Federal Advocacy Overview

Derek C. Brandt, JD Director, Congressional Affairs American Academy of Neurology @DerekBrandtDC



General Overview

- Why advocate?
- Key federal issues
- How to get involved
- How to support others
- Considerations for public employees



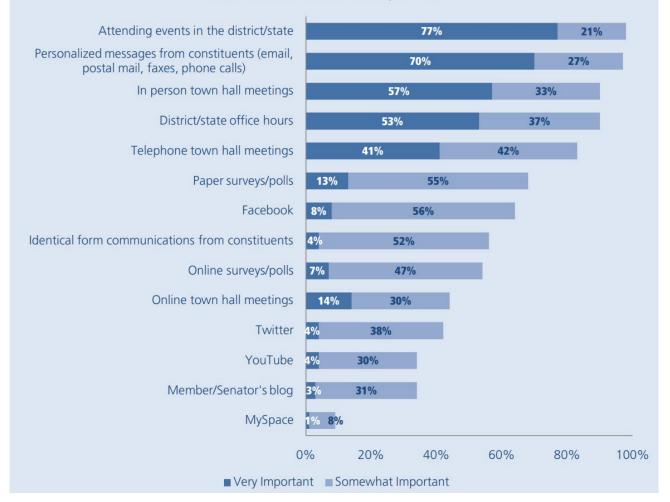
Why is Advocacy Important?

- Empower your staff
- Help staff fight burnout
- Raise the profile of your department
- Build network for future initiatives/issues
- Produce ROI from policy outcomes



Does Advocacy Really Matter?

In your opinion, how important are the following for understanding constituents' views and opinions?*



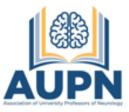


Success Comes in Many Forms

Headache Disorders Centers of Excellence.—The Committee recognizes that over 350,000 veterans sustained traumatic brain injury [TBI] during the Global War on Terror and that chronic migraine/post-traumatic headache is the signature symptom of TBI. The Committee is concerned that veterans with chronic migraine/ post-traumatic headache often do not receive specialty care, and that only three VA-affiliated physicians are certified with training in Headache Medicine by the United Council for Neurological Subspecialties. The Committee recognizes the importance of VA centers of excellence and the need for VA Headache Centers of Excellence. The Committee provides \$10,000,000 for the creation of at least five headache centers to be placed at the existing sites for polytrauma and traumatic brain injury [TBI] or at locations that the Secretary sees fit.



Key Federal Issues



Medicare Reimbursements

- Annual Fee Schedule
- Proposed rule is thousands of pages long
- AAN comments were 50 pages long for CY23



August 25, 2022

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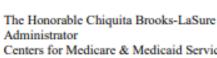
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Administrator Centers for Medicare & Medicaid Services 200 Independence Avenue, SW Washington, DC 20201

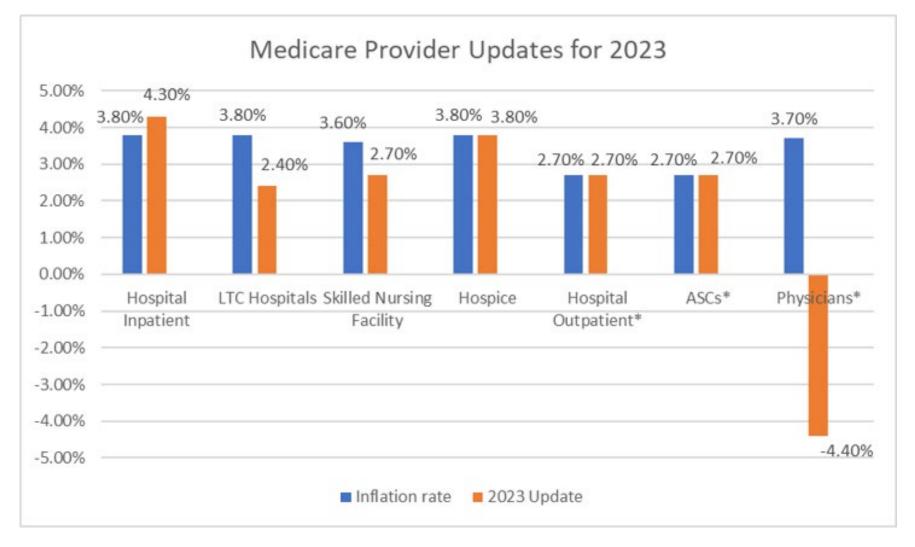
RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts [CMS-1770-P]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician

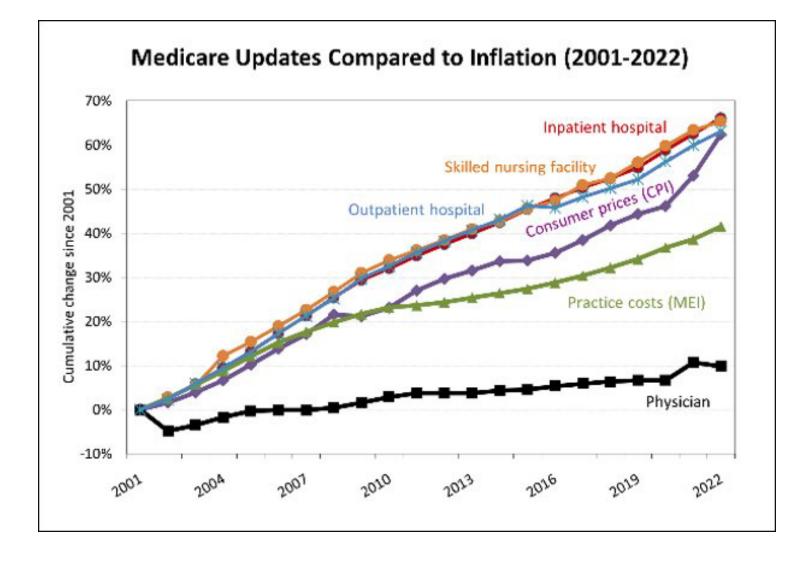


Medicare Reimbursements





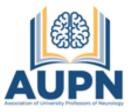
Medicare Reimbursements





Short Term Request to Congress

- Eliminate -4.42% budget neutrality cut (H.R. 8800)
- End the statutory annual freeze and provide a Medicare Economic Index (MEI) inflation update for the coming year
- Waive the 4 percent PAYGO sequester triggered by passage of the American Rescue Plan Act.
- Extend the 5 percent APM participation incentive for five more years



Looking Forward

- Republican & physician leaders have expressed a significant interested in broader reforms in the new Congress
- AAN is responding to RFI to build ideas for this effort



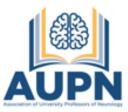
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Bera and Bucshon Lead Group of Representatives in Seeking Input on Medicare Payment System

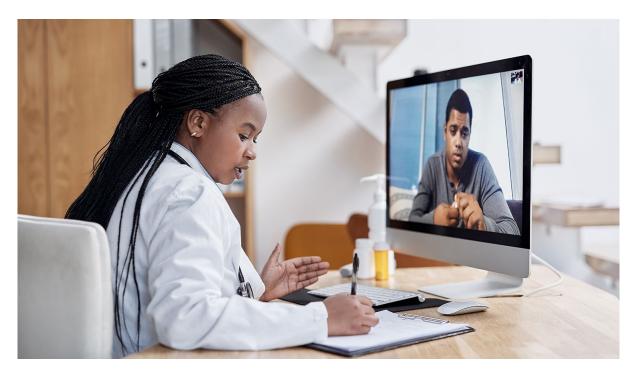
September 8, 2022 Press Release

WASHINGTON, DC – Representatives Ami Bera, M.D. (CA-07), Larry Bucshon, M.D. (IN-08), Kim Schrier, M.D. (WA-08), Michael Burgess, M.D. (TX-26), Earl Blumenauer (OR-03), Brad Wenstrup, D.P.M. (OH-02), Bradley Schneider (IL-10), and Mariannette Miller-Meeks, M.D. (IA-02) are requesting feedback from health care providers, advocacy organizations, health economists, health finance experts, and others on actions Congress should take to stabilize the Medicare payment system, without dramatic increases in Medicare spending, while ensuring successful value-based care incentives are in place.



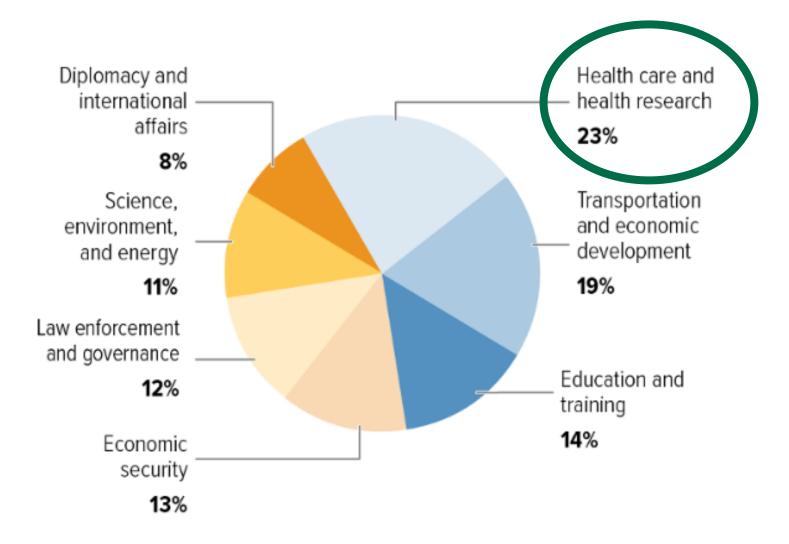
Telehealth

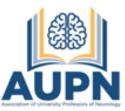
- Telehealth flexibilities were rapidly expanded as part of the Public Health Emergency
- Many states have scaled back
- Medicare flexibilities will likely last after PHE in some form
- Policymakers are working to establish what will be allowed going forward





Medical Research

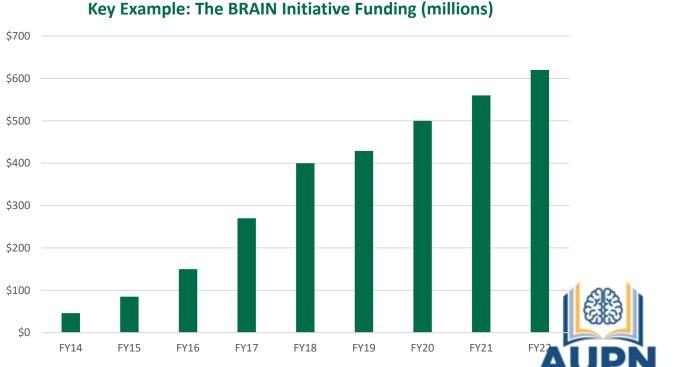




Medical Research

- Congress <u>must</u> enact legislation to fund the government every year!
 - New opportunities every year
 - Fierce competition
 - Gains compound overtime, se like planting a tree....





Workforce Policies

- Congress/Administration controls several key workforce policies including:
 - Funding for Graduate Medical Education (GME)
 - Visas for IMGs
 - Waiver programs like Conrad 30
- GME is broadly supported, but is very expensive
- Programs to support IMGs are supported, but caught in larger immigration debate



Other Federal Issues

- Just scratching the surface, many others including:
 - Drug Pricing
 - Affordable insurance/Affordable Care Act
 - Right to Try
 - Abortion/Dobbs



How to Support Others

- Can't force staff to advocate but can encourage through your actions, flexibility, and through information
- How you can support your department conducting advocacy:
 - Consider advocacy as part of Academic Mission
 - Support time spent like you do for education and research
 - Incorporate public policy speakers/ideas
- Example from a Neurology Department Chair
 - "My advocacy has led to our ability to give Botox to Medicaid patients, which in turn generates a lot of revenue for our program"

Constitutional Right to Advocate

 Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

-The First Amendment



Considerations for Public Employees

- Talk with your employer
- Understand whether they encourage or discourage discussing your employment with their institution
- Private practice is often different than publicly funded university
- Think about whether the issue benefit your employer directly
- Options if employer is hesitant:
 - Using personal, non-business email address
 - Different business cards
 - Being clear who vou're representing



Advocacy Programs

• AMA, subspecialties, disease specific orgs have similar offerings





Health Policy

US IMMIGRATION POLICY UPDATE

* NEUROLOGY. 2021 AAN Supported I						
Search by title Q 🕹 Download						
	Bill	Туре	Number of Cosponsors	Last Timeline Action		
1	S. 610: Dr. Lorna Breen Health Care Provider Protection Act	Senate bill	29	Held at the desk.		
2	H.R. 4122: REDI Act	House bill	1	Introduced in House		
3	S. 2304: DTC Act of 2021	Senate bill	3	Introduced in Senate		
4	H.R. 3541: Conrad State 30 and Physician Access Reauthorization Act	House bill	47	Introduced in House		
5	S. 1810: Conrad State 30 and Physician Access Reauthorization Act	Senate bill	11	Introduced in Senate		
6	H.R. 3173: Improving Seniors' Timely Access to Care Act of 2021	House bill	178	Introduced in House		
7	S. 1548: ENACT Act of 2021	Senate bill	3	Introduced in Senate		
8	S. 1512: CONNECT for Health Act of 2021	Senate bill	59	Introduced in Senate		

POSITION STATEMENT:

USE OF MEDICAL CANNABIS FOR NEUROLOGIC DISORDERS

DRUG APPROVAL PATHWAYS

There are multiple routes for approval of new drugs or indications for existing medications through the United States Food and Drug Administration (FDA), many of which are targeted for therapies in niche or rare disease treatment areas. Not all pathways require the same timelines or rigor of review, and in recent years, this has use IND, and treatment IND. All require information disproportionately affected the field of neurology.

Currently, there are more than 500 neurology-specific therapeutics in the drug-approval pipeline across various disease states.¹ A very high percentage of these drugs meet eligibility for consideration through an "alternative" FDA approval pathway and/or meet eligibility criteria for orphan drug designation (i.e., drugs intended to treat rare diseases defined as affecting <200,000 individuals nationwide). At present, nearly 15 percent of neurologic therapeutics have an orphan drug designation. As we continue to learn more about the genetics of neurologic disorders, additional targeted biologics and gene therapies are on the horizon, a considerable number of which may pass through an alternative FDA approval pathway. For this reason, understanding the nuances of FDA approval are of increasing importance.





Policy Brief

Background



There are several pathways by which drugs are approved by the FDA. This typically begins with an investigational new drug (IND) application which is commonly based on pre-clinical data. There are three

FDA Standard Approval Process²

types of IND applications: investigator IND, emergency regarding animal pharmacology and toxicology, manufacturing information on composition and stability and proposed clinical indications.

Following obtainment of clinical trial data which demonstrates efficacy on standard endpoints in a disease state, a sponsor will submit a new drug application (NDA). A sponsor can be an individual, corporation, manufacturer, etc. leading the development and regulatory compliance of the new drug. Not all drugs that have filed for an IND will move forward with an NDA since clinical benefit must be demonstrated. There are three types of NDAs:

1. 505(b)(1): Traditional pathway

- 2. 505(b)(2): Drugs with similar active ingredients to a previously approved drug
- Drug can rely on prior drug's data supporting an accelerated pathway because less "new" information is required
- 3. 505(j) Abbreviated New Drug Application: Bioequivalent drugs (generics)

FDA "Alternative" Approval Processes^{1,3}

There are four "alternative" approval processes currently used by the FDA. Each pathway has unique eligibility criteria and sponsor benefits. These pathways, except for a breakthrough therapy, are applied at the NDA stage of approval.

Social Media

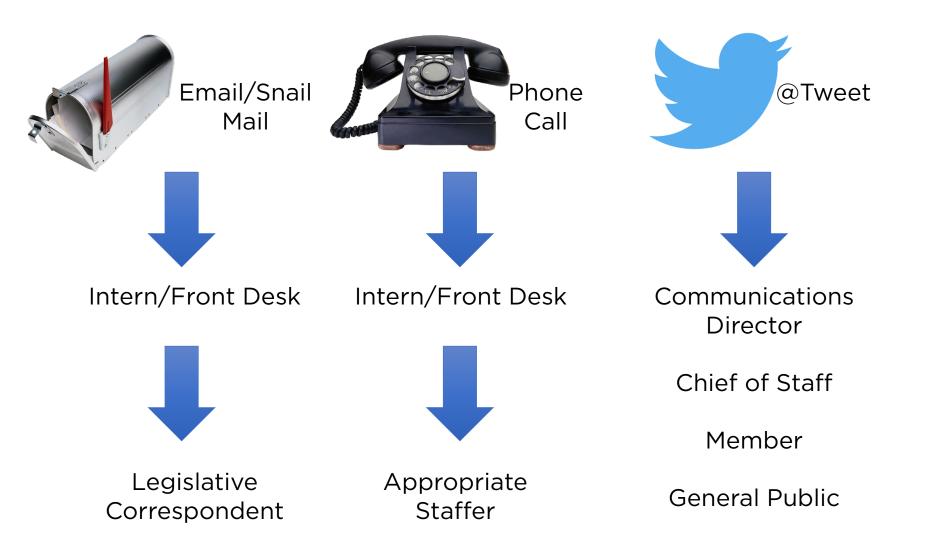
#AANadvocacy

Andy Southerland @ASouthStrokeDoc · Jun 10
Great meeting with these Congresswomen on the Hill yesterday discussing healthcare policy and issues important to patients with neurological disease. Thank you @RepKManning and @RepLBR!
@AANMember #BrainPAC





Social Media Works



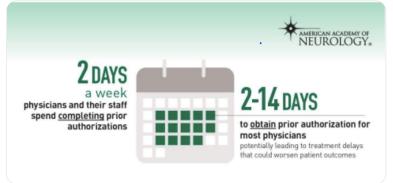


Neurology Patient Adian Charge Che Disorders Advocacy

- ALS Association
- Alzheimer's Association
- American Heart/Stroke Association
- Brain Injury Association of America
- Child Neurology Foundation
- Epilepsy Foundation
- National MS Society
- Michael J. Fox Foundation
- Muscular Dystrophy Associati
- Tourette Association

AHDA @AHDAorg

Prior authorization can cause unnecessary, potentially life-threatening delays for neurologic patients. We join @AANmember in urging Congress to pass #HR3173, the Improving Seniors Timely Access to Care Act. #FixPriorAuth



AAN 🤡 @AANMember

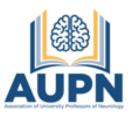
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Good luck to @MichaelJFoxOrg patient advocates meeting with their members of congress virtually today. You can show your support by following #act4pd or emailing legislators: bit.ly/3dm8KfN #AANadvocacy

<mark>e) michaeljfox.org 🤣</mark> @MichaelJFoxOrg · Mar 25

Take action! More than 200 Parkinson's advocates are holding virtual meetings with their members of Congress to ask for an increase in federal funding for Parkinson's research. We need your help to amplify our message by emailing your legislators.bddy.me/3IUkslp #Act4PD

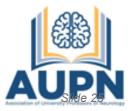






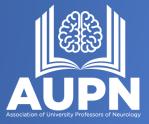
- AAN's federal political action committee
- Supports candidates for Federal House and Senate
- Tool used to build relationships with current and potential legislators to impact health care policy in support of the AAN's legislative goals





State Advocacy Overview

Eddie Patton Jr., MD, MBA, FAAN, FACHE President, Texas Neurological Association @Eddie_Patton_MD

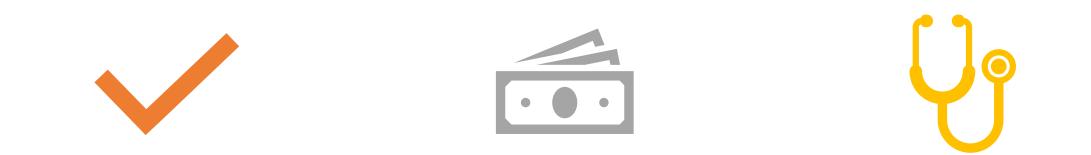


General Overview

- Why advocate on a state level?
- Key state issues
- How to get involved
- How to support advocacy at your institution



Why state advocacy is important?



Licenses are based at the state level

Medical funding comes from the state

Some medical training programs are state funded programs

State advocacy can be easier that federal advocacy

Not as much travel

Easier access to state house and state senate representatives

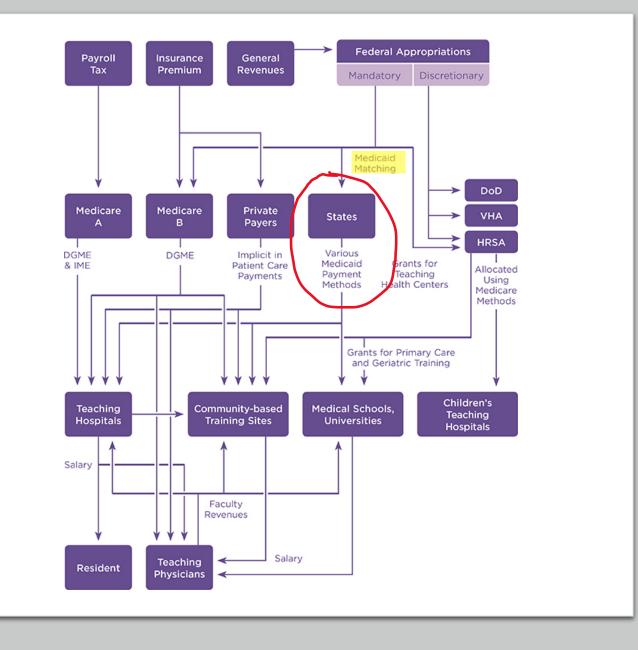
Issues hit "closer to home" More opportunities to advocate

Key State Legislative Issues



GME Funding

- The federal government provides the bulk of GME funding
- Most state support GME through Medicaid programs or state-based programs such as loan repayment incentives
- Medicare and Medicaid distribute over \$14 billion to GME
- Medicare (\$B) \$9.7
- Medicaid (\$B) \$3.9
- VHA (\$B) \$1.4
- HRSA (\$B) \$0.5



Texas voted to fully fund GME expansion

- Almost \$200 M of state budget for expanding GME in the state
- Looking to maintain 1.1 GME slots for every graduating medical student
- Having GME slots allows for you to maintain graduates in the state and build workforce

Funding the Future: Texas Legislature Fully Commits to GME

By Joey Berlin Texas Medicine October 2021



The future of Texas medicine isn't built on the strength of free agency. It comes from homegrown talent. Higher education is the farm system – the pipeline through which the state stockpiles and develops that talent.

So, when the Texas Legislature heeded Texas Medical Association advocacy earlier this year and fully funded the state's Graduate Medical Education (GME) Expansion Grant Program it was one of the most important moves to ensure Texas medical

GME Funding

Medical Education: The Texas Budget

HERE'S HOW the Texas Legislature funded medical education and graduate medical education in the 2022-23 state budget compared with the 2020-21 biennium.

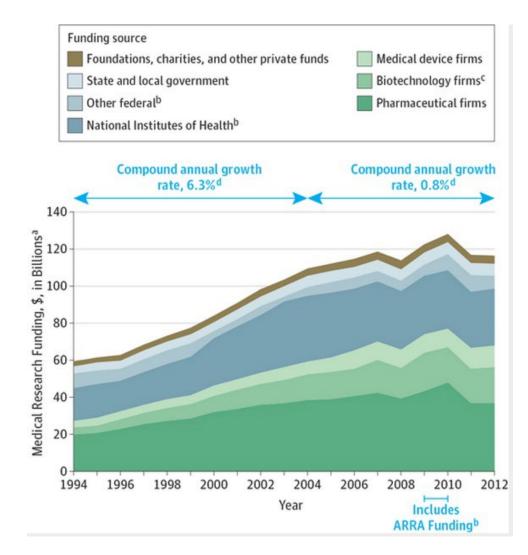
2020-21 funding	2022-23 funding	% Change		
\$157.2 million	\$199.1 million	26.6%		
\$98.5 million	\$103.5 million	5.1%		
\$762.4 million	\$776.8 million*	1.9%*		
\$10 million	\$9.5 million	-5.0%		
\$3 million	\$2.85 million	-5.0%		
\$29.9 million	\$28.9 million	-3.2%		
\$10.2 million	\$9.7 million	-5.0%		
Created in 2019, not yet funded				
	\$157.2 million \$98.5 million \$762.4 million \$10 million \$3 million \$29.9 million \$10.2 million	\$157.2 million\$199.1 million\$98.5 million\$103.5 million\$762.4 million\$776.8 million*\$10 million\$9.5 million\$3 million\$2.85 million\$29.9 million\$28.9 million\$10.2 million\$9.7 million		



surce: Texas Medical Association Medical Education Department

State Funding for Academic Research

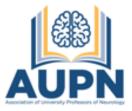
- NIH and federal programs provide
- Research money is also provided by the state
 - This can be general research
 - Research could be geared toward certain initiatives such as cancer or Alzheimer's disease





Public Health Related Issues

- Access to care
 - Medicaid
- Regulation of harmful behavior
 - E-cigarettes
- Vaccines
- Funding for local public health departments
- Mental health support
- Medical cannabinoid use



Public Health Emergency Preparedness

- Recent COVID pandemic was a harsh lesson on how unprepared we were for handling public health emergencies
- Vaccine distribution
- PPE
- Mobilization of aid and assistance to underserved communities



Scope of practice

- Physician extenders
 - Nursing associations have some, of the strongest lobbying groups
 - Chief argument is that with physician shortages they should be able to practice independently to fill in
- Non-physician groups
 - Chiropractors
 - Optometrist
 - Doulas



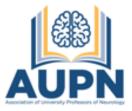
Brain death

- In certain states right to life groups are going submitting legislation for religious exemptions to the brain death determination
 - There is national documentation regarding brain death, but the language is vague to allow each institution to establish its own policy
 - State legislation usually mirrors federal, but states do have more freedom to set their own policy



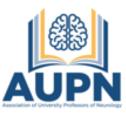
State policies to address the Dobbs decision

- Regardless of political party affiliation or views on abortion we still have an obligation to protect physician autonomy
- Monitoring how each state will handle this issue
- Issues surrounding the criminality of doctors doing what they feel is best for patient care



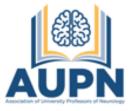
How to get involved

- Join your county medical society
 - Council of academic institutions
- Join your state medical society
- Join your state neurological society
 - Academic neurology section
- Get involved with AAN and ANA advocacy efforts
- Act
 - Respond to action alerts by phone or email to testifying at your state capital
- We must be more proactive and less reactive



How to support state advocacy at your institution

- Consider paying membership for state medical or neurological society for faculty
- Allow advocacy time for faculty to participate
- Bring in speakers to talk about pertinent state legislative issues



Questions?

