



Texas Healthcare
& Bioscience Institute

80th Texas Legislature End of Session Summary

THBI approached the 80th Legislative Session with another extremely full and difficult agenda. The State and Federal Government Relations Committee for THBI began in September of 2006 meeting every other week to develop THBI's legislative priorities for the session. The Committee compiled a list of 29 priorities in 7 categories and divided those issues into those that THBI would watch and monitor closely and those that the Committee knew from the beginning THBI would need to be actively engaged in. The priorities list was created with the understanding that there would emerge issues that THBI would need to engage upon that perhaps were not part of the list or that had previously been designated as items to watch and monitor. The State and Federal Government Relations Committee continued to meet every other week throughout session to monitor the progress of these priorities and eventually, in May, the Committee held weekly meetings to provide rapid updates coinciding with the increasing pace of the session.

The Texas Legislature filed 6374 bills and constitutional amendments this session, 1495 of which were sent to the Governor. THBI tracked over 277 bills with the potential to impact our membership, sending out updates weekly on the progress of these bills. Included in these tracking charts was a summary of each bill which was updated upon amendment or substitution. Testimony was provided by Tom Kowalski on 6 bills and THBI dropped 24 witness cards supporting 22 bills and opposing 2. Additionally, THBI provided 9 experts to testify on 10 different bills. Additionally, THBI regularly made rounds at the Capitol to speak with individual members and their staff on a variety of pieces of legislation and produced numerous written pieces intended to educate not only the Texas Legislature, but the public as well. The session concluded with the Legislature passing a \$152.5 billion budget in the final hours. The budget provides a 7% increase over the last biennium's budget. The Governor's veto period extends until June 17, 2007.

And now to the issues:

Economic Development

Texas Emerging Technology Fund - For the second session in a row, the Governor's Texas Emerging Technology Fund (ETF) was a priority for THBI. THBI worked diligently to educate legislators about the projects which have already been funded by the Emerging Tech Fund, the vital role played by the Regional Centers of Innovation and Commercialization and the statewide Life Science Center, and the process by which proposals are screened, vetted, selected, and eventually funded. Additionally, THBI



advocated for the two cleanup bills to the ETF (HB 1188 and SB 486). These identical bills allowed the state more flexibility in negotiating equity positions with companies being awarded ETF monies, and additionally allow for up to 2% of the Fund to be used to assist the RCICs and statewide Life Science Center with administrative capacity in the future. THBI held weekly meetings with AeA, TechNet, and the Metroplex Business Technology Council in a continuing partnership to trade information, formulate a strategy, and pinpoint potential pitfalls to the success of these two bills as well as the renewal of the Fund through the Appropriations process. THBI kicked off Tech Week the first week of February, again holding a week's worth of events designed to showcase emerging technologies and the importance of the continuation of the ETF. THBI members were on hand to advocate for the Fund with their respective legislators and did a fantastic job relaying the necessity of this fund. There were actually multiple processes to be dealt with since the funding for Emerging Tech was being handled through the Appropriations process while the framework was contained in the bills themselves.

House Bill 1188 eventually passed, and the Texas Emerging Technology Fund was renewed with \$75 million and the unexpended balance of the Fund from the previous biennium. Combined with interest, the Emerging Tech Fund should begin its second phase with close to \$180 million.

Texas Enterprise Fund – THBI supported renewal of the Enterprise Fund and included it in discussions with legislators about the Emerging Technology Fund. This particular economic development tool has proved extremely useful in helping existing life science companies and partnerships expand within the state and in helping large corporations relocate their facilities to Texas. The Texas Enterprise Fund was renewed and the unexpended balance from the previous biennium was rolled over. This amount with interest will begin the next cycle of the Fund with around \$200 million.

Research & Development Sales Tax Exemption – THBI, again working with AeA, TechNet, MTBC, and some newly added collaborative partners such as the Texas Chemical Council, Texas Association of Manufacturers, and the Texas Association of Businesses, pushed for a sales tax exemption on research and development equipment in manufacturing. During the special session on school finance in the previous year, the Texas Legislature revised the franchise tax into a business tax and eliminated many of the franchise tax credits associated with the older tax structure, including the credit for research and development activities. Currently, manufacturers receive an exemption from state sales tax on machinery and equipment used in manufacturing, however the law specifically excludes equipment used in research and development. House Bill 1731 filed by Representative Will Hartnett and Senate Bill 1059 filed by Senator Kyle Janek sought to extend that sales tax exemption to equipment used for research and development in the manufacturing process. Both bills received hearings in their



respective committees. THBI provided testimony as well as visited with committee members and their staff on the importance of providing this type of incentive to the life science industry. Unfortunately, neither bill was voted out of committee, however, THBI and our partners will renew efforts in the next legislative session to get this legislation passed.

Pharmaceutical Biotech Cleanroom Exemption – Legislation was passed in 2003 establishing an exemption from state sales tax on pharmaceutical-specific biotech cleanrooms built for manufacturing. Unfortunately, the original bill filed ran out of time and when the language was added to a general sales tax bill as an amendment, the exemption was limited to pharmaceutical biotech cleanrooms built between July of 2003 and August of 2004 as part of a facility that was \$150 million or more. This language limited the extent and applicability of the exemption thus limiting economic development corporations and chambers of commerce in their ability to use it as a recruiting tool. THBI approached Representative Brian McCall and Senator Kirk Watson to carry House Bill 1831 and Senate Bill 865 to try and reinstate this sales tax exemption and eliminate the monetary requirement of the new facility. The House Ways and Means Committee held a hearing on House Bill 1831 first and Tom Kowalski testified. Additionally, Susan Davenport with the Greater Austin Chamber of Commerce, Marc Scott with LCS Constructors, and Keith Zimmerman with Equis Corporation provided testimony to the committee providing solid information about the life science industry, the competitiveness of recruiting and retaining biotech and pharmaceutical companies, and the specifics of building cleanrooms. The Senate Finance Committee also held a hearing on Senate Bill 865, and, again, Tom Kowalski, Marc Scott and Susan Davenport provided testimony. Pike Powers testified on behalf of the legislation as well providing additional support. While neither bill was passed out of committee, Representative McCall was able to attach the language as an amendment to House Bill 3319, a broad sales tax bill. THBI worked the Senate to keep the cleanroom exemption in the bill, and eventually HB 3319 was passed, in the process reinstating a sales tax exemption on pharmaceutical biotech cleanrooms built as part of a new facility for manufacturing.

Higher Education

Licensing and Technology Transfer Issues – One bill of particular concern to not only higher education institutions but to emerging businesses and private industry partners as well was House Bill 598. This bill sought to require state agencies and higher education institutions which enter into agreements with private entities to market or develop a product that was created at least in part with state-funded research, and which does not utilize a competitive bidding process, to publish notice of its intentions in the Texas Register 30 days prior to entering into the agreement. The state agency or higher



education institution must include enough information in the published notice that another entity could make a potential offer. While this bill appears to many people to be a good, transparency of process piece of legislation designed to allow the public to see how state dollars are being used, from an emerging technology and technology transfer standpoint, it would have disastrous effects. The language was broad and significant intellectual property would need to be published. Additionally, the 30 day waiting period before the agreement could be finalized was not in the best interests of either the agency or institution not to mention the technology being developed. THBI worked to educate the author of the bill as well as members of the committee in which the bill was heard about the consequences on public-private business partnerships, emerging technologies, and patent and licensing issues from this bill. The bill was never passed out of committee.

Clinical Trials – Texas is consistently a leader in terms of the number of clinical trials conducted in the state. However, due to some restrictions by insurance companies, finding enough willing participants for a clinical trial can be challenging and is not always an efficient process. Senator Judith Zaffirini filed Senate Bill 674 which would have required insurance companies that provide coverage for routine health care costs associated with different diseases to continue to cover those routine costs if the patient enrolled in a clinical trial for treatment. For example, patients receiving treatment for cancer have certain routine health care costs such as blood-work, x-rays, and lab tests conducted at set intervals. If the patient however enrolled in a clinical trial for treatment of their cancer, some insurance companies refuse to cover those same routine costs, making it burdensome for some patients when faced with the decision to continue treatment or enroll in a clinical trial which may provide a more effective treatment for their particular situation. This bill would have required those companies to continue that coverage. The bill was heard by a subcommittee of the Senate State Affairs Committee. Stephanie Willis with Kelly Scientific came in to testify in support of the bill. Unfortunately, the bill ran out of time at the end of the session.

Research and Development

Biomedical Research – Legislators filed 14 bills which would have impacted stem cell research significantly. THBI felt that its role was to help educate legislators on the science of the research and the impact different pieces of legislation would have on either bolstering or chilling the research and development environment in Texas. With a coalition of supporters including the Texans for the Advancement of Medical Research, a panel of experts was assembled to testify in front of the House State Affairs Committee on these stem cell bills. The panel was composed of an economist, Bud Weinstein, who



had produced a report demonstrating the impact of legislation on the biotech industry; a member of the clergy; a scientist, Dr. Larry Denner; a patient advocate; Margaret Sampson, a patent attorney for Vinson & Elkins in Austin who also has a PhD and studied mouse embryonic stem cells; and an ethicist, Thomas George. The hearing began at 8 in the morning and concluded at 5 the next day. The committee sat and listened to hours of testimony before adjourning.

Among those 14 bills filed were the following:

- House Bill 225 by Representative Ken Paxton and Senate Bill 1834 by Senator Glenn Hegar were intended to prohibit academic research institutions that receive state funding from performing research on embryonic stem cells. HB 225 was killed in the Calendars Committee as it ran out of time to be set for debate. SB 1834 did not receive a hearing in the Senate.
- House Bill 1703 by Representative Charlie Howard was filed to require the adoption of a human embryo in order to transfer it. The bill created a penalty for human embryo trafficking and prohibited the reimbursement of medical expenses. This bill ran out of time while awaiting debate by the House.
- House Bill 537 and HJR 53 by Representative Senfronia Thompson would have established the Texas Institute for Regenerative Medicine and allowed the sale of up to \$900 million in general obligation bonds over a six year period for all forms of stem cell research. These pieces of legislation were not passed out of the House State Affairs Committee.
- House Bill 1486 by Representative Elliot Naishtat established a stem cell research grant program under the Higher Education Coordinating Board. This bill also was not passed out of the House State Affairs Committee.
- Several bills including House Bill 1533 by Representative Mark Homer, House Bill 1829 by Representative Richard Raymond, Senate Bill 56 by Senator Judith Zaffirini, Senate Bill 413 by Senator Elliot Shapleigh, and Senate Bill 646 by Senator Rodney Ellis sought to create a ban on human cloning. These bills defined human cloning as the implantation of a product of Somatic Cell Nuclear Transfer thus ensuring that research could continue on embryos, however, prohibiting unethical actions from occurring. None of these bills made it out of committee.
- House Bill 2704 by Representative Woolley created a safe harbour for all forms of stem cell research within the state and additionally created a research oversight



advisory committee. Again, this bill was one of those not voted on by the House State Affairs Committee.

- Senate Bill 1754 by Senator Rodney Ellis sought to clarify in statute that institutions of higher education are permitted to use private money to perform regenerative and reparative research for medical therapies or treatments. Senate Bill 1754 was not heard in committee.

Through much education and effort by all involved and by a core group of legislators and their staff, no amendments were added to any bill passed during the 80th Legislative Session which would have limited stem cell research for Texas academic institutions or in Texas in general.

House Bill 709 by Representative Robert Puente facilitated greater information sharing and education about umbilical cord blood storage. This bill was passed out of both chambers and sent to the Governor. Additionally, the Health and Human Services Commission was appropriated \$5 million in the budget to fund research and a donor umbilical cord blood bank.

Agriculture

Organic Advisory Board – House Bill 2345 by Representative Doc Anderson and Senate Bill 866 by Senator Kirk Watson established a Texas Organic Agricultural Industry Advisory Board. This Board is created to promote organic agricultural products in Texas. THBI members were concerned that practices in other states that have established similar Boards might spill over into Texas. There have been situations where organic products have been promoted using language and actions that were destructive to other agricultural processes including agricultural biotechnology. Language was added to the bill to require that when developing its statewide education and awareness campaign, the Board must be consistent with any Texas Department of Agriculture policies promoting Texas agriculture and that it must not refer negatively to any other agriculture process. House Bill 2345 has been sent to the Governor.

Animal Cruelty – There were several animal cruelty bills filed during the 80th Legislative Session including House Bill 2328 by Representative Beverly Woolley and Senate Bill 1100 by Senator Whitmire. THBI closely monitored these bills to ensure that language remained in statute to ensure that there is a defense to prosecution for those who perform scientific research utilizing animals. Those provisions remained in place and House Bill 2328 has been sent to the Governor.

Pharmaceutical



Transparency – The interim between the 79th and 80th Legislative Session witnessed numerous discussions about pharmacy benefits managers (PBMs) and pharmaceutical manufacturer rebates and whether those rebates were being realized by the state in contracts with PBMs. There was a desire by many legislators to create a transparency in the process by which rebates are passed on by PBMs to those state agencies contracting with them. Numerous bills were filed trying to address this issue and riders were added to the budget to accomplish the same intention. THBI monitored these bills closely to ensure that this transparency of process did not cross the line into a situation whereby the proprietary, confidential cost and pricing information of manufacturers was being accessed and used inappropriately. House Bill 1613 by Representative Dan Gattis, House Bill 1974 by Representative Sid Miller, House Bill 3280 by Representative Isett, House Bill 3454 by Representative Callegari, and Senate Bill 1834 by Senator Hegar all were filed with the intention of regulating pharmacy benefit managers and their contracts with the state regarding the purchasing of pharmaceuticals from manufacturers. All of these bills ran out of time as the session came to a close and the language was not included in the final version of the budget bill.

Sales and Marketing Disclosure Requirements – Senate Bill 414, filed by Senator Eddie Lucio, required that pharmaceutical manufacturers report individual expenditures on sales and marketing efforts that exceeded \$75. Tom Kowalski testified in front of the Senate Health and Human Services Committee of the potential damaging effect this bill could have on those emerging pharmaceutical companies beginning to market their products after 10-15 years of research, development, and investment. THBI contributed significantly to a joint letter from THBI, the Texas Association of Manufacturers, and the Texas Association of Business to the Senate Health and Human Services Committee. THBI visited continually with Senate staff on this issue to reinforce the fact that if Texas wants to continue to grow its life science industry cluster, it can not implement policies place that promote research and development at the beginning, yet hinder commercialization and access to those products in later stages. SB 414 remained in the Senate Health and Human Services Committee for the remainder of the legislative session.

Pedigree Legislation – The 79th Legislature passed some dramatic changes implementing pedigree legislation to safeguard the chain of distribution for pharmaceuticals. House Bill 2316 by Representative Vicki Truitt and Senate Bill 943 by Senator Kyle Janek were filed to clean up and tweak that previous legislation as well as bring it into compliance with federal law for the licensing and regulation of wholesalers of prescription drugs. The Senate version of the legislation was passed and has been sent to the Governor.



HHSC Meetings and Processes – A continuing issue for many THBI members who manufacture provider administered drugs, biologics, and vaccines has been the length and complication in the process by which those drugs are approved by the Texas Health and Human Services Commission for use by Medicaid patients. A rider was added to the budget bill, House Bill 1, that requires drugs and biologics to be deemed covered under Medicaid if they are approved by the FDA and satisfy the criteria of the Omnibus Budget Reconciliation Act of 1990. The rider requires manufacturers to obtain a HCPCS code of C, Q or J or another nationally recognized National Drug Code Number that will allow the Medicaid office to track the product for rebate purposes. The provision also eliminated the need by HHSC to submit an annual client services fiscal impact statement or seek review by other state agencies, which had caused the most significant delay in access to these pharmaceutical products in the past.

Prescriber Data Legislation – Senator Leticia Van de Putte filed Senate Bill 1620 which was modeled after legislation in New Hampshire prohibiting practitioner-identifiable data to be transferred, sold, or used by pharmaceutical manufacturers for sales and marketing purposes. During the course of Texas’ legislative session, a federal court issued a ruling that the New Hampshire law was unconstitutional. THBI provided written testimony against Senate Bill 1620 in an effort to educate the Senate Health and Human Services Committee on the implications of this bill. THBI tried to reinforce the fact that provider-identifiable data is useful to small emerging pharmaceutical companies on multiple fronts that all involve patient safety and effective treatment and access to the newest therapies. This bill was altered to require the issue be studied, including the benefits of access to this data. SB 1620 died in committee.

Healthcare and Access to Healthcare

Texas Cancer Prevention and Research Institute of Texas - Senator Jane Nelson and Representatives Jim Keffer, Patrick Rose, Diane Delisi, Geanie Morrison, and Senfronia Thompson authored Senate Bill 1292, SJR 43, House Bill 14, and HJR 90 which creates the Texas Cancer Prevention and Research Institute of Texas. A ballot initiative will be placed in front of Texas voters in November which will authorize the state to issue up to \$3 billion in general obligation bonds over the next ten years predominantly for cancer research with a portion being allocated for preventative efforts. The purpose of the Institute is to expedite innovation in cancer research, attract and expand research capabilities, and develop and implement a Texas Cancer Plan. The fund will allow up to \$300 million each year in grants to public and private entities, higher education, and advanced medical research to support finding causes and cures for all types of cancer in humans. An oversight committee is established to govern the fund as well as a research



and prevention programs committee. The bill received overwhelming support in both the House and Senate and HB 14 was sent to the Governor, while HJR 90 will be subject to voter approval in November.

Medicaid Reform – The Deficit Reduction Act allowed states more flexibility with regards to spending Medicaid dollars. The 80th Legislative Session provided Texas with its first opportunity to look at those options and design a Medicaid Reform Bill. Senate Bill 10 by Senator Jane Nelson was sponsored by Representative Diane Delisi in the House. It became a large omnibus bill for many healthcare reforms and other bills that ran out of time in the legislative process. Some of the reforms it includes are:

- A pilot program implemented by the Health and Human Services Commission to provide Medicaid recipients incentives to lead healthy lifestyles, including expanded benefits for enrollees participating in weight loss or smoking cessation programs.
- If feasible, the implementation of a Medicaid health savings account pilot program.
- Requires the Health and Human Services Commission to seek a waiver to develop tailored benefits packages for defined categories of Medicaid recipients.
- A study on the feasibility of increasing technology use to detect and deter Medicaid fraud
- Creates the Texas Health Opportunity Pool Trust Fund allowing the Health and Human Services Commission to seek a waiver to allow TX to use federal money to defray uncompensated health care costs by depositing federal money into the Pool. The Pool is to be administered on behalf of uninsured residents and providers offering uncompensated care
- Allows use of the Texas Health Opportunity Pool Funds to establish regional or local health care programs as demonstration projects. .
- Expands the breast and cervical cancer treatment in the medical assistance programs.
- Medical assistance with enrollment in group health benefit plans.
- Requires the adoption of cost-sharing provisions for high-cost medical services when lower-cost services are available. .
- Requires establishment of an electronic health information pilot program.
- Contains a study provision requiring the Texas Department of Insurance to study small employer health plan coverage.
- Requires the Texas Health Care Policy Council with the Institute for Demographic and Socioeconomic Research at UTSA, UTHSCSA, and TMA to conduct a study on increasing the number of medical residency programs and medical residents in TX and the number of physicians practicing medical specialties.



- Establishes a committee on health and long-term care insurance incentives to study/develop recommendations on how state can reduce need for Medicaid reliance through incentives.
- Creates the Medicaid Reform Legislative Oversight Committee to facilitate reform efforts in Medicaid, process of addressing issues of uncompensated hospital care, and establishment of programs addressing uninsured.

In keeping with a rigorous schedule, THBI, along with AeA, TechNet, and the Metroplex Business Technology Council, co-hosted **Texas Technology Week**, February 5 through February 9 at the Capitol in Austin. THBI held its annual fly-in on February 6 & 7, this time a two-day event, with 16 members walking the halls of the Capitol hitting over 25 offices on the following issues: the R&D Sales Tax Exemption, the Texas Emerging Technology Fund, and the Pharmaceutical Biotech Cleanroom Sales Tax Exemption. In all, the Tech Week Coalition visited more than 130 offices. During the Tech Week Breakfast on Wednesday, 100 attendees heard from Senators Janek and Shapiro on the Emerging Tech Fund as well as Representative Morrison. A reception for attendees, legislators and legislative staff took place at the Stephen F. Austin Hotel Wednesday evening, complete with technology demonstrations. A VIP cocktail reception for sponsors was held before the Tech Demo reception. Slots for technology demonstrations were rapidly filled in the weeks of planning preceding the event. THBI members sponsoring and/or demonstrating included: BioDFW, the Greater Dallas Chamber Technology Business Council, ViaGen Inc., Sanofi-Aventis, Vinson & Elkins, Texas Coalition for Capital, Tyler Economic Development Corporation, Temple Economic Development Council, Incell, and CenterPoint Energy.

During Tech Week, THBI also partnered on Wednesday, February 7, with national entities BIO, PhRMA, the National Venture Capital Association, the Association of University Technology Managers, the U.S. Chamber of Commerce and other state and regional sponsors including: the Arlington Chamber of Commerce, BioDFW, BioHouston, Greater Dallas Chamber Technology Business Council, Houston Technology Center, Temple Economic Development Corporation, Texas Association of Business (TAB), Texas Coalition for Capital, and the Tyler Economic Development Council to produce a one day event, BizBio – Texas’ Bioscience Community: Building on the Foundation. Biz Bio provided an opportunity to showcase the assets of Texas and explore the needs of the life science community and industry in Texas in order to continue growing and developing. Governor Rick Perry and Gino Santini from Eli Lilly delivered keynote addresses while other panelists included: Representative Dan Gattis, David Rosen from Pfizer, Bill Morrow with CSIdentity, and Aaron Demerson from the Governor’s Office. The event was standing room only with over 130 people in attendance at the Four Seasons.



THBI was pleased to add an additional benefit this legislative session called Coffee at the Capitol. Two coffees were hosted in an intimate, informal environment to enable THBI members to interact with key members of the Texas Legislature. Representative John Zerwas and Representative Diane Delisi attended the two coffees. The coffees were well received and played a critical role in discussing several key and timely pieces of legislation. THBI is looking forward to continuing this added benefit next session and increasing the number of coffees.

Tom Kowalski led a team of THBI members in the annual BIO Fly-In to discuss federal issues April 17-18. Attendees had an opportunity to discuss with the Texas Congressional Delegation and their staff issues ranging from noninterference, importation, follow-on biologics, SBIR, the 2007 Farm Bill and patent reform.

THBI is extremely pleased with the results of our agenda for the 80th Legislative session. We look forward to continue work and education efforts throughout the special session and into the interim on issues affecting the life science and biotechnology industry cluster.