MEDICAL ALLEY
ASSOCIATION

2017 State Legislative Session Wrap Up

June 2017

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SESSION SUMMARY

The 90th legislative session ended tumultuously without a budget deal and with state legislators immediately convening a 72-hour special session to try and get the job done. After nearly five and half months of work during regular session, the legislature was unable to craft a budget by the constitutionally mandated end date of May 22nd. A special session was convened immediately thereafter and lasted until about 3am on Friday May 26th. The final two-year budget for the state was roughly $47B.

Governor Mark Dayton is on track to have exercised the greatest number of vetoes in the state's history. In regular session, 99 Chapters were presented to the Governor and he vetoed 17 of those bills. In special session, 8 Chapters were presented and there was one full veto of the labor standards or preemption bill (see below) as well as a controversial line item of the legislature's budget. Governor Dayton enumerated his concerns with many of the provisions tucked into the budget bills, and had been vocal throughout session about his disappointment with how much policy was included in those bills. Governor Dayton's veto letters declared that he would release the legislative budget if, and only if, legislative leaders agreed to a second special session to remedy some of the provisions that he disliked.

Budget	Appropriation
Agriculture	$117M
Bonding	$1.4B
E-12	$18.9B
Environment	$313.9M
Health and Human Services	$16B
Higher Education	$3.1B
Jobs	$414.3M
Public Safety	$2.2B
Tax	$650M
Transportation	$243.6M

The legislative session started out with new GOP leadership in the Senate. Senator Paul Gazelka (R- Nisswa) began his first term as the Senate Majority Leader. House Speaker Kurt Daudt (R- Crown) began his second term as Speaker, alongside Rep. Joyce Peppin (R- Rogers) as Majority Leader. Senator Tom Bakk (R- Cook) and Rep. Melissa Hortman (R- Brooklyn Park) both were chosen by their caucuses as minority leaders.

Early on, GOP leaders announced early bill deadlines in an effort to avoid the need for a special session - which is exactly what has occurred. The deadlines required that all budget bills be done before the long legislative Easter/Passover break. This was an untraditional and

aggressive schedule that created a frenzied environment at the Capitol with many seasoned advocates scrambling to have their initiatives drafted and heard.

The Medical Alley Association (MAA) delivers solutions in the public policy arena. Many of MAA's priorities became law this session. With a focus on patient access, innovation, and economic growth our legislative agenda included targeted tax initiatives, economic development incentives, and changes to the pharmacy practice act, as well as provisions supporting the University of Minnesota and Mayo Clinic. MAA is looking forward to the next legislative session to continue to advocate on behalf of Minnesota's Medical Alley to ensure the legislature understands the impact that health innovation and care has on the state.

The legislature will convene for the second half of the biennium on Tuesday, February 20th, 2018--- giving us 274 days between adjournment and the start of the next legislative session.

New Legislative Members

The 2016 election cycle brought much change to the legislative landscape in Minnesota. Republicans retained control of the State House and expanded their majority by a net of 4 seats. The DFL lost control of the State Senate—Republicans gained a slim 1 seat majority, 34-33. This proved to be significant when members of the Senate GOP were missing from important votes. Senator Warren Limmer was out a few days after a heart attack and Senator Carla Nelson had to leave her ailing parent to vote for budget bills!

New State House Members (20)

(11 R | 9 DFL)

Last Update 5/30/17

Name	Party Affiliation	Previous Control	Current Control	District
Matt Grossell	R	DFL	R	2A
Matt Bliss	R	DFL	R	5A
Sandy Layman	R	DFL	R	5B
Barb Haley	R	R	R	21A
Duane Sauke	DFL	DFL	DFL	25B
Ann Neu	R	R	R	32B
Erin Koegel	DFL	DFL	DFL	37A
Nolan West	R	R	R	37B
Mary Kunesh-Podein	DFL	DFL	DFL	41B
Randy Jessup	R	DFL	R	42A
Jaime Becker-Finn	DFL	DFL	DFL	42B
Laurie Pryor	DFL	DFL	DFL	48A
Dario Anselmo	R	DFL	R	49A
Andrew Carlson	DFL	R	DFL	50B
Regina Barr	R	DFL	R	52B
Keith Franke	R	DFL	R	54A
Tony Jurgens	R	DFL	R	54B
Erin Maye-Quade	DFL	R	DFL	57A
Fue Lee	DFL	DFL	DFL	59A
Ilhan Omar	DFL	DFL	DFL	60B

New State Senate Members (20)

(12 R | 8 DFL)

Last Update 5/30/17

Name	Party Affiliation	Previous Control	Current Control	District
Mark Johnson	R	DFL	R	1
Paul Utke	R	DFL	R	2
Justin Eichorn	R	DFL	R	5
Erik Simonson	DFL	DFL	DFL	7
Jerry Relph	R	R	R	14
Andrew Matthews	R	R	R	15
Andrew Lang	R	DFL	R	17
Nick Frentz	DFL	DFL	DFL	19
Rich Draheim	R	DFL	R	20
Mike Goggin	R	DFL	R	21
John Jasinski	R	DFL	R	24
Mark Koran	R	R	R	32
Carolyn Laine	DFL	DFL	DFL	41
Jason Isaacson	DFL	DFL	DFL	42
Paul Anderson	R	DFL	R	44
Scott Jensen	R	R	R	47
Steve Cwodzinski	DFL	R	DFL	48
Matt Klein	DFL	DFL	DFL	52
Dan Schoen	DFL	DFL	DFL	54
Matt Little	DFL	R	DFL	58

MEDICAL ALLEY LEGISLATIVE AGENDA

HEALTH TECHNOLOGY DRIVES MINNESOTA'S ECONOMY

931 COMPANIES

167K MINNESOTA JOBS (DIRECT/INDIRECT)

$122K AVERAGE COMPENSATION

$23B ECONOMIC IMPACT (DIRECT/INDIRECT)

ATTRACTING INVESTORS & ENTREPRENEURS

$2.2B DEVELOPMENT CAPITAL RAISED BY **231** COMPANIES SINCE 2011

THE #1 GLOBAL HEALTH TECH CLUSTER

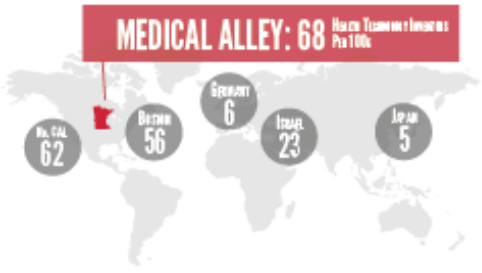
THE MOST APPROVED COMPLEX DEVICES EVER

10,000+ COMPLEX MEDICAL DEVICE APPROVALS

10% MORE THAN CALIFORNIA.

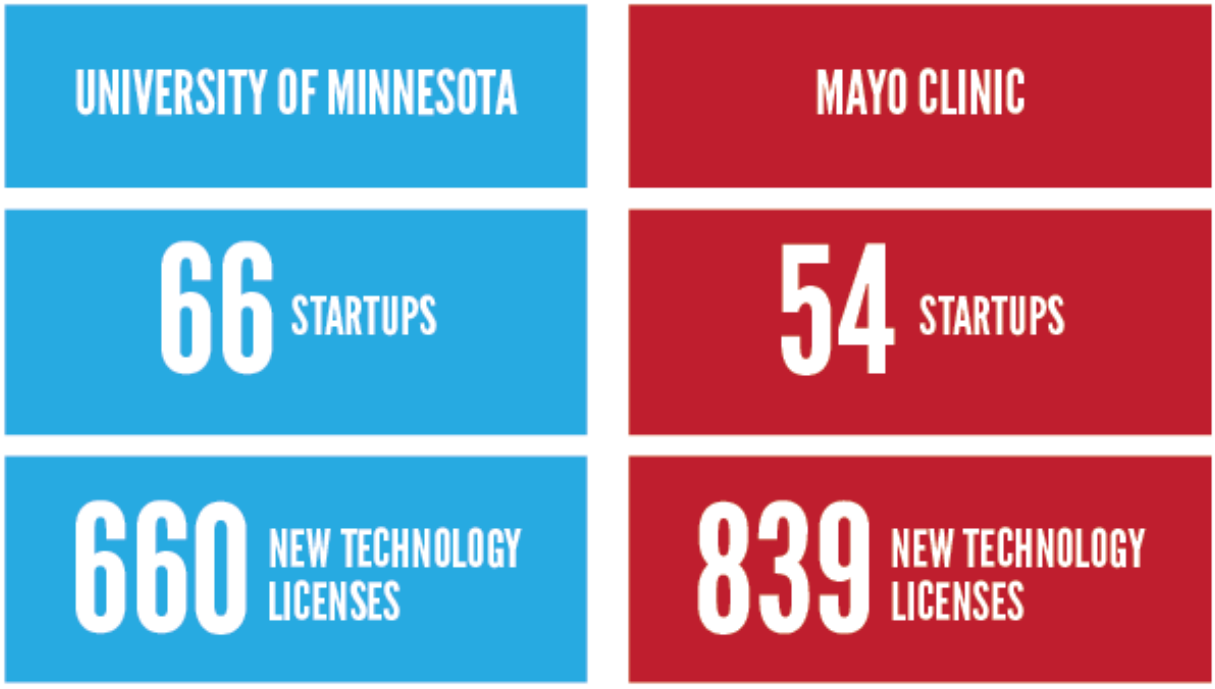
621 % MORE THAN MASSACHUSETTS.

THE MOST HEALTH TECH INVENTORS PER CAPITA



RESEARCH COMMERCIALIZATION

LAST FIVE YEARS



"In terms of talent, everything you need is here - research & development, regulatory, clinical, quality and manufacturing. Finally, the cost of doing business is a better value in Minnesota. We would likely have needed substantially more if we were located on the coasts."

- Doug Killion, President and CEO Pursuit Vascular

MEDICAL ALLEY ASSOCIATION

POWERING THE EVOLUTION OF HEALTHCARE

www.MEDICALALLEY.ORG

Medical Alley Association serves the individuals and organizations that comprise Minnesota's health industry by influencing policy, fostering connections and providing critical intelligence to improve the quality of health around the world.

OMNIBUS TAX BILL

HF 1 (Chamberlain & Davids)
Special Session- Chapter 1
The final omnibus tax bill had roughly $660M in tax cuts. The last time Minnesota had a tax bill was in 2014. MAA monitored many of the provisions in the tax bill and was influential in many of the changes that were discussed and ultimately became law on the Research & Development (R&D) Tax credit.
Tucked into the final budget package was language that eliminated the entire budget for the Department of Revenue if the Governor did not sign the bill. The Governor initially was not going to sign the bill—but with 20 minutes to spare at the end of the day—he received some additional counsel and signed the bill.

A full summary of the tax bill can be found here.
MAA support letter can be found in APPENDIX A.

Research & Development Tax Credit (R&D)

Minnesota's state R&D tax credit was revised in this year's tax bill to increase the competitiveness of the tax credit in comparison to many of the states vying for Minnesota's industries. MAA has actively supported these changes for the last two years and is ecstatic to report that one of those initiatives will become law this year. In the face of an unfavorable report from the Office of the Minnesota Legislative Auditor, MAA had to increase its lobbying efforts to ensure that some positive change occurred.
Minnesota has a rich history of research and development. We were the first state to institute an R&D tax credit in 1981 following the institution of the federal R&D credit. We applaud the renewed leadership that was demonstrated in this session. Increasing the competitiveness of the credit sends a message to innovators that Minnesota is serious about supporting their efforts, while also signaling to other states that we will continue to play a leadership role in attracting top R&D talent.

How to Calculate the R&D Credit today

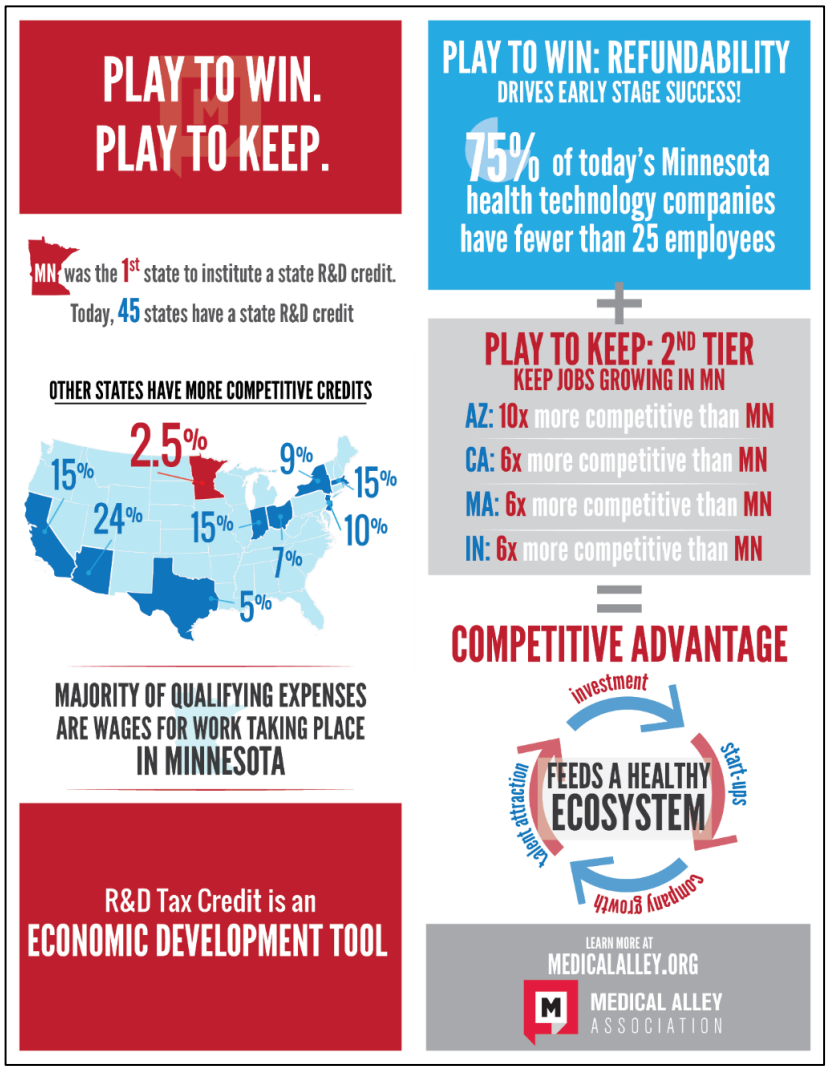
Under current law, the base amount is greater of the percentage of a business's Minnesota qualified research expenditures relative to its gross receipts from 1984-1988, multiplied by the average Minnesota gross receipts for the previous four years; or 50 percent of the Minnesota qualified research expenses for the current year. The percentage amount cannot exceed 16 percent. Most businesses use the 50 percent calculation.

Second Tier

The tax bill **increases the second-tier rate for the research credit from 2.5% to 4%**-- bringing us closer to our competing states in terms of competitiveness.

First Tier Refundability

MAA actively lobbied to include refundability of the first tier of the (R&D) tax credit. This provision would have directly impacted our smaller to midsize members, providing an actual infusion of capital while it could be used to grow the business. The language being considered would have made refundable the first $100,000 of the research credit that exceeded liability. MAA advocated for this change to ensure that Minnesota's early-stage ecosystem continues to grow, as 75% of today's Minnesota health technology companies have fewer than 25 employees.



Alternative Simplified Credit

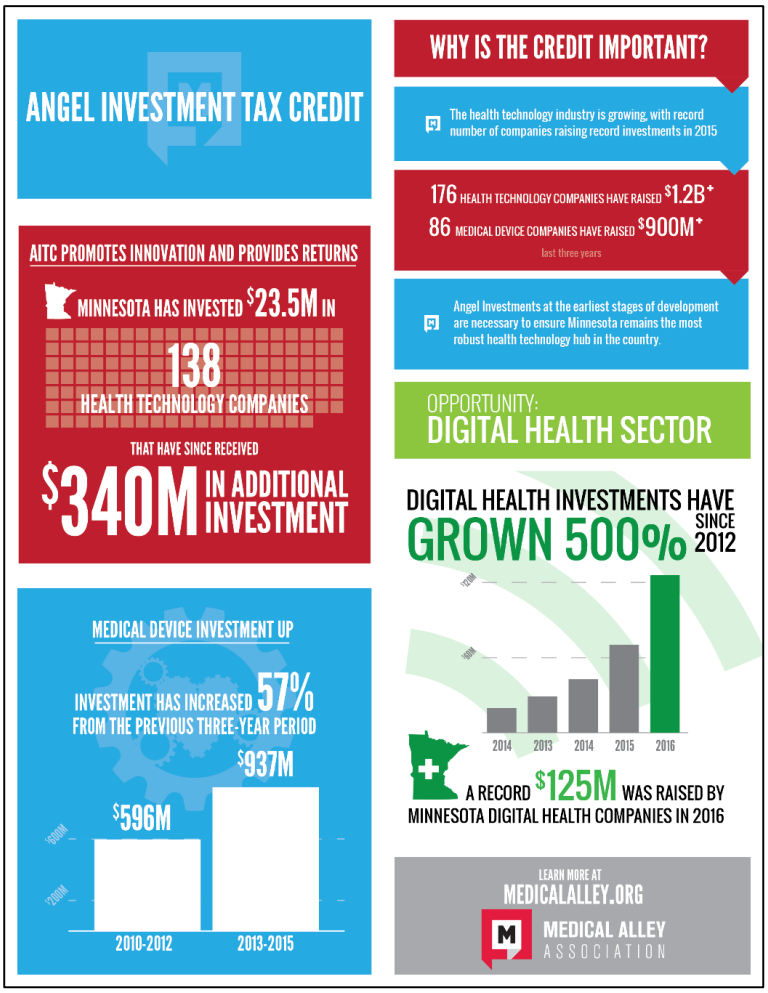
The Alternative Simplified Credit calculation is a method used at the federal level to calculate the amount of qualified research expenses for the R&D credit. The bill would have allowed a credit of 6% of Minnesota qualified research expenditures over the base amount. For those taxpayers electing the ASC calculation the base amount would be 50% of average Minnesota qualified research expenditures over the three years preceding the year the credit is determined. This method would have streamlined the tax preparation process for our members. This provision was very close to becoming law, but ultimately was not included in the final tax bill.

Angel Investment Tax Credit

NOT INCLUDED

One of the biggest disappointments of the legislative session was the fact that the Angel Investment Tax Credit Program was not funded for the 2018 year. At the end of 2017 the program will no longer be available to angel investors and our member companies will no longer benefit from this support. The AITC is one of the hallmark pieces of entrepreneurial support that the state of Minnesota has had since 2010. Since this time, many other states have modeled their tax credits to mimic Minnesota's, and there is a push on the national level to institute a federal credit that would emulate Minnesota's.

The program was also set to sunset at the end of 2017, but there was language included in the tax bill to ensure that the program language remained in statute. This is a silver lining for our members and it will be a top priority of MAA to fully fund the AITC in 2019 and beyond.



Section 179 Expensing

NOT INCLUDED

This proposed language would aim to bring Minnesota's tax law into conformity with current federal IRS tax law which would allow for up to 80 percent of the amount to be deducted under the federal section 179 tax law. This provision would have been beneficial to many of Medical Alley's members who made large equipment purchases which would be eligible under these provisions (if they were passed into law) to be able to write off the equipment to receive an immediate deduction for tax benefit purposes. Minnesota caps section 179 expensing at $25,000 in the year of purchase, with an investment limit of $200,000. The federal expensing limit is $500,000 with an investment limit of $2M.

Section 179 conformity was included in HF 4, which passed the House and the Senate and was sent to the Governor, but was vetoed and not signed into law. In the revised tax committee omnibus bill, HF 1, Section 179 language was removed as part of the compromise deal.

Statewide Property Tax Reform

The automatic annual inflator in the statewide property tax was eliminated, and the first $100,000 of a property's market will be exempt from the state levy and the overall levy was reduced. This critical tax change will benefit every business located in our state by lowering this uncompetitive fixed cost of doing business.

JOBS AND ECONOMIC DEVELOPMENT OMNIBUS BILL

SF 1456 (Miller)/HF 1620 (Garofalo)

Chapter 94

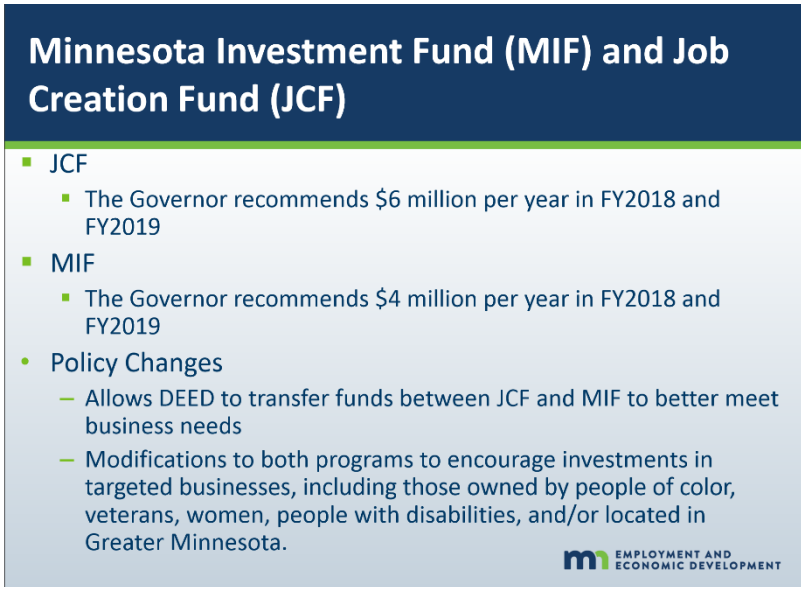
The jobs and economic development omnibus bill totaled approximately $264M in appropriations, and provided funding for general jobs and economic development, workforce development, remediation and rehabilitation, as well as funding for administration of the Department of Employment and Economic Development and the Department of Labor and Industry. The omnibus jobs bill covered not only budgetary necessities and advancement funding; it also provided changes in policy and implementation as well.

MAA support letter can be found in APPENDIX B.

Minnesota Investment Fund & Job Creation Fund

One of Medical Alley's top priorities this year was to reinstate funding for the Minnesota Investment Fund (MIF) and the Job Creation Fund (JCF). These economic development incentives assist Minnesota with business expansion and job growth Last session, the elimination of funding for these programs in last minute negotiations was one of the biggest disappointments of the session.

The Minnesota Investment Fund allows for upfront financing through a MIF Loan that is released with a private match. These funds are siphoned through local governments and are utilized by Economic Development authorities and public private partnerships to court companies to move to the state. The Job Creation Fund is a pay for performance grant mechanism which pays companies to hire new employees and retain them for a certain number of years. These incentives are responsible for the creation or retention of over 10,000 jobs. When the funds were removed from DEED's operating budget last year--- over 70 projects were in the pipeline that could have directly benefited from the incentives. Traditionally, about 20-30% of the projects awarded on a yearly basis are health technology companies--- a true testament to the importance of the health technology innovation cluster. In Minnesota's Medical Alley MIF/JCF made the difference on new headquarters: Smiths Medical, Cardiovascular Systems, Ability Network, Lifecore Biomedical, Prime Therapeutics, and Axis Clinical. These incentives made the difference in attracting Heraeus Medical Components and Olympus Surgical Center to MN. And they helped the breakthrough cell company Stemonix choose to revolutionize personal medicine in Minnesota and not California. MAA was pleased to see that the MIF program was funded at $12.5M per year and the JCF



program was funded at $8.5M. For years, robust financial incentives in other states have been overshadowing talent and quality. These funds will undoubtedly reinvigorate Minnesota's competitive edge.

(e)(1) $12,500,000 each year is for the Minnesota investment fund under Minnesota Statutes, section 116J.8731. Of this amount, the commissioner of employment and economic development may use up to three percent for administration and monitoring of the program. This appropriation is available until spent.

(f) $8,500,000 each year is for the Minnesota job creation fund under Minnesota Statutes, section 116J.8748. Of this amount, the commissioner of employment and economic development may use up to three percent for administrative expenses. This appropriation is available until expended. In fiscal year 2020 and beyond, the base amount is $8,000,000.

MIF Restrictions

Included in the jobs committee omnibus bill was a one-time exemption provided to local governments that would allow them to use uncommitted funds awarded from the Minnesota Investment Fund for purposes they deem fit. If local governments choose to use the funds in a state non-sanctioned manner, they may do so at a penalty of 20 percent of their MIF funding, leaving them with 80 percent of their MIF funding to use as general purpose aid for lawful expenditures.

Sec. 24.

(a) Notwithstanding Minnesota Statutes, section 116J.8731, a home rule charter or statutory city, county, or town that has uncommitted money received from repayment of funds awarded under Minnesota Statutes, section 116J.8731, may choose to transfer 20 percent of the balance of that money to the state general fund before June 30, 2018. Any local entity that does so may then use the remaining 80 percent of the uncommitted money as a general purpose aid for any lawful expenditure.

(b) By February 15, 2019, a home rule charter or statutory city, county, or town that exercises the option under paragraph (a) shall submit to the chairs of the legislative committees with jurisdiction over economic development policy and finance an accounting and explanation of the use and distribution of the funds.

Minnesota Trade Office

The jobs committee omnibus bill included a $4.584M appropriation for FY'20-21 for the budget of the Minnesota Trade Office (MTO). The MTO provides export assistance to Minnesota's manufacturers and service providers. Programs and services focus primarily on assisting small and medium-sized companies. The MTO also serves as the state's Office of Protocol, ensuring the state's interactions with foreign delegations and dignitaries are conducted with appropriate diplomatic etiquette and cultural practices.

28.7 Subd. 5.**Minnesota Trade Office** $ 2,292,000 $ 2,292,000

28.8(a) $300,000 each year is for the STEP grants
28.9in Minnesota Statutes, section 116J.979.
28.10(b) $180,000 each year is for the Invest
28.11Minnesota marketing initiative in Minnesota
28.12Statutes, section 116J.9781.
28.13(c) $270,000 each year is for the Minnesota
28.14Trade Offices under Minnesota Statutes,
28.15section 116J.978.
28.16(d) $50,000 each year is for the Trade Policy
28.17Advisory Council under Minnesota Statutes,
28.18section 116J.9661.

SciTechsperience Internship Program

Also included in the bill was a onetime $2.7M appropriation for FY'20-21 for the SciTechsperience internship program. This program aims to help match STEM interns with qualifying companies in similar, relevant industries, by providing matching funds to help employers attract interns. 50% of funds up to $2,500 per intern are matched. For more information about the grant matching program please visit: https://scitechmn.org/
MAA has been supportive of this program since its inception. On average, 22% of the internships were in the biotechnology and life sciences industries. MAA support letter can be found in APPENDIX C.

18.6(l) $1,350,000 each year is from the workforce
18.7development fund for a grant to the Minnesota
18.8High Tech Association to support
18.9SciTechsperience, a program that supports
18.10science, technology, engineering, and math
18.11(STEM) internship opportunities for two- and
18.12four-year college students and graduate
18.13students in their field of study. The internship

opportunities must match students with paid internships within STEM disciplines at small, for-profit companies located in Minnesota, having fewer than 250 employees worldwide. At least 300 students must be matched in the first year and at least 350 students must be matched in the second year. No more than 15 percent of the hires may be graduate students. Selected hiring companies shall receive from the grant 50 percent of the wages paid to the intern, capped at $2,500 per intern. The program must work toward increasing the participation of women or other underserved populations. This is a onetime appropriation. (m) $450,000 each year is from the workforce development fund for grants to Minnesota Diversified Industries, Inc. to provide progressive development and employment opportunities for people with disabilities. This is a onetime appropriation.

OMNIBUS HIGHER EDUCATION BILL

SF 943- Sen. Fishbach/Rep. Nornes
Chapter 89

MAA was supportive of the University of Minnesota's funding request included in the higher education bill, which totaled approximately $1.3B for 'FY 18-19. A breakdown of the areas of interest to our membership are enumerated below.

Academic Health Center

Subd. 5.
Academic Health Center

The appropriation for Academic Health Center funding under Minnesota Statutes, section 297F.10, is estimated to be $22,250,000 each year.

Mayo Clinic

Sec. 5.
MAYO CLINIC

Subdivision 1.		
Total Appropriation	**$ 1,351,000**	**$ 1,351,000**

University of Minnesota and Mayo Foundation Partnership

(e) **University of Minnesota and Mayo Foundation Partnership**	7,991,000	7,991,000

This appropriation is for the following activities:
(1) $7,491,000 in fiscal year 2018 and $7,491,000 in fiscal year 2019 are for the direct and indirect expenses of the collaborative research partnership between the University of Minnesota and the Mayo Foundation for research in biotechnology and medical genomics. An annual report on the expenditure of these funds must be submitted to the governor and the chairs of the legislative committees responsible for higher education finance by June 30 of each fiscal year.
(2) $500,000 in fiscal year 2018 and $500,000 in fiscal year 2019 are to award competitive grants to conduct research into the prevention, treatment, causes, and cures of Alzheimer's disease and other dementias.

MnDrive - Cancer Clinical Trials

The omnibus higher education bill included $8M in funding for 'FY 18-19 for the Minnesota Discovery, Research, InnoVation Economy (MnDrive) funding program for cancer research. The program aims to expand clinical access for cancer drug trials, which would benefit those residing in Greater MN by expanding their access to treatment sites within their area of residence.
(d) $4,000,000 in fiscal year 2018 and $4,000,000 in fiscal year 2019 are for the Minnesota Discovery, Research, and InnoVation Economy funding program for cancer care research.

Spinal Cord Injury and Traumatic Brain Injury Research Grant Program

The Spinal Cord Injury and Traumatic Brain Injury Research Grant Program received an additional $3M per year in the biennium to use for research grants in this space. The program was first instituted two years ago in the state at $1M. The funding was used on many projects that have started or were sewn at our member companies. A full description of the program and a listing of past recipients of the grant money can be found here.

Subd. 20.

Spinal Cord Injury and Traumatic Brain Injury Research Grant Program	3,000,000	3,000,000

For spinal cord injury and traumatic brain injury research grants authorized under Minnesota Statutes, section 136A.901.

The commissioner may use no more than three percent of this appropriation to administer the grant program under this subdivision.

Fetal Tissue Research

An issue that was left over from last session was resolution on the legislature's appetite to address the fetal tissue research happening at the University of Minnesota. Last year, MAA fiercely advocated to ensure that a statewide ban of fetal tissue research would not become law. As we educated legislators, a ban at the University of Minnesota was essentially a statewide ban since we only have one R1 research institution in the state. The language below represents a compromise between House Republicans and the University, creating a Fetal Tissue Research Committee within the IRB structure at the University. A yearly report is now required to the legislature with information on the projects utilizing fetal tissue.
Although MAA was NOT supportive of this language, we understood it was the best compromise that could have been reached under the circumstances and with the political players involved.

Sec. 19.
[137.47] FETAL TISSUE RESEARCH.
Subdivision 1.
Definitions.
(a) For purposes of this section, the terms in this subdivision have the meanings given them.
(b) "Aborted fetal tissue" means fetal tissue that is available as a result of an elective abortion.
(c) "Fetal tissue" means any body part, organ, or cell of an unborn human child. Fetal tissue does not include tissue or cells obtained from a placenta, umbilical cord, or amniotic fluid.
(d) "Institutional Review Board" or "IRB" means the University of Minnesota's Institutional Review Board, the primary unit responsible for oversight of human subjects research protections.
(e) "Fetal Tissue Research Committee" or "FTR" means an oversight committee at the University of Minnesota with the responsibility to oversee, review, and approve or deny research using fetal tissue.

(f) "Non-aborted fetal tissue" means fetal tissue that is available as a result of a miscarriage or stillbirth, or fetal tissue from a living unborn child.
(g) "Research" means systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research does not include a procedure or test administered to a particular patient by a physician for medical purposes.
Subd. 2.
Approval by the Fetal Tissue Research Committee.
(a) A researcher at the University of Minnesota must obtain approval from the FTR before conducting research using fetal tissue. The FTR must consider whether alternatives to fetal tissue would be sufficient for the research. If the proposed research involves aborted fetal tissue, the researcher must provide a written narrative justifying the use of aborted fetal tissue and discussing whether alternatives to aborted fetal tissue, including non-aborted fetal tissue, can be used.
(b) The FTR must submit its decision to the IRB. The IRB is requested to review the conclusions of the FTR to ensure that all alternatives have been considered.
Subd. 3.
Legislative report.
(a) No later than January 15 of each year, the Board of Regents must submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over higher education policy and finance and health and human services policy and finance. The report must describe:
(1) all fetal tissue research proposals submitted to the FTR or IRB, including any written narrative required under subdivision 2;
(2) whether the research proposal involved aborted fetal tissue;
(3) action by the FTR or IRB on all fetal tissue research proposals, including whether the proposal was approved by the FTR or IRB;
(4) a list of all new or ongoing fetal tissue research projects at the university, including:
(i) the date that the project was approved by the FTR or IRB;
(ii) the source of funding for the project;
(iii) the goal or purpose of the project;
(iv) whether the fetal tissue used is aborted fetal tissue or non-aborted fetal tissue;
(v) the source of the fetal tissue used;
(vi) references to any publicly available information about the project, such as National Institutes of Health grant award information; and
(vii) references to any publications resulting from the project.
(b) The report must not include a researcher's name, other identifying information, contact information, or the location of a laboratory or office.
Subd. 4.
Education on compliance to applicable laws and policies.
The University of Minnesota is requested to conduct education programs for all students and employees engaged in research on fetal tissue. Programs are requested to include mandatory comprehensive training on applicable federal and state laws, university policies and procedures, and other professional standards related to the respectful, humane, and ethical treatment of fetal tissue in research.

HEALTH AND HUMAN SERVICES OMNIBUS BILL

(Special Session) Chapter 6, SF 2
Senate: Benson; Abeler
House: Dean, M

Biomedical Research Grant

The health and human services omnibus bill, SF 2, contained a onetime appropriation of $5M for the establishment of a biomedicine and bioethics innovation grants program. The grants are to be awarded by a steering committee from the University of Minnesota and Mayo Foundation, and are aimed towards promoting research that leads to new discoveries that make advancements to health and strengthen the state's innovation economy. Research projects that include the use of fetal tissue are not eligible to receive the grant.

Sec. 55.

[137.67] MINNESOTA BIOMEDICINE AND BIOETHICS INNOVATION GRANTS.

Subdivision 1.

Grants.

(a) The steering committee of the University of Minnesota and Mayo Foundation partnership shall award grants to entities that apply for a grant under this subdivision to fund innovations and research in biomedicine and bioethics. Grant funds must be used to fund biomedical and bioethical research, and related clinical translation and commercialization activities in this state. Entities must apply for a grant in a form and manner specified by the steering committee. The steering committee shall use the following criteria to award grants under this subdivision:

(1) the likelihood that the research will lead to a new discovery;

(2) the prospects for commercialization of the research;

(3) the likelihood that the research will strengthen Minnesota's economy through the creation of new businesses, increased public or private funding for research in Minnesota, or attracting additional clinicians and researchers to Minnesota; and

(4) whether the proposed research includes a bioethics research plan to ensure the research is conducted using ethical research practices.

(b) Projects that include the acquisition or use of human fetal tissue are not eligible for grants under this subdivision. For purposes of this paragraph, "human fetal tissue" has the meaning given in United States Code, title 42, section 289g-1(f).

Subd. 2.

Consultation.

In awarding grants under subdivision 1, the steering committee may consult with interested parties who are able to provide technical information, advice, and recommendations on grant projects and awards. Interested parties with whom the steering committee may consult include but are not limited to representatives of private industries

with expertise in biomedical research, bioethical research, clinical translation, commercialization, and medical venture financing.

Palliative Care Advisory Council Established

This council was enacted to establish standards for palliative care in the state. Palliative care is a multidisciplinary approach to specialized medical care for people with serious illnesses by focusing on providing patients with relief from the symptoms, pain, physical stress, and mental stress of the illness. The goal of this type of care is to improve the quality of life of the patient and caregivers. The American Cancer Society actively lobbied for passage of this council. MAA was supportive of this initiative as many of our member companies are engaged in pain management and improvement of care delivery models. The makeup of the council is enumerated in the language below.

(h) **Palliative Care Advisory Council.** $44,000 in fiscal year 2018 and $44,000 in fiscal year 2019 are from the general fund for the Palliative Care Advisory Council under Minnesota Statutes, section 144.059. This is a onetime appropriation.

Sec. 57.
[144.059] PALLIATIVE CARE ADVISORY COUNCIL.
Subdivision 1.

Membership.

The Palliative Care Advisory Council shall consist of 18 public members.

Subd. 2.

Public members.

(a) The commissioner shall appoint, in the manner provided in section 15.0597, 18 public members, including the following:

(1) two physicians, of which one is certified by the American Board of Hospice and Palliative Medicine;

(2) two registered nurses or advanced practice registered nurses, of which one is certified by the National Board for Certification of Hospice and Palliative Nurses;

(3) one care coordinator experienced in working with people with serious or chronic illness and their families;

(4) one spiritual counselor experienced in working with people with serious or chronic illness and their families;

(5) three licensed health professionals, such as complementary and alternative health care practitioners, dietitians or nutritionists, pharmacists, or physical therapists, who are neither physicians nor nurses, but who have experience as members of a palliative care interdisciplinary team working with people with serious or chronic illness and their families;

(6) one licensed social worker experienced in working with people with serious or chronic illness and their families;

(7) four patients or personal caregivers experienced with serious or chronic illness;

(8) one representative of a health plan company;

(9) one physician assistant that is a member of the American Academy of Hospice and Palliative Medicine; and

(10) two members from any of the categories described in clauses (1) to (9).

(b) Council membership must include, where possible, representation that is racially, culturally, linguistically, geographically, and economically diverse.

(c) The council must include at least six members who reside outside Anoka, Carver, Chisago, Dakota, Hennepin, Isanti, Mille Lacs, Ramsey, Scott, Sherburne, Sibley, Stearns, Washington, or Wright Counties.

(d) To the extent possible, council membership must include persons who have experience in palliative care research, palliative care instruction in a medical or nursing school setting, palliative care services for veterans as a provider or recipient, or pediatric care.

(e) Council membership must include health professionals who have palliative care work experience or expertise in palliative care delivery models in a variety of inpatient, outpatient, and community settings, including acute care, long-term care, or hospice, with a variety of populations, including pediatric, youth, and adult patients.

Subd. 3.

Term.

Members of the council shall serve for a term of three years and may be reappointed. Members shall serve until their successors have been appointed.

Subd. 4.

Administration.

The commissioner or the commissioner's designee shall provide meeting space and administrative services for the council.

Subd. 5.

Chairs.

At the council's first meeting, and biannually thereafter, the members shall elect a chair and a vice-chair whose duties shall be established by the council.

Subd. 6.

Meeting.

The council shall meet at least twice yearly.

Subd. 7.

No compensation.

Public members of the council serve without compensation or reimbursement for expenses.

Subd. 8.

Duties.

(a) The council shall consult with and advise the commissioner on matters related to the establishment, maintenance, operation, and outcomes evaluation of palliative care initiatives in the state.

(b) By February 15 of each year, the council shall submit to the chairs and ranking minority members of the committees of the senate and the house of representatives with primary jurisdiction over health care a report containing:

(1) the advisory council's assessment of the availability of palliative care in the state;

(2) the advisory council's analysis of barriers to greater access to palliative care; and

(3) recommendations for legislative action, with draft legislation to implement the recommendations.

(c) The Department of Health shall publish the report each year on the department's Web site.

Subd. 9.

Open meetings.

The council is subject to the requirements of chapter 13D.

Subd. 10.

Sunset.

The council shall sunset January 1, 2025.

OMNIBUS BONDING BILL

HF 5 (Urdahl)
Special Session Chapter 8

A bonding omnibus bill is normally passed in the even-numbered year of a two-year biennium. In 2016, a bonding bill was not passed due to last minute complications in negotiations with leadership. However, this session, the legislature proposed and a passed a bonding bill with bipartisan support to make up for last session's lack of a bonding package. Passing a bill was a priority of Governor Mark Dayton. The bonding bill contains funding appropriations for many members' districts, as well as MAA priorities at the University of Minnesota.

Twin Cities Campus- Health Sciences Education Facility

Included in the bonding bill is approximately $66.6M for the University of Minnesota to

demolish out of date health sciences buildings and construct a state of the art health science facility that would meet the needs of the Medical School and Academic Health Center. Passage of this bill was an MAA priority to ensure that the University of Minnesota continues to be a leader in research and innovation in the state.

Subd. 4.

Twin Cities - Health Sciences Education Facility	66,667,000
To demolish obsolete health sciences facilities and to design, renovate, furnish, equip, and construct a health science education facility on the Twin Cities campus to meet the needs of the Medical School and the Academic Health Center.	

Higher Education Asset Preservation and Replacement (HEAPR)

The bonding bill includes approximately $20.6M in appropriations for asset maintenance, preservation, and replacement at the University of Minnesota. Examples of the usage of this funding would include building repairs and upgrades to existing infrastructure.

Subd. 2.

Higher Education Asset Preservation and Replacement (HEAPR)	20,600,000
To be spent in accordance with Minnesota Statutes, section 135A.046.	

BILLS MEDICAL ALLEY PROACTIVELY ENGAGED IN THIS SESSION

Medical Faculty Licensure

SF 815 (Nelson)/ HF 959 (Albright)
Chapter 82

This bill would help to ease medical faculty licensure requirements. MAA supports a permanent change to statue which will help to attract extraordinary physicians that could have an extraordinary impact on research happening in the state today. Relaxed medical faculty licensure requirements would allow Minnesota to stay competitive in attracting top notch talent from around the world to work at Minnesota's world class facilities. This bill passed and was signed into law by Governor Dayton on 5/19/17. We included a letter of support into the record.
MAA support letter can be found in APPENDIX D.

Section 1.
Minnesota Statutes 2016, section 147.381, is amended to read:

147.381 APPLICATION OF INTERSTATE MEDICAL LICENSURE COMPACT TO EXISTING LAWS.

(a) Uniform rules developed by the Interstate Commission established under section 147.38 shall not be subject to the provisions of sections 14.05 to 14.389.

(b) Complaints against physicians licensed in Minnesota under the expedited licensure process in section 147.38 shall be handled as provided in sections 214.10 and 214.103.

(c) All provisions of section 147.38 authorizing or requiring the board to provide data to the Interstate Commission are authorized by section 214.10, subdivision 8, paragraph (d).

(d) The provisions of sections 214.17 to 214.25 apply to physicians licensed in Minnesota through the provisions of section 147.38 when the practice involves direct physical contact between the physician and a patient.

(e) According to uniform rules developed by the Interstate Commission established under section 147.38, the board is authorized to perform a criminal background check for a physician who has designated Minnesota as the state of principal license. The criminal background check shall be conducted as provided in section 214.075. The board shall use the criminal background check data to evaluate a physician's eligibility for a letter of qualification pursuant to section 147.38, and shall not disseminate this data except as allowed by law. A physician seeking expedited licensure in Minnesota under section 147.38 who has not designated Minnesota as the state of principal license is exempt from the requirements of section 214.075 if the state of principal license has performed a criminal background check for the physician within the last 12 months.

Biosimilars Legislation

MAA actively led the lobbying effort to update the Pharmacy Practice Act to include biosimilars as an interchangeable product available for pharmacists to dispense. The national coalition of stakeholders included the national BIO association as well as a growing list of patient advocacy stakeholders. (See patient advocacy letter of support- APPENDIX E.)

Advanced biologic molecules are thousands of times larger and more complex than a typical pill molecule, and far more sensitive to changes in their environment. Today, there are over 200 FDA approved biologic therapies on the market, including products that treat diseases such as cancer, heart disease, arthritis, and MS. The Affordable Care Act amended federal law to create an abbreviated pathway for biosimilars that were found to be "interchangeable" with a prescribed reference product. Biosimilars have the potential to increase price competition and ultimately result in lower drug prices for patients.

At the time of this publication, Minnesota was the 28th state to adopt biosimilars legislation—in a bipartisan manner and without controversy. The bill was passed off the Senate and House floors unanimously.

Prior Authorization

HF 747 (Hamilton)/SF 593 (Nelson)

This bill was put forward by Representative Hamilton (R-Mountain Lake), and would change

existing laws to require plans to honor prior authorizations for the length of the enrollee's contract term, providing that the drug meets certain requirements. This bill is in response to concerns that plans would kick enrollees off the drug they desired, resulting in a less effective course of treatment and lack of access of desired medication. MAA joined a large coalition of groups led by the Minnesota Medical Association to actively push for this legislation.
As to be expected, PBMs and providers were against this legislation as well as the Minnesota Chamber of Commerce. The bill was introduced in both bodies and heard quickly in the Senate, but was not heard in the House until the week before the end of session. When it was heard in the House it was for the record only, and no legislative action was taken on the bill. MAA signed onto a letter in support of this bill.
(See letter of support – APPENDIX F)

(d) Any prior authorization for a prescription drug must remain valid for the duration of an enrollee's contract term, except that for the benefits offered under section 256B.69 or chapter 256L, the prior authorization must remain valid for the duration of the enrollee's enrollment or one year, whichever is shorter. These requirements related to the validity of prior authorization apply only if:

(1) the drug continues to be prescribed for a patient with a condition that requires ongoing medication therapy;

(2) the drug has not otherwise been deemed unsafe by the Food and Drug Administration;

(3) the drug has not been withdrawn by the manufacturer or the Food and Drug Administration;

(4) there is no evidence of the enrollee's abuse or misuse of the prescription drug; and

(5) no independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

This paragraph does not apply to individuals assigned to the restricted recipient program under Minnesota Rules, parts 9505.2160 to 9505.2245.

A full text of the bill can be seen here.

BILLS THAT DID NOT PASS

Opioid Stewardship Bill

MAA actively opposed a piece of legislation that would have taxed our biopharmaceutical member companies that manufactured opioids and sold those prescriptions lawfully in the state of Minnesota. The bill would have taxed each milligram of morphine sold in the state at a rate of one cent per milligram. The language was the first of its kind in the nation. At the time of publication there were nearly 20 other states that have introduced similar language. The legislation would have raised nearly $42M every two years and the money collected would have been used in education efforts, prevention, and rehabilitation services.

Although MAA fully supports all of those worthy causes and uses for the funding generated from this bill language, we felt that placing a significant burden on pharmaceutical companies

while other stakeholders were exempt from the legislation was not good policy. We also focused our advocacy efforts on the pain management side of the problem. And talked about the number of health technology companies right here in Minnesota that were proactively investing research and development dollars into finding solutions to the nationwide opioid crisis.

MAA is committed to continue to work with the legislature in the interim to ensure that we spotlight our potential leadership role in pain management and abuse deterrent formulations.

Right to Repair

SF 15 (Osmek)

The Right to Repair bill was reintroduced this session by Senator David Osmek (R-Mound), and aimed to establish standards allowing authorized third parties to repair and service electronics. Manufacturers of digital products were to be required to provide diagnostic and repair information as well as updates so that third parties would be able to work on the electronics. There was fierce opposition to this bill, including from MAA. As written, the bill would include medical devices and devices found in a medical setting. We met with Senator Osmek and were able to negotiate a compromise exempting medical devices from right to repair standards. This bill did not receive a hearing and did not move to committee or the floor, but we anticipate it percolating again in 2018.

R&D Authority

HF 2134 (Thissen)/SF 2063 (Dziedzic)

Representative Paul Thissen (DFL-Minneapolis) reintroduced this bill this session to begin having high level discussions about what the role of government should be in engaging and investing in entrepreneurship, commercialization, and economic growth around publicly funded research and development projects. The bill is modeled after a few programs throughout the country where there has been deliberate state investment in the life sciences. Specifically, there are many elements of the Massachusetts Life Sciences Center in this legislation. This bill was previously introduced during the 2016 legislative session.
The authority would be charged with the following directives:
(1) coordinate public and private efforts to procure federal funding for collaborative research and development projects of primary benefit to small- and medium-sized businesses;
(2) promote contractual relationships between Minnesota businesses that are recipients of federal grants and prime contractors and Minnesota-based subcontractors;
(3) work with Minnesota nonprofit institutions including the University of Minnesota, Minnesota State Colleges and Universities, the Hormel Institute, and the Mayo Clinic in promoting collaborative efforts to respond to federal funding opportunities;
(4) develop a framework for Minnesota companies to establish sole-source relationships with federal agencies;
(5) provide grants or other forms of financial assistance to eligible recipients for purposes of this chapter;

(6) coordinate assistance with business proposals, licensing, intellectual property protection, commercialization, and government auditing with the University of Minnesota and Minnesota State Colleges and Universities; and

(7) develop and implement a comprehensive research and development enhancement and investment strategy for the state.

Additionally, there was language included creating a technology matchmaking network and a center for Commercialization assistance to entrepreneurs, ultimately hoping to leverage additional federal NIH dollars into the state. Included in the commercialization section was Medical Alley language regarding a dollar for dollar grant matching program for SBIR/STTR grants.

SBIR/STTR Grant Matching

SF 1781 (Senjem/HF 1950 (Albright)

Introduced this session is a bill that would create a federal research and development support program for NIH funding entering Minnesota in the form of an Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) grant. The bill was not heard, but we hope it will be considered next session.

A bill for an act

relating to economic development; creating a federal research and development support program; appropriating money; proposing coding for new law in Minnesota Statutes, chapter 116J.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1.

[116J.8756] FEDERAL RESEARCH AND DEVELOPMENT SUPPORT PROGRAM.

Subdivision 1.

Establishment.

A grant program is established to award grants to eligible applicants in order to match funds received through the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Subd. 2.

Eligible applicant.

An eligible applicant is a company with headquarters in Minnesota that receives grants or contracts, awarded after state fiscal year 2016, under:

(1) phase I of the federal SBIR or STTR program; or

(2) phase II of the federal SBIR or STTR program.

Subd. 3.

Application process.

An eligible applicant must submit an application to the commissioner on a form prescribed by the commissioner.

Subd. 4.

Limitation.

No grant awarded to a recipient defined under subdivision 2, clause (1), shall exceed $250,000 per recipient per year. No grant awarded to a recipient under subdivision 2, clause (2), shall exceed $500,000 per recipient per year. Grants awarded to a single entity shall not exceed $750,000 per recipient per year.

Sec. 2. **APPROPRIATION.**

$8,000,000 in fiscal year 2018 and $8,000,000 in fiscal year 2019 are appropriated to the commissioner of employment and economic development for the purposes of administering the federal research and development support program under Minnesota Statutes, section 116J.8756.

EFFECTIVE DATE.

This section is effective the day following final enactment.

Regenerative Medicine Grant

HF 2256 (Murphy, E.)

This bill was proposed by Representative Erin Murphy (DFL-St. Paul), and aimed to appropriate a one-time $100M to the University of Minnesota and Mayo Clinic for regenerative medicine research. It did not receive a hearing and subsequently did not advance further this session. Had it found traction, MAA would have been supportive of this legislation.

Section 1. **APPROPRIATION**

$100,000,000 in fiscal year 2018 is appropriated from the general fund to the Board of Regents of the University of Minnesota for the collaborative partnership between the University of Minnesota and Mayo Clinic for regenerative medicine research, clinical translation, and commercialization. This is a onetime appropriation and funds are available until expended.

Step Therapy

HF 2342 (Hamilton)

This bill aimed to modify current law statues by allowing for overrides to PBMs' step therapy requirements. Principally, the bill would change statues so that required drugs in the step therapy order may be skipped or bypassed if there is a drug that is already working for the patient prior to the step therapy change. This bill was proposed shortly after the Prior Authorization bill was introduced. It did not receive a hearing, and died before reaching committee. This language did not reflect language being developed by a National step therapy coalition of drug manufacturers and patient advocacy stakeholders.

Step therapy override.

(a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by the plan sponsor through the use of a step therapy protocol, the prescriber may override the step therapy protocol. A step therapy override may be appealed by a plan sponsor using its own appeals procedure.

(b) When determining whether to grant an appeal and sustain or revoke the step therapy override the plan sponsor must take into consideration whether:
(1) the required prescription drug is contraindicated or will likely cause an adverse patient reaction or physical or mental harm to the patient;
(2) the required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;
(3) the patient has tried the required prescription drug while under their current or previous health coverage, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
(4) the required prescription drug is not in the best interest of the patient, based on medical necessity; and
(5) the patient was stable while on a prescription drug prescribed by their health care provider for the medical condition under consideration while covered under their current or previous health coverage.
(c) When an appeal is resolved and it is determined that a step therapy override is sustained, the plan sponsor shall authorize coverage for the prescription drug.
(d) A prescriber may file a complaint regarding the revocation of a step therapy override using the complaint procedure in sections 62Q.68 to 62Q.72.
(e) This subdivision shall not be construed to prevent:
(1) the plan sponsor from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug; and
(2) a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

A full text of the bill can be seen here.

Enhanced Vaccination Requirements

HF 96 (Freiberg)

This proposed bill aimed to enhance vaccination requirements language by striking current statue which allows for a simple notarized statement from the parent or guardian of a child for an exemption if there is a conscientiously held belief against vaccination.

Instead, new language in this bill would make it so a child would be exempt after submitting an exemption certificate form developed by the commissioner of health, and state must certify that the child is declining vaccination due to conscientiously held beliefs. This bill did not receive a hearing and was not brought up for debate or a vote this session.

Preemption

SF 3 (Miller)/HF 4 (Garofolo)
SPECIAL SESSION Chapter 2 (VETOED)

This bill was introduced by Senate and House Republicans, and aims to streamline labor standards across the state. Currently, cities and municipalities may set their own minimum wage and requirements for paid or unpaid leave. Business groups such as the Minnesota Chamber of Commerce have been supportive of this legislation, while labor groups such as the AFL-CIO and AFSCME have been against it. Partisan support for this legislation has broken along party lines, with Republicans for it and DFLers against it. Governor Dayton threatened to veto this legislation, even as Republicans presented it as a standalone bill. If it had been signed into law, cities and municipalities would not be able to mandate higher wages than the state minimums or enact their own rules on paid and unpaid leave.

UNIFORM LABOR STANDARDS
Section 1.
[181.741] EXPRESS PREEMPTION; UNIFORMITY OF PRIVATE EMPLOYER MANDATES.
Subdivision 1.
Definitions.
(a) For the purposes of this section, the terms defined in this subdivision have the meanings given them.
(b) "Employer" means a private person employing one or more employees in the state.
(c) "Local government" means a home rule charter city, statutory city, town, county, the Metropolitan Council, a metropolitan agency as defined in section 473.121, subdivision 5a, or a special district.
Subd. 2.
Express preemption.
(a) A local government must not adopt, enforce, or administer an ordinance, local resolution, or local policy requiring an employer to pay an employee a wage higher than the applicable state minimum wage rate provided in section 177.24.
(b) A local government must not adopt, enforce, or administer an ordinance, local resolution, or local policy requiring an employer to provide either paid or unpaid leave time.
(c) A local government must not adopt, enforce, or administer an ordinance, local resolution, or local policy regulating the hours or scheduling of work time that an employer provides to an employee. This paragraph does not preempt an ordinance, local resolution, or local policy limiting the hours a business may operate.
(d) A local government must not adopt, enforce, or administer an ordinance, local resolution, or local policy requiring an employer to provide an employee particular benefits or terms of employment.
Subd. 3.
Local governments as employers and contractors.
This section does not regulate wages, hours, benefits, paid or unpaid leave, attendance policies, or other terms of employment that a local government:
(1) provides to its own employee;

(2) requires an employer to provide to its employee, to the extent that employer is providing goods or services, including construction, to the local government, and the requirement applies specifically to work performed in providing goods or services to the local government; or
(3) requires an employer to provide to its employee, to the extent that employer is receiving funding from the local government or is providing goods or services, including construction, funded in whole or in part by the local government, when the requirement is an express condition of the funding.
EFFECTIVE DATE.
This section is effective upon final enactment and applies to ordinances, local policies, and local resolutions enacted on or after January 1, 2016.

APPENDIX

Appendix A - MAA Supports Tax Provisions

MEDICAL ALLEY ASSOCIATION

March 24, 2017

Members of the Minnesota House Tax Committee,

The Medical Alley Association would like to thank Chair Greg Davids and members of the House Tax Committee for their leadership in crafting a tax bill that enhances Minnesota's unique leadership position in health technology and care and supports accelerated growth in health innovation.

Minnesota is the "Great State of Health" and the "Medical Alley" has been enshrined in the Smithsonian as one of America's great "Places of Invention." Today, Minnesota is home to the most densely concentrated health technology cluster in the world, ranks as the #1 region in the world for health technology innovation and is leading the digital health revolution. The Medical Alley Association represents nearly 700 members in the medical device, biopharmaceutical, diagnostics, digital health, health provider and health insurance sectors. Our members employ more than 167,000 Minnesotans with an average compensation package of greater than $120,000 annually.

The Medical Alley Association supports the following provisions:

Article 1. Sec. 25: Research and Development Tax Credit second tier credit rate increased from 2.5 percent to 4 percent, $24.2M allocated for the biennium

With increasing competition from around the world and within the U.S., *Minnesota must remain a research & development destination!* This change to the second tier will improve Minnesota's competitiveness – this is an important factor into where a company deploys its capital and locates its R&D facilities. Raising the rate will keep Minnesota in the game, giving us the opportunity to compete for growth in our health technology ecosystem. (see map for comparison) This change supports more opportunities to attract expansions and relocations of more established companies investing millions of dollars into new discoveries that benefit patients.

technology companies have fewer than 25 employees. This refundable credit will immediately translate into additional jobs, investments in research, and further collaboration with our renowned research institutions.

With intellectual property, capital, and labor more mobile than ever, a more competitive second tier credit rate and refundability in the first tier will help to strengthen a powerful economic development tool that is essential to ensuring that Minnesota remains a premier technology hub.

Medical Alley promotes Minnesota as the greatest health technology ecosystem in the world and these changes will strengthen our message. However, it is critical that Minnesota's Medical Alley provide an ecosystem that leaves no gaps and an economy that works for everyone. We are disappointed to see that the Angel Investment Tax Credit is noticeably missing from the House Tax Provisions. This program has been a differentiator and is responsible for many of our early stage companies choosing to locate or stay in Minnesota. The vast majority of venture capital resides on the coasts. This program draws investment to Minnesota and helps companies to avoid the draw to another state. We sincerely hope that the committee will keep an open mind as we navigate the legislative process to include this program once again.

We appreciate that members recognize the value and impact that these provisions can make on the medical and health technology industry and the significance they can have in moving Minnesota's Medical Alley forward. Thank you for your work on these critically important issues for our state and industry. We support these provisions and look forward to working with you to ensure that they become law this session.

Thank you for your consideration,

Shaye Mandle
President & CEO
Medical Alley Association

Appendix B - MAA Supports Jobs Bill

MEDICAL ALLEY ASSOCIATION

April 28, 2017

Members of the Minnesota House and Senate Joint Jobs Conference Committee,

The Medical Alley Association would like to thank Senate Jobs Chair, Senator Jeremy Miller, and House Jobs Chair, Rep. Pat Garofolo for their leadership in crafting bills that enhance Minnesota's unique leadership position in health technology and care and supports accelerated growth in health innovation.

Minnesota is the "Great State of Health" and the "Medical Alley" has been enshrined in the Smithsonian as one of America's great "Places of Invention." Today, Minnesota is home to the most densely concentrated health technology cluster in the world, ranks as the #1 region in the world for health technology innovation and is leading the digital health revolution. The Medical Alley Association represents nearly 700 members in the medical device, biopharmaceutical, diagnostics, digital health, health provider and health insurance sectors. Our members employ more than 167,000 Minnesotans with an average compensation package of greater than $125,000 annually.

The Medical Alley Association supports the following provisions:

Article 1. Section 3. Minnesota Investment and Job Creation Funds (Senate Jobs Bill)

The funding of the Investment and Job Creation Funds will allow the state to leverage important tools in attracting and retaining business and innovation in Minnesota. To stay elite in health technology we must be able to compete as a state. Economic development inventive like the JCF and MIF funds assist Minnesota with business expansion and growth. These programs have been responsible for the creation of over 10,000 jobs and have made the difference in Minnesota's Medical Alley. We can now tout as a state new headquarters for Smiths Medical, Ability, and Cardiovascular Systems. This year's MN Cup winner, Stemonix, was also a recipient of these programs. When the legislature cut these programs last year, they put over 70 projects that were in the pipeline in peril. These incentives are absolutely necessary to ensure that Minnesota remains the world's top health technology innovation cluster!

Article 1. Section 5. SciTechsperience Internship Program (House & Senate Jobs Bill)

The SciTechsperience internship program has a proven track record of placements in the science and technology space. This request for funding will go toward increasing the number of internships the SciTechsperience program is able to place, offering program administrators the ability to match more intern wages and help to meet the expected 188,000 STEM jobs Minnesota will need to fill by 2018. This will aid in spurring innovation and company growth in Minnesota as well as inspire young people to work within the STEM fields.

We appreciate that members recognize the value and impact that these provisions can make on the medical and health technology industry and the significance they can have in moving Minnesota's Medical Alley forward. Thank you for your work on these critically important issues for our state and industry. We support these provisions and look forward to working with you to ensure that they become law this session.

Thank you for your consideration,

Shaye Mandle
President & CEO
Medical Alley Association

Appendix C - SciTechsperience

MEDICAL ALLEY ASSOCIATION

March 1, 2017

Dear Members of the Senate Jobs and Economic Growth Finance and Policy Committee,

On behalf of The Medical Alley Association, we are writing to voice support for the request for the Minnesota High Tech Association's (MHTA) SciTechsperience Internship Program, S.F. 988, proposed by Senator Paul Anderson.

As the leading trade association for Minnesota's health technology industry, we understand the need to train and place talent in Science, Technology, Engineering and Math (STEM) fields to keep our companies strong and growing. Providing real-world experience for STEM students is critical to building our current and future workforce, as the number of positions in the industry has continued to grow steadily.

The request for funding will go toward increasing the number of internships the SciTechsperience program is able to place, offering program administrators the ability to match more intern wages and help to meet the expected 188,000 STEM jobs Minnesota will need to fill by 2018. From 2015-2016, the program placed 230 interns in Minnesota companies spread throughout the Twin Cities and Greater Minnesota. 22% of those internships were in the biotech and life sciences industry. Additionally in 2016, 96,895 paid hours were worked by SciTechsperience interns.

Minnesota's life science and health technology industry employs more than 48,000 individuals directly and acts as a critical economic driver for the state. The average salary for employees at our companies is $97,600/year. State support for S.F. 988 will help to ensure that we are building the future STEM workforce of our industry with local talent and providing them with real-world training. This will aid in spurring innovation and company growth in Minnesota.

Thank you for your time and attention to this matter.

Sincerely,

Shaye Mandle, President & CEO
Medical Alley Association

Appendix D - Medical Faculty Licensure

The Medical Alley Association
4150 Olson Memorial Hwy, Suite 430, Golden Valley, MN 55422
Phone 952.542.3077 | www.MedicalAlley.org

February 23, 2017

Dear Members of the Senate Health and Human Services Finance and Policy Committee,

On behalf of the Medical Alley Association and its 700 members representing Minnesota's Health Technology ecosystem, we urge you to support Senator Nelson's bill, S.F. 815, regarding medical faculty licensure.

Minnesota has two academic medical centers that are engaged in a very real global race for talent. This bill will help to ensure Minnesota continues to be a world-leading research and innovation hub—creating a legacy that will translate to successes to Minnesota's future.

As you know, our history of pioneering health and medical breakthroughs and solutions is so highly regarded that the American History Museum of the Smithsonian included Minnesota's Medical Alley as one of the six great "Places of Invention" in an exhibit that opened last year. This unique health technology and medical community has an unparalleled impact on Minnesota, with an annual economic impact of $14.2B. Over the last five years, emerging companies in this space have raised $1.73B in investment capital to put to work in Minnesota and, just between the University of Minnesota and Mayo Clinic, 120 new companies have been created around our research.

The Medical Alley community helps to define Minnesota. We are home to more than 800 health technology companies and more than 125,000 Minnesotans are employed directly or in support of this industry. For those Minnesotans working directly in the health technology arena, the average annual salary is $122,000. Clearly, this industry and the ecosystem that generates new discoveries in Minnesota is both an economic driver for our state and a source of civic pride for our accomplishments. The world knows "The Great State of Health" and "Medical Alley" because of what we have accomplished.

Last session, the legislature worked to ease medical faculty licensure requirements. A permanent change to state statue will help to attract extraordinary physicians that could have significant impacts on research happening in the state today.

We believe that the passage of S.F. 815 will be of extraordinary benefit to our great state of research. We urge you to consider this change so that our state can continue to attract and recruit the best talent from around the world.

Thank you for your consideration,

Shaye Mandle
President & CEO
The Medical Alley Association

Appendix E - Biosimilars Patient Advocacy Coalition Support Letter

March 6, 2017

Rep. Joe Schomacker
509 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
Saint Paul, Minnesota 55155

Dear Chair Schomacker and members of the committee,

We are writing to urge your support of HF 712, related to interchangeable prescription biologic products. The development of biologic drugs has provided patients and their physicians with access to improved therapeutic options. Biologic drugs are some of the most expensive drugs on the market today. However, as generics have done for small-molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs, and result in lower cost burdens for patients.

In order for biosimilars to provide increased access and affordability through competition, state pharmacy laws have to be amended to create the ability for biosimilar substitution at pharmacies. As biosimilar policies are developed, they must focus on ensuring the safety and efficacy of all biologic drugs, whether the original innovator or biosimilar, and policies must also ensure access and affordability of biosimilars for cancer patients.

We appreciate that this bill limits biosimilar substitution to products that the Food and Drug Administration (FDA) has designated as an interchangeable biologic product. We agree that pharmacy substitution should only happen under the circumstance where the FDA has deemed a product to be interchangeable. We further agree with the proposal to allow physicians the ability to prevent substitution via prescription instructions. In addition, we support the language to require that when there is an interchangeable biosimilar, the prescribing physician must be notified of the actual biologic dispensed within five business days to ensure an accurate and enduring patient medical record.

As interchangeable biologics are approved by the FDA, patients and their providers need a safe and transparent process by which they can receive access to these medications. By creating a new pathway for biologic substitution where none currently exists in Minnesota, this legislation enhances patient access to new and potentially less costly medications. We urge you to support HF 712.

Sincerely,

Appendix F – Prior Authorization

MINNESOTA MEDICAL ASSOCIATION

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Put Patients First!

HF 747 (Hamilton) & SF 593 (Nelson)

The medication prior authorization (PA) process too often interferes with patient care and is burdensome, inefficient and expensive. While progress is being made to streamline the PA process through the use of new electronic tools, more needs to be done now to put patients first.

Patients with chronic conditions often shop for insurance products to ensure coverage for their medications. Unfortunately, nothing prevents health plans from restricting or changing access to those medications in the middle of an enrollment year. Patients with chronic conditions can also face delays in obtaining their ongoing medications due to repeated requests for PA. Under this bipartisan bill, patients will be protected from mid-year negative changes to their drug coverage and will be assured that any advance approval for medications do not have to be repeated during the insurance contract year. Patients are obligated to honor the terms of an insurance contract; health plans should be required to honor it too.

The cost of PA is staggering. Estimates put the annual administrative cost approaching $83,000 per physician per year, an annual total of nearly $950 million in Minnesota. Delayed care and its consequences add even more expense to the health care system.

Physicians and health care professionals should make decisions about patient care, not insurance companies or pharmacy benefit managers. This bill preserves PA as a tool to manage medication safety and to support cost-effective medication coverage, while putting patients first and reducing needless expense and inefficiencies.

Protecting Consumers

- The bill limits negative formulary and medication coverage changes during a patient's enrollment year. Under the bill, patients who are undergoing a drug therapy that is working will not have their formulary changed in the middle of their enrollment year. HF 747 and SF 593 protect patients by preventing harmful disruptions in medication use.
- Under the bill, approved prior authorizations must remain valid for the duration of an enrollee's contract term.

Increasing Transparency

- Deciphering a health plan's formulary shouldn't take a medical degree. Under this bill, health plans would be required to disclose to patients their drug formulary, related benefit information, and cost-sharing and out-of-pocket expenses prior to purchasing coverage and when formularies or benefit classes change.

A Broad Coalition of Support

- A coalition of nearly 50 groups supports this important, patient-focused bill. Advocates for patients with a range of both chronic and acute diseases, provider groups including physicians, advance practice registered nurses, and pharmacists support the bill, as do groups that advocate for rural health care.
- See reverse for a complete list of supporters of HF 747 & SF 593.

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