



THBI End of Session Report 86th Regular Session

**Julie Haerber
THBI Policy Director**



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THBI Mission Statement

THBI was created in 1996 and is a non-profit public policy research organization comprised of biotechnology, medical device, and pharmaceutical companies, as well as academic institutions, research organizations and economic development corporations. The mission of the Texas Healthcare and Bioscience Institute is to research, develop, and advocate policies and actions that promote biomedical science, biotechnology, agriculture, and medical device innovation in Texas.



THBI End of Session Report 86th Regular Legislative Session

On Tuesday, January 8, 2019, the 86th Regular Session of the Texas Legislature convened its 140-day legislative efforts. Comptroller Glenn Hegar announced that for FY2020-21, the state could expect to have \$119.1 billion in funds available for general-purpose spending, along with an extra \$15.4 billion in the Rainy Day Fund. This represented an 8.1 percent increase from the corresponding amount of funds available for the 2018-19 biennium. The regular legislative session adjourned on May 27, 2019 and Governor Abbott's veto period expired on June 19, 2019 with a total of fifty-eight vetoed measures – none of which directly affect the Texas Life Sciences industry.

Lawmakers this year filed 10,877 bills and resolutions and passed 4,581. In 2017, 10,682 measures were filed and 4,960 passing – with 50 vetoes in 2017.

THBI Innovation and Social Media Campaigns: Over the last 18 months, THBI has focused on the theme of life science innovation in Texas throughout its messaging and policy briefings. As the leading policy voice for the life sciences in Texas, THBI has hosted a series of policy briefings to educate the legislature and members of their staff to explain the process of innovation and what it takes to bring a drug or medical device to the marketplace.

In addition to protecting patient access, THBI was instrumental in legislation that would benefit the State of Texas through drug rebates, cancer research, and economic development. An active social media campaign helped bolster the outreach to our targeted audience along with email newsletters, and events. The efforts increased visibility among legislators, their staff and the patient community. Facebook and Twitter messaging was utilized to help inform members of the legislative body and staff on the process to bring a product to the marketplace. The THBI newsletter included industry and legislative news; member updates, upcoming events, and calls to action and continues to serve as a voice of news and innovations targeting the Texas Life Sciences industry.

Legislative Priorities/Push Card: The THBI State and Federal Government Relations Committee began meeting in the Fall of 2018 to prepare for the session and started creating a list of legislative priorities. The full membership was asked to weigh-in and provide suggestions on this priority list. The result was a legislative agenda of issues that ensured the most efficient use of THBI's resources when working towards its members' goals of developing policies important to the life sciences industry and maintaining an active research and development environment.



THBI Legislative Priorities

The Texas Life Sciences industry is committed to expanding the boundaries of science by discovering, developing and delivering innovative and needed medications to patients. It is the patient that is the ultimate beneficiary of such advances. The membership of the Texas Healthcare and Bioscience Institute (THBI) is committed to creating an environment where such discoveries flourish and thrive. To that end, THBI supported the following initiatives in the 86th Texas legislative session:

Access to Innovation

- It is critical that all patients fighting diseases have access to needed treatments and cures that allow patients to live longer, healthier, and more productive lives.
- THBI is committed to safeguarding and preserving timely patient access to new medicines while maintaining the integrity of those who utilize the latest innovations in creating these products.
- Preserve and foster Texas' investments to continue to grow a productive infrastructure.

Encourage Research & Development and Incentives

- Encourage Research and Development and the incentives Texas companies need to compete in the drug and medical innovative process.
- The Texas Life Sciences industry supports private-public collaborations that will allow Texas to compete globally and also supports efforts to build and sustain a highly skilled technology workforce in the state.
- Support policies to keep Texas' life science entrepreneurs and small businesses healthy and flourishing.

Appropriate Funding for Higher Education/Research

- Encourage the Texas Legislature to support a consistent and transparent mechanism to fund research at our Texas Institutions of Higher Education.
- Encourage the Texas Legislature to meaningfully fund research to ensure national competitiveness and to improve the ability of our Texas Institutions of Higher Education to continue a robust technology transfer system and product development process.
- Support the Governor's University Research Initiative Grant Program (GURI) as Texas continues to recruit the best and brightest researchers in the world.

Cancer Prevention & Research Institute of Texas (CPRIT)

- Cancer Prevention & Research Institute of Texas (CPRIT) continues to foster cancer research and prevention in Texas as well as fund product development. THBI supports the funding and agency reauthorization for CPRIT for another 10 years.



Focused Initiatives/Collaborations

THBI continues to work with diverse groups across the state in an effort to identify and discuss strategies each legislative session. Focus groups discuss the ongoing debate centered on state initiatives and current funding levels, operations of CPRIT, newborn screening, state economic growth, the public information act and patient access. These groups work together as coalitions and some are outlined below:

We Work For Health - Texas

- The economic footprint of the biopharmaceutical industry can be measured not only by the traditional indicators of employment and output, but also in part by its impact on the vendors, large and small, that provide services or supplies to America's biopharmaceutical research companies. We Work For Health - Texas (WWFH) is a grassroots initiative that unites health consumers, biopharmaceutical company employees and retirees, vendors, suppliers and other business, academic and community partners to demonstrate how these diverse groups work together to improve America's healthcare system and strengthen our economy. THBI President & CEO, Tom Kowalski serves as the Vice-Chair for We Work For Health - Texas, working closely with the rest of WWFH national partners to achieve these goals.
- As part of the WWFH Texas Initiative, a Texas Vendor Map was published and discussed with members of the Texas US Legislative Delegation and the Texas State Legislative Members and staff. The statewide map shows the vendor strength of the Texas Life Sciences industry.

Please visit www.weworkforhealth.org/in_our_states/texas or www.thbi.com for more information.

Patient Access Coalition

- With strong bipartisan support, Texas legislators have passed laws to protect some of our state's most vulnerable Texans by ensuring they have access to the medicine their doctor determines is best for their care and well-being.
- Thanks to the protections provided by these laws and agency rule-making and processes, insurance companies are prohibited from implementing arbitrary administrative and medical hurdles for patients in the Texas Medicaid program that decrease access to needed medicines initially prescribed by doctors for their Medicaid patients. These protections are critical for patients whose health is dependent on a specific medicine or a targeted combination of therapies and whose well-being could be seriously threatened by a change of course in or delay in receiving medicines.
- Patient protections of this type are crucial as insurance companies move to impose



rules requiring a patient to be moved from the drugs proven to best treat their condition and instead placed on medicines that may prove less effective or even ineffective under the misconception that these medicines are always lower cost. Under some of these insurance mandates, patients must “fail” using lower cost drugs or therapies before they are allowed to return to the medicine initially prescribed by a doctor and proven to work.

Texas Cancer Partnership

- The Texas Cancer Partnership (TCP) brings together a number of organizations in Texas with the shared mission of ending cancer as we know it. The shared focus toward achieving that mission is to ensure the state of Texas maintains its status as a world leader in the fight against cancer by continuing its investment in cancer research and lifesaving prevention services through the Cancer Prevention & Research Institute of Texas (CPRIT).
- TCP and its members were very successful during the 86th Session as Governor Abbott signed HB 39 by Appropriations Chairman Zerwas which relates to the repeal of certain time limitations on the award of grants by CPRIT. In addition, HJR 12 which proposes a constitutional amendment authorizing the legislature to increase the maximum bond amount authorized for CPRIT has been added to the November 5th, 2019 ballot as Proposition 6.

Texas 2050

- The Texas 2050 Coalition consisted of the state’s key trade organizations as well as business organizations focused on Texas competitiveness now and through the year 2050. True to coalition form, the organization focused on the key elements of the following:
 - Infrastructure
 - Investment Capital
 - Innovation
 - Education

BIOTexas Leadership Roundtable

- The Roundtable’s membership consists of the State’s Regional Leadership of BioHouston, BioMed SA, BioAustin, BioNorthTX and Bio El Paso/Juarez.
- The group meets to discuss strategies to further strengthen the Texas Life Sciences industry, participates in the purchasing program and also plans for the annual BIO International Convention. The roundtable is also an enthusiastic participant in the THBI state legislative fly-in.



Council of State Biotech Associations (CSBA)

- THBI is an active participant in the Council of State Biotech Associations (CSBA). The CSBA is a confederation of state-based, non-profit trade organizations each governed by its own board of directors. The common mission of the members of CSBA is to promote public understanding and to advocate for public policies that support the responsible development of the bioscience industry. THBI is recognized by BIO as the affiliate organization for the state of Texas and THBI President & CEO, Tom Kowalski serves on the Executive Committee.

Federal Priorities

THBI's policy focus expands into the federal arena as well. Our three national partners include PhRMA, BIO, and AdvaMed; and our key programs have been the We Work for Health/BioTexas Initiative, the BIO Fly-in, and the Campaign for Modern Medicines.

Each activity includes legislative visits both in Washington D.C. and in the respective home districts of the relevant national officials. Our goal is to position THBI as a “go-to” resource and to utilize THBI's statewide grassroots network. Outlined below is a partial description of our federal agenda.

- **Drug Pricing: Ensuring Access to and Affordability of Innovative Medicines**
- **Medicare Part D: Patients' Cost-Sharing Should be Affordable, Access Unhindered**
- **Medicare Part B: Preserve Market-based Reimbursement Structure**
- **Intellectual Property: Protect the Bedrock of American Innovation**
- **Rebates: Patients Should Benefit from Rebates Middlemen are Exploiting**
- **340B: Reform the Drug Discount Program**

Activities and Events

THBI Statewide Tour – Fall 2018

In the Fall of 2018 and in preparation for the 86th legislative session, THBI visited with over 180 Texas Life Science leaders. Traveling across the state, THBI partnered with regional allies including bionorthTX, BioMed SA, UT Health San Antonio, BioHouston, Medical Center of the Americas Foundation, and the newly created, BIO El Paso/Juarez to collect statewide input on how to better serve and connect the industry in Texas. The roundtable discussions allowed the organization to take a “pulse” on the industry.

THBI Study - The Texas Life Sciences Landscape: Innovating for Today and Tomorrow

Released in February 2019, the study provided an in depth look at Texas and the Life



Sciences innovation landscape. The study was delivered to members of the Texas legislature as well as members of the Texas congressional delegation. Please visit www.thbi.com to read the study in its entirety.

Innovation & Patient Access Campaign for the Texas Legislative Session

This successful campaign included the development of messaging and digital content aimed at raising awareness about the bioscience industry's economic, scientific and human impact on the state of Texas, while connecting the industry's impact more clearly to the lives of ordinary Texans through public policy.

Texas Life Sciences Week

In February, THBI hosted Life Sciences Week at the Texas State Capitol as a way to share the successes of the life sciences and biotechnology industry with the state legislature. The week included the annual policy Summit and Luminary Dinner and continued the next day with an advocate fly-in and concluded with a Genomics Medicine roundtable discussion.

Life Sciences Week allowed legislators and their staff members the chance to learn about our priorities, hear patient's stories, and be prepared to support the life sciences industry during the legislative session.

2019 THBI Summit

The sixth Annual Texas Healthcare and Bioscience Summit was a huge success and focused on the 86th legislative session and health policy issues impacting patient access, research and development, and the future of healthcare and life sciences industries in Texas.

Attendees heard panel discussions over access to innovation, new technologies, the value of research and the impact of the life sciences on the state's economy. Highlights included a keynote from Peter Pisters, MD, President, UT MD Anderson Cancer Center, along with panel discussions with Robert Popovian, PharmD, Vice President, US Government Relations, Pfizer; Wayne Roberts, CEO, Cancer Prevention and Research Institute of Texas (CPRIT) and Denise Trauth, PhD, President, Texas State University.

Day two of the Summit moved to the Texas State Capitol grounds and started with a Chiefs of Staff panel, followed by a Genomic Medicine roundtable discussion. THBI members and advocates walked the halls of the Texas Capitol to speak with legislators and their staffs about key pieces of legislation and the development of the industry in their respective regions throughout the state. THBI members covered the full extent of capitol offices, leaving behind materials listing issue priorities.

THBI Luminary Dinner

THBI's Luminary Awards are presented to legislators, industry leaders, and advocates who



have made a substantial impact on the life sciences community through their dedication to bettering the lives of Texas patients.

THBI hosted its annual Luminary Dinner on February 11, 2019, at the Intercontinental Stephen F. Austin Hotel. This year, THBI honored Senator Kirk Watson and Representative John Zerwas as the legislative honorees for their dedication to the healthcare industry and to patients. The patient advocate honorees included Nobel Prize winner James (Jim) Allison, PhD, University of Texas MD Anderson Cancer Center and Debra Miller, Founder and CEO, CureDuchenne.

The dinner boasted a lengthy list of leaders in healthcare as well as patient advocates serving as honorary hosts. The honorees were introduced to a full room of attendees and were chosen for their efforts and leadership in helping foster medical advancements through legislation and protecting the interests of patients. The 2019 Luminary Dinner was attended by members and staff of the legislature, leaders in many different healthcare sectors from across the State, patient groups, and life science and healthcare industry leaders.

Genomic Medicine BIO Policy Briefing

To wrap-up Life Sciences week, THBI in conjunction with the Biotechnology Innovation Organization (BIO), hosted a genomic medicine policy luncheon focused on the transformative potential of genomic medicine and its implications on patients and the future. This event was attended by legislative staff, patient advocates, and industry leaders.

State/Federal Relations Committee

THBI's State and Federal Government Relations Committee began meeting in the Fall of 2018 after legislative pre-files started holding telephonic meetings in January and weekly in-person meetings at the Capitol starting in February to update members on our legislative priorities and bills we tracked. The State and Federal Government Relations Committee heard from occasional speakers from different associations/groups on their legislative priorities for the session. We found it very helpful to both hear from these groups and to share THBI's legislative priorities with them as well. We believe that these exchanges proved beneficial to our committee members.

During the course of the 86th legislative session, THBI tracked over 150 pieces of legislation in 19 different policy areas with the potential to affect Texas biotechnology, life sciences, and higher education. Our thanks go out to those of you who participated in these meetings, and we appreciate the efforts you put in over the course of the session.

THBI Taco Tuesday's/Sam's Law Breakfast

Over the last year, THBI has hosted two policy conferences and four Taco Tuesday events (staff and legislator briefings). These policy meetings are typically held in the Capitol to



educate the legislature and help them understand the process of innovation and what it takes to bring a drug or medical device to the marketplace.

This session, THBI partnered with UCB, the Epilepsy Foundation, and the Purple Warriors of Texas to hold a breakfast briefing over HB 684 by Representative Clardy – also known as “Sam’s Law.” This legislation, pertaining to training requirements for public school nurses and certain other school personnel regarding seizure recognition and related first aid, has since been passed into law.

THBI Hallway Lunches

In March, THBI partnered with Pfizer to host a hallway lunch in Representative John Wray’s capitol office for the E1.300 hallway. These lunches provide a good way to interact with key members and staff and was well attended by members of the THBI State/Federal Relations Committee.

Monthly Presidents Calls

Every month, Tom Kowalski hosts a membership call to update THBI members on the status of the Institute’s legislative interests. These calls are conducted on a “listen only” basis and Mr. Kowalski routinely interviews key leaders pertinent to the issues in the life sciences industry.

BIO International Convention in Philadelphia

THBI, in partnership with the Texas Department of Agriculture and CPRIT, lead a Texas delegation to the BIO 2019 Convention in Philadelphia in June 2019. Our delegation had a productive show with over 50 meetings arranged and over 350 leads collected.

This year’s convention drew over 17,000 attendees from 49 states, the District of Columbia, Puerto Rico and 65 countries to Philadelphia and its burgeoning biotech community. The Texas Pavilion included representatives from more than 25 communities, universities and companies.

2019 Texas Pavilion Participants

- 10/35 Economic Development Alliance
- The Beck Group
- BIO El Paso/Juarez
- BioMed SA
- bionorthTX
- Brazos Valley Economic Development Corporation
- Cancer Insight
- Cancer Prevention & Research Institute of Texas (CPRIT)
- Capital City Innovation



- Ceutical Laboratories, Inc.
- City of Georgetown
- L7 Informatics
- Medical Center of the Americas Foundation
- Odessa Development Corporation
- San Antonio Economic Development Foundation
- Southwest Research Institute
- Temple Economic Development Corporation
- Texas Department of Agriculture
- Texas Healthcare & Bioscience Institute (THBI)
- Texas State University
- Tyler Economic Development Council
- University of St. Thomas, Cameron School of Business
- USWoundCo
- UT Health San Antonio
- UT Southwestern Medical Center

The BIO 2020 International Convention will be held in San Diego from June 8-11. Contact the THBI office for more information or participation opportunities.

2018-2019: THBI Grassroots Outreach

THBI engages in events to continue stressing the strength of the life sciences industry while educating legislators and clearly conveying the importance of policy development for Texas. Outlined below is the series of events in which we participated prior to the start of the Texas legislative session and beyond.

October 2018

- THBI hosted our Fall Policy Conference at the Texas State Capitol.
- THBI President and CEO, Tom Kowalski was a keynote at the BionorthTX annual meeting.
- THBI began its Statewide Life Sciences Tour and held roundtable discussions on the Texas Life Sciences industry with community and business leaders in Austin, Dallas, El Paso, Houston and San Antonio.
- THBI hosted our monthly President's Call.

November 2018

- THBI concluded our Statewide Life Sciences Tour in El Paso and attended and participated in a press conference for the establishment of BIO El Paso/ Juarez.



- THBI hosted the Council of State Biotech Associations (CSBA) Winter Retreat in Austin, TX.
- The THBI State/Federal Relations Committee began meeting in preparation for the 86th legislative session.

December 2018

- THBI held its Annual Meeting and Holiday Party at the Austin Club.

January 2019

- Mr. Kowalski presented the THBI legislative priorities at the MD Anderson conference.
- THBI hosted our monthly President's Call.
- The THBI State/Federal Relations Committee began meeting weekly by phone for the 86th session.

February 2019

- THBI held our 2019 Policy Summit, Luminary Dinner and Fly-In with strong industry wide attendance.
- THBI released its industry report, **The Texas Life Sciences Landscape: Innovating for Today and Tomorrow.**
- Mr. Kowalski spoke at the University of Texas at Austin Incubator regarding the 86th legislative session.
- THBI was a panelist at the Texas State University Healthcare Showcase conference in San Marcos, TX.
- THBI hosted its monthly President's Call.
- The THBI State/Federal Relations Committee started in-person, weekly meetings at the State Capitol.

March 2019

- Tom Kowalski keynoted at Austin Healthcare Think Tank and provided an update on the current legislative trends in the industry.
- Mr. Kowalski also keynoted at the Medical Innovation Collaborative conference regarding the 86th legislative session.
- THBI hosted our monthly President's Call.
- The THBI State/Federal Relations Committee continued meeting weekly at the Capitol.

April 2019

- Tom Kowalski lead the Texas Delegation to BIO's Fly-In in Washington, DC.



- Mr. Kowalski presented to the visiting delegation of UK's healthcare executives.
- THBI hosted its monthly President's Call.
- The THBI State/Federal Relations Committee continued meeting weekly at the Capitol.

May 2019

- Tom Kowalski moderated the life sciences panel for opportunity for the Austin Economic Development Council.
- Mr. Kowalski was a guest speaker at the BioHouston Life Science CEO Summit in Bastrop.
- THBI hosted its monthly President's Call.
- The THBI State/Federal Relations Committee continued meeting weekly at the Capitol.

June 2019

- THBI lead a Texas delegation (comprised of 25 companies and organizations, including state and regional groups, economic development organizations and universities) to the 2019 BIO International Convention in Philadelphia, Pennsylvania. The Texas Pavilion managed by THBI was a popular location to tout the Texas Life Sciences industry.

Legislative Tracking

THBI reviewed all bills filed and tracked any legislation related to the Texas Life Sciences industry. In tracking this legislation, THBI sent out weekly updates detailing the progress of these bills with a short summary of each that was updated upon amendment or substitution. Tom Kowalski testified publicly on three occasions and the organization submitted written testimony on two occasions. The THBI State/Fed Committee met a total of 17 times either by phone or in-person at the Capitol during the 86th session and registered the organization's position on nearly 30 bills.

THBI tracked legislation throughout the session in 19 different categories:

1. Agriculture
2. Budget/Tax Policy
3. CPRIT
4. County Issues
5. Disclosure/PIA
6. Federal Healthcare
7. Fetal Tissue
8. General Healthcare
9. General Medicaid



10. Higher Education
11. Immunizations
12. Incentive Programs/Eco Devo
13. Licensing/Regulatory
14. Medical Device
15. Mental Health
16. Newborn Screening
17. Opioids
18. Pharmaceutical
19. Stem Cell

Agriculture

No pertinent bills in this track were passed.

Budget/Tax Policy

Two major bills were passed under this THBI designation during the 86th session: HB 1 by Representative Zerwas and SB 500 by Senator Nelson.

HB 1 relates to the general appropriations bill (detailed summary begins on page 22).

Riders in the General Appropriations Bill

HB1 includes the development of a clear process for including prescription medications on the Texas Drug Code Index requiring HHSC to clarify their process for the inclusion of prescription drugs in both Medicaid and CHIP. (Rider 107)

- **Clear Process for Including Prescription Drugs on the Texas Drug Code Index.**
The Health and Human Services Commission (HHSC) shall make clear their process for the inclusion of prescription drugs in the Medicaid and Children's Health Insurance Programs. In maintaining the prescription drug inclusion process, HHSC shall ensure that the timeline for review, including initiation of drug review, clinical evaluation, rate setting, Legislative Budget Board notification, and making the product available, does not extend past the 90th day of receipt of the completed application for coverage on the Texas Drug Code Index. After the applicable Drug Utilization Review Board meeting and approval by the HHSC Executive Commissioner, HHSC will complete the public posting of medical policies associated with the product.

The bill also includes a provision of notification related to orphan drug rates and rate increases (Article II Special Provisions, Section 14.b.). An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition.



- **Orphan Drug Notification.** HHSC shall provide notification of a new or increased rate for an orphan drug within 60 calendar days following expenditures for this purpose if managed care capitation rates are to be adjusted or the annual fiscal impact to fee-for-service expenditures is expected to exceed \$500,000 in General Revenue Funds. An orphan drug must meet criteria specified in the federal Orphan Drug Act and regulations at 21 C.F.R. §316 and be required to be covered by the Medicaid program under federal law. With the notification, HHSC shall provide the fiscal impact including the amount of General Revenue Funds, and All Funds, by fiscal year; the amount of drug rebates projected; and an estimate of the population to be served.

SB 500 relates to making supplemental appropriations and giving direction and adjustment authority regarding appropriations.

The supplemental bill also provided funds to meet additional important public health needs of Texas such as the newborn screening for X-Linked Adrenoleukodystrophy (X-ALD), which will begin in August.

Cancer Prevention & Research Institute of Texas (CPRIT)

CPRIT is funded at \$600.1 million for the 2020–21 biennium. This amount includes \$436 million in remaining available bond proceeds, and \$164 million in new General Obligation Bond Proceeds, contingent upon enactment of House Joint Resolution 12 from the session and voter approval to increase bond authority for the agency from \$3 billion to \$6 billion in November. In addition, THBI tracked several bills under this designation during the 86th legislature with two major pieces of legislation passing into law.

HB 39 by Appropriations Chairman Zerwas relates to the repeal of certain time limitations on the award of grants by the CPRIT Oversight Committee passed and **HJR 12** also by Chairman Zerwas proposing a constitutional amendment authorizing the legislature to increase the maximum bond amount authorized for CPRIT has been set as Proposition 6 by the Secretary of State for the November 5, 2019 ballot.

County Issues

No pertinent bills in this track were passed.

Disclosure/Public Information Act (PIA)

During the 86th session, THBI participated in a large working group focusing on legislation related to company disclosure and the public information act. The group was successful in adding language that would better clarify and protect the definition of a trade secret.



THBI tracked eight bills in this designation – four of which passed into law.

Senator Watson passed SB 943, 944 and 988 all relating to open-government laws and the public information act.

The main bill that passed was **SB 943** which relates to the regulation of contracting information and certain entities that handle contracting information that would be considered public.

The bill defines "contracting information" and establishes it as public unless excepted under other provisions. The bill creates specific contracting information exceptions for confidential and proprietary information of vendors and contractors, amends timelines, and requestor options to compel an entity to comply with certain provisions. The bill also lists certain types of entities that would be considered governmental bodies for the limited purpose of the disclosure of contracting information and requirements that must be included in a contract between a governmental body and an entity. The bill better clarifies and protects the definition of a trade secrets, including those for pharmaceutical products.

In addition, **HB 4390** by Representative Capriglione passed into law, which will study privacy of personal identifying information and creates of the Texas Privacy Protection Advisory Council.

Federal Healthcare

No pertinent bills in this track were passed.

Fetal Tissue

No pertinent bills in this track were passed.

General Healthcare

Two bills were passed under this THBI designation during the 86th session: HB 2425 by Representative Price and SB 2151 by Senator Kolkhorst.

HB 2425 relates to the authority of physicians to delegate to certain pharmacists the implementation and modification of a patient's drug therapy.

It has been noted that a physician is already allowed to delegate to a pharmacist the ability to implement or modify a patient's drug therapy under a protocol if the pharmacist practices in certain health care facilities. The bill allows a physician to delegate this same authority to pharmacists working in federally qualified health centers (FQHC's).



SB 2151 relates to the Texas Diabetes Council and the state plan for diabetes and obesity treatment and education.

The Texas Diabetes Council was established by the legislature in 1983 and addresses issues affecting people with diabetes in Texas. The bill updates the council's statute to reflect its functions, purview, and composition.

General Medicaid

One major bill passed under this THBI designation during the 86th session: SB 1096 by Senator Perry.

SB 1096 relates to the Medicaid managed care program, including the provision of pharmacy benefits. The bill requires the Health and Human Services Commission (HHSC) in contracts with Medicaid managed care organizations to prohibit use of non-clinical prior authorizations, or prior authorization imposed by HHSC to minimize fraud, waste, or abuse, or other barriers to a drug prescribed to a child enrolled in STAR Kids if the drug is on the vendor drug program formulary. The bill takes effect September 1, 2019.

Higher Education

One bill passed under this THBI designation during the 86th session: SB 25 by Senator West.

SB 25 relates to measures to facilitate the transfer, academic progress, and timely graduation of students in public higher education. The legislation aims to streamline the process that will allow a student to transfer from a two-year college or technical institute to a four-year university and reduce costs.

Immunizations

THBI tracked numerous bills in this designation during the 86th session with none passing. The immunization bills covered issues such as non-medical exemptions from immunizations, data included in and excluded from the immunization registry, informed consent, and right to contentious refusal.

Incentive Programs/Economic Development

Funding for the Trusteed Programs within the Office of the Governor totals \$1.4 billion in All Funds for the 2020–21 biennium, a decrease of \$121.9 million, or 8.2 percent, from the 2018–19 biennium. Funding in the strategy for various economic development programs such as the Texas Enterprise Fund and the Governor's University Research Initiative (GURI) totals \$534.2 million in All Funds for the 2020–21 biennium, including the following amounts:

- \$74 million in General Revenue Funds and \$76 million in estimated unexpended



balances remaining at the end of fiscal year 2019 in the Texas Enterprise Fund for incentive grants, a decrease of \$7.3 million in All Funds

- \$17.1 million in General Revenue Funds and \$22.9 million in estimated unexpended balances remaining at the end of fiscal year 2019 in the Governor's University Research Initiative for recruitment grants, a decrease of \$13.3 million in All Funds

No pertinent bills in this track were passed.

Insurance

One bill passed under this THBI designation during the 86th session: HB 1584 by Representative Senfronia Thompson. **HB 1584** relates to health benefit plan coverage of prescription drugs for stage-four advanced, metastatic cancer.

The bill amends the Insurance Code relating to health benefit plan coverage of prescription drugs for stage-four advanced, metastatic cancer and applies only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2020. The bill takes effect on September 1, 2019.

Licensing/Regulatory

No pertinent bills in this track were passed.

Medical Device

No pertinent bills in this track were passed.

Mental Health

Several major bills were filed this session relating to mental health, grants and programs for researching and treating behavioral health and psychiatric issues. Highlighted below are HB 19 & HB 2813 by Representative Price and SB 11 by Senator Taylor.

HB 19 relates to mental health and substance use resources for certain school districts. The bill would require a local mental health authority to employ a non-physician mental health professional to serve as a mental health and substance use resource for school districts located in regions served by a regional education service center and in which the local mental health authority provided services.

HB 2813 relates to the statewide behavioral health coordinating council. The bill (re)establishes the statewide behavioral health coordinating council to develop and monitor implementation of a five-year behavioral health strategic plan; develop a coordinated biennial statewide behavioral health expenditure proposal; annually publish an updated inventory of behavioral health programs and services funded by the state; and facilitate



opportunities to increase collaboration for the effective expenditure of state and federal funding for behavioral and mental health services.

SB 11 relates to policies, procedures, and measures for school safety and mental health promotion in public schools and the creation of the Texas Child Mental Health Care Consortium. The bill establishes various new programs and requirements related to improving public school safety and student mental health.

Newborn Screening

Throughout the 86th session, THBI and several member companies and other organizations were involved with a newborn screening working group with the goal of adding additional core newborn conditions recommended by the Recommended Uniform Screening Panel (RUSP) added to the Texas panel for screening.

Several bills related to newborn screening passed during the 86th session, of particular importance was SB 748 by Senator Kolkhorst.

SB 748 relates to maternal and newborn health care, including the newborn screening preservation account.

The bill establishes the Newborn Screening Preservation Account as a dedicated account in general revenue to be administered by the Department of State Health Services (DSHS). The bill would require the Comptroller to transfer unexpended and unencumbered funds from Medicaid reimbursements collected by the agency for newborn screening services to the new account. The account will be composed of grants, gifts, donations, legislative appropriations, and interest earned on the investment of money in the account. Money in the account can only be appropriated to DSHS and only for the purposes of carrying out the newborn screening program, performing additional newborn screening tests, or for certain capital expenditures. The bill takes effect September 1, 2019.

Opioids

THBI tracked several bills related to passed during the 86th session, of particular importance was HB 2174 by Representative Zerwas, HB 3285 by Representative Sheffield and SB 436 by Senator Nelson.

HB 2174 relates to controlled substance prescriptions and reimbursement for treatment for certain substance use disorders. The provisions of the bill amend dispensing requirements related to controlled substances to require electronic prescriptions in certain circumstances and authorize written prescriptions and oral or telephonic communication of prescriptions by a prescriber or designated agent in certain circumstances.



The bill authorizes certain regulatory agencies to grant waivers to electronic prescribing of controlled substances for practitioners and would amend continuing education requirements related to opioid prescription limits.

HB 3285 would amend the statewide behavioral health strategic plan, establish opioid antagonist programs, require Medicaid reimbursements for certain substance use disorder treatments, increase awareness of opioid risks, and require continuing education in pain management for certain providers.

SB 436 relates to statewide initiatives to improve maternal and newborn health for women with opioid use disorder and directs the Department of State Health Services to work with the Maternal Mortality and Morbidity Task Force to develop tools and best practices necessary to assess and treat opioid use disorders among pregnant women and to prevent opioid-related overdose among pregnant and post-partum women.

Pharmaceutical

Several bills under this THBI designation passed during the 86th legislature, here are some highlights: HB 1264 by Representative Senfronia Thompson, HB 2536 by Representative Oliverson, HB 3147 by Tan Parker, SB 1056 by Senator Zaffirini, SB 1283 by Senator Miles and SB 1780 by Senator Paxton.

Biosimilars: In 2015, legislation was passed that allowed interchangeable biological products to be substituted for brand-name biological products under certain circumstances. A “biosimilar” is a biological product that is highly similar to another biological product apart from minor differences in clinically inactive components and that has no clinically meaningful differences between the safety, purity, and potency of the two products.

HB 1264 removes the expiration on the requirement for a pharmacist to communicate to a prescribing practitioner within three business days certain information about a biological product dispensed to a patient.

Drug Pricing/ Transparency: **HB 2536** requires pharmaceutical drug manufacturers (PDMs) to annually report to the Health and Human Services Commission (HHSC) on the current wholesale acquisition costs of certain FDA-approved drugs sold in the state. HHSC would be required to develop a website to provide this information to the public. The bill would also require PDMs to report information on certain drug price increases. HHSC would be required to publish these reports online. The bill further requires pharmacy benefit managers and health benefit plan issuers to submit reports to the Insurance Commissioner, who would be required to publish the combined aggregated data from those reports online. For each drug having a Wholesale Acquisition Cost (WAC) of at least \$100 for a 30-day supply, and having an increase in WAC of 40% or more in the preceding three calendar years, or 15% or more in



the preceding calendar year, that manufacturer must report: (1) Name of the drug; (2) Whether its brand or generic; (3) Effective date of the change in WAC; (4) Aggregate, company-level research and development costs for the most recent year that data is available; (5) Name of each drug approved in the previous three calendar years; (6) Name of each drug having lost patent exclusivity in the previous three calendar years; (7) A statement regarding the factors that caused that increase in WAC and an explanation of each factor's impact on the costs; and (8) only publicly disclosed information is required to be made known.

HB 3147 relates to a cancer clinical trial participation program. This legislation would allow independent, third-party organizations to develop and implement a cancer clinical trial participation program. The program would provide reimbursement to subjects for costs associated with participation in a cancer clinical trial, including costs for travel, lodging, parking and tolls, and other costs considered appropriate by the organization.

SB 1056 relates to the authority of physicians to delegate to certain pharmacists the implementation and modification of a patient's drug therapy and clarifies that under the delegation of a physician, pharmacists have the authority to implement or modify a patient's non-dangerous drug therapy regardless of whether they practice in a hospital setting.

SB 1283 relates to the availability under Medicaid of certain drugs used to treat human immunodeficiency virus or prevent acquired immune deficiency syndrome. The bill would prohibit the Health and Human Services Commission (HHSC), or managed care organizations, from requiring certain actions in Medicaid related to dispensing of antiretroviral drugs.

Value Base Payment Arrangements with Prescription Drug Manufacturers: SB 1780 relates to value-based arrangements in the Medicaid vendor drug program.

The bill authorizes the Health and Human Services Commission to enter into certain value-based arrangements with prescription drug manufacturers. A value-based purchasing arrangement is a written agreement that links payment for a drug to its value in terms of patient outcomes.

Stem Cell

One bill was passed under this THBI designation during the 86th legislature: HB 3148 by Representative Tan Parker.

HB 3148 relates to the administration and oversight of investigational adult stem cell treatments administered to certain patients. The bill requires that institutional review boards that oversee investigational stem cell treatments either be affiliated with a medical school, affiliated with a hospital, accredited by the Association for the Accreditation of Human



Research Protection programs, registered by the United States Department of Health and Human Services, or accredited by another national accreditation organization acceptable to the Texas Medical Board (TMB).

The bill further requires the DSHS to establish and maintain an investigational stem cell registry.

Budget/Article II

This section is provided to address many of the key issues identified during the 86th legislative session and summarizes appropriation issues at a high level. Only items addressed in HB1 are included - items requested, but not funded are not included.

Appropriation Summaries

The Conference Committee Report for HB1 was filed and distributed on May 25, 2019 just two days before the end of the 86th legislative session. The bill provides \$250.7 billion in all funds for the 2020-2021 biennium. This is \$500 million below the house bill and \$3 billion above the senate bill.

2020-21 BIENNIAL RECOMMENDATIONS by Article, All Funds (IN MILLIONS)			
	House 2020-21	Senate 2020-21	Conference 2020-21
ARTICLE I - General Government	\$7,484.7	\$6,971.9	\$7,430.0
ARTICLE II - Health and Human Services	\$87,634.6	\$84,655.8	\$84,368.7
ARTICLE III - Agencies of Education	\$91,567.1	\$92,151.1	\$83,006.8
<i>Public Education</i>	\$70,019.6	\$70,595.0	\$61,154.0
<i>Higher Education</i>	\$21,547.5	\$21,556.1	\$21,852.8
ARTICLE IV - The Judiciary	\$955.0	\$874.0	\$892.3
ARTICLE V - Public Safety and Criminal Justice	\$15,884.6	\$15,998.8	\$16,040.3
ARTICLE VI - Natural Resources	\$9,115.0	\$8,928.0	\$9,013.0
ARTICLE VII - Business and Economic Development	\$37,406.3	\$37,063.9	\$37,057.1
ARTICLE VIII – Regulatory	\$644.5	\$651.4	\$647.4
ARTICLE IX - General Provisions	\$0.0	\$0.0	\$11,804.4
ARTICLE X - The Legislature	\$392.0	\$403.5	\$392.1
Total, All Functions	\$251,083.6	\$247,698.4	\$250,652.1

The bill provides \$84.4 billion for the biennium for health and human services, Article II which is \$3.2 billion below the house bill and \$300 million above the senate bill.



METHOD OF FINANCE	ESTIMATED/BUDGETED 2018–19	CCR HB1 2020–21	BIENNIAL CHANGE	% CHANGE
General Revenue Funds	\$34,716.3	\$33,728.7	(\$987.6)	(2.8%)
General Revenue– Dedicated Funds	\$566.9	\$527.8	(\$39.0)	(6.9%)
Federal Funds	\$46,704.3	\$48,784.8	\$2,080.5	4.5%
Other Funds	\$1,596.7	\$1,327.3	(\$269.4)	(16.9%)
Total, All Methods of Finance	\$83,584.2	\$84,368.7	\$784.5	0.9%

All Funds for the Health and Human Services agencies total \$84.4 billion, an increase of \$0.8 billion from the 2018–19 biennium. General Revenue Funds and General Revenue–Dedicated Funds total \$34.3 billion, a decrease of \$1 billion from the 2018–19 biennium.

Appropriations for Health and Human Services encompass multiple programs, but the biennial All Funds increase is primarily the result of the following areas:

- an increase of \$0.2 billion associated with child protective services programs, including foster care;
- an increase of \$0.6 billion for Medicaid client services, including rate increases for certain providers and expansion of community-based long-term care;
- an increase of \$0.3 billion in All Funds for other client services programs at the Health and Human Services Commission, including women’s health, community mental health, and early childhood intervention services;
- a decrease of \$0.5 billion in Federal Funds associated with onetime disaster-related federal funding and the Opioid State Targeted Response federal grant;
- more favorable Federal Medical Assistance Percentages result in a higher proportion of the Medicaid program being funded with Federal Funds, more than offsetting increased General Revenue Funds demand associated with caseloads and costs, resulting in an overall decrease to General Revenue Funds;
- an increase of \$141.2 million in All Funds for operation of state supported living centers and state mental health hospitals and to increase capacity at community mental health hospitals; and
- an increase of \$236 million in All Funds for deferred maintenance projects and other repairs at state-owned facilities, offset by a decrease of \$460.0 million in Other Funds associated with funds from the Economic Stabilization Fund appropriated for capital repairs and renovations at state-owned facilities during the 2018–19 biennium.

Texas Medicaid

The Legislative Budget Board reports that funding of \$66.4 billion in All Funds, including \$24.7 billion in General Revenue Funds and \$0.1 billion in General Revenue–Dedicated Funds,



is provided to the three health and human services agencies for the Texas Medicaid program. This amount is an increase of \$0.8 billion in All Funds and a decrease of \$1.9 billion in General Revenue Funds and includes the following:

- \$61.5 billion in All Funds for Medicaid client services, \$1.8 billion in All Funds for programs supported by Medicaid funding, and \$3.1 billion in All Funds for administration of the Medicaid program and other programs supported by Medicaid funding. The increase in Medicaid funding is due to increases of \$0.6 billion in All Funds for Medicaid client services, \$0.1 billion in All Funds for other programs supported by Medicaid funding, and \$0.1 billion in All Funds for administrative funding;
- Increased All Funds provided for Medicaid client services support caseload growth, maintain fiscal year 2019 average costs for most services, and provide funding for cost growth associated with average costs established by the federal government. Funding also is provided to support community-based long-term-care and includes \$259.8 million in All Funds to provide for 1,628 additional waiver slots to reduce the interest list for certain community-based waiver services, attendant wage and rate enhancement program increases, and rate increases for consumer-directed services and certain waivers. Funding also includes \$232.6 million in All Funds for rate increases for inpatient services and labor and delivery services provided by rural hospitals, intermediate care facilities for individuals with intellectual disabilities, Texas Health Steps private-duty nursing, and certain therapy services. More favorable Federal Medical Assistance Percentages result in a higher proportion of the program being funded with Federal Funds, more than offsetting increased General Revenue Funds demand associated with caseload and costs, resulting in an overall decrease to General Revenue Funds of \$1.9 billion. Funding levels assume savings of \$0.9 billion in All Funds for Medicaid cost-containment initiatives. Full funding for anticipated increases in cost due to medical inflation, higher utilization, or increased acuity is not included;
- The 2018–19 biennial amounts for Medicaid assume supplemental funding to complete fiscal year 2019 expenditures.

Women's Health

Funding for Women's Health Programs includes \$347 million in All Funds, including \$209.3 million in General Revenue Funds, for the 2020–21 biennium, representing an increase of \$67.9 million in All Funds, including \$9.4 million in General Revenue Funds, from 2018–19 biennial spending levels.



Department of State Health Services Laboratory Services

Funding includes \$125.9 million in All Funds, including \$41.9 million in General Revenue Funds, for laboratory services at the Department of State Health Services. This amount includes an increase of \$41.1 million in All Funds from 2018–19 biennial spending levels primarily to address the agency’s loss of certain laboratory revenue, for repairs and renovations of the South Texas and Austin laboratories, to upgrade laboratory software applications, to meet increased testing volumes related to public health, and for salary increases for certain laboratory personnel.

Tuberculosis Prevention

Funding includes \$68.7 million in All Funds, including \$50.5 million in General Revenue Funds, for tuberculosis (TB) prevention activities, an increase of \$11.4 million from the 2018–19 biennial base. This amount includes increased funding and additional FTE positions to expand contracts with local health departments, to provide staffing and contracts for large-scale TB exposures, to provide salary increases for public health nurses, and for video direct observation technology.

In addition to assumed supplemental funding described previously for Medicaid, the supplemental appropriations bill includes funding for newborn screening for X-linked adrenoleukodystrophy, trauma capacity grants, an emergency laboratory generator, women’s health, state-owned facilities, community mental health services, early childhood intervention services, and children’s hospital rate increases.

The figure below shows the All Funds appropriation (in millions) for each agency in Article II, and the General Revenue Funds appropriation (in millions) for each agency is in the following chart.

Article II, Health and Human Services (All Funds)				
FUNCTION	ESTIMATED/ BUDGETED 2018–19	HB1 2020–21	BIENNIAL CHANGE	% CHANGE
Department of Family and Protective Services	\$4,175.1	\$4,428.0	\$252.9	6.1%
Department of State Health Services	\$1,688.2	\$1,674.4	(\$13.8)	(0.8%)
Health and Human Services Commission	\$76,381.5	\$76,805.3	\$423.8	0.6%
Subtotal, Health and Human Services	\$82,244.8	\$82,907.6	\$662.9	0.8%
Employee Benefits and Debt Service	\$2,131.7	\$2,234.1	\$102.4	4.8%
Less Interagency Contracts	\$792.2	\$773.1	(\$19.1)	(2.4%)
Total, All Functions	\$83,584.2	\$84,368.7	\$784.5	0.9%



Article II, Health and Human Services (General Revenue)				
	Budgeted 2018-19	CCR HB1 2020-21	BIENNIAL CHANGE	% CHANGE
Department of Family and Protective Services	\$2,389.5	\$2,584.5	\$195.0	8.2%
Department of State Health Services	\$475.6	\$555.7	\$80.1	16.8%
Health and Human Services Commission	\$30,417.1	\$29,084.5	(\$1,332.6)	(4.4%)
Subtotal, Health and Human Services	\$33,282.3	\$32,224.7	(\$1,057.5)	(3.2%)
Employee Benefits and Debt Service	\$1,434.1	\$1,504.0	\$69.9	4.9%
Total, All Functions	\$34,716.3	\$33,728.7	(\$987.6)	(2.8%)

Department of State Health Services

DSHS’s total appropriations are \$1.67 billion which represents an overall increase of \$100.3 million in exceptional item funding for the fiscal years 2020 – 2021, representing 72 percent of the agency request. Eight of the nine DSHS exceptional items were funded to some degree:

- Item 1: closes a dangerous gap in funding for the state public health laboratory
- Item 2: fully funds seat management and data center service cost increases
- Item 3: fully funds continued efforts to improve maternal health and implement statewide safety initiatives
 - This item allows DSHS to launch the implementation of opioid bundles statewide and a high risk maternal care coordination pilot
- Item 4: to improve vital records customer service, processing times, and security was almost fully funded when accounting for alternative funding mechanisms now put into place
- Item 5: to improve staff retention for public health nurses, meat inspectors, lab positions, and finance staff was funded at 45% of the request
- Item 6: fully funds improvements for the Texas enhancement of the National Electronic Disease Surveillance System, which serves as a backbone to infectious disease reporting and investigations statewide
 - This item allows DSHS to be more predictive when identifying emerging outbreaks
- Item 7: enhances efforts to control tuberculosis in Texas
 - This item increases local capacity, funds the Texas Center for Infectious Disease, and allows DSHS to offer better support for local TB investigations
- Item 8: not funded
- Item 9: funding will replace 39% of the DSHS vehicle fleet



- Supplemental bills provided funds to meet additional important public health needs of Texas such as:
 - Newborn screening for X-Linked Adrenoleukodystrophy (X-ALD), which will begin in August
 - EMS and trauma partners such as the Regional Advisory Councils, Hurricane Harvey area hospitals, and Valley hospitals seeking Trauma I designations



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86th Session End of Session Report

Acknowledgement

THBI would like to acknowledge and thank Texas Insight for their extensive research, analysis, and reporting in areas of Health and Human Services and Article II. The real time reporting of events as they occur within the legislative and regulatory branches of Texas state government was an indispensable resource for our efforts to stay on top of upcoming actions that can affect THBI members.

THBI would also like to acknowledge and thank the JHL Company for their commitment to quality and professionalism in all activities associated with THBI.

THBI Staff

Tom Kowalski – President and CEO
Julie Haerber – Policy Director
Virginia Rothenflue – Business Manager