AdvaMed Proposed Legislation – January 25, 2019

AdvaMed Floats Legislation To Allow User-Fee Submissions During Shutdowns
Ferdous Al-Faruque, *Medtech Insight* - 1/24/19
"...Whitaker cautions that the legislative "fix" AdvaMed is proposing wouldn't entirely solve the backlog problem, but, he said, it would allow FDA to continue to collect user fees and review user-fee based applications...."
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Advamed floats FDA shutdown legislation for user fee access
Mark McCarty, *Medical Device Daily* - 1/25/19
"...Scott Whitaker, president and CEO of the Advanced Medical Technology Association (Advamed), said on a Jan. 24 conference call that the association has floated language that could be applied toward a bill that would give the agency the authority to continue to collect user fees and process applications...."
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AdvaMed Pitches Leg Proposal To Let FDA Accept User Fees In Shutdown
David Roza, *Inside Health Policy* - 1/24/19
"..."We have no ability to impact the backlog of submissions ... other than allow them to accept user fees right now," she said in response to a question from IHP. "Once the shutdown is over, there will be an influx of submissions FDA will have to deal with."...
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Overnight Health Care: Industry group launches ads against 'Medicare for all' | Wisconsin AG says state can't leave ObamaCare lawsuit | Medical device makers warn of shutdown effects
Jessie Hellmann and Peter Sullivan, *The Hill* - 1/24/19
"...AdvaMed, the medical device industry group, on Thursday warned that the shutdown has left the FDA unable to approve new device applications and therefore "the innovation pipeline is becoming dangerously clogged."...
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Shutdown’s Latest Victim: Hundreds Of Delayed Life-Saving Medical Devices
Bruce Japsen, *Forbes* - 1/24/19
"...AdvaMed is proposing legislation "to ensure FDA continues to have access to funds to conduct medical device reviews during a lapse in appropriations." Device makers want Congress to allow FDA to be granted the authority to continue processing "new device applications and their associated user fees during a lapse in appropriations."...
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Med Device Lobby Seeks Shutdown Solution (1)
Jacquie Lee, *Bloomberg BNA* - 1/24/19
"...The legislation would allow the Food and Drug Administration to accept new device applications under this and future shutdowns to prevent a build-up of the agency's application backlog, the CEO of the Advanced Medical Technology Association told reporters in a briefing Jan. 24...."
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Capsule: Revived AIDS Council, Opioid Efforts, and Watchdog Wins
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"...The lobbying group AdvaMed is "reading the political tea leaves," its CEO Scott Whitaker, said. He imagines lawmakers won't reach an agreement to end the shutdown altogether, but anticipates Congress will start making concessions about bipartisan funding for TSA agents or Federal Trade Commission employees...."

**FDA Shutdown Prompts Call for Short-Term Fix**

*Andrew Siddons, CQ Roll Call - 1/24/19*

"...Whitaker said that the device industry group is talking to lawmakers about authorizing the FDA to collect the so-called user fees from the industry even during a lapse in appropriations, and tap into other funds that the agency potentially has in reserve...."

**Medical device industry floats idea to pay user fees during shutdown**

*Jim Spencer, Minneapolis Star Tribune - 1/24/19*

"...Whitaker called the device industry's attempt to pay new user fees to the FDA "completely nonpartisan."...

**AdvaMed Seeks to Keep Device Reviews Running During Shutdown**

*Ana Mulero, Regulatory Affairs Professionals Society - 1/24/19*

"...As a result of the lapse in appropriations, several from FDA and industry have estimated that CDRH will run out of Medical Device User Fee Amendment user fees within two months. The best case scenario for these funds is three months, Whittaker argued...."

**Device lobby pushes bill to let FDA take user fees amid shutdown**

*David Lim, MedtechDive - 1/24/19*

"..."These are unprecedented times in terms of the shutdown, and some Hill reactions may be less about the merits of our language and more a reflection of the larger political climate we’re offering it in," Greg Crist, AdvaMed Chief Advocacy Officer, told MedTech Dive. ...

**AdvaMed Unveils Proposal to Keep FDA Review Process Vibrant During Shutdown**

*Omar Ford, MDDI - 1/24/19*

"...AdvaMed said it began having conversations with Congress earlier this week about the proposal. The agency remained tight-lipped about the specific legislators that had seen the proposal and their reactions...."

**Device Industry Asks Congress for Relief From FDA Shutdown**

*Staff Writer, Medscape Headlines - 1/25/19*

"...AdvaMed said that as many as 300 applications a month will not be acted on during the shutdown. [Subscription Required to View Full Text] ...

**AdvaMed's Legislative Proposal Seeks to Ease Issues Related to User Fees and Device Submissions During Shutdown**

*Maria Fontanazza, MedTech Intelligence - 1/24/19*

"..."We're not assuming that this helps resolve the government shutdown," said Whitaker, but they are anticipating a "protracted shutdown" and are trying to stay ahead of the game. He said thus far, reaction to the proposal has been positive...."
AdvaMed Proposed Legislation Full Text Articles

AdvaMed Floats Legislation To Allow User-Fee Submissions During Shutdowns
Ferdous Al-Faruque, Medtech Insight - 1/24/19

As the partial US government shutdown enters its second month, the backlog of device pre-market applications is building. AdvaMed is proposing language that would allow FDA to accept and review new user-fee-funded submissions during government shutdowns.

Applications for new devices and diagnostics have stalled at US FDA, which is blocked from accepting and reviewing any new submission that requires user fees until the ongoing partial government shutdown is over. AdvaMed is floating legislation that would allow user-fee-funded submissions to come through regardless of political stalemates.

As the US government shutdown continues into its 34th day, the device industry says it is starting to feel more of the pain. Medtech companies file, on a monthly basis, about 300 FDA pre-market submissions, including PMAs, 510(k)s and other varieties, according to AdvaMed CEO Scott Whitaker.

The rate of submissions is typically much lower during the end-of-year holiday period, so the beginning of the shutdown was less impactful. But as the shutdown continues, it will complicate business plans for more companies that planned to file applications and that comes with financial consequences.

"If we're at the end of February and this hasn't been addressed then this is extremely material," one industry insider who didn't want to be named said.

On Jan. 24, AdvaMed announced it has floated legislation with members of Congress that would ensure FDA continues to be able to accept user-fee funds to support device reviews during a lapse in appropriations. The lobby group says the agency should be allowed to continue processing new device applications under the Medical Device User Fees Amendments (MDUFA). It's also asking Congress to authorize FDA to tap into its pool of unearned user fees to help support device reviews during lapses in appropriations.

"Every year, a number of companies essentially 'pre-pay' application or facility registration fees to the agency, and for whatever reason, never submit an application or register a facility," said AdvaMed in a statement.

"While FDA eventually tries to return these fees or 'save' them to pay a company's future fees, these 'unearned' fees often just sit in the agency's account, not dedicated to any specific task. These fees accumulate each year and, at the end of FY 2017, amounted to $7.5m. AdvaMed's proposal would allow the agency to utilize these funds."

Whitaker cautions that the legislative "fix" AdvaMed is proposing wouldn't entirely solve the backlog problem, but, he said, it would allow FDA to continue to collect user fees and review user-fee based applications. Furthermore, he says the proposed legislation is "very thoughtful and reasonable" and does not affect appropriations funding so it would not get embroiled in any appropriations debates.

AdvaMed began floating the draft language earlier in the week but declined to say which members of Congress it has spoken to. Association officials specified that they have shared the idea with key committees in the two chambers and, for the most part, the reaction has been positive.

Whitaker says he hasn't seen any major legislation that would end the shutdown to attach the proposed language to, but he said AdvaMed is looking for a smaller bill that can be passed with sufficient bipartisan support to serve as a vehicle for its proposed legislation. Whitaker suggested there are several potential bipartisan issues that have a chance of passing in advance of a full resolution of the shutdown, including measures to fund the Transportation Security Administration and Securities and Exchange Commission.
"I don’t see any specific vehicle today but there are enough rumors [on Capitol Hill] that we hear about trying to take care of things that we want to be positioned to be a part of. So we’re trying to get ahead of the rumors,” he added.

A similar proposal to try carve out a budgetary exception for FDA user fees has been attempted in the past. In 2013, industry groups collaborated to try to get legislation passed that would exempt user fees from sequestration.

**Advamed floats FDA shutdown legislation for user fee access**

*Mark McCarty, Medical Device Daily - 1/25/19*

The government shutdown is starting to take a toll on the U.S. FDA's review of premarket applications, and Scott Whitaker, president and CEO of the Advanced Medical Technology Association (Advamed), said on a Jan. 24 conference call that the association has floated language that could be applied toward a bill that would give the agency the authority to continue to collect user fees and process applications. Whitaker said Advamed sees the proposal as entirely reasonable, and that if adopted, such a bill "should not in any way affect appropriated accounts."

Whitaker noted that the shutdown has passed the one-month mark and that there are "increasing concerns about how the shutdown is going to impact this industry." While premarket applications are a concern, Whitaker also noted that the agency will have a tough time getting to inspections other than for-cause inspections, which ordinarily deal strictly with a potential public health concern.

The FDA's device center is making use of existing carryover user fee balances, and Whitaker said new applications are starting to queue up. As matters stand, the agency is currently able to review "only those [applications] that would have been received by the FDA prior to the shutdown," Whitaker said.

The carryover user fee balances are expected to last only another two months or so, and Whitaker said, "I think three [months] is the best-case scenario." He said that the typical monthly volume of premarket applications consists of roughly 300 filings, five each of which are usually PMAs and de novos. The remainder consists of 510(k) applications, and Whitaker said each succeeding month of the shutdown will add to an already accumulating backlog. However, he declined to address how industry and the FDA would address the question of application timelines under the user fee schedule. Advamed was also unable to address the question of whether third party reviewers would be in a position to take up a significant portion of the backlog.

Regarding the House and Senate, Whitaker said "the general reaction has been positive," but he said the proposal is directed toward only the device user fee program. Nonetheless, Advamed is not opposed to a coalition approach with other industries regarding FDA user fees, although the Coalition for a Stronger FDA is probably already engaged in that kind of effort.

Advamed is in possession of no solid information suggesting there is a legislative vehicle that could be used to move this proposal any time in the next few weeks, and Whitaker said Advamed is keen on drumming up bipartisan interest on both sides of Capitol Hill in this type of resolution. He declined to speculate as to whether the proposed legislation would go through the process as a stand-alone bill. Whitaker said Advamed would like to see legislation that would handle the current and any future shutdowns, but that the association will take a current-year-only fix if that proves to be the only option that is amenable to legislators. He said the FDA is doing everything it can to keep applications moving along, but that "there's only so much they can do."

Unused fees also cited

The Advamed proposal principally addresses ongoing user fees paid for new applications, but there is another source of monies available to the agency. The association's proposal would give the FDA access to those monies, which in times gone by has amounted to several million dollars.

The summary of the proposal states that Congress should allow the FDA "to continue processing new device
applications and their associated user fees during a lapse in appropriations," which would eliminate any backlog and would be "in the best interests of the agency, med-tech companies, and most importantly, American patients." The proposal also would authorize the agency to access unearned user fees to finance review activities during a lapse in appropriations.

The association noted that a number of device makers pre-pay application and facility registration fees, and in some instances, the sponsor files no premarket application or ultimately never opens the site for which a facility fee was paid. Such fees may end up in the FDA account without a specific use, and AdvaMed says the FDA had $7.5 million in such fees at the end of fiscal 2017. The proposal would allow the FDA to tap into those funds.

**AdvaMed Pitches Leg Proposal To Let FDA Accept User Fees In Shutdown**

David Roza, *Inside Health Policy* - 1/24/19

Top medical device lobbyists are pitching a legislative proposal that would let FDA accept user fees for new device applications during the partial federal government shutdown. Lobbyists say the proposal would prevent the agency's device center from running out of funding during the shutdown and allow reviewers to work on a growing backlog of new device submissions. But House Energy & Commerce Committee Democratic staff told Inside Health Policy that committee leadership would oppose the proposed legislation.

The industry's proposal also says Congress should authorize FDA to tap into a pool of "unearned" user fees, which occur when companies pay for a device application or facility registration but never follow through by submitting an application or facility registration.

The medical device lobby, the Advanced Medical Technology Association (AdvaMed), floated the proposal as a way to address the lack of funding flowing into FDA due to the month-long partial government shutdown, which FDA chief Scott Gottlieb recently pegged as "one of the most significant operational challenges in FDA's recent history."

While FDA's device premarket review activities are still running on user fees collected before the shutdown began, those funds are expected to run out in the next few months. And without authorized appropriations, FDA cannot collect and process medical device applications and their associated user fees, AdvaMed explained in a press statement on Thursday.

During a conference call with reporters on Thursday, AdvaMed President and CEO Scott Whitaker said the device industry usually submits 300 device applications to FDA every month. Without the ability to process those applications and their user fees, the backlog of applications will build up and ultimately swamp FDA when the shutdown ends. It also will delay patient access to new devices and disrupt medical technology companies' business plans, the device group added.

Janet Trunzo, senior executive vice president for technology and regulatory affairs at AdvaMed, said there is really nothing the group can do to try to reduce that backlog.

"We have no ability to impact the backlog of submissions ... other than allow them to accept user fees right now," she said in response to a question from IHP. "Once the shutdown is over, there will be an influx of submissions FDA will have to deal with."

In light of the lapse in appropriation funding, Whitaker said a proposal allowing FDA to accept user fees "seems to me a good way to deal with the issue."

In its Thursday press announcement, AdvaMed described the proposal as having two components. The first component involves Congress allowing FDA to continue processing new device applications and user fees despite a lack of appropriations.

In the second component, Congress would allow FDA to use its collection of "unearned fees," which AdvaMed estimates was worth $7.5 million at the end of fiscal 2017. While FDA often tries to return or save those fees to
pay a company's future fees, they "often just sit in the agency's account not dedicated to any specific task," AdvaMed wrote.

Whitaker and his staff, including Greg Crist, head of government affairs at AdvaMed, started speaking with lawmakers about the proposal earlier in the week. Whitaker did not specify which lawmakers he met with, but he said they were generally "positive" about the proposal.

Crist added that the group has met with members from both chambers and parties of Congress. While he wouldn't characterize how the proposal was received, he said there was "lots of curiosity and questions and a lot of agreement in concept."

Medical devices are not the only product category funded by FDA's user fee programs, but Whitaker said AdvaMed's proposal doesn't address drugs, biologics, animal drugs or other products.

The House Energy & Commerce Committee Democratic majority staff told IHP they would oppose the proposed legislation, but they didn't say why.

Meanwhile, Senate health committee Chair Lamar Alexander (R-TN) seemed enthusiastic about measures that would get FDA, and the government in general, back on its feet.

"Shutting down the government is always wrong," Alexander said in a statement sent to IHP. "The work done by FDA is critical for all medical products and helps ensure innovative and life-saving treatments can get to patients. We should be doing everything we can to re-open the government so that agencies re-open and people can get back to work."

When asked whether AdvaMed is looking for a legislative vehicle to which it can attach its proposal, Whitaker said he anticipates a scenario where Congress might try to address the lack of funding in multiple essential areas of government, such as the Transportation Security Administration. The proposal might fit in that kind of legislation, he said.

"If that situation arises, we want to make sure we're in the queue for that conversation," Whitaker said.

The AdvaMed president and CEO said the group has not met with FDA about the proposal, though it has discussed the impact of the lack of user fees with the agency. He added FDA "wouldn't have the bandwidth" to deal with the proposal anyway, as the agency's employees tasked with dealing with legislative proposals are furloughed.

Steven Grossman, deputy executive director of the Alliance for a Stronger FDA, said AdvaMed's proposal is an interesting one. He added the shutdown has exposed how limited the agency's public health capabilities are during a federal shutdown.

"AdvaMed's proposal is thoughtful and represents one element of what will be needed to keep more of FDA working-and the American people protected-were there to be another shutdown or similar event," Grossman told IHP.

Grossman wouldn't comment on whether other industry groups are seeking similar proposals for their products.

During a Food and Drug Law Institute webinar on Thursday about the shutdown's effects on FDA, former agency officials said FDA might issue guidance on how it will deal with the backlog of medical product submissions.

"The interesting question will be what guidance FDA will issue for how they will address that queue," said Rebecca Wood, a partner at Sidley Austin and former chief counsel at FDA.

Howard Sklamberg, a partner at Akin Gump Strauss Hauer & Feld and former deputy commissioner for global regulatory operations and policy at FDA, noted the agency has the ability to prioritize reviews based on certain
In AdvaMed's press release, Whitaker described the group's proposal as a "common-sense" solution to a problem that is stifling innovation.

"We're putting forth common-sense solutions to a bureaucratic obstacle that is stifling the pipeline of new medtech innovations that patients depend on," Whitaker said. "We can't allow this situation to continue, and we want to work with Congress, FDA and other stakeholders on moving this legislative fix forward." -- David Roza

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Overnight Health Care: Industry group launches ads against 'Medicare for all' | Wisconsin AG says state can't leave ObamaCare lawsuit | Medical device makers warn of shutdown effects

Jessie Hellmann and Peter Sullivan, The Hill - 1/24/19
Welcome to Thursday's Overnight Health Care. The Senate rejected two measures to end the government shutdown on Thursday, with no signs the two sides are any closer to a deal.

The shutdown is already the longest in U.S. history and it's sucking all of the air out of the room.

The House Energy and Commerce Committee postponed three hearings it planned to have this month on topics including ObamaCare, the Trump administration's family separations policy and climate change.

Instead, it will have a hearing next week on the shutdown.

"I never thought the shutdown would still be going on when we had the chance to organize," Chairman Frank Pallone (D-N.J.) said Thursday.

Those hearings will still occur, Pallone said, but not next week.

In other healthcare news...

Wisconsin's attorney general says state can't withdraw from Texas' ObamaCare lawsuit

Wisconsin Attorney General Josh Kaul (D) on Thursday told newly sworn-in Gov. Tony Evers (D) that he does not have the authority to withdraw the state from a lawsuit filed by 20 states seeking to overturn ObamaCare.

The state signed on to the lawsuit under the previous Republican-led administration.

Kaul told Evers in a letter that only the Republican-led state legislature could withdraw Wisconsin from the suit, according to The Associated Press.

Why this matters: Both Evers and Kaul ran against the lawsuit in their campaigns. But then the state legislature passed last minute legislation weakening the power of the executive branch, which was signed by outgoing Gov. Scott Walker (R).

Read more here.

Health care industry group launches digital ads against 'Medicare for all'

A new sign that the health care industry is taking the threat of Medicare for All seriously: a coalition is running ads against it.
"Whether it's called Medicare for all, single-payer or a public option, a one-size-fits-all health care system will mean all Americans have less choice and control over their doctors, treatments and coverage," states the two-and-a-half minute video, which will run as a digital ad on Facebook, Twitter and YouTube.

The group behind the ad is the Partnership for America's Health Care Future, whose members include major industry players such as America's Health Insurance Plans and the Pharmaceutical Research and Manufacturers of America, who last year came together to form the group to fight Medicare for all.

The politics: Medicare for All has no chance of passing in the next two years, given GOP control of the Senate, but the Democratic House has put the industry on edge to begin fighting and laying the groundwork for the larger battle that could come if a Democrat wins the presidency in 2020.

Read more here.

And for more on the industry group, check out our story from last year here.

Gum disease bacteria may be cause of Alzheimer's: study

Today in research findings you might not expect: Gum disease may lead to the development of Alzheimer's, according to a new study.

A team of scientists led by the pharmaceutical company Cortexyme found "strong evidence" of a link between Alzheimer's and Porphyromonas gingivalis, the key bacteria in gum disease, University of Louisville researcher Jan Potempa said.

Potempa added that "more research needs to be done" to show causation, rather than simply correlation, between gum disease and Alzheimer's.

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The research team's paper revealing the link between the disease and gum's disease was published Wednesday in the scientific peer-reviewed journal Science Advances.

Read more here.

Medical device industry warns of shutdown effects

AdvaMed, the medical device industry group, on Thursday warned that the shutdown has left the FDA unable to approve new device applications and therefore "the innovation pipeline is becoming dangerously clogged."

The group proposed legislation to allow the FDA to restart reviewing the applications.

What we're reading

After 'CRISPR babies,' medical leaders to tighten genome editing rules (STAT)

Furloughed federal workers will have to pay dental, vision premiums or risk losing coverage (philly.com)

Hospitals are asking their own patients to donate money (The New York Times)

State by state

New Wisconsin poll shows public support for Medicaid expansion (Wisconsin State Journal)

Massachusetts governor has plan to rein in soaring drug costs in state Medicaid program (bostonglobe.com)
ShUTDOWN'S LATEST VICTIM: HUNDREDS OF DELAYED LIFE-SAVING MEDICAL DEVICES
Bruce Japsen, Forbes - 1/24/19

The government shutdown is creating a backlog of hundreds of medical device applications awaiting review at the Food and Drug Administration, triggering a cascade of delays for new medical technology to reach patients, the medical device industry said Thursday.

With the partial federal government shutdown, the FDA cannot collect and process new applications for medical devices nor their associated user fees under existing law. That is creating a delay dating back to before Christmas of hundreds of submissions to the FDA for review, the medical device industry said.

"We worry about the long-term impact," Scott Whitaker, CEO of the Advanced Medical Technology Association (AdvaMed) told reporters on a conference call Thursday morning. AdvaMed, which represents the world's biggest medical device makers including Abbott Laboratories, Baxter International, Johnson & Johnson, Medtronic and Stryker.

Thousands of FDA employees were among the 800,000 federal government workers furloughed by the shutdown, bringing to a halt the previously routine regulatory and compliance activities of the agency. "The longer it goes, the longer the backlog is," AdvaMed's Whitaker said of the shutdown's impact on medical technology and device submissions to the FDA.

The FDA is typically receiving 300 submissions a month from medical device and technology companies , AdvaMed said, so a long-term backlog of applications is cause for alarm. FDA has said there is "carryover" user fee money that is collected from companies under the Medical Device User Fee Act, known as MDUFA, but that isn't expected to last much longer.

"While the agency is able to continue these premarket review activities using fees collected before the lapse in appropriations, these funds can quickly be exhausted," AdvaMed said in a statement. "In addition, without the ability to process new user fees, a backlog of new product applications can build quickly, delaying patient access to new medical technologies and disrupting medtech companies' business plans. Once the lapse in appropriations is over, FDA is still faced with the task of processing the backlog of applications before its operations can return to normal."

With members of Congress beginning to propose legislation this week, medical device makers are hoping to get on lawmakers' radar should any bipartisan legislation emerge to reopen the government.

AdvaMed is proposing legislation "to ensure FDA continues to have access to funds to conduct medical device reviews during a lapse in appropriations." Device makers want Congress to allow FDA to be granted the authority to continue processing "new device applications and their associated user fees during a lapse in appropriations."

Though Congress and the Donald Trump White House are still hung up on Trump's demand for funding for a border wall, there's hope that legislation could emerge to at least allow more parts of the government to re-open. FDA is an agency device makers say is critical to patient safety, particularly as the shut down continues.

"If that situation arises, we want to make sure we are in the cue," AdvaMed's Whitaker said of the potential for legislation that would re-open even parts of the government.
For more information on healthcare, read Bruce Japsen's book, Inside Obamacare: From Barack And Michelle To The Affordable Care Act.

**Med Device Lobby Seeks Shutdown Solution (1)**

**Jacquie Lee, Bloomberg BNA - 1/24/19**

The leading medical device industry lobbying group is asking lawmakers to produce legislation that would allow the FDA to collect new application fees from medical device companies despite the partial government shutdown.

The legislation would allow the Food and Drug Administration to accept new device applications under this and future shutdowns to prevent a build-up of the agency’s application backlog, the CEO of the Advanced Medical Technology Association told reporters in a briefing Jan. 24.

AdvaMed representatives said they’ve met...

**Capsule: Revived AIDS Council, Opioid Efforts, and Watchdog Wins**

**Jacquie Lee, Bloomberg BNA - 1/25/19**

By Jacquie Lee

Welcome to Capsule—your weekly dose of health-care news, where we give you a recap of this week's highs and lows for key players in the health-care industry. You can expect us every Friday morning as a bookend for your week.

The one bit of solace an American can have right now during this shutdown: At least things aren't as crazy here as they are in Venezuela. Of course, there's still time for things to get rowdy in the U.S., especially because senators rejected legislative efforts Jan. 24 to reopen the rest of the government. Before you suit up in your protest gear though, catch up on your health-care news.

Here's who ended the week on a high note:

**Watchdogs**

Consumers finally have an idea of what goes on behind closed doors with drug supply middlemen thanks to a new watchdog group analysis, Robert Langreth for Bloomberg News writes. Pharmacy-benefit managers are taking increasingly large markups on generic drugs in New York, according to the analysis of Medicaid prescriptions at independent pharmacies in the state.

Meanwhile watchdogs on Capitol Hill are gearing up for a hearing Jan. 29 that will dig into drug pricing and why costs for patients are so high. The first set of experts to testify before the House Oversight Committee will include patient advocates and researchers, Shira Stein reports. Drugmakers are feeling the pressure from Congress and their leading lobbying group disclosed this week it spent a record $27.5 million on lobbying in 2018, Bill Allison of Bloomberg News writes.

House Democrats are also calling for Health and Human Services Department head Alex Azar to testify about President Donald Trump's child separation policy, Alex Ruoff reports. Azar this week refused to testify, but Democrats say they're willing to drag him to Capitol Hill with a subpoena.

Finally, the HHS could reclassify drugs, impose penalties, and recover rebate payments under legislation prompted by Mylan's 2017 settlement with the Justice Department over classification of the allergy-shot EpiPen, John Hughes of Bloomberg News writes.

The AIDS Council
A White House panel on HIV/AIDS policy that Trump scuttled is set to make its comeback with two new leaders at the helm, Madison Alder writes.

Carl Schmid, deputy executive director of the AIDS Institute, and Washington state Secretary of Health John Wiesman will lead the Presidential Advisory Council on HIV/AIDS when it convenes in March. That will be the panel's first meeting since Trump fired its remaining members in December 2017 after six members left in protest, saying the administration didn't have a plan to address HIV/AIDS issues.

The council is especially important since the opioid epidemic has led to an uptick in the spread of the immune system disease in certain areas.

The Centers for Disease Control and Prevention has a silver lining, though: America's drug overdose epidemic eased in 10 states, primarily in the West, with flat or declining levels between June 2015 and June 2018, Alex Tanzi from Bloomberg News writes.

Alexa Look-Alikes

You've probably used one to DJ your favorite playlist. Now, doctors are using voice-activated digital assistants like Alexa to boost patient engagement and simplify the work of doctors and nurses, James Swann reports.

The voice-activated devices are being used both in hospitals and at home and can help patients check their medications, look up wait times at the ER, and even help doctors pull data from patient electronic health records.

New York-based Northwell Health, for example, is a month away from rolling out a program that will put Alexa devices in every private room and let patients access data from their medical records.

But privacy issues abound. Alexa has faced privacy concerns since the device debuted in 2014, including charges that it's recording conversations even when seemingly turned off. So any systems using this technology have to make sure they're also complying with federal health privacy laws.

It was a bleak week for others. Here's whose Thursday closed on a downswing:

Utah Voters

Two Utah lawmakers are fashioning a bill that would repeal and replace the voter-approved ballot measure extending Medicaid coverage to an additional 150,000 low-income state residents, Trip Baltz writes.

Legislators are "trying to take Prop 3 and mold it into something completely different," state Rep. James Dunnigan (R) told Baltz. "This is not what the public voted on."

There's also tension in Wisconsin as the governor pledged in his first State of the State address to withdraw the state as a plaintiff from a federal court case in Texas seeking to invalidate the Affordable Care Act, Stephen Joyce reports. These and other health-policy goals will have to overcome entrenched opposition from the state's Republican-controlled Legislature.

Opioid Efforts

Congress's latest response to the opioid crisis could be stymied by the partisan fight over border wall funding that led to the partial government shutdown, Jeannie Baumann and Alex Ruoff report.

Since the bill that funds the HHS for fiscal year 2019 (Pub. L. 115-769) was enacted, agencies like the Substance Abuse and Mental Health Services Administration and the National Institutes of Health can carry out their opioid-related work. But the FDA's funding lapsed in December, although the agency is still working on carrying out some of the opioid law's provisions, a spokesman said.
The shutdown could hinder the ability of the states and federal government to coordinate their efforts, senators and lawyers told Baumann and Ruoff.

Medical Device Makers

The leading medical device lobbying group is angling for legislation that would allow the FDA to collect new application fees from medical device companies despite the partial government shutdown. But the House Energy and Commerce Committee—one of the congressional panels with jurisdiction over this sort of legislation—would never for it, a committee staffer told me.

The lobbying group AdvaMed is "reading the political tea leaves," its CEO Scott Whitaker, said. He imagines lawmakers won't reach an agreement to end the shutdown altogether, but anticipates Congress will start making concessions about bipartisan funding for TSA agents or Federal Trade Commission employees.

The group is hoping to ride that conciliatory wave. Right now, device makers are worried about potential blocks in the FDA's device application pipeline, which is what the legislation is intended to resolve.

Thanks for joining us this week and have a great weekend. I'm all ears when it comes to your two cents, tips, critiques, or coordinating exclusive interviews. Send them my way at jlee1@bloomberglaw.com.

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**FDA Shutdown Prompts Call for Short-Term Fix**

*Andrew Siddons, CQ Roll Call - 1/24/19*

The Food and Drug Administration's drug and medical device divisions were supposed to be spared from the brunt of the shutdown's impact given their reliance on industry-paid fees instead of a government appropriation.

But as the shutdown drags on into a second month, the FDA says those divisions are also running out of money - and work to do - and at some point will have to furlough employees that the agency has struggled to recruit and retain in recent years. One concerned industry group wants Congress to consider a short-term solution if it can't pass any spending bills.

Without a fiscal 2019 appropriation from Congress, the FDA can't legally collect fees from the industries it regulates. So while employees can finish working on reviews that were already paid for and started, new applications that require fees can't be accepted during the shutdown.

"We're concerned that as those languish now, the long-term impact on the health care system can be real and potentially very negative," Scott Whitaker, the president of the Advanced Medical Technology Association, told reporters on Thursday.

Whitaker said that the device industry group is talking to lawmakers about authorizing the FDA to collect the so-called user fees from the industry even during a lapse in appropriations, and tap into other funds that the agency potentially has in reserve.

That would help keep medical product reviews moving and prevent FDA employees from being furloughed and potentially looking for work elsewhere, which would compound the challenge of addressing a review backlog when the agency is funded.

"Uncertainty in employment creates problems in recruitment and retention," Whitaker said.

While it's unclear if such a proposal would become law given that House Democrats have been passing standalone spending bills each week since the new Congress started but the Senate has not accepted them, Whitaker said AdvaMed was "trying to stay ahead and anticipate the possibility that Congress solves small issues when there's unity."
The FDA's medical device division has around three months of funding remaining, but other parts of the agency will run out sooner. At an all-hands meeting with FDA staff on Tuesday, FDA Commissioner Scott Gottlieb said that prescription drug user-fee funds will run out sometime between Feb. 17 and Feb. 28.

Safety surveillance of drugs and devices already on the market will continue even when the user fee money runs out. However, the situation is prompting concern that the FDA could fall behind on more than just individual product approvals.

"Shutdowns do have consequences for the FDA and those consequences last beyond the shutdown itself," said Mark McClellan, an FDA commissioner during the George W. Bush administration, who currently leads the Duke Margolis Center for Health Policy. "This one's getting longer and I'm quite concerned."

McClellan sees the issues occurring later due to the FDA's inability to hire during a shutdown and the lack of staff who can work with drug developers in the early stages of their clinical research processes. The shutdown also will slow down the FDA's efforts to establish new methods for sorting through real-world health records to aid in product approvals.

"If FDA is now going slower on refining its methods for data submission and refining its understanding and approach to designing efficient trials, well, that has an impact not on drugs that are necessarily going to be approved in 2019, but on drugs that are going to be approved in 2020 or beyond," McClellan said.

On Tuesday, dozens of doctors' and patients' groups wrote a letter to Congress that echoed these concerns.

"We fear that this continued shutdown not only puts the current health and safety of Americans at risk, but has begun to put future scientific discovery and innovation in jeopardy," the groups said in a letter.

Drug Industry's Views

Drugmakers themselves have been slightly more muted about the shutdown's impacts, but at a briefing with reporters last week, one of the industry's top lobbyists expressed concern.

"We are concerned, especially as it relates to the FDA, that the FDA has the resources its needs to promote and protect public health," said Stephen Ubl, president of Pharmaceutical Research and Manufacturers of America. "I would commend the commissioner, who I think is doing an exceptional job using resources creatively in terms of carry-over funds and the like, but you know, he's going to run out of resourceful ways to do that eventually, and we're all hoping that the shutdown is resolved quickly."

For now, the FDA predicts that it has multiple months of funding left for its generic drug reviews. But generic launches are also contingent on a parallel process related to the lifetime of patents and exclusivity periods that plays out in the courts - which also do not have fiscal 2019 funding.

Generic drugmakers, who usually make money off of drug supply-chain intermediaries, risk a business disruption if they can't meet a deadline specified in a contract, said Joel Wallace, a partner at the Chicago law firm Schiff Hardin who focuses on pharmaceutical patent issues.

"You run risks of generics missing these agreed-upon launch dates that they've been planning around for possibly years," said Wallace.

So far, that hasn't happened, according to the generic industry trade group Association for Accessible Medicines. "We are not yet aware of specific instances where generic drug or biosimilar approvals have been affected by the shutdown," said Jeff Francer, the group's general counsel.

Medical device industry floats idea to pay user fees during shutdown

Jim Spencer, Minneapolis Star Tribune - 1/24/19

Product approval requests made to regulators since the shutdown began are not moving forward.
WASHINGTON - The trade group that represents dozens of Minnesota's medical technology businesses wants to pay user fees included in the unapproved federal budget to keep medical device reviews going at the U.S. Food and Drug and Administration (FDA) during the partial government shutdown.

The Advanced Medical Technology Association (AdvaMed) is shopping a legislative proposal that lets the device industry pay user fees that currently are not allowed in the shutdown.

The FDA is currently applying user fees paid under the last federal budget to review product approval request that were made before the shutdown, AdvaMed CEO Scott Whitaker told reporters Thursday. But any product approval requests made since the shutdown began more than a month ago are not being considered.

The left over user fees will run out in "two to three months," Whitaker said. With roughly 300 new device submissions submitted each month the backlog grows quickly, he added.

AdvaMed external affairs director Greg Crist said discussions had taken place with legislators on "both sides of the aisle and both sides of the [Capitol] dome." But the trade group would not name the members it had talked to. It does not yet have a sponsor for its legislative proposal.

Whitaker called the device industry's attempt to pay new user fees to the FDA "completely nonpartisan."

He also said AdvaMed is "not assuming that this helps resolve the government shutdown."

Industry-paid user fees are a critical part of funding for the FDA product review process.

**AdvaMed Seeks to Keep Device Reviews Running During Shutdown**

*Ana Mulero, Regulatory Affairs Professionals Society* - 1/24/19

With only about two or three months left of medical device user fees, AdvaMed has drafted a new legislative proposal aimed at continued US Food and Drug Administration (FDA) reviews.

AdvaMed CEO Scott Whittaker and head of regulatory affairs Janet Trunzo discussed the legislative proposal during a conference call with reporters on Thursday. The industry group began discussing the proposal with members of Congress earlier this week, Whittaker said.

The proposal seeks to address the inevitable backlog of premarket submissions to FDA's Center for Devices and Radiological Health (CDRH) because of a government shutdown by ensuring the work on applications continues, and that patient access to medical technologies is safeguarded. The proposal comes as the US faces the longest government shutdown in history.

Whittaker noted that CDRH has historically received about 300 applications for devices in just one month. These include 290 510(k) submissions, five premarket approval applications and five de novo classification requests on average. But "the longer the shutdown goes on, the more and more the backlog will build up and for us, that is a real concern," Whittaker added. This is because FDA cannot accept user fees in a shutdown so any new submissions "just sit there."

As a result of the lapse in appropriations, several from FDA and industry have estimated that CDRH will run out of Medical Device User Fee Amendment user fees within two months. The best case scenario for these funds is three months, Whittaker argued.

The industry group's proposal is two-fold. The first component of the proposal relates to allowing the agency to "continue processing new device applications and their associated user fees during a lapse in appropriations," whereas the second calls for enabling the agency to "tap into" an existing pool of unused user fees for continued user fee-related work. "These fees accumulate each year and at the end of FY 2017 amounted to $7.5 million," AdvaMed said.
Howard Sklamberg, a partner at Akin Gump Strauss Hauer & Feld, discussed some additional details around FDA's budget during a live webinar hosted by the Food and Drug Law Institute on Thursday.

Based on his past experience as an FDA compliance director during the government shutdown in 2013, Sklamberg argued that user fee funds "are quite fluid" compared to appropriations in place and the "lines are somewhat difficult to draw" so FDA "is probably prioritizing the work that it can do" regarding user fee programs. FDA is going to have a lot of submissions to deal with after the shutdown is over and this is going to impact how backlogged devices will be evaluated over time, Sklamberg said.

**Device lobby pushes bill to let FDA take user fees amid shutdown**

*David Lim, MedtechDive - 1/24/19*

Medical device makers are increasingly worried about the negative impact the partial government shutdown will have on their business, AdvaMed executives told reporters on a call Thursday. With FDA unable to accept new medical device applications and user fees, the device lobby estimates approximately 300 applications per month will pile up in a backlog.

AdvaMed is pushing lawmakers to take up draft legislation to allow FDA to process new device applications and user fees during a government shutdown. The idea, the lobby says, is to avoid a delay in patient access to novel medical products and disruption to medtech companies' bottom lines.

But the proposal does not appear to be poised for movement. Democrats on the House Energy & Commerce Committee oppose the legislation, a Democratic committee staffer told MedTech Dive.

Dive Insight:The partial government shutdown, now in its second month, has furloughed more than 40% of FDA employees. That number is set to grow as user fee programs relying on carryover funds run out of money.

AdvaMed CEO Scott Whitaker noted the FDA has three months of device user fee funds remaining in a best-case scenario, and new applications - which average 300 per month - are beginning to pile up.

"For us, that's a bit of a concern: we're talking new and innovative therapies that can help patients," Whitaker said. "As those languish in the pipeline now, the long-term impact on the healthcare system can be real and obviously very negative."

The draft bill language would allow FDA to process new device applications and collect user fees during a shutdown. It would also enable the agency to access "unearned" user fees that are pre-paid by companies, a pool that amounted to $7.5 million at the end of fiscal 2017.

The committee is slated to hold a hearing on the government shutdown on Jan. 31 where FDA is certain to be a topic of conversation.

"These are unprecedented times in terms of the shutdown, and some Hill reactions may be less about the merits of our language and more a reflection of the larger political climate we're offering it in," Greg Crist, AdvaMed Chief Advocacy Officer, told MedTech Dive.

Prescription drug user fees are set to run out within a month, but PhRMA spokesperson Holly Campbell said the drugmaker lobby cannot comment on the AdvaMed proposal.

"As the gold-standard for regulatory review, it's critical the FDA continue to fulfill its public health mission. As an innovative industry, our companies depend on certainty and predictability to bring tomorrow's treatments and cures to patients. We support FDA using its existing authority to deploy user fee funds to continue to review applications," PhRMA said in a statement.

The Alliance for a Stronger FDA, which advocates for FDA appropriations, said its efforts are focused on getting Congress and President Donald Trump to reach an deal to put FDA back to work.
“FDA touches every American every day, usually multiple times. Yet, the protection that FDA provides is largely unseen by the public,” Alliance Executive Director Ladd Whiley told MedTech Dive. “It’s a vast responsibility and, at the moment, that mission is not fully-staffed nor fully-active.”

If the shutdown continues for long, it is possible FDA will employ “creative re-interpretations of the law” around user fees, according to Howard Sklamberg, a former FDA deputy commissioner for global regulations operations and policy. FDA has a good system to track user fees, he said on a webinar Thursday, but it is not like a law firm where employees track billing by the minute.

"It is a very big challenge for the people running the place to say you can work on this and this but not this other thing,” Sklamberg said.

In the event the shutdown drags on and a hefty device application backlog develops, Whitaker said AdvaMed doesn't plan to blame FDA if it cannot meet user fee program timelines such as the 90-day clock for 510(k)s.

"I don't think that will be FDA's fault, it is the reality of what we're dealing with," Whitaker said. "It is something we are reminding Congress, however. In the MDUFA agreement they established certain timelines, and if Congress doesn't act to deal with this issue in the short term, those timelines will be threatened and create a problem for everyone."

AdvaMed Unveils Proposal to Keep FDA Review Process Vibrant During Shutdown

Omar Ford, MDDI - 1/24/19

FDA has about two or three months of device user fees as the backlog of unreviewed devices continues to grow.

As the partial government shutdown drags on, the backlog of unreviewed FDA submissions continues to grow. On Thursday, AdvaMed unveiled a proposal to help chip away at the submissions.

The proposal calls for FDA to continue processing new applications and the associated user fees under the Medical Device User Fee Act (MDUFA). Because of the shutdown, FDA cannot accept these user fees to process new applications.

AdvaMed gave some scope of the problem noting that there are roughly about 300 device applications that are submitted to FDA in a month. Roughly 295 of those are 510(k)s and the remaining 10 are split in half between de novo and PMA applications. The group noted the submission backlog could get out of hand pretty quickly if the issue continues to drag on.

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“Right now, Centers for Device and Radiological Health (CDRH), as I understand, it is using existing user-fee carry over balances to support staff and review submissions,” Scott Whitaker, president and CEO of AdvaMed, said during a call with media. “But those submissions they are reviewing are only the submissions that would have been sent in or received by FDA prior to the shutdown. None of the new applications ... that have come into FDA in the past month are being reviewed now.”

AdvaMed’s measure is also asking legislators to authorize FDA to tap into its pool of "uneearned" user fees to fund device review activities during a lapse in appropriations.

Every year, a number of companies essentially "pre-pay" application or facility registration fees to the agency, and for whatever reason, never submit an application or register a facility. While FDA eventually tries to return these fees or "save" them to pay a company's future fees, these "uneearned" fees often just sit in the agency's account, not dedicated to any specific task. AdvaMed said these at the end of FY 2017 the fees amounted to
$7.5 million.

As it stands now the carryover balances from the device user fee would run out in about another two or three months. Whitaker noted that three months is the "best case" scenario.

AdvaMed said it began having conversations with Congress earlier this week about the proposal. The agency remained tight-lipped about the specific legislators that had seen the proposal and their reactions.

"We're not assuming this helps resolve the government shutdown in any form and we're not getting specific intelligence from anyone who says there is a specific vehicle moving in the next week," Whitaker said. "But what we are trying to do is anticipate what appears to be a protracted government shutdown ... and anticipate the possibility that Congress resolves smaller issues where there's unity. If that situation arises we want to make sure that we're in the que for that conversation."

FDA has also been hit across the board and has even stopped most of its food inspections. The agency said it will resume some inspections, but that would require workers to come in without pay. In the meantime, the country as well as the medtech industry is holding its breath for the matter to be resolved. Whitaker said there is a great sense of uncertainty in the medtech industry right now.

"There's a long and protracted process that companies go through to get a product queued up for FDA, and they've gone through that process," Whitaker, told MD+DI during the call. "It's difficult for [medical device companies] when they have hit a wall and face the uncertainty of when a user-fee program that we've all agreed to isn't operational. It complicates a company's operations significantly not to mention the impact it has on the patients or health systems who might be waiting for a new product."

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