each year, it is impossible to reschedule a fair for a different time.

According to the IAFE, each year the operation of agricultural fairs results in $4.67 billion for the US economy and provides thousands of jobs.

Fairs and their carnival partners on the midway have been devastated by the cancellation of events thus far. IAFE estimates a loss of revenue exceeding $1.4 billion to the fair and festival core organizations just for March through May.

The Outdoor Amusement Business Association (OABA) represents some 200 carnivals, 15 circuses and hundreds of traveling food/game concessionaires in the United States. The vast majority of their members are small, family businesses, many in their third or more generation of ownership. The OABA estimates 350 carnival events have currently been closed through May I. Based on historical attendance data and this estimated performance cancellations, the lost revenue to carnival operators is near $250 million.

Should the need for social distancing or total quarantine exist into the summer, the economic devastation will inevitably put these community organizations as well as many of the small businesses in the allied sectors out of business. Thousands of jobs will be lost.

Because both the not-for-profit fair sector and the outdoor amusement business segment are unique subsets of our economic and commercial activities, we must ensure they are not excluded from any current or new SBA programs and they are just as eligible for federal support from the new $500 billion fund provided to the Treasury as any Wall Street traded company.

Ms. LOFGREN. Mr. Speaker, I rise in support of the bipartisan agreement reached on the Senate Amendment to H.R. 748, the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

This bill will provide immediate relief to my constituents in California's 19th District by providing direct cash payments to families, expanding unemployment, infusing $150 billion investment in our healthcare system, and supporting small businesses with hundreds of billions that will also ensure continued employment for America's workers.

As one of the hardest hit communities in the country, we know that Santa Clara County cannot afford to wait any longer. Our hospitals, health centers, and county health officials specifically need the healthcare investment immediately to add capacity, work toward universal testing, and procure more masks, gloves, and gowns to guarantee our healthcare workers have the appropriate protections to do their jobs safely and effectively.

Families in our community and around the country need immediate assistance in the form of direct cash payments and expanded unemployment insurance (UI). This week a record number of Americans filed unemployment claims. They need this substantial expansion and reform of UI benefits, which includes a $600 increase in the weekly maximum benefit and coverage for self-employed and gig economy workers, like the thousands of tech industry workers in Silicon Valley.

California small businesses need the $350 billion lifeline to help cover rent, mortgage, and utility payments and keep workers employed so that they can pick up where they left off when this crisis is over. In addition, the $10 billion for small business emergency grants will provide entrepreneurs and family-sustaining employers in Santa Clara County with more immediate assistance.

The CARES Act also includes $25 billion for public transit agencies, like the Santa Clara Valley Transportation Authority, to keep service running while keeping employees and passengers safe. An additional $3 billion dollars in grants will keep contracted workers employed at our nation's airports, including at San Jose Mineta International Airport.

This bill will provide much needed and awaited relief for American workers, families, small businesses, and healthcare systems, but it is apparent that more will need to be done. I will continue to work with my colleagues in the House and Senate to address specific community needs in future legislation.

Ms. LOFGREN. Mr. Speaker, Americans have voted during times of great strife in the past. They voted during the Civil War, and in the shadow of World War II. Americans stand united to vote this year, as well. Coronavirus must not impede our elections.

Some states are postponing primaries and planning for a large increase in absentee voting this November. State and local officials need time and adequate resources to ensure an orderly election.

The Senate Amendment to H.R. 748, the Coronavirus Aid, Relief, and Economic Security (CARES) Act, provides $400 million to the Election Assistance Commission to make grants that prevent, prepare for, and respond to the pandemic and the 2020 elections. The money will be provided as ''Election Security Grants.'' Although this is an important down payment and a first step, I am concerned that it falls short of what is necessary.

By contrast, the House's Take Responsibility for Workers and Families Act (H.R. 6379), which I coauthored, would have provided $4 billion in funding to states to carry out this year's elections. It would require officials to mail an absentee ballot to all registered voters during an emergency, including COVID–19. The ballot would be provided with prepaid return postage and a self-sealing envelope. It would set a minimum nationwide standard of 15 consecutive days of early voting and no-excuse absentee voting. The House bill would also require online voter registration and same-day registration—important solutions to cover voters who may have been wrongfully purged or otherwise unregistered.

There is more to do to protect our democracy and bolster its resilience. The House's package provides those milestones. I will continue to work with my House and Senate colleagues to address election preparedness in future legislation to respond to this pandemic.

Ms. FOXX of North Carolina. Mr. Speaker, time is of the essence. Our country has been upended by COVID–19. Businesses have shuttered their doors, families sitting around their kitchen tables are struggling to make ends meet, our healthcare workers are stretched thin, and our economy has been hurt.

Yet, earlier this week, some of my colleagues across the aisle attempted to commandeer negotiations to advance socialist provisions that are antithetical to combatting COVID–19. Now is not the time for political showmanship. The eyes of our nation are affixed to Congress, and it's our solemn duty to protect the American people.

To our nation's deeply committed healthcare workers who put their lives on the line to treat and protect patients, our nation's truck drivers who deliver food and critical supplies to grocery stores and businesses, manufacturers who have stepped up to the plate to produce PPE's and other essential equipment, and our steadfast police officers and first responders on the front lines of this crisis, we truly owe you a debt of gratitude. May God bless you all.

Mr. WILSON of South Carolina. Mr. Speaker, during a time when our nation is facing an unprecedented crisis, I am grateful to join President Donald Trump in supporting the CARES Act to provide American families recovery from the coronavirus. Even though I am not completely happy with every aspect of this bill, it does addresses multiple parts of our economy, specifically, it expedites resources to healthcare providers and patients, supports small businesses, to keep jobs alive, and provides direct assistance to American families.

To fast track a national recovery, I ask that we all do our part in stopping the spread of the coronavirus by following the Center for Disease Control's guidelines. The health and safety of our nation is the top priority, I am confident we will push through and come out of this crisis stronger than ever.

Mr. LATTA. Mr. Speaker, I include in the RECORD this Statement of Intent on Data Required for General Recognition of Safety and Effectiveness.

The OTC drug monograph reform legislation requires that nonprescription drugs be shown to be generally recognized as safe and effective. This standard of general recognition is based on statutory language that has been in the Federal Food, Drug, and Cosmetic Act since its enactment in 1938, and it was incorporated in the regulations issued by the Food and Drug Administration when the OTC Drug Review was established in 1972. In particular, 21 CFR 330.10(a)(4)(i) states that:

. . . Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

Similarly, 21 CFR 330.10(a)(4)(ii) states that:

. . . Proof of effectiveness shall consist of controlled clinical investigations as defined in §314.126(b) of this chapter, unless this requirement has been waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical trials by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific investigation will not be considered. General recognition shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

These regulations clearly recognize the importance of what is now termed ''real world evidence,'' including experience from marketing, in determining general recognition of

safety and effectiveness. In addition, they recognize that results of clinical studies supporting general recognition of safety and effectiveness will in most instances be contained in the published scientific literature. Such publications seldom, if ever, contain the same level of detail as the clinical study reports and data tabulations submitted in support of new drug applications, but it has long been understood that they may form the basis for determinations of general recognition of safety and effectiveness under the OTC monograph system. Finally, the regulations clearly permit determinations of general recognition of safety and effectiveness to be based on sources of information other than the published scientific literature, including, for example, unpublished data from studies carried out by federal government agencies or other competent bodies which are made available to the FDA in the process of administering the OTC monograph system. It is our intent that the FDA should continue to apply these standards in making determinations of general recognition of safety and effectiveness under the monograph reform legislation.

STATEMENT OF INTENT AS TO MINOR CHANGES PROVISION

Under current law, dosage forms for monograph OTC drugs have largely been limited to the technology in use in 1972, when the OTC Drug Review began. The only mechanism for introducing truly innovative dosage forms has been through the new drug application (NDA) process, which entails disproportionate costs and delays. This has proved to be a significant hurdle to use of new technologies that could offer consumers greater convenience and choice in OTC drug products.

The legislation creates two new procedures for introducing innovative dosage forms for monograph OTC drugs that would not otherwise be permitted under subsection (b).

First, sponsors may initiate proceedings for the issuance of administrative orders under subsection (c) to provide for use of novel dosage forms.

Second, in appropriate cases, sponsors may make minor changes in dosage forms without prior approval from FDA, using the procedure in subsection (d). The sponsor must maintain information necessary to demonstrate that the change will not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the drug in comparison to a suitable reference product. The sponsor must also submit updated drug listing information to FDA within 30 days of introducing the new product to the market. FDA will have the right to demand access to the relevant files, and there will be a quick and simple procedure to resolve any disagreement between FDA and the sponsor as to the adequacy of the data supporting the change. Before the subsection (d) procedure takes effect, FDA must issue administrative orders setting out the type of information required to support minor changes in dosage forms. In issuing those orders, FDA will take account of standard procedures and practices for evaluating the quality of drug products, including applicable provisions of the United States Pharmacopeia/National Formulary, as well as special needs of populations, including children.

The procedures in subsections (c) and (d) will only be required for changes that would not otherwise be permitted under subsection (b). Thus, changes in excipients or other inactive ingredients and similar aspects of formulation of monograph OTC drug products will be permitted without prior approval provided they are fully consistent with requirements of applicable monographs or administrative orders and with general requirements for monograph OTC drugs, including, among other things, requirements for the use of suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays. When such changes are made, sponsors will be required to submit updated drug listing information to FDA within 30 days of introducing a product to the market.

USP AND INTERNATIONAL CONFERENCE ON HARMONIZATION AS SOURCES FOR STANDARDS DESCRIPTIONS IN MINOR CHANGES ADMINISTRATIVE ORDER WITH GUIDANCES BY ROUTE OF ADMINISTRATION

An important objective of this legislation is to create procedures that will promote innovation by permitting manufacturers to introduce certain new and improved dosage forms for nonprescription monograph drugs without the need for prior FDA approval. Manufacturers will be required to maintain files containing data showing that such changes will not affect the safety or effectiveness of their products and provide those files to FDA on request. The bill directs FDA to issue administrative orders and guidances describing the types of changes that can be made without prior approval and the data that manufacturers should have on file. Subsection (d)(3)(B) requires that, in issuing such orders and guidances, FDA should take account of relevant public standards for evaluating the quality of drug products. Examples of the standards that FDA should take into account include the monographs and other provisions of United States Pharmacopeia/National Formulary and guidelines issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). FDA is a major stakeholder in both organizations, and it is appropriate that any administrative orders it adopts should take account of relevant requirements issued by them.

LABELING CONSIDERATIONS UNDER MINOR CHANGES PROVISION

This bill establishes procedures under which FDA can issue binding administrative orders setting forth the requirements under which nonprescription drugs will be regarded as generally recognized as safe and effective and may be lawfully marketed without an approved new drug application. It is intended that these orders will be similar in content to the monographs that FDA has issued under the current procedures of the Over-the-Counter (OTC) Drug Review. That is, they will contain provisions concerning active ingredients, dosages and dosage forms, and instructions for safe use of the products to which they apply and, where appropriate, other conditions required to assure safety and effectiveness. Nonprescription drugs marketed under such orders must also comply with general requirements of the Federal Food, Drug, and Cosmetic Act and applicable FDA regulations, including general requirements for labeling and quality. As is true under the current regulatory system, labels and labeling for nonprescription drugs may contain additional information, including brand names, promotional statements, and other information, provided that any such information is truthful and non-misleading.

Mr. HILL of Arkansas. Mr. Speaker, the health and economic crisis caused by COVID–19 is unprecedented in our lifetimes. We are seeing the number of cases rise throughout the country, including in my home state of Arkansas. After being in nearly constant communication with the Arkansas Governor's office, hospitals, first responders, and business leaders in Arkansas, relief from the federal government is needed to help fight this virus and help keep our businesses from going under. It is for these reasons that if a roll call vote is called for the vote on the Coronavirus Aid, Relief, and Economic Security Act, I will vote yes.

Mr. FLORES. Mr. Speaker, I rise to state that if there is a recorded vote, I would vote: ''yea'' on H.R. 748, Coronavirus Aid, Relief, and Economic Security Act, as amended.

As referenced in my earlier remarks during the H.R. 748 debate, this legislation takes vital steps to send cash to struggling Texas families, provide economic relief for small businesses and working Americans, and give our healthcare providers more of the resources they need.

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to House Resolution 911, the previous question is ordered on the motion.

The question is on adoption of the motion.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. MASSIE. Mr. Speaker, I demand a recorded vote.

A recorded vote was refused.

Mr. MASSIE. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. The Chair will count for a quorum.

A quorum is present.

The motion to concur was agreed to.

A motion to reconsider was laid on the table.

ADJOURNMENT

The SPEAKER pro tempore. Pursuant to section 7(b) of House Resolution 891, the House stands adjourned until 3 p.m. on Tuesday, March 31, 2020.

Thereupon (at 1 o'clock and 27 minutes p.m.), under its previous order, the House adjourned until Tuesday, March 31, 2020, at 3 p.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

4184. A letter from the Director, Regulations Management Division, Department of Agriculture, transmitting the Department's final rule — Special Servicing of Telecommunications Programs Loans for Financially Distressed Borrowers (RIN: 0572-AC41) received March 17, 2020, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Agriculture.

4185. A letter from the Deputy General Counsel, Office of Elementary and Secondary