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

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

Farmers and their carnival partners on the midway have been devastated by the cancellation of events thus far. IAIE 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 1. 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 cancellation persist 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 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 communities with hundreds of millions of dollars that will also continue 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 to 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 include 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, 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 the regulations issued by the Trump Administration, 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 do our part in eradicating 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 to be safe when prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition 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 not inadequate for 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 would be required for General Recognition of Safety and 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.

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 of 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 a new product to the market.

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 will not necessarily include 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, hospital 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 to reconsider.

The motion to reconsider was laid on the table.

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 reconsider was agreed to.

A motion to reconsider was laid on the table.

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)(18)(A); Public Law 104-121, Sec. 501; (110 Stat. 868); to the Committee on Agriculture.

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