
FEDERAL RELATIONS

21st Century Cures Act

Pharmaceutical companies, medical-device manufacturers and patients with hard-to-cure diseases have a stake in [H.R. 6](#), a bill that would make changes at the Food and Drug Administration to speed the development of new treatments. Approved 51-0 by the [Energy and Commerce Committee](#), the sweeping legislation would reauthorize the National Institutes of Health through fiscal 2018 and create medical-research grant programs. Congress could consider this bill as early as next week.

The measure includes some offsets to reduce the cost of the appropriations and increased authorization levels in the bill. It would direct the Energy Department to sell 8 million barrels of crude oil from the Strategic Petroleum Reserve each year from fiscal 2018 to fiscal 2025. The measure also would delay the timing of payments to Medicare prescription drug plan sponsors in order to allow the government to retain interest generated by the funds. Health insurers and companies that manage prescription drug benefits will [fight that offset](#).

The Pharmaceutical Care Management Association said in May that using Part D plans to pay for the legislation could have unintended consequences such as making it harder for beneficiaries to get needed medicine. The group, America's Health Insurance Plans (AHIP) also opposes using changes in Part D as a pay-for.

The bill would allow the FDA, when deciding whether to approve drugs or biological products, to review evidence from "clinical experience" that isn't generated through randomized clinical trials, such as double-blind studies. Among the things to be worked out later is a framework for what sort of information would be acceptable. Watchdog and consumer groups expressed concern the bill could be a step away from standards that the FDA developed to ensure the safety of medicines before they go on the market.

The great thing about this bill is that it would appropriate -- not just authorize -- \$110 million annually in fiscal 2016 through 2020 for a new Cures Innovation Fund to supplement research funding provided by NIH or FDA. The fund would provide grants and support for high-risk medical research. It also would both authorize and appropriate \$2 billion a year for an NIH innovation fund in fiscal 2016 through 2020.

Under this bill, the FDA would have to create a priority review process for "breakthrough" devices, which would represent new, advanced technology, have no comparable alternative treatment or offer significant advantages compared with existing treatments. Under that process, a manufacturer could request priority review and, in consultation with the agency, design clinical trials for the device, which could be shorter or use a smaller pool of subjects. The measure would allow case history, peer-reviewed

studies and certain international data to be considered “scientific evidence” for the purpose of determining a device’s effectiveness.

Furthermore, drug makers could request that the FDA approve, after smaller-than-standard clinical trials, new antibiotic or antifungal medications to treat serious and life-threatening conditions for use in a “limited population.” The bill would direct Medicare to pay more for inpatient hospital treatments using new, qualified antimicrobials starting in fiscal 2018.

A new change for universities and medical schools is that, under this bill, scientists and health professionals participating in federal research could be eligible for as much as \$50,000 in loan forgiveness.

The bill would allow the sharing of health data between researchers. NIH would have to ensure that data is provided in a standardized format that is publicly accessible.

Organizations in support of this bill, among others, include APLU, the Science Coalition, the Association of American Medical Colleges, AARP, the Cystic Fibrosis Foundation, and the American Medical Association (over 50 organizations support this bill). APLU has asked that Wayne State University lobby the Michigan delegation in support and to co-sponsor the legislation, which we have begun in earnest.

Innovation Act/Patent Law (H.R. 9)

The House and Senate Judiciary committees have now approved bills to address “trolling” abuses of the patent system that differ in key respects. Both committees promised changes even before the bills reach their respective floors for vote. The House Judiciary Committee voted 24-8 last week to approve a substantially modified Innovation Act (H.R. 9) targeting litigation abuses in patent-related cases. All but one Republican voted in favor; the 14 Democrats were split.

The bottom line on this bill is, while there were substantial changes made to the rest of the legislation, it does nothing for universities or small inventors. Both focus on changing the economics of patent infringement litigation that currently favors a patent assertion entity, whose lawsuit-related costs are low, seeking a settlement from a questionably infringing defendant whose suit-related costs would be very high if pursued on the merits to the end.

The June 11, 2015 markup prior to the vote did nothing to eliminate the key difference between the House and Senate bills as to litigation—a “loser pays” provision that makes shifting attorneys’ fees far more likely in H.R. 9 than in S. 1137. An amendment that would have aligned the two bills was defeated along partisan lines. (Universities are not supportive of the “loser pays” provision). The “loser pays” approach generates a partisan dispute independent of patent law, as trial lawyers generally see it as a move

away from the “American system” where each party is almost always responsible for its attorneys' fees (this is also the controversial "fee shifting" provision).

Fee shifting remains the same. The bills' initial target was the litigation abuse of suing with the knowledge that the defendant was more likely to settle—regardless of the merits of the case—rather than incur the multi-million dollar expense of seeing the case through to the end. The Republicans have repeatedly told all of our universities that a loser-pays provision is key to the legislation in that it changes the economics underlying the abuse.

The fighter and leader for the position for universities was Ranking Minority Member John Conyers, Jr., who said “this bill makes every bill a fee-shifting case.” Rep. Hank Johnson (D-GA) proposed an amendment, which would have replaced Section 3(b) of H.R. 9 with the more favorable to universities text of the Senate bill, failing along party lines.

Other than fee-shifting, the following provides a picture of issues related to litigation in federal court of patent infringement assertions.

- Venue. The H.R. 9 manager's amendment added a new Section 3(g), not previously in either bill, limiting the venue where a domestic plaintiff may bring an infringement case. Besides venue based on the defendant's location, the patent owner would be limited to courts in districts where the invention was conceived or where the patentee has a manufacturing presence.
- Joinder. Section 3(c) of H.R. 9 tries to prevent cases where the plaintiff is a shell company that, should it lose, would not be able to pay the other side's attorneys' fees, if awarded. The manager's amendment creates exceptions disallowing joinder of university technology transfer organizations and those that have only “an equity or security interest” in the patents asserted.

More importantly, though, it tries to give a definition to the types of parties likely to abuse this aspect of litigation. It says that the defendant can challenge—as prospectively unable to pay—those without “a substantial interest” in the patent. And it defines those with substantial interest to be inventors or those who commercially practice or are “engaged in research and development” in the patented subject matter. **This provision was not challenged during markup.**

Higher Education Act Reauthorization

While the Financial Aid Simplification and Transparency (FAST) Act was introduced by the Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP), no action has been occurring in the House Education and Workforce Committee. This bill would dramatically simplify the federal financial aid system while

improving transparency and access. The FAST Act also includes many issues for which NASFAA has been advocating.

The FAST Act would:

- Eliminate the Free Application for Federal Student Aid (FAFSA) and utilize prior-year (PPY) data. The application would be reduced to two questions:
 - What is your family size?
 - What is your household income (adjusted gross income) from two years prior?

Other aspects of the bill include:

- Providing early information for students and families through a “look-up” table that students and families would have access to as early as the beginning of the junior year of high school.
- Establishing a one-grant/one loan program
- Make the Pell Grant more flexible by restoring the year-round Pell Grant.
- Providing some authority for aid administrators to be able to limit loan amounts on a categorical basis in certain well-documented cases.
- Prorate loans based on enrollment status.
- Streamline repayment plans into two programs: one income-based repayment plan and a 10-year repayment plan.

Labor/HHS/ Education Appropriations Mark Up

The Department of Education faces the biggest cut in the House’s \$153 billion draft Labor-HHS spending bill, which overall would slash programs by \$3.7 billion. This bill was scheduled to be considered by the subcommittee on Wednesday, June 17, 2015, but it has since been postponed.

The bill authored by subcommittee Chairman Tom Cole would end 19 education programs - including Preschool Development Grants, School Improvement Grants, the Striving Readers program and Math & Science Partnerships -- to save \$2.8 billion next year. House appropriators released the bill, which rarely makes a stand-alone appearance, before the previously scheduled subcommittee markup. The bill is designed to pick multiple fights with minority Democrats and President Barack Obama.

On the president’s signature health law, the measure would provide no new funding to implement the Affordable Care Act and would rescind prior-year funds -- reprising the battle over the Access to Care Act’s funding that shut down the government in 2013. One winner in the bill would be the National Institutes of Health. The measure would increase its funding to \$31.2 billion from \$30 billion. That would put funding very close to the maximum

proposed authorization of \$31.8 billion in H.R. 6, the “21st Century Cures” bill, coming to the House as soon as this month.

Other winners in the draft version of the bill:

- **FOR-PROFIT, CAREER COLLEGES:** The bill would block the Education Department from implementing rules aimed at saving students from crippling debt. Such rules would require colleges to train students for “gainful employment” and would more tightly link “credit hours,” with actual hours spent in the classroom.
- **SENIORS AND DISABLED:** The bill would increase Social Security Administration funding to \$11.8 billion, a gain of \$12 million. The SSA has a large backlog of disability claims. The measure also would provide \$220 million for the Meals on Wheels program, increasing its resources by \$3.5 million.
- **HEAD START:** The Head Start program would get \$8.8 billion, or a \$192 million increase.

Losers in the draft version of the bill include:

- **EDUCATION:** Democrats said that when counting the Fund for the Improvement of Education programs separately, a total of 27 education programs would be eliminated by the bill. Pell Grants would lose \$370 million, compared with the current year and the President’s request which would have kept funding for them level.
- **JOB TRAINING:** The Employment Training Administration would receive \$9.5 billion, a cut of \$196 million. The Labor Department portion of the bill would provide \$11.7 billion, \$206 million below what was provided for fiscal 2015.
- **UNIONS:** The National Labor Relations Board would be in line for a 27 percent cut to \$74.2 million. The bill also contains many riders, including prohibitions on enforcing Fair Pay and Safe Workplace orders.

STATE RELATIONS

GME Meeting with SBO

In early August, the School of Medicine and the Division of Government and Community Affairs met with the new director of the Office of Health and Human Service within the State Budget Office (SBO) in Lansing to discuss Graduate Medical Education (GME).

The Office of Health and Human Services is responsible for budgetary analysis and preparation of the Governor’s budget for health and human services. This includes the recently formed Department of Health and Human Services.

The SBO reached out to us because they wanted to get a deeper sense of GME from Wayne State's perspective and how our Medical School and its students benefit from the program.

In talking about GME at WSU, a good deal of the conversation centered on the MiDocs initiative that our office and the Medical School has been working on for the last few years.

In general, we thought this was a very good meeting with potential for increased collaboration on not only GME, but other health care-related issues as well.

Meetings re Community College Baccalaureate Legislation

During the last couple months, we have been meeting with various members of the legislature regarding the legislation that would allow community colleges to offer baccalaureate degrees in several areas.

Senate Bill 98, sponsored by Senator Mike Shirkey (R-Jackson), would allow community colleges to offer four-year degrees in nursing, ski area management, allied health, information technology, and manufacturing technology.

As you will recall, cement technology, maritime technology, energy production technology, and culinary arts, are currently allowed.

There has been no legislative movement on this legislation since the last Board of Governors meeting.

Detroit Delegation Tour

This fall, the Division of Government and Community Affairs, in collaboration with the College of Nursing (CON) and School of Medicine (SOM), will provide the Detroit Delegation with a tour on campus and host a lunch for the attending legislators.

Detroit legislators will tour the College of Nursing and have a discussion with, and presentation from, Dean Clabo. A nursing student might attend, as well. Lunch will be at the College of Nursing.

Following lunch, a shuttle will take lawmakers to the Tolan Park Psychiatry Facility. The School of Medicine will provide a briefing on the benefits the Department of Psychiatry provides to the Medicaid population in Wayne County, and will then provide a short tour of the HIV-AIDS clinic.

Originally planned for this month, another event that conflicted with many in the delegation required us to reschedule. A new date has yet to be confirmed.

Pain and Symptom Management Committee

In early July, Governor Snyder appointed Mohamad Maher Fakhouri, to the Advisory Committee on Pain and Symptom Management. Fakhouri is an assistant professor of neurology and clerkship director at Wayne State University (WSU) School of Medicine. He represents the WSU College of Medicine and replaces Todd Lininger on the committee.

HJR O

In June, the House Oversight and Elections Committee reported House Joint Resolution O (HJR O) to the floor of the House. The constitutional amendment, sponsored by Rep. Martin Howrylak (R-Troy) would require that all university board meetings be held in public.

Most of the universities put in a card indicating opposition to the committee during the hearings it had on the resolution.

If both the House and Senate approve the resolution by at least a two-thirds vote at least 60 days before the date of a general election, it would then be placed on the ballot at that general election for voter approval or rejection.

It is unclear at this time whether or not the House will act on the resolution this fall.

Meeting with Student Senate Director of Government Affairs

The Division of Government and Community Affairs recently met with the newly elected director of Governmental Affairs for Wayne State's Student Senate, Tejeshwar "Tiger" Bawa. He reached out to our office and wanted to learn more about our efforts in Lansing and hoped to be able to work with us to further the goals of the university.

We discussed the potential of having a lobby day in Lansing for the students to come and meet with their lawmakers and discuss issues that are vital to the students and the university. Our goal is to hold this event in late winter or early spring before the budget for the coming year is finalized.

We also discussed the possibility of just a few members of the Student Senate coming to Lansing on somewhat of a quarterly basis (or whenever an issue may arise) to meet with elected officials.

Tejeshwar also wanted to discuss voter registration drives and organizations that may help them in putting one on. They apparently had not been very happy with the organization that previously had helped them put on a drive. As we did not have a great deal of knowledge of these type of organizations, I mentioned that I would ask my colleagues from other institutions for their input on the matter and get back with him.

We are very encouraged that Tejeshwar was so eager to get involved and we will definitely keep in touch with him and other members who are willing to participate.

Rep. Banks Community Day

Representative Brian Banks (D-Detroit) held his annual Community Day in his district recently. Per the requests from his office, WSU was able to send students from the School of Medicine (SOM), College of Nursing (CON) and the Law School to provide free services to his constituents. We also arranged for "W," WSU's mascot, to attend.

The law students from Wayne Law's Advocates for Warriors Program were there from Noon - 2pm that day to talk to attendees about the law school's Advocates for Warriors Program and the Free Legal Aid Clinic (FLAC).

The students from the SOM and CON provided free health screenings.

Constituent Matters

The Division of Government and Community Affairs recently helped Senator Bert Johnson (D-Detroit) secure space on campus for two meetings. We have also assisted the offices of Representatives Laura Cox (R-Livonia) and Kristy Pagen (D-Canton) with constituent matters.

Legislative Calendar

The House and Senate are now on break until after the Labor Day holiday. Following the holiday, they will be back to a normal schedule.