here, and you would have elongated, deliberative debate. What we see happening right now is more like scripted Kabuki theater.

You don't get to offer an amendment, unless we know exactly what the final outcome is going to be. For me, why not have open debate? Have people offer amendments. Debate these bills individually on their own merit.

I think the American people think that is actually what happens here. It is not. And when I go back home to Missouri and talk to people about the process here, it is like from a foreign land. It doesn't make any sense. It is not how State legislatures do it. But this vaulted arena of our Republic has been diminished by the fact that we can't have debate on individual appropriations bills.

We didn't have it, by the way, at the last deadline. We extended the deadline to November 17, which is exactly 30 days from now. And for anybody keeping score at home, that is 9 working days, according to the majority leader's calendar—9 working days.

We are going to end up at the exact same place. On top of that, now there is a supplemental funding request coming related to foreign aid. And my message on that would be the same. These disparate issues—Israel, Ukraine, border, Taiwan—should be debated on their own merits.

There are different considerations. Israel has a lot of support right now. What is happening, the terrorism that has happened, been inflicted upon that country by Hamas and the people, the beheadings, people being burned alive, they have every right to defend themselves. We should consider that request when it comes. It is a very different dynamic when it comes to Ukraine.

We are $112 billion in. No one can define what victory looks like. Seemingly, each round that we get to one of these deadlines, there is more money being asked. It could be $100 billion next year. We don't really know.

These things being lumped together makes no sense. And when it comes to border security funding, color me skeptical of the Biden administration's desire to actually spend that money thwarting illegal immigration. This administration has been hostile to the whole idea. I speak from some experience. My previous job as attorney general of Missouri, we litigated with the Biden administration in court over the ''Remain in Mexico'' policy, title 42, the money that had already been allocated to build a wall that he used for contractors to not build the wall.

This administration is not only complicit, they have encouraged a flood across our southern border. So we ought to have a debate on that on its own as well. And any of the other issues we want to try to lump in or bootstrap an idea that is losing popularity or a proposal that is losing popularity with one that might be popular is something we ought to reject in this Chamber. This is supposed to be the shining example, a unique American institution, a Senate that debates things in long form.

And I come back again. We have spent 0.0 minutes in this place debating the most important thing that we can do each and every year, which is to debate our priorities about funding—what we should increase, what we should decrease. And the result of that, quite frankly, are omnibuses that appear in the middle of the night, no time to read them, that add to our $33 trillion worth of debt. Take it or leave it. If you don't support it, you support a government shutdown.

I think people have had enough. So this is our opportunity. Let us spend the time. Let us be here more than 2 days a week. Let us actually get the work of the people done, debate these bills individually—on their own merit—and restore what this place should be, which is a deliberative body.

I yield back.

The PRESIDING OFFICER (Mr. KELLY). The majority leader.

## EXECUTIVE CALENDAR

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Executive Calendar No. 209; that the Senate vote on the nomination without intervening action or debate; and that the motion to reconsider be considered made and laid upon the table, and the President be immediately notified of the Senate's action.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the nomination.

The legislative clerk read the nomination of Ana A. Escrogima, of New York, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Sultanate of Oman.

Thereupon, the Senate proceeded to consider the nomination.

The PRESIDING OFFICER. The question is, Will the Senate advise and consent to the Escrogima nomination?

The nomination was confirmed.

## LEGISLATIVE SESSION

### MORNING BUSINESS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Senate proceed to legislative session and be in a period of morning business, with Senators permitted to speak therein for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

(At the request of Mr. SCHUMER, the following statement was ordered to be printed in the RECORD.)

## CONFIRMATION OF JENNIFER L. HALL

● Mr. DURBIN. Mr. President, today, the Senate voted to confirm U.S. Magistrate Judge Jennifer Hall to the U.S. District Court for the District of Delaware.

Judge Hall's significant courtroom experience—as both a litigator and as a jurist—will make her an excellent addition to the bench. She received her B.A. from the University of Minnesota, her M. Phil and Ph.D. from Yale University, and her J.D., magna cum laude, from the University of Pennsylvania Carey Law School. Judge Hall clerked on the Federal Circuit and the Third Circuit before beginning her legal career in private practice, working on patent infringement and complex contract disputes. In 2011, Judge Hall became an assistant U.S. attorney in the U.S. Attorney's Office for the District of Delaware, rising to chief of the civil division in 2015. As a prosecutor, she handled a wide range of criminal and civil matters. In 2019, Judge Hall was selected to serve as a magistrate judge in the District of Delaware. Since joining the bench, she has presided over four cases that have gone to verdict or judgment.

Judge Hall has strong support from her home State Senators, Mr. CARPER and Mr. COONS. In addition, she was unanimously rated ''well qualified'' by the American Bar Association.

I strongly support the nomination of Judge Hall, and I am glad to see her confirmed on a broad bipartisan basis.●

(At the request of Mr. SCHUMER, the following statement was ordered to be printed in the RECORD.)

## CONFIRMATION OF JULIA KATHLEEN MUNLEY

● Mr. DURBIN. Mr. President, today, the Senate voted to confirm Julia Kathleen Munley to the U.S. District Court for the Middle District of Pennsylvania.

Born in Carbondale, PA, Judge Munley received her B.A., magna cum laude, from Marywood College and her J.D. from the Dickinson School of Law. She then clerked for Judge Stephen J. McEwen, Jr., on the Superior Court of Pennsylvania before entering private practice in Scranton. During her more than 20 years as a litigator in both State and Federal court, she tried 23 cases to verdict. Notably, she also provided pro bono representation to a Ground Zero emergency responder before the September 11th Compensation Fund and helped him recover an award to compensate him for the health issues that stemmed from his emergency work. In 2016, Judge Munley was appointed to the Lackawanna County Court of Common Pleas by then-Governor Tom Wolf. She won election to a 10-year term in 2017. Over the past 7 years, she has handled both civil and criminal matters, and she has presided over approximately 57 trials.

The American Bar Association unanimously rated Judge Munley ''well qualified'' to serve on the Middle District of Pennsylvania. She has the strong support of both of her home

State Senators—Mr. CASEY and Mr. FETTERMAN—as well as the Pennsylvania legal community. She has deep ties to the Middle District of Pennsylvania, and her significant litigation background and experience as a State court judge will serve her well on the Federal bench.

I strongly support this nominee, and I am glad to see her confirmed.●

## ANIMAL DRUG AND GENERIC DRUG USER FEE AMENDMENTS OF 2023

Mr. SANDERS. Mr. President, I ask unanimous consent to have printed in the RECORD at the appropriate place the commitment letters for the Animal Drug User Fee Amendments of 2023 and the Animal Generic Drug User Fee Amendments of 2023.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

ANIMAL DRUG USER FEE ACT REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2024 THROUGH 2028

The goals and procedures of the Food and Drug Administration (FDA or the Agency) as agreed to under the ''Animal Drug User Fee Amendments of 2023'' are summarized as follows:

I. DEFINITIONS

1. For the application/submission goals below, the term ''review and act on'' is understood to mean the issuance of a complete action letter after the complete review of an animal drug application, supplemental animal drug application, or investigational new animal drug (INAD) submission which either (1) approves or conditionally approves an animal drug application or approves a supplemental application or notifies a sponsor that an INAD submission is complete or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or INAD submission and, where appropriate, the actions necessary to place such an application, supplemental application, or submission in condition for approval.

Within 30 days of receipt, FDA shall refuse to file an animal drug application, supplemental new animal drug application, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the Agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed.

Within 60 days of receipt, FDA will refuse to review an INAD submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110.

A decision to refuse to file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The Agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

2. A minor amendment is understood to mean information requested by FDA during the review of the application or investigational submission. FDA may request minor amendments to animal drug applications, supplemental new animal drug applications, and INAD submissions during its review of the application or submission. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. The same policy applies for INAD submissions.

3. The term ''submission date'' or the date of receipt means the date the FDA Center for Veterinary Medicine (CVM) Electronic Submission System (ESS) receives an application or submission. Upon receipt of an application or submission, the CVM ESS creates an electronic receipt that contains the date of receipt and is sent to the submitter.

4. The term ''labeling supplement'' is understood to mean certain applications as described in 21 CFR 514.8(c)(2)(i)(A) and (D) that require approval of a supplemental application prior to distribution of the drug made using the change.

5. The term ''presubmission conference'' is understood to mean one or more conferences between a potential applicant and FDA as described in 21 CFR 514.5 to reach a binding agreement establishing a submission or investigational requirement.

6. The term ''dosage characterization'' is understood to mean a justification of the dosage (dose or dose range, dosing frequency, and the dosing duration) and a characterization of the critical aspects of the dose-response relationship related to each intended use and associated conditions of use.

II. APPLICATION/SUBMISSION GOALS

All applications and submissions under the Federal Food, Drug, and Cosmetic Act sections 512(b) and 571 must be created using the CVM eSubmitter tool and submitted to the Agency through CVM's ESS.

The submissions in this section are sentinel submissions. CVM's performance toward meeting the associated goals will be included in the performance reports required by section 740A(a) of the FD&C Act.

Work Queue Review Procedures: The Agency will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Application/Submission Goal timeframe will be reviewed with the highest possible priority among those pending.

*1. Original New Animal Drug Applications (NADAs), Applications for Conditional Approval (CNADAs), and Reactivations*

Review and act on 90 percent of original NADAs and CNADAs within 180 days after the submission date.

An application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the issue(s) presented in the application.

The Agency will review and act on 90 percent of reactivated applications:

i. Within 180 days after the reactivated application submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;

ii. Within 135 days after the reactivated application submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the application reactivation must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and

iii. Within 180 days after the reactivated application submission date if the reactivation is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the reactivated application.

The Agency will generally favor using the shorter reactivation timeframe of 135 days, where possible. The Agency will state in the incomplete letter the appropriate timeframe for review of the reactivation. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to reactivation of the application. The shorter review time of 135 days for reactivated applications for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of an application.

*2. Administrative NADAs and CNADAs*

Review and act on 90 percent of administrative NADAs and CNADAs [(C)NADAs filed after all scientific decisions already have been made as part of the investigational new animal drug process] within 60 days after the filing date.

*3. Non-manufacturing Supplemental NADAs*

Review and act on 90 percent of non-manufacturing supplemental NADAs (i.e., supplemental NADAs for which safety or effectiveness data are required) within 180 days after the submission date.

A supplemental NADA is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the supplement and reach a decision on the issue(s) presented in the supplement.

The Agency will review and act on 90 percent of reactivated supplements:

i. Within 180 days after the reactivated supplemental NADA submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;

ii. Within 135 days after the reactivated supplemental NADA submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the reactivation to the supplemental application must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and

iii. Within 180 days after the reactivated supplemental NADA submission date if the reactivation to the supplemental application is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the reactivated supplement.

The Agency will generally favor using the shorter reactivation timeframe of 135 days, where possible. The Agency will state in the incomplete letter the appropriate timeframe for review of the reactivation. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to the reactivation of the supplement. The shorter review time of 135 days for reactivated supplements for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of a supplemental application.

*4. Prior Approval Manufacturing Supplemental Animal Drug Applications and Reactivations*

Review and act on 90 percent of Prior Approval manufacturing supplemental animal drug applications within 120 days after the submission date. A Prior Approval manufacturing supplemental application includes: one or more major manufacturing changes as described in 21 CFR 514.8(b)(2)(ii) and in accordance with Guidance for Industry 83 (Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA); and, changes submitted as ''Supplement-