

Indonesia got a \$500 million loan from a Chinese state-owned company.

So a bipartisan group of Senators, myself included, said let's figure out a way to reinstate the penalties against ZTE as a part of the annual defense authorization bill, but when it came time to hammer out the differences between the Senate's bill and the House's bill, Republicans watered down the ZTE penalties. Republicans in both Chambers caved to the White House and handed a big gift to China at the expense of American jobs and national security.

In my view, it is inexcusable that the plan put together by Senators on both sides—a plan that would have protected our security and punished a serial violator of U.S. sanctions—was stripped out of this bill. The weaker House proposal that took its place doesn't go nearly far enough to fight the espionage threat that the Trump administration's own counterintelligence nominee testified to.

Bottom line, Trump's ZTE deal is bad for American security and American jobs. The House got it wrong with their weaker legislation. The Senate was under no obligation to accept their watered-down bill. That is why I voted no, and that is why members who voted for this proposal cannot claim innocence when it comes to letting ZTE off the hook for its violations of our sanctions.

#### NOMINATION OBJECTION

Mr. WYDEN. Mr. President, today I am placing a hold on the nomination of Justin Muzinich to be Deputy Secretary of the Treasury. I will maintain that hold until the Treasury Department provides the Senate Finance Committee information and documents related to Russia and its financial dealings with President Trump and his associates, as well as outside organizations Russia used to help elect him. I originally asked for these documents on May 10, 2017, and have yet to receive an answer of any kind.

I have stated repeatedly that we must follow the money if we are going to get to the bottom of how Russia has attacked our democracy. That means thoroughly reviewing any information that relates to financial connections between Russia and President Trump and his associates, whether direct or laundered through hidden or illicit transactions.

The Treasury Department for which Mr. Muzinich is nominated to serve as the No. 2 official is responsible for much of this information. The Treasury Department authorities include intelligence and enforcement functions to combat financial crimes and threats, including money laundering.

For these reasons, I will object to any unanimous consent request concerning the nomination of Mr. Muzinich.

#### REMOVAL OF NOMINATION OBJECTION

Mr. WYDEN. Mr. President, I am lifting my hold on the nomination of Mr. Jason Klitenic to be General Counsel of the Office of Director of National Intelligence. Senator GRASSLEY and I have received a response to our March 6, 2018, letter regarding the Intelligence Community Office of Inspector General, OIG, and the termination of its Executive Director of Intelligence Community Whistleblowing and Source Protection, "Executive Director." In addition, I have been provided access to documents related to the Executive Director's termination. I remain concerned about the circumstances surrounding that termination and look forward to reviewing them further, even as I work with my colleagues to strengthen protection for intelligence community whistleblowers. My hold on the nomination of Mr. Klitenic was based on these concerns and not on the qualifications of the nominee.

#### AFGHAN RELIGIOUS MINORITIES

Mr. MENENDEZ. Mr. President, today I would like to raise concerns about violence perpetrated against religious minorities in Afghanistan, particularly the Sikh and Hindu communities.

One month ago today, on July 1, a suicide bomber attacked a crowd of Afghan Sikhs and Hindus as they gathered to meet with Afghan President Ashraf Ghani on his visit to Jalalabad. At least 19 innocent civilians lost their lives, and 10 more were wounded. The attack also claimed the life of Awtar Singh Khalsa, the only Sikh candidate running in Afghanistan's upcoming Parliamentary elections, and Rawail Singh, a prominent community activist.

Of the 19 killed, 17 belonged to the minority Sikh and Hindu religious groups.

I condemn this cowardly and heinous attack and all those like it in the strongest possible terms. The Islamic State in Afghanistan claimed responsibility for the July 1 attack and multiple attacks on civilian targets since then. It is impossible to overstate the depravity of this group that resorts to killing innocent people when it fails to otherwise advance its cause.

We cannot allow attacks such as this on civilians to pass unremarked, nor can we ignore violence specifically targeted toward Afghanistan's diverse religious minorities. Sikhs and Hindus in Afghanistan have long faced systemic discrimination, economic marginalization, and, as this latest attack only serves to further illustrate, unspeakable violence. Members of Sikh and Hindu communities report facing prejudice, harassment, bullying of children, and attacks from militant groups; disproportionate denial of their rights in Afghan courts; and even interference in their efforts to cremate

the remains of their dead and peacefully adhere to other tenets of their faiths. Only a few places of worship remain available to Sikhs and Hindus in Afghanistan, many of whom face discrimination so severe that they choose to leave the country.

For his part, Mr. Khalsa's candidacy was a testament to the strength and resiliency of Afghan Sikhs who, even in the face of unrelenting hardship, remain dedicated to their country's democratic future. After last month's attack in Jalalabad, that kind of political engagement has been dealt a terrible blow.

The recent and ongoing attacks against Sikhs and Hindus come against a broader backdrop of sustained violence in Afghanistan. According to recent figures from the U.N. Assistance Mission in Afghanistan, more Afghan civilians were killed in the first 6 months of 2018—1,692 deaths—than in any other 6-month period over the last 10 years. This figure demonstrates the continuing devastation caused by the past 17 years of war in Afghanistan and the need for the United States and our partners in the international community to redouble efforts toward reaching a negotiated political settlement that can bring this long war to an end. Without peace in Afghanistan, the scourges of terrorist and insurgent violence, illegal narcotics trafficking, corruption, and limited government capacity to deliver justice and other public services will remain, and the Afghan people will continue to suffer.

All Afghans, of all beliefs, stand to benefit from the end of bloodshed. Cowardly attacks against religious minorities such as the one that took place in Jalalabad only serve to damage prospects for a peace that can benefit all.

The Jalalabad attack is also a stark reminder of the sectarian violence facing religious minorities in many parts of South Asia. Across the region, members of minority religious groups are being denied their basic human rights and the ability to live free from discrimination or violence. Attacks like the one in Jalalabad underscore the urgent need for governments in the region to hold perpetrators accountable and to enact laws and policies that foster tolerance, protect minorities' rights, and respect individual freedoms.

America is also home to many Sikh and Hindu communities living in every U.S. State, who, like so many minority groups in our diverse country, have played a positive role in the social, cultural, and economic development of the United States. In my home State of New Jersey, I am reminded every day of how much better off we all are for the contributions of Sikh and Hindu communities to our great State and Nation. This is despite the fact that individuals in the United States of South Asian heritage and representing diverse faiths have faced attacks on account of their identity, including harassment, discrimination in employment and schooling, or even violent

hate crimes, such as the devastating mass shooting in Oak Creek, Wisconsin Sikh Gurdwara in 2012.

Just as we as a country will not stand for religious intolerance at home, we must not fail to speak out against it abroad. Respect for religious and other basic human freedoms worldwide is a core American value, one that bears repeating whenever and wherever those freedoms are threatened.

In closing, I will say it again: I condemn the July 1 attack against Afghan Sikh and Hindu civilians and any individual or group that would harm innocent people based on their peaceful religious beliefs. We stand in solidarity with religious minorities in Afghanistan, in South Asia, and around the world.

#### ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2018

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD the commitment letter for the Animal Generic Drug User Fee Agreements of 2018.

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

##### ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2018

##### AGDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FOR FY'S 2019 THRU 2023

The goals and procedures of the Food and Drug Administration (FDA or the Agency) as agreed to under the "Animal Generic Drug User Fee Amendments of 2018" are summarized as follows:

##### APPLICATION/SUBMISSION GOALS

Beginning October 1, 2018, all applications and submissions under the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 512(b) must be created using the eSubmitter tool and submitted to the Agency through the FDA Center for Veterinary Medicine (CVM) Electronic Submission System (ESS).

##### 1. Original Abbreviated New Animal Drug Applications (ANADAs) and Reactivations

Review and act on 90 percent of original ANADAs within 240 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. If the Agency determines that the deficiencies are not substantial, the Agency will review and act on 90 percent of reactivated applications within 120 days after the reactivated ANADA submission date. This shorter review time for reactivated ANADAs 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. If the Agency determines that the deficiencies are substantial or new substantial information is provided, the Agency will review and act on 90 percent of reactivated applications within 240 days after the reactivated ANADA submission date.

##### 2. Administrative ANADAs

Review and act on 90 percent of administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the generic investigational new animal drug (JINAD) process, i.e., prior to the submission of the ANADA) within 60 days after the sub-

mission date. Paragraph IV certification applications (FD&C Act section 512(n)(1)(H)(iv)) submitted as administrative ANADAs will be excluded from the administrative ANADA cohort.

##### 3. Prior Approval Manufacturing Supplemental ANADAs and Reactivations

Review and act on 90 percent of Prior Approval manufacturing supplemental ANADAs within 180 days after the submission date. A Prior Approval manufacturing supplemental ANADA includes: one or more major manufacturing changes according to 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-Changes Being Effectuated in 30 Days" that require prior approval according to 21 CFR 514.8(b)(3)(v)(A). If a Prior Approval supplement does not clearly identify any major manufacturing changes, the Prior Approval supplement will be designated by the Agency as a "Supplement-Changes Being Effectuated" with a 270 days review goal (see "Supplement-Changes Being Effectuated Manufacturing Supplemental ANADAs and Reactivations" below).

A submission is incomplete if it requires additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission. If the Agency determines that the deficiencies are not substantial for manufacturing supplements requiring prior approval, the Agency will allow the manufacturing supplements to be resubmitted as "Supplement-Changes Being Effectuated in 30 Days" as described in 21 CFR 514.8(b)(3) and the drug made with the change can be distributed 30 days after the resubmission according to 21 CFR 514.8(b)(3)(iv). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 270 days after the resubmission date of a complete submission. If the Agency determines that the deficiencies remain substantial or new substantial information is provided, prior-approval is required according to 21 CFR 514.8(b)(3)(v)(A). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 180 days after the re-submission date of a complete submission.

##### 4. Supplement—Changes Being Effectuated Manufacturing Supplemental ANADAs and Reactivations

Review and act on 90 percent of "Supplement—Changes Being Effectuated" manufacturing supplemental ANADAs and reactivations submitted according to 21 CFR 514.8(b)(3)(vi) and in accordance with Guidance for Industry 83 (Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA), including manufacturing changes not requiring prior approval according to 21 CFR 514.8(b)(3)(iv), within 270 days after the submission date.

##### 5. Generic Investigational New Animal Drug (JINAD) Study Submissions

Review and act on 90 percent of JINAD study submissions within 180 days after the submission date. A submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission. If the Agency determines that the deficiencies are not substantial, the Agency will review and act on 90 percent of resubmitted JINAD study submissions within 60 days after the receipt date of a complete study submission. This shorter review time for resubmitted JINAD study submissions is not intended to prevent

the use of minor amendments during Agency review of a study submission. If the Agency determines that the deficiencies are substantial or new substantial information is provided, the Agency will review and act on 90 percent of resubmitted JINAD study submissions within 180 days after the receipt date of a complete study submission.

##### 6. JINAD Protocols

Review and act on 90 percent of JINAD submissions consisting of protocols without substantial data, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA, within 75 days after the submission date. Allow comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as protocols without substantial data in a JINAD file. The Agency will review and act on 90 percent of JINAD submissions consisting of protocols without substantial data within 75 days after the submission date of the protocol. For potentially more complex comparability protocols, for example sterile process validation protocols, the sponsor should discuss and have Agency concurrence regarding the appropriate filing strategy.

For the application/submission goals above, the term "review and act on" means the issuance of either: (1) a complete action letter that approves an original or supplemental ANADA or notifies a sponsor that a JINAD submission is complete; or (2) an "incomplete letter" that sets forth in detail the specific deficiencies in an original or supplemental ANADA or JINAD submission and, where appropriate, the actions necessary to place such an original or supplemental ANADA or JINAD submission in condition for approval. Within 30 days of receipt of the application, FDA shall refuse to file an original or supplemental ANADA, or their reactivation, that 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 of the submission, FDA will refuse to review a JINAD submission that 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.

FDA may request minor amendments to original or supplemental ANADAs and JINAD 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 JINAD submissions.

Sponsors are not required to submit study protocols for review. However, for each voluntarily submitted protocol for a study that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an original