorado, Illinois, Michigan, Minnesota, Nevada, and Oregon. A recent publication detailing some of these activiteis can be accessed at: https://www.azcentral.com/in-depth/news/local/arizona-health/2019/06/10/despite-state-law-arizonas-body-donation-industry-still-unregulated/2918524002/. Additional details and references of this type of publicized issues can be made available if desired.

The Sunset Review Report very clearly states (page 3) that "Texas has a continuing need to regulate the donation of human remains for teaching and research". The only state agency performing this continuing need is the Anatomical Board of the State of Texas. It is the position of the SAB that donation of human bodies is a practice that should not be left unregulated. Allowing numerous autonomous educational or commercial Willed Body Programs to operate without any official state regulation or oversight is not desired by any of our existing WBP's or educational institutions. Removing the only state agency with the experience and ability to set and enforce proper and ethical standards for all Willed Body Donation Programs could plausibly lead the State of Texas back to the days of unsavory business practices for obtaining human cadavers that are not in the best interest of our state or its citizens.

The SAB has a long record of serving the public needs without any state appropriations or formal staff. Despite this, that SAB is still able to register all willed body donations and keep track of all cadaver and anatomical specimen transfers. The SAB ensures that all donor bodies are treated ethically and are maintained in appropriately inspected and approved facilities. The

SAB ensures that all existing WBP's distribute donor bodies to institutions needing them to fulfill their educational, research or training missions in a cost-efficient manner.

While the prevailing statutes governing the SAB (THSC 691 and 692A) do need to be addressed and updated, this is a much more cost-efficient method than eliminating an existing state agency that is self-sustaining. Assigning its duties to another agency will result in new personnel costs to that agency, in addition to the training and travel requirements associated with their newly acquired duties. Assigning its duties to a voluntary educational institutional consortium does not ensure that all WPB's will join that consortium and will result is numerous different standards for operating WBP's. This model also does not provide governance or oversight to any commercial or public WBP's that wish to operate within our state as they are excluded from the consortium as recommended in the report.

The SAB stands ready and willing to work with the Sunset Advisory Commission in your consideration for the continuation of the important work of this agency and improving the functions being performed by the Anatomical Board of the State of Texas.

With sincere regards,

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Chair, Anatomical Board of the State of Texas

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Anatomical Board of the State of Texas Members