AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2019

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2019

WEDNESDAY, MARCH 7, 2018.

COMMODITY FUTURES TRADING COMMISSION

WITNESS

J. CHRISTOPHER GIANCARLO, CHAIRMAN, U.S. COMMODITY FUTURES TRADING COMMISSION

Mr. ADERHOLT. Good morning, and the subcommittee will come to order. And this is our first hearing for 2018 for the Ag Subcommittee where we will be looking at the 2019 budget request for the Commodities Future Trading Commission.

So, while it has been an interesting and we have had a busy year so far with ongoing discussions and negotiations revolving around funding levels for the current fiscal year, our full committee chairman, Mr. Frelinghuysen, has requested that we begin our work and start reviewing the President's budget request for 2019. And during this extremely busy time for my colleagues, I appreciate my colleagues for taking time to be here, of course, and certainly our ranking member, Mr. Bishop.

This is my sixth year to chair the Ag Subcommittee of Appropriations, and as I have done in past years, we are establishing goals for the subcommittee as we make our way through the fiscal year 2019 appropriations process: The first goal is to bolster prosperity and economic wellbeing in rural America and the farm economy; the second goal, conduct fair and transparent oversight to agencies' activities and public resources; third, promote economic growth through effective and efficient regulation and minimization of regulatory overreach; and, last, and certainly not least, to protect the health and safety of people, plants and animals.

The Commodity Futures Trading Commission continues to face new challenges as an ever-shifting swaps, futures, and option markets adapt to evolutions in technology and to the new actors which enter and operate within these markets. Meanwhile, we so often hear the phrase in my home State of Alabama that the agency must maintain its roots that grew out of the agriculture sector.

We will discussion the President's fiscal year 2019 budget request of $281.5 million and other matters related to the Commission. The President's request, budget request, is in line with the Commission's own request and includes the repeated proposal many prior administrations have made to fund a portion of the

Commission with user fees, an issue that we think should be left up to the authorizing committee to debate that.

The CFTC has been a popular topic of conversation over years, and we will discuss some of the management and budget issues that have arisen during and prior to your term as Chairman and what you have done to address them. Additionally, I am sure that some policy issues will arise, not the least of which will be the topic of bitcoin futures and cryptocurrencies.

Briefly, I would like to recognize one of your accomplishments, Mr. Chairman, that I have brought up over the years, and it is related to the topic of leasing costs and related issues. Last year, you informed the committee that you were able to actually save money on your Kansas City office lease over its lifetime, and the committee wants to commend you for this action, and it is one that I requested of your predecessors on numerous occasions. And we will revisit this matter to ensure that we actually see that it materializes in savings.

With regard to new developments in the marketplace, I have spoken before on the need for the Commission to invest in technology, and that is why we have included a set-aside specifically for this purpose each fiscal year of my chairmanship. This is the best way for the Commission to leverage its resources in terms of enforcement and allowing for new innovation in the marketplace. Simply hiring more people won't stop the advanced degrees to which algorithmic trading and cryptocurrencies go to rip-off customers inside the marketplace.

Over the past 8 years, we have had a healthy debate on this subcommittee over the size of the swap markets. I was glad to see the Commission weighing in on this matter and look forward to exploring it further. I think most everyone on this subcommittee was glad to see a single market could equate to several times the size of the entire world's economy, and very curious of how that happens.

But, Chairman Giancarlo, we look forward to discussing these matters with you as we start our hearing today. There is a lot of work before this Congress and this administration and your agency in order that we keep moving in the right direction.

Finding the right balance between over-regulation and a safe and effective marketplace is essential, and it fits within the main focus of this subcommittee, which is to find the right size for your agency's budget. Again, thank you for being here, and we look forward to the discussion today and as we go through the members as they ask questions.

And before I do recognize the ranking member, Mr. Bishop, for his opening statement, I would remind everyone that we will try our best to strictly adhere by the 5-minute rule. And when you are asked to speak, please push the talk button on your microphone, and then you will be ready to go.

Mr. Bishop, thank you again for your presence and for your work on subcommittee, and the floor is yours.

Mr. BISHOP. Thank you very much, Mr. Chairman. And I appreciate your cordiality and our working together.

I would like to again take this opportunity to welcome Mr. Giancarlo, Chairman, to our subcommittee.

We find ourselves again in the uncomfortable position of having a hearing on the agency's 2019 budget request when we haven't finalized the 2018 appropriation.

Last year, the CFTC and OMB differed on the funding level, but this year, it appears that the request is on the same page, which makes our jobs a little easier. As I said last year, CFTC is extremely relevant to our farmers, our ranchers, and persons and other industries who use financial instruments to hedge their risk. I don't want to be the prophet of doom and gloom, but we need to understand the damage that our economy suffered in the Great Recession. We lost about 8½ million jobs. The unemployment rate increased from 4.7 to 10.1 percent in October of 2009. Ten million families lost their homes, and nearly a quarter of a million small businesses had to close their doors for good. Many on Wall Street and elsewhere tell us that those days will never come again, and we hope that that is true. We don't know that, and the historical record may suggest otherwise.

Dodd-Frank has been the biggest defense that we have had against another catastrophe.

I know, Chairman Giancarlo, that you are not one who wants to undo or unravel Dodd-Frank, and we thank you for that. You have reached across the aisle to me and to my colleagues, and I also thank you for that.

I look forward to working with you, and I look forward to your testimony today. And I thank you for the opportunity to welcome the Chairman, Mr. Chairman.

And at this time, I will yield back my time.

Mr. ADERHOLT. Thank you, Mr. Bishop.

Chairman Giancarlo, without objection, your entire written testimony will be included in the record, and I recognize you now for your statement, and then we will proceed with questions.

Mr. GIANCARLO. Thank you, Chairman Aderholt, and thank you, Ranking Member Bishop and members of the subcommittee.

For over a century, U.S. business and farmers have relied on commodity futures and derivative markets to hedge their cost of production. These markets have allowed farmers and ranchers to control production risk and commodity prices so that Americans, ordinary Americans, can find plenty of food on grocery store shelves.

These markets influence the price and availability of everything from heating fuel in American homes, the energy used in factories, the interest rates that borrowers pay on home mortgages, and the returns that workers earn on their retirement savings. Derivatives serve the need of society to help moderate price, supply, and other commercial risks to free up capital for economic growth, job creation, and overall prosperity.

Our fiscal year 2019 budget reflects the true needs of a policy setting and civil law enforcement agency to ensure that our derivative markets operate effectively. At a time when these markets are rapidly transforming with new digital technologies, this budget will provide the resources we need to oversee markets that are safe and competitive at home and abroad.

In fiscal year 2019, we are requesting $281.5 million and 716 full-time equivalents. This is an increase of $31.5 million and 46

FTEs in current resources. It is the same level of funding that the Commission requested in fiscal year 2018. When I appeared before this subcommittee last year, I spoke about our approach to budgeting. The approach is based upon my experience in the private sector, where each dollar budgeted had to serve the core mission. It is not based on using a prior year's budget and adding a percentage.

So, working with our leadership team, we built this budget up from zero. Every dollar we seek properly serves the agency's mission to foster open, transparent, competitive, and financially sound markets free from fraud and manipulation, while respecting the American taxpayer through careful management of our resources. And I am certain, as I sit here today, that the $281.5 million is the right level of funding for the CFTC.

Since becoming Chairman, I have made efforts to normalize operations and maximize resources. That means a return to greater care and precision in rule drafting, more thorough econometric analysis, and a right size docket of new rules and regulations to be absorbed by the marketplace.

As you know, modern financial technology is transforming our derivative markets. We must respond with a regulatory framework that stays ahead of the curve to harness those innovations. The CFTC seeks appropriate funding to set and enforce rules that foster innovation while promoting market integrity and confidence. This includes resources for our LabCFTC initiative to prepare us to be a 21st century digital regulator. The budget request also seeks to boost the CFTC's analytical expertise and monitoring of systemic risk, especially with central counterparty clearinghouses. This includes the expansion of sophisticated econometric and qualitative analysis for risk modeling, stress testing, and other stability-related evaluations.

As market regulators, we must take every step to thwart cyber attacks on the world's financial markets. That is why, in fiscal year 2019, we will devote more resources to cybersecurity, especially our examination of critical market infrastructure providers. The day after the White House announced its intention to nominate me as chairman, I issued a warning to those who would manipulate America's derivative markets. I said: There will be no pause, no let-up, and no reduction in our duty to enforce the law and punish wrongdoing; the American people are counting on us.

Full funding of our budget request will allow us to continue to send a clear signal to the marketplace that we will punish bad behavior and compensate its victims.

In closing, Mr. Chairman, I am reminded of a quote from Winston Churchill: We shall not fail or falter. We shall not weaken or tire. Give us the tools, and we will finish the job.

I am grateful for your consideration of our budget request. With the right tools, we will do the job of overseeing American markets that are safe and competitive, markets that help grow our economy and increase our prosperity. Thank you.

[The statement of J. Christopher Giancarlo follows:]

SUBMITTED WRITTEN TESTIMONY OF
J. CHRISTOPHER GIANCARLO
CHAIRMAN, COMMODITY FUTURES TRADING COMMISSION
BEFORE THE
U.S. HOUSE COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT AND RELATED AGENCIES

MARCH 7, 2018

Thank you, Chairman Aderholt, Ranking Member Bishop and Members of the Subcommittee for the opportunity to testify before you today on the Commodity Futures Trading Commission ("Commission" or "CFTC") FY 2019 Budget Request.

For more than a century, U.S. businesses have relied on the derivatives markets to hedge their cost of production. These markets have allowed farmers and ranchers to hedge their costs of production and delivery price so that Americans can always find plenty of food on grocery store shelves. The derivatives markets influence the price and availability of heating in American homes, the energy used in factories, the interest rates borrowers pay on home mortgages and the returns workers earn on their retirement savings. More than 90 percent of *Fortune* 500 companies use derivatives to manage commercial or market risk in their worldwide business operations. In short, derivatives serve the needs of society to help moderate price, supply and other commercial risks to free up capital for economic growth, job creation and prosperity.

The FY 2019 budget submitted by the Commission reflects the true needs of a policy setting and civil law enforcement agency that has the duty to ensure the derivatives markets operate effectively. At a time in history when the nature of our financial markets are rapidly transforming, as digital technologies are having an increasing impact on everything in the early Twenty-First Century from information transfer to retail shopping to personal communications, this budget will provide the Commission with the resources it needs to put in place and oversee responsible regulations that allow for innovation and enable our markets to remain competitive and safe at home and abroad.

Just as the Industrial Revolution changed the world within years and decades, the current technological revolution is now changing our world every day, with time compressing years into days, and days into minutes. Therefore, we must reset our own thinking and shape an appropriate regulatory response.

In order for the CFTC to fulfill its duty to oversee these vital derivatives markets in FY 2019, the Commission is requesting $281.5 million and 716 full-time equivalents (FTE.) This is an increase of $31.5 million and 46 FTE over the resources provided under the *Further Extension of Continuing Appropriations Act, 2018*, P.L. 115-123, and is the same level of funding that the Commission requested in FY 2018.

When I appeared before this subcommittee last year, I spoke about my approach to budgeting. In the private sector, we would never simply take last year's budget number and add a percentage increase. Rather, each dollar requested had to serve a purpose. So, when I sat down with our leadership team, my budget baseline was zero. I pledged to carry out the Agency's mission to foster open, transparent, competitive and financially sound markets, free from fraud and manipulation, in a way that best fosters broad-based economic growth and prosperity while respecting the American taxpayer through careful management of our agency resources.

The Commission's budget request for FY 2019 reflects and builds on the efforts from 2018. I believed then and I believe now that $281.5 million is the level of funding necessary to fulfill our statutory mission.

21ST CENTURY TECHNOLOGY

Technology is impacting trading, markets and the entire financial landscape with far ranging implications for capital formation and risk transfer. These technologies include machine learning and artificial intelligence, algorithm-based trading, data analytics, "smart"

contracts valuing themselves and calculating payments in real-time and distributed ledger technologies, which over time may come to challenge traditional market infrastructure.

It is no surprise that these technologies are having an equally transformative impact on U.S. derivatives markets. One thing is certain: ignoring these changes in the market would be a disaster. They will not go away. Nor is it a responsible regulatory strategy. As the axiom of Moore's Law[1] states, technological power doubles about every 18 months. We must not respond in a reactive way; chase to catch up with technology. We must be proactive with a regulatory and statutory framework that is ahead of the curve, prevents and punishes fraud and criminality, gives clarity and coherence to this dark and often inaccessible technology, and anticipates the evolution of virtual currencies. The same technology can give us advantages in market regulation. Our task, as market regulators, is to set and enforce rules that foster innovation while promoting market integrity and confidence.

We are at the juncture of changing times and the American public deserves a well-equipped regulator overseeing these vital markets

AGENCY REFORM AND THE KISS PROJECT

Since I became Chairman, I have made efforts to normalize operations and practices, and found opportunities to reinvest and maximize current resources. That means a return to greater care and precision in rule drafting; more thorough econometric analysis; and a reduced docket of new rules and regulations to be absorbed by market participants. The CFTC has embraced the Administration's directive that each federal agency minimizes the costs borne by their regulation. The KISS initiative I launched last March included a review of rules and processes, and the invitation for public comment to collect ideas on how we can be a more effective regulator. The effort has produced a tiered list of significant efforts[2] the Commission is undertaking that will lessen regulatory burden. Recently, we released[3]

[1] *Moore's Law and the Future of Information Technology,* Reviewed, Tyler Wells Lynch , September 03, 2013
[2] Remarks of CFTC Chief of Staff Michael Gill at the National Press Club, CFTC Kiss Policy Forum, Washington, D.C. February 12, 2018
[3] Giancarlo: We're Making Government Function More Efficiently for Taxpayers and Market Participants, February 15, 2018

notification on the proposed replacement for the complex and confusing lettering for defined terms with a simple alphabetical list. The replacement will remove unnecessary complexity from our rules and should help to make regulatory compliance less burdensome.

Internally, I have embraced the Administration's Reform Plan concept and have implemented in-depth organizational reviews to ensure that as an agency, we are staffed and providing the most effective services to the American tax-payer. This is an on-going effort but it has already borne results. We are now leveraging knowledge gained from enforcement actions and surveillance efforts to enable the provision of more efficient, and timely consumer education materials to the public. The Primer on Virtual Currency, Bitcoin webpage, and podcasts are just a few of the initiatives resulting from these efforts.

ECONOMIC MODELING AND ECONOMETRIC CAPABILITIES

The budget request, if met, would boost the CFTC's analytical expertise and monitoring of systemic risk in the derivatives markets, especially with central counterparty clearinghouses. These investments include the expansion of sophisticated econometric and quantitative analysis devoted to risk modeling, stress tests, and other stability-related evaluations necessary for market oversight. Furthermore, such analysis conducted by the CFTC will aid in rulemaking, policy development, and enhance the Commission's ability to provide high-quality cost benefit considerations for decision-making.

INCREASED EXAMINATIONS OF CLEARINGHOUSES

The Commission expects the number of designated clearing organizations (DCOs) to continue to increase in FY 2019, with many expanding their business to other jurisdictions around the world. As the number of DCOs increase, the complexity of the oversight program will increase. It is imperative that the Commission strengthen its examinations capability to enable it to keep pace with the growth in the amount and value of swaps cleared by DCOs pursuant to global regulatory reform implementation. As the size and scope of DCOs increase, so too has the complexity of the counterparty risk management oversight programs and liquidity

risk management procedures of the DCOs under CFTC regulation here and abroad. In addition, funding will also enable the Commission to enhance its financial analysis tools used to aggregate and evaluate risk across all DCOs.

CYBER SECURITY

Cyber security is critically important to protecting infrastructure and financial markets around the world. I feel strongly that it is the most important single issue facing our markets today in terms of market integrity and financial stability.

As market leaders and regulators, we must take every step possible to thwart cyber-attacks on the world's financial markets. The cyber threat must take priority, which is why we will devote more resources to cybersecurity in FY 2019. Threats and attacks occur on DCOs regularly. Vulnerabilities are continually discovered that require the Commission to analyze the vulnerability, understand the root cause of the vulnerability, and to engage in discussions with the DCOs as to how they are protecting the organization, and the marketplace, against the vulnerability. It is through the examination of systems safeguards that the Commission helps to ensure the DCOs are prioritizing cyber security activities. With this budget request, the CFTC will be able to address some of the needs to support these unplanned occurrences.

As an agency, the Commission is faced with growing pressure to protect terabytes of data, and maintain compliance with FISMA and OMB mandates. Protecting our information comes with a price. Some of the additional funding requested will also allow us to make internal cyber security improvements including implementation of additional cyber security sensors and defenses to further protect the market data we collect on a daily basis.

FINANCIAL TECHNOLOGY

The requested budget will also allow the Commission to also address market-enhancing innovation through financial technology (FinTech). FinTech comprises a range of technology in

the financial services sector and includes innovations in retail banking, investment, and virtual currencies like bitcoin.

LabCFTC is the focal point of the CFTC's efforts to facilitate market-enhancing innovation and fair competition for the benefit of the American public. It also helps to ensure that we can keep pace with changes in our markets, and proactively identify emerging regulatory opportunities, challenges, and risks. We have situated LabCFTC within the CFTC's Office of the General Counsel. It allows LabCFTC to leverage the expertise of the CFTC's legal team to manage the interface between technological innovation, regulatory modernization, and existing rules and regulations.

LabCFTC has hosted innovators across the nation, ranging from startups to established financial institutions to leading technology companies. These outreach efforts are designed to make the CFTC more accessible to FinTech innovators, and to serve as a platform for informing the Commission's understanding of emerging technologies. The information gathered in these meetings also provides important insights to CFTC staff on market innovations that may influence policy development. In fact, through its engagement with—and study of—innovative technologies, LabCFTC was recently able to recommend new virtual currency surveillance tools to our Enforcement division. Our Enforcement team has been able to avail itself of this new technology, and is now able to enhance certain surveillance and enforcement activities. This important development helps underscore the value of LabCFTC, and its effort to ensure that we are prepared to be a 21st century digital regulator.

In addition to LabCFTC's efforts undertaken domestically, the Commission has been proactive in working with international regulators on FinTech applications to harmonize approaches and to share best practices. Last month the CFTC and the UK's Financial Conduct Authority (FCA) signed an arrangement that commits the regulators to collaborating and supporting innovative firms through each other's financial technology (FinTech) initiatives – LabCFTC and FCA Innovate. This is the first FinTech innovation arrangement for the CFTC with a non-US counterpart. We believe that by collaborating with the best-in-class FCA FinTech

team, the CFTC can contribute to the growing awareness of the critical role of regulators in 21st century digital markets.

OVERSIGHT OF VIRTUAL CURRENCIES

In FY 2018, the exchanges self-certified several new contracts for futures products for virtual currencies. These innovations impact the regulatory landscape and with this budget request, the Commission will invest more in new technologies and tools that support important surveillance and enforcement efforts.

Under the CEA and Commission regulations and related guidance, exchanges have the responsibility to ensure that their Bitcoin futures products and their cash-settlement process are not readily susceptible to manipulation, and DCOs have the responsibility of risk management to ensure that the products are sufficiently margined. The CFTC has the authority to ensure compliance with both. In addition, the CFTC has legal authority over virtual currency derivatives in support of anti-fraud and manipulation including enforcement authority in the underlying markets.

The CFTC has been in close communication with the SEC with respect to policy and jurisdictional considerations, and in connection with our recent enforcement cases. We have also been working with the U.S. Treasury and the FSOC. In addition, we have been in communication with our foreign counterparts through bilateral discussions and the International Organization of Securities Commissions.

In the past several weeks the CFTC has filed a series of civil enforcement actions against perpetrators of fraud and market abuse involving virtual currency. These actions and others to follow confirm that the CFTC, working closely with the Security and Exchange Commission (SEC) and other fellow financial enforcement agencies, will aggressively prosecute those who engage in fraud and manipulation of US markets for virtual currency.

ENFORCEMENT

The day after the White House announced its intention to nominate me as CFTC Chairman, I spoke to hundreds of industry executives at the annual Futures Industry Conference.[4] I issued a warning to those who may seek to cheat or manipulate America's derivatives markets. I said, "There will be no pause, no let up and no reduction in our duty to enforce the law and punish wrongdoing in our derivatives markets. The American people are counting on us." I am committed to punishing bad actors in the marketplace and to do so with swift justice to stop their bad actions. Through robust enforcement of our laws and regulation, we will continue to send a clear signal to the marketplace about our seriousness in punishing bad behavior and compensating victims.

In the fiscal year that ended September 30, 2017, the CFTC brought 49 enforcement-related actions, which included significant actions to root out manipulation and spoofing and to protect retail investors from fraud. The CFTC also pursued significant and complex litigation, including cases charging manipulation, spoofing, and unlawful use of customer funds.

One-third of the way through FY 2018, the Commission has filed 11 manipulative conduct cases. The most manipulation cases the CFTC has ever filed in a single year is 12, which the CFTC filed in FY 2017. Below is a chart that shows the numbers over the past several years.

[4] Remarks of Acting Chairman J. Christopher Giancarlo before the 42nd Annual International Futures Industry Conference, Mar. 15, 2017, at: http://www.cftc.gov/PressRoom/SpeechesTestimony/opagiancarlo-20

CFTC Enforcement Actions Manipulation, Attempted Manipulation, Spoofing, and/or Manipulative or Deceptive Device	
FY 2018 (through 2/13/18)	11
FY 2017	12
FY 2016	4
FY 2015	11
FY 2014	6
FY 2013	5
FY 2012	2
FY 2011	4
Total	**55**

But it is not just about the numbers; it is about making our markets safer and removing bad actors from the marketplace. We believe that to adequately deter future misconduct, we must prosecute not just the companies responsible, but also the individuals involved in the wrongdoing. We also believe that, to maximize deterrence, we must work with our criminal law enforcement partners to ensure that wrongdoers face not just civil liability, but also the prospect of criminal prosecution and time in jail.

In the January 2018, the CFTC filed manipulation and spoofing cases against six individuals in coordination with the Department of Justice and the FBI, which brought criminal charges against the same individuals. This constitutes the largest coordinated prosecution with the criminal authorities in the history of the CFTC. These prosecutions were equally significant

for DOJ: In a press statement, the Assistant Attorney General characterized it as "the largest futures market criminal enforcement action in Department history."

Complementing its enforcement efforts, the CFTC has also strengthened its Whistleblower Program, and provided whistleblowers additional incentives to report wrongdoing to the CFTC. In May 2017, to further protect whistleblowers, the CFTC added protections prohibiting employers from retaliating against whistleblowers and from taking steps that would impede would-be whistleblowers from communicating with the CFTC about possible misconduct. In the near future, the CFTC also anticipates issuing its largest ever whistleblower awards. These incentives are working. In FY 2017, the Commission received a record number of whistleblower reports—nearly twice as many as in any other year, and FY 2018 is on track to receive nearly twice as many as in FY 2017.

The Commission takes its enforcement efforts very seriously and prides itself on being a premier Federal civil enforcement agency dedicated to deterring and preventing manipulation and other disruptions of market integrity.

Full funding of our budget request will allow us to continue to carry out our mission in the area of enforcement.

CONCLUSION

Thank you again for this opportunity to appear before the subcommittee regarding the CFTC's FY 2019 budget request. As I said earlier, we meet at a time in history when a familiar world is disappearing and a new one emerging.

Like millions of Americans, I have been impressed with the new movie about Winston Churchill, "Darkest Hour." I am reminded of an insightful quote from Winston Churchill, "We shall not fail or falter; we shall not weaken or tire... Give us the tools, and we will finish the job."

We need the tools to do our job of protecting the markets that Americans rely on each day. With the proper balance of sound policy, regulatory oversight, and private sector

innovation, new technologies and global trading will allow American markets to evolve in responsible ways, and continue to grow our economy and increase prosperity.

I look forward to answering your questions.

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Mr. ADERHOLT. Thank you, Mr. Chairman.

Let me start out talking a little bit about bitcoin and cryptocurrencies. The advent of new futures approved just last year for bitcoin and other cryptocurrencies seem to have taken up the headlines recently. And we read stories of people mortgaging their homes to invest in the market and those that have thrown away their bitcoin keys wanting to go through the city dumps and try to recover them in some way. Millionaires were made and lost overnight.

You briefly mentioned the steps you are taking to regulate the market in your written statement. Can you go a bit further into detail as to what role your agency plays regarding the regulation of this market and what other role agencies have?

VIRTUAL CURRENCY

Mr. GIANCARLO. Yes, Mr. Chairman. Thank you for that. You know, the amount of press coverage on this whole issue of virtual currencies far outweighs the impact of the entire marketplace on either the U.S. or the global economy. Nevertheless, it is, as you say, very, very much in the news.

The approach we are taking at the CFTC is really sixfold. And briefly—and then I will come back to it—it is to assert our legal authority where appropriate; increase our staff competency in the entire matter, our understanding of these products; and then a very robust consumer education effort to make sure what we understand is translated to the marketplace; very aggressive enforcement against fraud and manipulation in these markets; and then interagency cooperation, working very carefully with our fellow regulators.

And let me just go back and talk about that a little bit. As you know, the CFTC's authority is to regulate derivative markets comprehensively. That means setting standards for operation of trading platforms in derivatives, all of their financial adequacy, system safeguards, cyber requirements, customer handling, the full gamut, when it comes to derivative markets, so derivatives on any given asset, in this case, virtual currencies.

When it comes to underlying spot markets, whether those are markets for commodities, whether they are markets for precious metals, we do not have regulatory authority. What we do have is fraud and manipulation authority, the ability to bring enforcement actions for fraud and manipulation in underlying markets. That has been the case for our history at the CFTC, and that is now how we approach virtual currencies. So, in the case of the two launched bitcoin futures at the CME and CBOE, we have comprehensive regulatory oversight. In the case of underlying cash markets—well, they are not really cash markets because they are trading in bitcoin—what we will call spot markets in bitcoin, our authority is limited to enforcement for fraud and manipulation.

We have been active on both of those levels. And in the case of fraud and manipulation, we brought three cases just in January alone. And just yesterday, a Federal judge in New York, in response to a motion to dismiss by the defendants in this case, ruled in favor of the CFTC and confirmed our jurisdiction in these products as commodities.

In the case of the bitcoin futures exchanges, the two that I mentioned, our approach to this is comprehensive. So, whereas, spot bitcoin markets are, you might say, dark markets, in the case of bitcoin futures, they are lit markets. There is public transparency in our weekly Commitment of Traders report, but there is full regulatory transparency in terms of everybody who is transacting on those markets, and we know their positions. We know they are—it is not an anonymous market as it is, or a pseudo-anonymous market, as it is in the underlying spot markets. It is a fully disclosed market. It is a margined market. It is a full KYC, know your customer, antimoney laundering marketplace. So they are comprehensively regulated and are highly margined. And I might mention, as a final point, in the recent market disruption on the 5th and 6th of February, not a single margin breach in bitcoin futures market. So that is our jurisdiction, and that has been our approach in those areas, Chairman.

Mr. ADERHOLT. Let me move quickly. Recently, you made some comments regarding the right sizing of the swaps markets, and, of course, it is refreshing to see someone else that raises those questions that this subcommittee has raised in the past about the notional size of swap markets. In fact, I believe you mentioned these questions in your recent speech at a derivative conference in New York.

Following the financial crisis of 2008, the swaps market became a topic of much debate in the public discourse. And the only number being thrown around was that of notional value. At the time, the number discussed was in excess of $600 trillion.

Can you take just a minute, before I recognize Mr. Bishop, and just explain the difference between notional value and the new metrics you are using and the number associated with each?

ENTITY-NETTED NOTIONALS

Mr. GIANCARLO. So thank you for that. In fact, it was this committee who wrote to the CFTC a few years ago and asked us if we could have a more precise measurement of what the true risk presented by these derivative markets are, and it was one of the first tasks that I assigned to our new chief economist when he joined the agency to do some research and see if we could provide some light here.

For years, the notional value of these derivative markets have been cited, often in requests for funding and other areas in the hundreds of trillions of dollars. And, yet, as we have long known in the marketplace, many of those positions are netted against each other to the neutral position. So, if you ask yourself, what is the true risk, well, the analysis we did—and we call it entity-netted notional, is our new nomenclature—applying this approach to $179 trillion of interest rate swaps, nets that down to $15 trillion. And if you use the $15 trillion, the whole thing suddenly makes sense because the measurement of the size of the U.S. Treasury market is $16 trillion. The size of the U.S. mortgage market is $15 trillion. The size of the U.S. corporate bond market is $12 trillion. Suddenly, the interest rate swaps market at $15 trillion makes sense in comparison to markets that we have normally sized in these ways. Suddenly, this $100 trillion measure that has been put on

the swaps markets I think comes down to its true risk element and what it is vis-a-vis the other markets.

Now, this notion has been put forward in scholarly papers. We are looking for peer review. I think there are some good uses for this, but I don't think it necessarily addresses every issue. So I don't want to say that we have come up with the last word on this, but we have certainly come up, I think in some cases, with the first word on this in getting to something that is really the true measurement of the risk profile of our global derivative markets.

Mr. ADERHOLT. As my time is far gone, Mr. Bishop.

Mr. BISHOP. Thank you very much, Mr. Chairman.

Mr. Giancarlo, in the hearing last year, I asked for your views on using user fees to supplement or fund the CFTC, and you were commendably frank, as usual, and you said, quote: I am very concerned that imposing transaction costs on our markets will contribute to greater liquidity challenges than we now have. And so I do not support user fees.

The 2019 budget request, which OMB and CFTC both support, calls for user fees to pay for the $31.5 million increase over the fiscal year 2017 level of $250 million. It looks like the administration moved from its 2018 position of a freeze at $250 million in exchange for your endorsement of a user fee of $31.5 million.

Do you know now support user fees? And I would note that you may get the short end of the deal because Congress has been resistant for decades to CFTC user fees. If that continues to be the case, is the administration's position that the budget should be $250 million?

USER FEES

Mr. GIANCARLO. Thank you, ranking member. If I may begin with just a distinction between user fees as a whole and then perhaps a subset of that, which would be transaction fees. I have long been opposed to transaction fees and remain opposed to transaction fees because they provide a tax on the use of these risk-hedging markets. And my concern there is, that we—when you think about the very folks that this committee is concerned with, farmers and ranchers, you know, they face an array of risk-hedging mechanisms. One, of course, is our commercial futures—ag futures markets. Another, in cases where they are interchangeable, is crop insurance. And we, in a sense, don't want to put a tax on one that is not on the other. We want them to make choices in their economic interests and not face a taxation in the form of transaction fees.

Mr. BISHOP. That seems like it is just nomenclature: a user fee or a tax. I mean, you know, a rose is still a rose. It seems to me that it is just a matter of calling one a tax and one a user fee. It seems like they are one and the same because it goes to the people who actually use it.

Mr. GIANCARLO. Ranking Member, I will note that every administration going back to Ronald Reagan has proposed user fees. And this administration is in favor as well, similar to their predecessor, and it is in our budget. At the end of the day, it is for this committee to decide how much we are funded, and so our appropriators

decide what that is. We will employ whatever tools our ppropriators and our authorizers put before us.

Mr. BISHOP. I am not going to try to put a wedge between you and the administration. Let me move on to diversity. At the last hearing and in the meetings we have had, we discussed diversity at CFTC. And a couple of questions on the topic. Could you update us on what the agency has done on diversity, including recruiting? Could you tell us whether you were able to offer paid internships the past summer to the 11 students who accepted internships? Have you had permanent staff from those internships? Can you describe the strategic workforce plan that includes increasing minorities and women in positions at CFTC?

INTERNSHIPS

Mr. GIANCARLO. Thank you for that. As we discussed last time we met, we are committed to a strong diversity program at the agency, not just in our employment practices but also in our recruitment efforts. For 2 years now, we have had a summer—a diversity-based summer internship program.

With our current funding, we have not been able to offer paid stipends. We would like to think with the budget proposal before the Committee—we would be able to offer modest, quite modest, stipends.

Mr. BISHOP. Excuse me. You found funds for podcasts in a frozen budget. And you also spent $365,000 on your fintech initiative between May and November. Those funds could have helped pay for the cost of those interns, couldn't it?

Mr. GIANCARLO. Well, money is fungible. We do have a core mission in consumer education. We have a core mission in trying to stay ahead of the curve in terms of the rapidly changing nature of these markets. So we believe those were well-spent funds, but as you know, we are committed to diversity-based recruitment. And we would like to be in a position, and with the budget proposal we have before you, we would be able to offer a modest stipend to interns.

Mr. BISHOP. And that is without the user fees?

Mr. GIANCARLO. With the budget number of the $281.5 million that is before the committee, we would be able to.

Mr. BISHOP. If you only get the 250 without the user fees?

Mr. GIANCARLO. Ranking member, if we only get the 250, we will be making a lot of hard choices at the agency, significantly hard choices.

Mr. BISHOP. Thank you. I think my time is up.

Mr. ADERHOLT. Dr. Harris.

Mr. HARRIS. Thank you very much.

And welcome back. Let me first just followup on something that we have spoken about before, which is swap dealer de minimis levels. And I think that you have—you delayed the effective date of the reduction from $8 billion to $3 billion, but actually I guess, in response to one of your—to your response to the chairman, is it because you are looking at this idea of entity-related notional value and we have been basing this all on gross notional value? Is that why there is a delay in what the final ruling will be?

DE MINIMIS THRESHOLD

Mr. GIANCARLO. That is not the reason for the delay. The reason for the delay is, is that any change in that de minimis will require a commission vote. I only received two additional Commissioners last September because of the way the confirmation process went in the Senate. The amount of data to be analyzed to come to the right conclusion, and then the process of being able to put something out for notice and comment just meant we couldn't have gotten it done between September and December of last year.

So it was my decision as Chairman to say: We will get this done in 2018. The process has begun of briefing the two Commissioners on the data sets which we now have through 2017, and it is good, it is robust data. So I expect to get this done in a matter of months.

Mr. HARRIS. And does this entity-netted notional value, will that enter into it? I mean, it kind of makes sense that that is the way you should gauge what the risk is of what you are regulating.

Mr. GIANCARLO. So this is an issue that many in the marketplace feel has gone on for too long. And I think if we were to use this new metric—which, by the way, is new, and I do think it requires a degree of peer review and analysis—I think we would struggle to get this done this year. So I think the marketplace has a legitimate expectation that we get it done. I think the entity-netted notionals will take some time to work its way through the firmament. But there are now a number of academics who are looking at it and testing it, and I would hope that a year from now, in a number of other areas where we have to do risk assessment, it might become the basis for that.

Mr. HARRIS. And with regards to the swap dealer de minimis, is it your feeling that it is a good idea to keep it near the $8 billion level?

Mr. GIANCARLO. Well, I would like to see if we can get to a unanimous decision. I would like to see if we can do that. So I would like to hear from my two fellow Commissioners. We will get it done one way or the other. And if we have to get it done 2 to 1, we will get it done, but I would love to get it done on a 3–0 vote.

Mr. HARRIS. Sure. OK. The second issue is something that regards—something not from under your watch, but with regards to some of the leases that were issued in the Antideficiency Act. I know there was a letter I guess sent from the GAO to the chairman of the committee yesterday—this week—about this question of whether or not the CFTC has entered into leases that, because of various provisions that don't limit government liability, that they would appear to be in violation of the Antideficiency Act and may require statutory changes or other things to bring the Commission into compliance. If you would comment on that.

LEASING ISSUES

Mr. GIANCARLO. So we received that letter about 4 o'clock yesterday afternoon, and I had a brief word with our general counsel. I haven't had a chance to read the letter itself. I understand it does open concerns about open liabilities. As you know, these leases go back to the 1990s and, in some cases, the early 2000s. It does look like errors were made. I don't want to shirk responsibility. We will

correct what needs to be corrected. If there are deficiencies to be reported, we will report the deficiencies, and we will bring ourselves whole in this.

There have been other issues raised over the last few years, and in each case, we have done the right thing, reported the deficiencies, and recently received a clean audit opinion. So we will take the right steps. I think the bigger issue is that we are an agency that, years ago, leased too much space, and that is still something we are fighting with. And as the chairman noted, we have been able to successfully offload some of our space in the Kansas City office. We are making a significant reduction. We are looking to do the same thing in New York. We have a very active effort to do that. We don't have as much of a problem in Chicago and in Washington. We will look to see what we can do, but I take this very seriously. As a former businessman, that empty space is not a good use of taxpayer money. So we will try to find a way to continue on the success we had in Kansas City and do more with it.

Mr. HARRIS. Well, thank you very much.

I yield back, Mr. Chairman.

Mr. ADERHOLT. I recognize the gentleman from Wisconsin, Mr. Pocan.

Mr. POCAN. Thank you, Mr. Chairman.

Thank you for being here today.

If I can follow up on something that the subcommittee chairman asked around derivatives. So, in the budget, you know, this is an added responsibility; you went through an extensive amount of work that you are doing in this area and what areas you are not in this area.

With the budget that you have, is that sufficient to continue to do all this work in this new area? And, you know, what is going to get put aside if not?

ADEQUATE FUNDING

Mr. GIANCARLO. Thank you very much. I mean, it is a big job. The biggest challenge—so great credit to my predecessors; they got the bulk of the Dodd-Frank swaps reforms done at the CFTC. We are not only the leading agency in the United States in terms of completing the workload, but we are the leader around the world. So we take great pride in that.

But I often think about what is ahead. When Dodd-Frank was passed, it didn't address cyber. It didn't address algorithm trading. A lot of the issues we are facing now are what is coming at us. A lot of what we are trying to do in this budget is prepare ourselves for this next phase of market evolution, what I call the digitization of markets. Markets are recently being driven by computer training and, increasingly, computers that are using artificial and machine learning to learn from other activities in the market and then adjust their trading screens.

So we have a lot to learn from that, which is why we started our LabCFTC initiative. We have got great people at the agency, but some people who have been tracking markets for the last 30, 40 years, not necessarily—despite all that experience are not necessarily on the cutting edge of where technology is going. And, you know, when it comes to technologists, we are competing with some

of the biggest, most sophisticated companies in Silicon Valley and others to get that expertise.

And so LabCFTC gives us a way to learn and then train ourselves internally. So do I think the budget is the right number? I have worked this budget very, very hard. I think it is a responsible budget number. I think it gives us the resources we need. We may have to talk in the future, but I think this is the right budget for now and for the mission we have.

Mr. POCAN. Thank you. And you brought me right to the second question that I had, which is—and I said this last year, too—you have established a very good relationship with your employees. They speak very highly of the relationship they have built with you. The question is, you know, a lot of the folks are being rated, so to speak, by other financial agencies, by private firms. Do you feel that you have been able to make some progress, the question we asked was, you know, to keep those people in this very competitive area? How is that working from a year ago when I asked the question, and do you need additional resources in this area?

HIRING FREEZE

Mr. GIANCARLO. So, with the flat funding we have had for 3 or 4 years, it almost imposes something of a hiring freeze. You can't backfill. And the problem with that is you can't control attrition. You can't say, well, we have too many people in this unit; maybe that unit will suffer more attrition than another. You have no control. Often, sometimes, it is the very best people who are recruited away by either competing government agencies or in the private sector.

Some of our best technologists we have lost recently to private sector concerns because of the experience they have gotten at the CFTC. So that is a real challenge.

You know, again, I spent 30 years in the private sector and 14 in a public company working with personnel, and so it is a big part of my management style to meet frequently. I do frequent townhalls. I have one coming up in just two weeks with the agencywide staff. I talk a lot about goals. I try to be very transparent with personnel at the agency as to what our mission is, and we spend a lot of time talking about mission.

I will just leave you with one thing. The message I give the staff is the message that the coach of the New England Patriots gives to them. And that is every person to their job. I say: If every person does their job to the level of excellence, the whole agency will take an approach of excellence. And not withstanding their loss in the Super Bowl, they still bring excellence to the game, and that is what we try to do as well.

Mr. POCAN. And how about specifically to the incentive question for some of these folks, because if they are being rated for more money, are you able, with the budget you have, to be able to do what you need to do to keep the staff?

Mr. GIANCARLO. We just reached—and I am very proud of this—we just reached a 3-year pay package with our union, first time ever. In fact, when I arrived at the agency, we were in a dispute with the union. We have gone from dispute to a very successful 3-

year arrangement, and it has in it an up to 3 percent performance-based, merit-based reward for employee performance.

So we are trying to move more into a reward performance basis at the agency. And I must say, the union brought the same goodwill back to the bargaining table that we brought, and I think that is a recipe for good progress in the future.

Mr. POCAN. Thank you very much.

I yield back.

Mr. ADERHOLT. Mr. Yoder.

Mr. YODER. Thank you, Mr. Chairman.

And, Chairman, good to have you here today. I want to sort of associate my comments a little bit with the comments of the ranking member regarding user fees. And you and I have had a conversation about this as well and the concern being that that ultimately passes down to farmers and producers in our States that are already struggling under low commodity prices and, as you correctly stated, would tax efforts from them to protect their risk and to hedge and might push them into taxpayer-funded options. So I appreciate your comments on that.

And I think this committee and this Congress has been pretty clear over the years that it doesn't support those user fees, and of course, the good things you are trying to do in your budget, we will try hard to find general fund dollars to spend as opposed to taxing the markets and ultimately our producers.

I want to talk to you a little bit about the plans that the Fed has to replace CEM with SA–CCR. And, as we know, these are methodologies for calculating how much capital a bank has to hold to comply with the SLR rule, or supplemental leverage ratio, in relation to a cleared option. CEM is a very old risk insensitive method while SA–CCR is accepted generally to better gauge risk.

It is my understanding that the Fed intends to move in this direction, but is likely to do via rulemaking, which interested parties suggest could take up to 3 years. Meanwhile, markets are operating in an artificially constrained state because they are under these old rules. And some say this was evident in the February market behavior.

So I guess my question for you is, given the increased volatility we have seen in markets this year, I am interested in your view of whether this may be an indication that swifter action is needed than the potential 2- to 3-year rulemaking process.

CAPITAL REQUIREMENTS

Mr. GIANCARLO. Thank you for that, and I think that is a very perceptive insight. In fact, we do have some anecdotal information that has come to the agency that, during the 5th and 6th of February, during that market swoon, suggests we may have seen the impact of the current form of the supplementary leverage ratio impacting the ability of larger market makers to take on positions. And, therefore, the market movement may have been exacerbated because of the current form of the supplementary leverage ratio.

And let me just talk about that for a minute. I find myself in kind of an odd position. I am a Republican who supported the provision in title VII that says, we want to move bilateral swaps into central clearing, only to find that some of my fellow regulators in

the system have a supplementary leverage ratio approach that actually deters moving more products into clearing. These are at issue.

I think that we made a policy choice in title VII that we want to see more central clearing of derivatives, and yet in its current form, the supplementary leverage ratio, which is not mandated specifically in title VII, has this opposite or this deterring impact.

So we have got some work to do here. I have been very candid in my views with folks at the Fed, including a new Chairman, Powell, and look forward to actually sitting down with Randall Quarles soon to talk a little bit about this as well. So I think we can get it right, but we don't have it right currently.

Mr. YODER. Well, I think the Fed is heading in that direction. My concern is that it can take a while for the wheels of the Fed to turn, and a rulemaking process could take 2 to 3 years. Are you concerned about the length of time it could take to fix this because we continue to have this challenge and this arcane requirement that affects, you know, the options markets at the same time?

Mr. GIANCARLO. I must say: I spent 30 years in the private sector; the length of time things take here in Washington is just sometimes astounding.

Mr. YODER. You get it, and I appreciate your work in that regard. I also want to ask you a little bit about CFTC's decision last year to approve a variable storage rate on Kansas City Hard Red Winter wheat. As you know, I am from Kansas. We are the biggest wheat-producing State in the country, and America is the biggest wheat-producing country in the world. So wheat is a critical part of our economy.

And this was a particularly important decision given the significant disparity between the wheat farmers' local cash price and futures price. Could you provide the committee with an update about the current market situation and your views about how VSR could fully work once implemented and describe the CFTC's role in implementing VSR?

VARIABLE STORAGE RATE

Mr. GIANCARLO. Thank you for that. I think sometimes people look at us as regulators and think, as rules evolve or change, we then walk away and move on to something else and don't review the evolution. But that is not the case. As our exchanges bring forward rule changes, we are actively engaged both in advance, but then thereafter to monitor how those rule changes are working in the marketplace. And I think it is a critically important part of what we do.

We don't want markets that are static. We want markets that evolve as market participation evolves, but we also need to stay very close to it to see how those evolutions impact. So, in the case of the variable storage rate, we have a team that watches this very carefully and are watching it now to see if the evolution is meeting the needs of our core users but also those who also provide liquidity to them as well.

Mr. YODER. Thank you, Mr. Chairman. Thank you.

Mr. ADERHOLT. Ms. Pingree.

Ms. PINGREE. Thank you very much, Mr. Chairman. Thank you for being in front of us today and for all the topics we have already considered. I have got just a couple of questions for you. You have been very articulate in discussing why the budget number that you have gotten comfortable with is important, and I think people have asked you a lot of questions, but I just want to give you one more chance.

And I was thinking particularly of some of the things you had mentioned around cybersecurity, surveillance enforcement. So, if you don't get the number you want, how will it impact some of those really critical things?

BUDGET IMPACTS

Mr. GIANCARLO. It is very challenging. So let me just give you a couple of figures. So I am going to give you four Federal agencies and tell you what their cyber—I will give you three, and then I will tell you what the CFTC proposal is and what their cyber spending is.

So the SEC, their budget for cyber is $60 million. The FDIC, it is about $110 million. And the Treasury, it is about $500 million. Our budget request is $7 million. Now, I think that is still the right number. So, in the most recent FISMA cybersecurity risk assessment, the CFTC had the highest ranking of any of those agencies, and yet the smallest budget.

So I am proud of what we are doing, and I think this is where I bring some of my business management experience. I can assure this committee: Every dollar we are asking for we will spend, and it is my intention to be the best cost-effective dollar spender. So I think we are the best at our cybersecurity, and yet we have the lowest budget, and I am very proud of that. But we need that $7 million. We don't need 6.5; we need the 7. And I say that goes to our budget as a whole. In every case, we have tried to make it as tight as possible, but knowing that every dollar is extremely well-devoted.

Ms. PINGREE. Thank you for being so articulate and exacting about that. I think it does help, when sometimes these numbers become very arbitrary and the cuts just become a slash.

One of the things—your testimony talks a little bit about the communication you have had with foreign counterparts through bilateral discussions in the IOSC. Can you just tell me a little bit more about your engagement with European counterparts on cooperating on some of these new challenges in a global—and maybe the Asian side as well?

INTERNATIONAL DISCUSSIONS

Mr. GIANCARLO. Thank you. So I take the international engagement of the agency very, very seriously. Within weeks of becoming Acting Chairman, I flew to Brussels and met with our counterparts there. I met with them in London and Asia as well. I was just in Asia in the autumn. These global relationships are very important. And I believe in the initiative that was begun in 2009 in Pittsburgh of the G20 to reform the global derivative markets and support the CFTC's efforts, and as I mentioned, we have been a leader in that area.

And as other countries come online, working out harmonization between us has been a very big part of the process. One of the big accomplishments of my predecessor, Chairman Massad, was, in 2016, to negotiate an equivalence determination for clearinghouse supervision between the United States and Europe. And since that time, in 2017, under my leadership, we were able to negotiate two more equivalence determinations for margin on uncleared swaps, as well as on trading platforms. So, again, the CFTC has been a leader.

I am concerned, however, that, in the wake of Brexit, the European Parliament is taking up some new legislation, and it is unclear in that legislation what the impact would be on the 2016 agreement that we negotiated less than 2 years ago, I think it was in May, less than 2 years ago with Europe.

So I was in front of the European Parliament 2 weeks ago. I had the pleasure of testifying in front of them as I am testifying before you today. And I made very clear that having negotiated a deal, we expect that deal to stand, and we expect the parties to that deal to stand behind that deal.

Ms. PINGREE. Are there big challenges in sort of a harmonizing?

Mr. GIANCARLO. Again, there are benefits, but there are also challenges in being a leader. And because we are out in front, as we see other nations come online, we need to look at those regulations very carefully and find out where the gaps are between what we are doing and where the overlap is. So I would say that there are issues all around but nothing I would bring to this committee's attention at this point, other than saying it is a constant challenge. We have got a very good group in our international affairs group at the CFTC. They are on the road constantly. They are reading briefing papers, constantly coming into my office, keeping us abreast of the issues, but it is a big challenge.

Ms. PINGREE. Well, thank you for that.

I yield back, Mr. Chairman.

Mr. ADERHOLT. Mr. Valadao.

Mr. VALADAO. Well, thank you, Mr. Chairman, for being here, and I appreciate you answering a few of the questions I was concerned with as well from my fellow members up here.

But I do want to touch a little more on one issue. So, Mr. Chairman, in 2017, a report by the CFTC's inspector general criticized the CFTC's outdated method in collecting data on derivatives markets activity and called some of the data essentially unusable. Other reports have raised concerns that the CFTC's technology is outdated and unable to keep pace with that of the derivatives markets participants overseas.

While I understand the CFTC has been taking a preliminary look at new ledger technology, such as blockchain, that it hopes will help better analyze data. Specifically, could you please tell us the steps you have taken in the last 6 months towards modernizing the CFTC's IT system? And how would you currently rate today's system as to whether you are behind, ahead of, or just keeping pace with IT systems among market participants that you regulate?

TECHNOLOGY SYSTEMS

Mr. GIANCARLO. Thank you. That is a critically important question. You know, one the core mandates of title VII to come out of the financial crisis was greater regulatory transparency into market positions of large market participants. And a big initiative was to collect data, create swap data repositories, and make that data available both to us as regulators and to the marketplace.

I support that core reform and that initiative. Since that time, however—and I read very carefully that inspector general's report and took a lot away from it. Again, not to shirk responsibility, the time period covered was that of the prior Commission. But what I read in that report and what I have taken away from that report is really a failure of project management.

Again, from my experience in the private sector, project management is the difference between success and failure in any large project, and this is an enormous project. So I have changed both the leadership of the project, their goals, and their deliverables. And as a result, in the second half of 2017, the agency issued, under my direction, a road map to this data project. We actually said—and my dad used to say to me: If you don't know where you are going, you will never get there. We said where we are going, and we said when we want to get there. And we laid it out in a series of deliverables over the course of 2018. And by the end of 2019, we intend to complete this project of data transparency into our swaps marketplace. Now, that may sound like a long time, but, unfortunately, progress hadn't been made earlier and so we need to take where we are today and go forward.

And I thank the OIG for their work because I think it helped our thinking on this. I think we now have the right people in place. We have the right goals in place. We have the right deliverables. We are actively engaged in this, not just domestically, but internationally as well. We are chairing some of the key groups at CPMI-IOSCO, which is the International Association of Securities Regulators, and elsewhere in putting together the global standards that need to be used because these are not domestic markets anymore, they are global markets. And it is only—it will only do us so good if we have the correct data for our domestic trades but don't have it on a global basis. So we need to reach the global standard.

And the last thing I would say is that, built into our budget is allocation for upgrading a number of key systems. The hardware that is necessary to deliver on this project as well. So full funding for our budget also means that we will meet the deliverables of that road map. If we are not able to get there, then we will have to see how we triage other resources to be able to stay on target for that timetable.

Mr. VALADAO. So, on the second part of that question, which is, how do you rate the current system? Give us some examples. Tell me a little bit about how the current system is working in comparison to what is going on around the world and even some of the participants in the marketplace that you regulate?

SWAPS DATA ANALYSIS

Mr. GIANCARLO. Well, first of all, I don't want to get too critical because we still do absorb 60 million records a day. I mean, we take in an enormous amount of data, equal to perhaps any other financial regulator and probably greater than most around the world. So we successfully analyze—we are a data analysis agency. We do a lot with what we have.

However, the next frontier is to do the kind of thing that eBay and Google and others do with enormous amounts of data, and they automate the data analysis. You know, our data analysis is still partially manual, partially automated. You know, where we want to go in the future would be to bring a much higher level of automation. That may be a 2020–2021 project. We still have to complete what we have started. But, that is on the horizon for not just the CFTC but for financial regulators everywhere, to be able to analyze the data the way, big Silicon Valley companies analyze commercial shopping data and all that. They do amazing things with data analysis. We are not there yet, but that has got to be the path forward.

Mr. VALADAO. Thank you.

Thank you, Chairman. My time has expired.

Mr. ADERHOLT. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman. Nice to see you, Mr. Chairman. Thank you very much. I think we all know how catastrophic the impact of years and years of deregulation was. I mean, it culminated in the 2008 crash. Dodd-Frank, which I was proud to support, has put us on the path to reducing that threat of the too-big-to-fail firms. It protects consumers and investors so that they are not swindled, they are not ripped off, and focusing on supporting an economy that works for all Americans.

And I will just say, took the most dangerous and most unreasonable risks in the financial system, they have been greatly reduced. And a financial crash, and I think you probably would agree, is much less likely due to Dodd-Frank rules and with everything that was encompassed there. And like with most laws, it is not perfect, but an imperfect law is better than no law at all. I think you would agree.

I am, frankly, troubled by the efforts that are supported by both Democrats and Republicans that would scale back some of the regulations that have been put in place, and that is to really unravel Dodd-Frank in many respects. I am equally concerned with what looks like the Commission's desire to work on new, bright, shiny object cryptocurrency when there is so much work to be done in the financial markets that impact so many more Americans.

For example, we know that just 1,000 individuals own 40 percent of all bitcoin. Bitcoin's own website published a survey of 5,761 adults on January 24 of this year, and it showed 60 percent of Americans had heard of bitcoin, and only 5 percent owned any bitcoin. In past year, CFTC has successfully managed to protect consumers, imposing billions of dollars of sanctions on bad actors.

So why should the committee support the diversion of resources to regulate a new financial world when there is so much that still needs to be done in looking at what is going on with unraveling the

regulations in Dodd-Frank? Why shouldn't we continue to stay the course, focus our energies on what has been successful. The regulations were put into place to prevent another crisis. Why are we going to—how are we going to continue to maintain the protection of the majority of Americans if we are going to divert our time, attention, and resources to some of these other areas?

CRYPTOCURRENCY

Mr. GIANCARLO. Thank you for the question.

So it was my predecessor who looked at our law, the Commodity Exchange Act, and reached the conclusion that cryptocurrency, at least in the form of bitcoin, meets the definition of commodities under our act and began the process there for doing what we are legally obligated to do, which is enforcing our rules against fraud and manipulation. And so the process of enforcing laws against fraud and manipulation in cryptocurrencies began by Chairman Massad, and I have continued that process.

We don't have statutory authority to ban bitcoin. It is not within our authority to do that. It would require an act of Congress.

Ms. DELAURO. It is not a point of banning it, but we are—when I say 5 percent own bitcoin. This is a very small piece of the overall picture here. Again, you have a limited budget, and believe me, I have chaired this subcommittee and increased funding for the CFTC. But a limited—and why are we then moving our limited resources to an area where—I understand you want to do some looking, but it has a very just small piece of the——

Mr. GIANCARLO. I would be concerned though because, as you say, there are scammers out there that are taking advantage of people's interest in these cryptocurrencies, especially young people. And for us to say, "You know what, we can't spend the resources to bring enforcement actions against fraud and manipulation," would in a sense leave those people vulnerable. So I think we have a duty, if it fits within the definition of our statute, have a duty to take enforcement action.

Ms. DELAURO. I would just finish with this because my time is almost up. I understand that, and I think we ought to, you know, look at the new areas and rooting out fraud and all those pieces. But as I started my commentary, I am very, very troubled by how in fact—and as I say, this is both Democrats and Republicans—are unraveling Dodd-Frank. It was put into place for prevention purposes given the enormity of the crash.

Quite frankly, I sat in the room with Secretary Paulson and Ben Bernanke when they told our leadership that—this was a Friday—that, by Monday, we were going off a financial cliff if we didn't do something. And I am—I don't come out of your world or their world, but it was troubling. So we put these preventions in place.

This is like saying to me, in some regards, where I think you ought to pay attention—and you are, don't misunderstand me, you are—and you need to pay focused attention on what is going to happen. You know, after—we put protections in place after Hurricane Katrina, okay. Now since we haven't had a hurricane of that scale, now we are going to dismantle the protections. That is essentially what is being done in Dodd-Frank.

And it is my view that that is something that you need to pay very, very close attention to and what the risks are going to be to the majority of Americans if some of these things continue to be unraveled and there is no protection as we started to—as we tried to put in place.

Thank you.

Thank you, Mr. Chairman.

Mr. ADERHOLT. Mr. Young.

RIN MARKETS

Mr. YOUNG. Thank you, Mr. Chairman. Welcome. Nice to see you.

I want to talk about RINs. You know what those are: renewable identification numbers. So the point of the RFS, as you know, was to blend more biofuels. When it was adopted the refiners themselves asked Congress to include an alternative compliance method comprised of tradeable credits so refiners would have more flexibility. So RINs are free. You get one when you blend a gallon of biofuel. If you choose not to blend, which some refiners do, then you have to buy a RIN.

I want to talk about RIN transparency. In March of 2016, the CFTC did an MOU with the EPA related to the RIN markets. So the purpose of the MOU was to, in part, to permit sharing of business information on the RIN market so that CFTC could advise EPA on, quote, techniques that could be employed to minimize fraud, market abuses, or other violations, and to conduct appropriate oversight in RIN and renewable fuel markets.

What kind of advice have you given EPA? What have you learned?

Mr. GIANCARLO. Thank you for the question. So we entered into that MOU and the project that commenced following it was that the EPA provided the CFTC with trading data in the cash markets. Let me actually just draw a jurisdictional picture for you. The EPA has jurisdiction over the physical RINs market. As you know, CFTC has jurisdiction over the RINs derivative markets, RINs futures.

And just by way of background, there is virtually no trading in RINs futures. I mean, less than a dozen. So, arising from the MOU, my predecessor, Tim Massad, reached an agreement with the EPA that they provide us with their trading data in that underlying cash market, and we would review it using our tools to look for fraud and manipulation if we saw it in that market.

Unfortunately, as anybody who has worked in data knows, the ability to draw conclusions depends on the quality of the data. We were able to go back to the EPA, and say: We do not see signs of fraud and manipulation in this market. But then, again, the data is not terribly good. And we gave them some advice, one regulator to another, as to perhaps steps they could take to improve the quality of the data.

Mr. YOUNG. So is the data not good because it is just not transparent, you are not getting the information? Tell me why the data is not good.

Mr. GIANCARLO. Again, it is their process of collecting the data. It is not our process, but——

Mr. YOUNG. How would you change that process to get better data?

RIN DATA

Mr. GIANCARLO. I would have to go back to our folks that did that analysis and met with the EPA, but my understanding is they gave them advice about the very nature of how it is collected, what is collected, what are the time series of what is collected, the thoroughness. And it was—it had issues from soup to nuts.

Now, what I will share with you, Congressman, is recently I had a chance to sit down with Ag Secretary Perdue, and he brought up this very issue and his concern that we try to find a path forward. And I have asked our chief economist to sit down with his chief economist and maybe folks from EPA as well to pick up this conversation and to see what can be done going forward. So there is a dialogue that has begun. I don't know what their meeting schedule is to see what can be—when I report to you that process, it was a process that was done under my predecessor so the information I am giving you is a little bit secondhand, but it is my understanding as I have described it to you.

Mr. YOUNG. Well, I think Congress should be kept abreast of this. I would love to work with you and, you know, working with the stakeholders as well within the industry in making sure that we all have a complete understanding of what is happening, why it is happening, the process, and if there is a need for better transparency and accountability along the way.

And I just have a few seconds left so I am just going to yield back, and I will wait for the next round, Mr. Chairman.

Mr. GIANCARLO. Thank you. I would be happy to come in and visit with you once that meeting has taken place amongst the economists and keep you abreast of the discussions.

Mr. YOUNG. I look forward to that.

Mr. ADERHOLT. Thank you, Mr. Young.

Mr. Chairman, I am sure you are aware of our fiscal year 2018 bill carries a provision that would amend the Commodity Exchange Act to require a lower level of margin or capital, known as variation margin, in transactions of a swap between one party and its affiliate with whom it has some type of shared ownership interest. This is in contrast to the current requirement for a higher amount of capital, known as initial margin.

Additionally, the bill carries a provision that will require a more stringent analysis of the cost benefits to CFTC actions. The question would be, could you explain why the initial margin requirements were put in place by prudential regulators but were not initially required by your agency, which specializes in regulating swaps and has the knowledge and expertise on these matters?

INTER AFFILIATE

Mr. GIANCARLO. I will add to that that not only did we not follow that approach, but the rest of the world didn't follow that approach of our prudentials. So our prudentials on this are a bit of an outlier in global markets. As an agency that oversees markets that are global, we understand the implications of a margin requirement that really doesn't address that the systemic risk is the

counterparty to counterparty not internally within an organization. And the reason we didn't follow the prudentials approach is we believe that it actually makes it more difficult for American users of these products, end users, whether they be manufacturers or other large businesses to—it is disadvantageous for them to use an American financial service firm to transact in global markets because the American firms are the ones paying that initial internal margin. And it gives an advantage to foreign financial service firms. And what we find unhelpful about this approach is essentially it puts our firms in a competitive disadvantage in operating in global markets. And it causes American end users to choose foreign financial service firms over American financial service firms in engaging in foreign markets. So that is the reason we took the approach we did. We think it is anticompetitive for American business. And we don't think it really enhances systemic stability because that is enhanced simply by the margin being posted when one distinct firm trades with another distinct firm.

Mr. ADERHOLT. What was the position of your predecessors on this issue? And where do you see your policies differ on the issue?

Mr. GIANCARLO. My position on this is completely consistent with Chairman Massad's position. We came to a similar conclusion when we were together at the Commission. He voiced it on behalf of the Commission as Chairman. I know he voiced that position with the prudentials at the time. And I continue to believe Chairman Massad got that right, and I think we have got it right at the Commission.

Mr. ADERHOLT. In regard to the cost-benefit analysis requirement, what is your opinion of placing a mandate on the agency?

Mr. GIANCARLO. So I am a big believer on cost-benefit, and not to be used in the event of a lawsuit. It is just to get the rule right in the first place. I think that if you do proper economic analysis, you come up with a better rule and a rule that serves the passage of time. And so I believe in it. Now, we don't have as robust a standard of cost-benefit analysis at the CFTC as does say a comparable agency like the SEC. So there has been a number of conversations over the years about enhancing the CFTC standard. And I think that there is a lot of value in some of those considerations. But at the end of day, I think good cost-benefit analysis is simply a matter of good government.

Mr. ADERHOLT. The House passed both of these provisions in both the CFTC authorization and the ag approps bill. Are you aware of opposition either on the Hill or in the administration that would prevent enactment of these provisions——

Mr. GIANCARLO. I am not.

Mr. ADERHOLT. You mentioned this briefly, you referred to it, but let me just go a little deeper into labor and union negotiations. During our hearing last year, we discussed the situation around your labor union negotiations and we included in our bill a provision that will allow you to adjust the pay and benefits to your employees should furloughs or reductions in force occur as a result of these negotiations. This was done because there were reports that CFTC would have to lay off employees if they did not receive its budget request and a Federal Service Impasse Panel imposed excessive financial burdens on your agency. I also stated at the time

that it would be difficult to give your agency more funding unless the situation resolved because the money would not be used to invest in high priority resources for overseeing the markets the Commission continues to claim, of course, it needs. Can you give us a little bit of an update on the labor negotiations for the current fiscal year and even future years?

UNION NEGOTIATIONS

Mr. GIANCARLO. The labor negotiations proceed in, I think, a satisfactory pace. The very first phone call I made upon being sworn in as Acting Chairman was to the head of union and to say that I look forward to good relationships with them. At that time, we were in a bad place vis—vis us and the union. We were in dispute mediation. We have resolved those issues, and we are—as I mentioned earlier, we achieved a 3-year pay package with the union. We have other items to resolve before we can get to a similar 3-year collective bargaining agreement, but we are making good progress on that. And I believe that the good will continues on both sides. It certainly will continue on management's side. With the continued good will, I think, and honesty—that we have brought to the table and that they have as well, I think we can continue to make progress.

Mr. ADERHOLT. Thank you. I think my time is up.

Mr. Bishop.

Mr. BISHOP. Thank you very much. Let me return to another issue. The Futures Industry Association wrote you last December to express concern about the process by which several CFTC-regulated exchanges and clearinghouses self-certified certain futures and options contracts on cryptocurrencies. The letter said, quote: "Under law, exchanges may self-certify a product for trading by the close of business one day and then list the product for trading the next day. This process does not require CFTC approval or input and allows little or no time for public review. While suited for standardized products, this process does not distinguish for a products risk profile or unique nature. We believe that this expedited self-certification process for these novel products does not align with the potential risks that underlie their trading and should be reviewed."

I do understand that your staff had extensive discussions with these entities prior to the announcement, but, frankly, it sounds like the agency had to ask for changes, not insist on them. Given the volatile nature of the bitcoin market, this is a bit troubling, no pun intended. Would you discuss this?

SELF CERTIFICATION

Mr. GIANCARLO. Yeah. So the self-certification process goes back almost two decades at the agency, it has been long-standing. And I think that, until recently, it hasn't been controversial. Over 12,000 products have been self-certified over that period of time. And to my knowledge, it hasn't been the subject of a great deal of controversy.

Under those provisions, the exchanges did approach the CFTC over the course of the second half of last year. And we did require them to make a number of enhancements that we refer to as our

heightened review process for cryptocurrencies. You are absolutely right; it was on a voluntary basis. I have asked the staff to go back and consider whether that can be put into staff guidance. And even though the process doesn't provide for public hearings, Commissioner Behnam held, as part of our Market Risk Advisory Committee, held I think a very well-attended, very well-considered, very well-thought-through public hearing on the self-certification process. A number of ideas came out of that. And I am open to discussing with my fellow Commissioners whether there should be some adjustments to the self-certification process, and we will hear ideas amongst the Commissioners.

Having said that, I do want to make it clear that the self-certification process is a longstanding feature of the agency. I think we were able to utilize it to get some quite unprecedented concessions from the two bitcoin futures providers, and we will require that on a going-forward basis for any future self-certifications that we might see for bitcoin or otherwise.

Mr. BISHOP. It seems like the timeframe is so short in that particular instance that it raised concerns. So I hope that you will look at that and perhaps get back to us.

On cybersecurity, obviously, that is a constant concern for both Federal agencies and the industry. And I believe you said last month that you don't have the authority to impose cybersecurity regulations on the cryptocurrency industry where hacks have occurred with relative frequency. Can you give us the state of cybersecurity at CFTC itself and at the companies that you oversee, including the cryptocurrency world?

CYBER SECURITY

Mr. GIANCARLO. Thank you for that. I am actually glad you drew a distinction between the CFTC itself and the companies we oversee. As I mentioned before, the CFTC recently had its audit, its annual audit, as do all Federal agencies, and we ranked ahead of many of our fellow agencies. I am very pleased with the results there.

Mr. BISHOP. Is that a good thing?

Mr. GIANCARLO. Well, you know, let's hope it is. You know, when it comes to cyber, you can never say it will never happen to you. You have to assume it will happen at some point. And so—which is why I put in a number of reforms since I have become chairman. I meet monthly with our head of cyber. He reviews all of the cyber activities every month. We receive almost 9,000 attacks—attempts a month. So the attacks are relentless.

We are also looking at human error. So we are upping our game in terms of doing internal testing of what is called phishing exercises. I feel we are doing a lot of good things at the CFTC. I wish I had as good of a feeling—and I will be very candid with you—of our ability to monitor what is going on in the ecosystem in the markets we oversee. Right now, we should have four cybersecurity examiners for the players in our market. Through attrition, we are down to one. And in our budget is the resources to fill those gaps, but we desperately need to do that because I would much rather that our examiner goes into an exchange or to a clearinghouse and say, "There is a gap in your cyber defenses," and they fix it. I

would much rather that than to get a phone call the next day or some other time saying that they have been hacked and now we have got some problems in the marketplace. So a pound of prevention is worth—whatever it is. An ounce of prevention is worth a pound of cure. I would like to make sure we have got that ounce and fill those three missing——

Mr. BISHOP. Are you going to be able to find the resources to do that not including that $31.5 million?

Mr. GIANCARLO. I said in the opening: Give us the tools, we will do the job. Give us the tools, we will do the job. We will fill them. I am a persuasive recruiter.

Mr. ADERHOLT. Mr. Young.

Mr. YOUNG. Thank you, Mr. Chairman.

Mr. Chairman, speed, technology, algorithms, artificial intelligence. I have got concerns based on the concerns of farmers. The producers back home ask about the ability of the CFTC to effectively provide oversight for our farmers, producers, with all this happening, particularly the balance between fundamental market users versus the algorithmic trader. Do we have balance? How do you get it? We need it.

HIGH FREQUENCY TRADING

Mr. GIANCARLO. That is a great question. When I meet with farmers and travel around the country, the question that seems to be the common question is, what is going on in these markets? When I go in the market, am I getting run over by a speeding train of algorithmic traders? What is the role they play in the market? What is the balance between them and us, the natural hedgers? It is not an easy question to answer. There are a lot of anecdotal stories, but that doesn't prove anything. And this is why we are seeking to really redouble our economists unit. We want answers to these questions, and we want good, solid data-driven answers, not answers that are driven by a story or an experience in the marketplace. You know, healthy markets are like environments in the natural world, the healthiest ones, the most durable ones are the ones that have the most biodiversity, and the same thing is true about economic markets. You couldn't have a market if you just had naturals because everybody would be long, there would be nobody to go short. You need the balance. But balance is the operative word. What is the right balance? And our markets are changing so dramatically, so what is a responsible agency to do? It is to first understand these changes and then decide what are the right policy responses. The one thing I won't do is, based on some anecdote, go in and start setting restrictions on who can be in the market and who can't, because they may be the very valuable liquidity providers the market needs. What we need to do is really understand the role of these algorithmic trades and the proprietary traders that are not natural—they are not naturally long. They are just taking the other side of a trade all day long; they can be long or short. And so we need to understand that dynamic, which is why we are asking for additional resources for the Office of the Chief Economist.

Mr. YOUNG. As you the witness the rise of algorithmic trading, have you seen a rise in volatility? Can you measure that somewhere? Can you pinpoint it? Is it there? Is it——

Mr. GIANCARLO. It is not an exact correlation.

Mr. YOUNG. OK. It is not a correlation. How do you manage volatility? Should you?

Mr. GIANCARLO. Well, that—in many ways, that is what these products do, the more volatile the market—in fact, somebody mentioned bitcoin. In fact, what is interesting is the impact that the bitcoin futures has had on the underlying price. The day the bitcoin futures launched on CME was the high watermark of the bitcoin price. And since then, it seems to be stabilizing around 10,000. So the launch of the future—a healthy futures market often brings a stability to underlying markets.

Mr. YOUNG. Can you measure during a trading day which are—how many are algorithmic trading from computers, and how many are the true market makers? Is it 10 to 1? Is it 50–50?

Mr. GIANCARLO. Again, it is different in virtually every marketplace. Some markets' financials tend to be more dominated than the commodity and natural and softs markets. But yet the markets we live in today are majority automated and increasingly algorithmic. I mean, the day of the manual trading is passing with the day of the trading floor. And we have to accept that markets are becoming digital in the same way the rest of our world is becoming digital, and they are becoming increasingly automated and increasingly algorithmic. That is the world we heading toward, and that is why, as an agency, we need to be up to that challenge. We need to be as digital as these markets.

Mr. YOUNG. It reminds me of a line from a Pink Floyd song: Welcome to the Machine.

I yield.

Mr. ADERHOLT. Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman.

SUNSHINE

Chairman Giancarlo, you convened a meeting of the CFTC on February 28. It was with the SEC Chairman Clayton, SEC Commissioner Peirce, CFTC Commissioner Quintenz, and the staff from both the CFTC and the SEC. This is a tweet from your February 27 gathering at 9:18 p.m., and it reads: Earlier today, at CFTC, staff at CFTC, Quintenz, and I hosted Chairman Clayton and SEC colleagues to discuss better harmonizing Dodd-Frank regs and rules. We are off to a great start.

This was not a public meeting, but one that was behind closed doors and one among only Republican members of both Commissions as I understand it. It is troubling, but even more troubling than the partisanship of the meeting is the fact that the meeting appeared to potentially violate the Government in the Sunshine Act, and you know that act. It may require that, for the CFTC in its current form, you have got two of three members of the CFTC meeting, that it must be open to the public unless an exemption applies. It appears to me, based on your tweet, discussing better harmonization of Dodd-Frank regulations and the rules involve policy discussions that, to my mind, should have been open to the pub-

lic. So let me run down just a few questions for which I was just looking for a yes-or-no answer.

Did the information shared during the meeting relate to national defense?

Mr. GIANCARLO. No.

Ms. DELAURO. Was the meeting related solely to internal personnel rules and practices?

Mr. GIANCARLO. The meeting was a briefing by staffs of the two agencies on progress that had or had not been made in the—statutorily required harmonization of Dodd-Frank rules between the two agencies.

Ms. DELAURO. Did the meeting have any discussion of the current state of looking at what is going on with the unraveling of the Dodd-Frank regulations?

Mr. GIANCARLO. No.

Ms. DELAURO. Was the meeting related to accusing a person of a crime?

Mr. GIANCARLO. No.

Ms. DELAURO. Was the meeting related to information where disclosure would constitute a breach of privacy?

Mr. GIANCARLO. No.

Ms. DELAURO. Was the meeting related to investigatory records where the information would harm the proceedings?

Mr. GIANCARLO. You know, can I say what the meeting was?

Ms. DELAURO. Sure.

Mr. GIANCARLO. The meeting was a briefing by staffs that had worked on harmonization efforts as statutorily required. And the meeting was overseen by the Office of General Counsel to make sure that it did not breach the—what is called regulation in the Sunshine Act.

Ms. DELAURO. Was the meeting related to information which would lead to financial speculation or endanger the stability of any financial institution?

Mr. GIANCARLO. The meeting did not concern any particular financial institution.

Ms. DELAURO. Was the meeting related to the agencies participation in legal proceedings?

Mr. GIANCARLO. You know, I am almost uncomfortable calling it a meeting. It was a briefing. And no legal proceedings were discussed.

Ms. DELAURO. Why then was the meeting not open to the public when that is something that is required and you are talking about, as you said, the harmonization of Dodd-Frank? And making it such a partisan effort——

Mr. GIANCARLO. It is not a partisan effort, first of all, because any rulemaking that would come out of this would have to go through the Administrative Procedure Act. My fellow Democratic Commission was briefed on all the issues discussed at the meeting in advance of the meeting.

Ms. DELAURO. Why wasn't——

Mr. GIANCARLO. The harmonization efforts are Chairman-led efforts at both the SEC and the CFTC. So Chairman Massad never involved me in any——

Ms. DELAURO. I am not asking about Chairman Massad's——

Mr. GIANCARLO. Of course. But it is a Chairman-led effort, and the staff was briefing us on progress that had been made so we could get up to speed when our predecessors left the agencies and to see what needs to be done going forward.

Ms. DELAURO. I don't know what your general counsel said, but as I understand the Sunshine Act requires that CFTC—when two of the members of the CFTC meet, it must be open to the public, unless an exemption applies.

Mr. GIANCARLO. And we were assured that an exemption applied for briefings. In fact, meetings take place routinely at the agency where staff brief Commissioners, and those meetings are closed to the public.

Ms. DELAURO. What was the exemption? What is the nature of the exemption?

Mr. GIANCARLO. It is nondeliberation of Commission matters. It was a briefing only; it was a one-way information flow.

Ms. DELAURO. Well, thank you. Thank you for the clarification of that, but I just think when we are talking about these critical issues these days, it would be good to have the transparency that we have so lacked in the past with regard to so many of the these critically important areas.

Thank you.

Mr. ADERHOLT. Thank you, Ms. DeLauro.

Mr. Chairman, thank you for being here. I think we had a good hearing today to discuss some of these issues and bring up some issues that the members of this subcommittee feel are important. Thank you for sharing and bringing us up to date. And we look forward as we continue on with the fiscal year 2019 appropriation bill that affects your agency. So we look forward to working with you, and thank you for your service.

And the hearing is adjourned.

COMMODITY FUTURES TRADING COMMISSION (CFTC)
QUESTIONS FOR THE RECORD
HOUSE AGRICULTURE APPROPRIATIONS SUBCOMMITTEE HEARING
MARCH 7, 2018

QUESTIONS SUBMITTED BY CHAIRMAN ROBERT ADERHOLT

Bonuses, Performance Awards, and Special Pay

1. **Mr. Aderholt: How much in bonuses, special pay, incentive awards, merit pay, and performance pay, were distributed to CFTC employees and contractors in FY 2017 and estimated in FY 2018 and in the FY 2019 President's Budget?**

Response: The table below shows the FY 2017 costs for the CFTC employees' merit pay and awards as well as estimates for FY 2018 and included in the FY 2019 budget request:

Please note that CFTC contractors are not CFTC employees, and individuals working on CFTC contracts are paid by their respective employers.

FY 2017 estimates reflect actuals paid during the fiscal year for 690 full-time equivalents (FTE).

FY 2018 estimates reflect the cumulative impact of FY 2017 actuals, and the decrease in FTE levels from the actual of 690 FTE in FY 2017 to 670 in FY 2018 based on the budgetary constraints of the FY 2018 appropriation.

FY 2019 estimates reflect the assumptions contained in the FY 2019 President's Budget Request, including the merit pay increase contained in the union agreement, the increases in FTE levels from the FY 2018 Spend Plan estimate of 670 FTE to 716 in FY 2019. These estimates are subject to change based on the enacted FY 2019 appropriation.

Category	**FY 2017**[1,3] Actual	**FY 2018**[2,3] Estimate	**FY 2019**[3] Estimate
Merit pay[3]	$1,600,472	$2,347,575	$3,219,154
Awards[4]	$1,224,861	$0	$0
Total	**$2,825,333**	**$2,347,575**	**$3,219,154**

Notes:

[1] FY 2017 merit pay amount includes expenses from the FY 2016 Impasse Panel Decision. In addition to merit pay increase resulting from the Impasse Panel Decision, FY 2017 merit pay line also includes expenses from the National Treasury Employee Union (NTEU) agreement made in FY 2017.

[2] FY 2018 merit pay amount includes expenses from the FY 2017 merit pay increase, and for merit pay approved in July, 2018 which was also included in the FY 2018 President's Budget request.

[3] Merit pay increases occur in the last quarter of the fiscal Year. CFTC staff does not receive step increases as do Federal employees under the General Schedule (GS) pay system.

[4] Awards include bonuses, incentive awards, and performance awards. In FY 2017, as a result of FY 2016 Impasse decision a 1% bonus was paid to all qualified employees.

2. Mr. Aderholt: Please provide the costs associated with pay increases for FY 2017, FY 2018, and FY 2019.

Response: Figures in the table below include the amounts budgeted in each fiscal year to accommodate the portion of the previous year's award, payable in the subsequent year.

- General adjustments are similar to the General Schedule (GS) pay systems cost of living increase received annually, and are usually payable beginning the first pay period of the calendar year.
- Merit pay is a performance-based increase and is payable in the fourth quarter of the fiscal year. Employees receive the increase based on their annual performance ratings and it is distributed to only those employees that receive a rating of three (3) or higher on their annual performance plan. Employee annual salary and bi-weekly pay as a result of any merit pay increases are increased beginning in the fourth quarter.
- FY 2017 actual costs include expenses of a one percent (1%) general adjustment payable from the first pay period of calendar year 2017 and a three percent (3%) merit pay increase payable beginning in the fourth quarter of FY 2017 for the 2016-2017 performance cycle. FY 2017 also includes an additional one percent (1%) merit pay increase resulting from the Impasse Panel Decision.
- In FY 2018, CFTC approved a two percent (2%) general adjustment and a three percent (3%) merit pay increase, in accordance with the CFTC and National Treasury Employees Union (NTEU) *Agreement on Compensation and Benefits for Fiscal Years 2018, 2019, and 2020* on December 26, 2017, for the 2017-2018 performance cycle. The merit pay amount in the table below represents the three quarters payable in FY 2018 from the FY 2017 increase and the estimated merit pay amount payable in the fourth quarter of FY 2018.
- FY 2019 President's Budget Request includes estimated costs for the general increase and merit pay in accordance with CFTC and NTEU *Agreement on Compensation and Benefits for Fiscal Years 2018, 2019, and 2020*. The merit pay amount in the table below represents the three quarters payable in FY 2019 from the FY 2018 increase and the estimated fourth quarter amount payable for the anticipated July 2019 increase.

Pay Adjustments[1]	Effective Pay Period (PP)	FY 2017 Actual Cost[2]	FY 2018 Estimated Cost*	FY 2019 Estimated Cost
General Adjustment	Jan PP 01	$1,196,062	$1,741,187	$1,929,061
Merit Pay Increase of 1%	Oct PP 20	$931,080	$0	$0
Merit Pay Increase of 3%	Jul PP 14	$669,392	$2,347,575*	$3,219,154

[1] Pay Adjustments exclude benefits paid by the Commission

[2]Merit pay increase payable in FY 2018 is $629,858 in the last quarter.

Budgetary Effects of FY 2018 Budget

3. **Mr. Aderholt: Please describe in detail what effect the FY 2018 budget level of $249 million will have on the agency including whether furloughs, Reduction in Force (RIFs), or other negative employee actions could result from the budget being reduced by $1 million.**

Response: The Commission made decisions to prevent actions that would negatively impact current employees when the 2018 budget of $249 million was received. The Commission was operating under a carefully crafted hiring freeze to remain within the existing funding environment that held the enacted appropriation at $250 million for the last three fiscal years. Maintaining the hiring freeze for a fourth year has further limited the Commission's ability to perform the number and scope of examinations presented in its budget requests, and reduced our capacity to produce robust research and cost/benefit analysis, and slowed the Commission's ability to review existing regulations, and determine which regulations are no longer relevant, and/or propose changes that support an open market. In addition, the Commission severely curtailed contracted services supporting infrastructure activities, reduced training for staff beyond mandated government-wide training, and limited involvement to essential conferences and participation with international counterparts, which weakens the U.S. voice as international standards are developed. The reduction to the information technology account further compounded these efforts and hindered the Commission's ability to preserve its technological capacity with constantly evolving technologies in the markets, and it limits the Commission ability to respond to and protect the markets from emergent speculative instruments like virtual currencies.

4. **Mr. Aderholt: Will the reduction in funding for the IT set-aside of $2 million allow for increased funding of Personnel Compensation and Benefits and provide flexibility for the agency?**

Response: No, the $2 million reduction in the Information Technology (IT) set-aside did not provide sufficient flexibility to fully address the inflationary cost pressures on the Salaries and Expenses (S&E) account. The Commission further reduced FTE levels from FY 2017 by maintaining a hiring freeze and implementing other constraining actions to compensate for increases in the inflationary costs of leases, shared-services, contracts, and personnel costs in all areas.

Unionization of Employees at CFTC

5. **Mr. Aderholt: Please provide the most recent Memorandum of Understanding and any other contractual agreement or understanding between the CFTC and the National Treasury Employees Union (NTEU).**

Response: The following is a list of agreements with NTEU in response to the question.

1. Memorandum of Understanding between CFTC and NTEU regarding the parties' Interim Agreement dated January 13, 2015 – attachment A.
2. Memorandum of Understanding between CFTC and NTEU regarding FY 2018 –

FY 2020 Compensation and Benefits dated December 26, 2017 –attachment B.
3. Memorandum of Understanding between CFTC and NTEU regarding FY 2017 Compensation and Benefits dated May 15, 2017 –attachment C.

6. Mr. Aderholt: Please provide the most recent draft of the negotiated collective bargaining agreement between the NTEU and the CFTC.

Response: CFTC and NTEU negotiated an interim CBA in FY 2015 that will remain in effect until a new CBA is executed; this agreement is provided as attachment A. In addition, the parties executed a multi-year compensation and benefits agreement that spans the 2017-2018 to the 2019-2020 annual performance cycles, see attachment B. CFTC and NTEU are in continuing negotiations for a comprehensive CBA.

7. Mr. Aderholt: As a result of the current negotiations with the NTEU, please provide the estimated increased costs to CFTC's budget at a minimum and a maximum (even if only based upon preliminary discussions with the NTEU for the next fiscal year) that could result from the negotiations broken down by line items as defined by OMB object class and by CFTC division.

Response: The CFTC signed an *Agreement on Compensation and Benefits for Fiscal Years 2018, 2019, and 2020,* with the NTEU on December 26, 2017. The FY 2019 Budget Request reflects the terms of this agreement, and includes $5.5 million for increases to salaries and benefits for existing staff. The increase, by budget object class and division, are shown below:

Division	Budget Object Class		Total
	11.0 Personnel Compensation	12.0 Personnel Benefits	
	$'s in thousands		
Enforcement	$ 1,309	$ 105	$ 1,414
Market Oversight	$ 655	$ 52	$ 707
Clearing & Risk	$ 502	$ 40	$ 543
Swap Dealer & Intermediary Oversight	$ 563	$ 45	$ 608
Chief Economist	$ 114	$ 9	$ 123
General Counsel	$ 327	$ 26	$ 353
International Affairs	$ 84	$ 7	$ 90
Data and Technology	$ 617	$ 49	$ 666
Executive Director	$ 655	$ 52	$ 707
Chairman & Commissioners	$ 206	$ 16	$ 222
Inspector General	$ 69	$ 5	$ 74
Total	**$ 5,100**	**$ 408**	**$ 5,508**

8. Mr. Aderholt: According to the documents provided in the previous question, what would the number of potential furlough days have been in FY 2017 that could have

resulted from the "worst case scenario" described in the budget document as a result of an FSIP decision?

Response: At the time of the briefing (October 20, 2016), the CFTC estimated that the worst case scenario could have potentially required 17 furlough days, after taking cost cutting measures. The CFTC has since signed a multi-year agreement with NTEU that brings some cost certainty to the Commission's resources.

Administrative Overhead and Contractors

9. **Mr. Aderholt: Please provide a table showing the breakdown of the number of administrative contractors, CFTC employee and FTE, and total cost for each for fiscal years 2014-2018.**

Response: Please see the table below for the requested information. The number of administrative contractors is defined as the number of contractor positions in the Office of the Executive Director.

Fiscal Year	Number of Administrative Contractors	Cost of Contract	CFTC Administrative Employee FTE	Total Cost of CFTC Administrative Employees
2014	25	$ 7,910,586	76	$ 10,119,849
2015	62	$ 9,037,752	77	$ 15,094,932
2016	75	$ 8,131,273	76	$ 15,974,486
2017	73	$ 7,893,928	85*	$ 17,713,812
2018	56	$ 6,875,596	81*	$ 17,456,536
*CFTC reorganized business management staff from the divisions/offices into the Office of the Executive Director in FY 2017, see congressional notification letter dated March 7, 2017 letter from Acting Chairman Giancarlo.				

10. **Mr. Aderholt: What is the cost per contractor and per CFTC FTE cost of a typical administrative employee at the CFTC?**

Response: The average cost in FY 2018 for a typical administrative contracted position in FY 2018 is $122,778. Typical administrative contracted positions at CFTC include executive assistants for Division Directors, paralegal support for Enforcement attorneys, human resources assistants, budget analysts and travel specialists, procurement professionals, internal controls and audit testing assistance, and logistics support.

The average cost for a typical administrative position at CFTC is $215,513 per a FTE including benefits. Typical administrative positions at CFTC include business management professionals, human resources professionals, financial management and accounting professionals, strategic planning and facilities management professionals, librarians, privacy professionals, judgement officers and staff.

11. Mr. Aderholt: Please provide a table showing the number of contractors by division and mission area for fiscal years 2014-2018.

Response: The information is provided in the below table:

CFTC Contractors by Division					
Division	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
Chairman and Commissioners	0	0	0	0	3
Office of the Executive Director	25	62	75	73	56
Chief Economist	1	1	1	2	1
Clearing & Risk	0	0	0	0	0
Data & Technology	169	159	193	219	215
Enforcement	8	6	7	2	3
General Counsel	0	0	1	7	4
International Affairs	0	0	0	0	0
Inspector General	1	9	12	12	4
Market Oversight	0	1	2	2	1
Swap Dealer & Intermediary Oversight	0	1	1	0	1
Total	204	239	292	317	288

Office of the Chief Economist (OCE)

12. Mr. Aderholt: Please provide a table showing the amount of funding and FTE for fiscal years 2014-2018 for the OCE.

Response: The table below provides the requested information for the OCE:

Office of the Chief Economist					
FYs	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Actual	FY 2018 Spend Plan
	$' in thousands				
Funding	$ 2,380	$ 3,154	$ 3,833	$ 4,071	$ 3,682
FTE	9	11	13	14	12

Leasing

13. Mr. Aderholt: What is the total amount of leasing costs CFTC is required to pay down due to the ADA violations related to the recording statute and the voluntary services statute?

Response: The remaining unfunded lease liability estimated as of September 30, 2018, is $149.4 million. This amount will be funded by Commission's annual Salary and Expense (S&E) appropriation received for FY 2019 through FY 2025, as long as permissible

authorizing language is included in the annual appropriation act.

The Commission's failure to provide notification of available appropriations to its Chicago and New York property owners in accordance with the applicable lease terms and Federal Acquisition Regulation (FAR) 52.232-18, Availability of Funds (1984), resulted in the acceptance of voluntary services. It did not result in any additional unfunded deficiency beyond what was reported for the entire lease term for each location.

14. Mr. Aderholt: What is the effect of the most recent GAO legal opinion on the agency and will the Commission be forced to obligate any funds as a result of the opinion?

Response: The most recent GAO opinion "*Commodity Futures Trading Commission—Liabilities Outside of the Government's Control*", B-328450 was issued on March 6, 2018. The Commission is reviewing clauses contained in all four leases based on the GAO recommendation to determine the amount of liabilities incurred when the leases were signed that were outside of the Government's control and were not subject to a fixed limit. The result of the findings of the review will determine if recording entries will be required for potential liabilities and if an Antideficiency Act violation should be reported. CFTC will also need to report an Antideficiency Act violation for agreeing to clauses containing uncontrolled liabilities, which had no fixed limit.

15. Mr. Aderholt: What is the amount of costs the CFTC will incur related to the GAO's identification of a violation of the miscellaneous receipts statute?

Response: The Commission is researching and analyzing all available historical records, some dating back to the expiration of the 1986 lease, to determine the amount of potential liabilities associated with GAO opinion "*Commodity Futures Trading Commission—Consistency of Real Property Leases with the Miscellaneous Receipts Statute*", B-327830 issued on February 6, 2017. In this opinion, CFTC violated the miscellaneous receipt statute by having a third-party pay a contractor for items that were properly payable by the Commission.

CFTC IG Overhead

16. Mr. Aderholt: Please provide a table showing the amounts charged to the IG for overhead for fiscal years 2014-2018

Response:

Fiscal Year:	2014[1]	2015	2016	2017[2]	2018
IG Carve-Out	$ 1,420,000	$ 2,620,000	$ 2,620,000	$ 2,700,000	$ 2,700,000
Explanatory Statement - Overhead Amount	$ -	$ -	$ 330,000	$ 479,000	$ 350,000
Calculatored IG Overhead	$ -	$ 338,364	$ 451,900	$ 539,771	$ 546,000
Charged as IG Overhead	$ -	$ 338,364	$ 330,000	$ 356,830	$ 350,000
IG FTE	6	7	9	9	9

[1]FY 2014 was the first year the IG carve-out was included in the appropriation langauge. The appropriation was not sufficient to cover the base IG operational costs. Therefore, no overhead was charged.

[2]FY 2017 amount chargeable as IG overhead was limited per the explanatory statement, however the amount was reduced to accommodate higher than expected contracted costs for the IG.

17. Mr. Aderholt: What is the amount of overhead the IG would be charged in FY 2018 under current funding levels and under a funding level of $281.5 million?

Response: In accordance with the FY 2018 explanatory statement for the IG overhead, the amount chargeable to the IG is $350,000. Based on the CFTC's calculation contained in the FY 2018 budget request the Commission would have allocated $510,410 to the IG in overhead charges. In FY 2019, the Commission would charge the IG an amount equal to its proportional share of operating expenses; estimated to be $502,509 if the budget were to be enacted as requested.

Recoveries of Prior Year Obligations and Carryover of Funds

18. Mr. Aderholt: Please provide a table from FY 2013 to present detailing recovery of Prior Year Obligations with amounts for each year. In separate tables, please break down each year's recovered funds by object class. Please also in include a table displaying unliquidated obligations for the past five fiscal years.

Response: As reported annually in the Commission's Agency Financial Report for FY 2017, total audited recoveries of prior year obligations by year for FY 2013 through FY 2017 are summarized in table 1 below, table 2 provides the unliquidated obligations, and table 3 provides the object class data requested.

Table 1

COMMODITY FUTURES TRADING COMMISSION - PRIOR YEAR RECOVERIES

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	Grand Total
Customer Protection Fund	$ -	$ 24,004	$ 89,205	$ 235,289	$279,083	$1,494,452	$ 2,122,032
General Fund	$ 3,885,172	$ 1,866,402	$ 3,972,470	$ 4,212,871	$5,078,199	$5,837,977	$ 24,853,091
Grand Total	**$ 3,885,172**	**$ 1,890,406**	**$ 4,061,675**	**$ 4,448,160**	**$5,357,282**	**$ 7,332,429**	**$ 26,975,124**

Table 2

COMMODITY FUTURES TRADING COMMISSION
UNLIQUIDATED OBLIGATIONS AT END OF YEAR (FIVE FISCAL YEARS)

FY 2013	FY 2014	FY 2015[1]	FY 2016	FY 2017
$ 25,798,406	$ 40,564,762	$270,333,727	$255,636,819	$ 228,779,264

Salaries and Expenses	$ 25,243,753	$ 244,807,926	$ 195,589,119
Information Technology	$ 11,650,117	$ 21,234,594	$ 26,594,176
Customer Protections Fund	$ 3,670,892	$ 4,291,207	$ 6,595,969

[1] FY 2015 are the restated amounts provided. See GAO Decision B-327242

Table 3

COMMODITY FUTURES TRADING COMMISSION - PRIOR YEAR RECOVERIES

FUND	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018 Estimated
Customer Protection Fund						
11.1	$ -	$ -	$ 23,466	$ 41,327	$ 4,322	$ 113
11.3	$ -	$ -	$ -	$ 1,033	$ -	$ -
11.5	$ -	$ -	$ -	$ 1,085	$ -	$ -
12.1	$ -	$ -	$ -	$ 12,033	$ 22,144	$ 205
21.0	$ -	$ 834	$ 18	$ (153)	$ 372	$ 179
22.0	$ -	$ -	$ -	$ -	$ -	$ -
23.1	$ -	$ -	$ -	$ 116,371	$ -	$ -
23.2	$ -	$ -	$ -	$ (115,771)	$ -	$ -
24.0	$ -	$ 11,779	$ 3,826	$ 10,654	$ 45	$ -
25.1	$ -	$ 11,391	$ 61,895	$ 168,704	$ 251,888	$ 1,491,096
25.2	$ -	$ -	$ -	$ -	$ 240	$ -
25.7	$ -	$ -	$ -	$ 6	$ 72	$ 41
26.0	$ -	$ -	$ -	$ -	$ -	$ 2,817
CPF Total	**$ -**	**$ 24,004**	**$ 89,205**	**$ 235,289**	**$ 279,083**	**$ 1,494,452**
Emergency Fund						
25.1	$ -	$ -	$ -	$ -	$ -	$ -
25.3	$ -	$ -	$ -	$ -	$ -	$ -
EF Total	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
General Fund						
11.1	$ -	$ -	$ 11,649	$ -	$ -	$ 206,218
11.3	$ -	$ -	$ -	$ -	$ -	$ 12,316
11.5	$ -	$ -	$ -	$ -	$ -	$ 7,699
11.8	$ -	$ -	$ -		$ -	$ -
12.1	$ -	$ -	$ -	$ 104,630	$ 4,149	$ 888,629
21.0	$ -	$ 1,711	$ 30,882	$ 44,649	$ 26,795	$ 22,170
22.0	$ -	$ 6,008	$ -		$ 11,284	$ 5,892
23.1	$ -	$ -	$ 142,602	$ 78,695	$ 6,532	$ -
23.2	$ -	$ 1,215	$ -	$ 44,356		$ 657,526
23.3	$ -	$ 36,519	$ 399,197	$ 169,971	$ 419,985	$ 192,391
24.0	$ -	$ 3	$ 554,735	$ 260	$ 13,815	$ 5,226
25.1	$ 3,885,172	$ 1,577,155	$ 1,756,317	$ 4,353,233	$ 3,615,108	$ 2,839,271
25.2	$ -	$ 106,095	$ 759,328	$ 511,728	$ 763,930	$ 790,032
25.3	$ -	$ 55,194	$ 24,467	$ 21,590	$ 25,818	$ 54,565
25.4	$ -	$ 60,117	$ 49,294	$ 6,882	$ 16,277	$ 36,138
25.6	$ -	$ 1,924	$ -	$ 3,315	$ 14,555	$ -
25.7	$ -	$ 493	$ 2,239	$ 50,248	$ 143,772	$ 15,763
26.0	$ -	$ 5,500	$ 190,569	$ 84,040	$ 5,467	$ 19,366
31.0	$ -	$ 14,468	$ 43,447	$ (1,260,726)	$ 10,712	$ 84,775
32.0	$ -	$ -	$ 7,744	$ -	$ -	$ -
GF Total	**$ 3,885,172**	**$ 1,866,402**	**$ 3,972,470**	**$ 4,212,871**	**$ 5,078,199**	**$ 5,837,977**
Grand Total	**$ 3,885,172**	**$ 1,890,406**	**$ 4,061,675**	**$ 4,448,160**	**$ 5,357,282**	**$ 7,332,429**

Swap Dealer de Minimis

19. Mr. Aderholt: Does CFTC plan to comply with the Swap Dealer de Minimis directive in the FY 2018 Omnibus Appropriations Act? If so, when does it plan to comply? If not, why?

Response: On June 4, 2018, the Commission proposed to amend the de minimis exception within the swap dealer definition in the Commission's regulations.[1] The proposed amendments include setting the aggregate gross notional amount threshold for the de minimis exception at $8 billion in swap dealing activity entered into by a person over the preceding 12 months.

In his testimony before the House Agriculture Committee on July 25, 2018, Chairman Giancarlo committed to completing a final rule by the end of 2018.[2]

The swap dealer de minimis public comment period closed on August 13, 2018.[3]

Commission staff are currently reviewing the comments and formulating a series of recommendations for the Commission to adopt final rule amendments.

20. Mr. Aderholt: What are the agency's plans for the Swap Dealer de Minimis threshold scheduled to be reduced by $5 billion under current regulation?

Response: On June 4, 2018, the Commission proposed to amend the de minimis exception within the swap dealer definition in the Commission's regulations. The proposed amendments include setting the aggregate gross notional amount threshold for the de minimis exception at $8 billion in swap dealing activity entered into by a person over the preceding 12 months.

In his testimony before the House Agriculture Committee on July 25, 2018, Chairman Giancarlo committed to completing a final rule by the end of 2018.

The swap dealer de minimis public comment period closed on August 13, 2018.

Commission staff are currently reviewing the comments and formulating a series of recommendations for the Commission to adopt final rule amendments.

FY 2018 Budget Planning

21. Mr. Aderholt: What is CFTCs current rate of attrition? What is the estimated rate of attrition at the end of fiscal year 2018?

Response: The attrition rate is annualized at 3.7% at the middle of the 4th quarter, FY 2018. The final attrition rate for FY 2018 will be determined after the conclusion of the fiscal year.

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[1] See De Minimis Exception to the Swap Dealer Definition, 83 FR 27444, 27459 (June 12, 2018).
[2] See Testimony of Chairman J. Christopher Giancarlo before the House Committee on Agriculture, Washington, D.C., July 25, 2018, available at https://www.cftc.gov/PressRoom/SpeechesTestimony/opagiancarlo50.
[3] Comments are *available at* https://comments.cftc.gov/PublicComments/CommentList.aspx?id=2885.

CFTC Enforcement

22. Mr. Aderholt: Please provide a table showing: the number of staff, the number of cases opened, the number of cases closed, the level of funding, the monetary amount of sanctions and orders obtained, and the monetary amount actually recovered for the CFTC's Division of Enforcement, by fiscal years 2000 through estimated 2018. This table should be similar to the one submitted for FY 2017.

Response: Projected case data and estimated FTEs for FY 2018 in the table below are derived from the 2018 Spend Plan. Final data for 2018 will be available after end of the fiscal year.

Commodity Futures Trading Commission

Fiscal Year (FY)	FTEs	Level of Funding for Enforcement	Cases Opened/ Filed[2]	Cases Closed/ Resolved[2]	Restitution & Disgorgement	Civil Monetary Penalties	
					Assessed[4]	Assessed[4]	Collected[4]
FY 00	152	$18,746,000	53	81	$156,354,057	$179,811,562	$3,299,362
FY 01	150	$20,988,000	44	32	$7,687,379	$16,876,335	$3,170,252
FY 02	143	$21,406,000	40	43	$25,748,536	$9,942,382	$5,922,387
FY 03	146	$24,336,000	64	47	$106,785,796	$110,264,932	$87,699,077
FY 04	144	$25,343,000	83	70	$96,274,375	$302,049,939	$122,468,925
FY 05	135	$25,913,000	69	53	$87,424,932	$76,672,758	$34,163,077
FY 06	131	$26,245,000	38	53	$258,475,451	$192,921,794	$12,364,509
FY 07	112	$25,791,000	41	63	$296,623,405	$345,614,139	$12,137,848
FY 08	116	$28,730,000	40	66	$402,967,919	$234,835,121	$140,745,252
FY 09	121	$36,168,000	50	48	$176,185,109	$99,489,609	$17,362,486
FY 10	149	$42,217,000	57	38	$65,523,151	$136,040,764	$75,111,676
FY 11	164	$37,051,000	99	76	$181,844,807	$316,682,679	$11,343,236
FY 12	168	$36,020,000	102	97	$456,581,900	$475,360,925	$257,068,130
FY 13	157	$39,728,000	83	84	$201,409,408	$1,570,700,568	$1,040,966,258
FY 14	149	$47,247,000	67	70	$1,432,741,328	$1,840,237,619	$766,891,065
FY 15[1]	158	$48,767,000	69	67	$59,198,415	$3,143,742,434	$2,841,045,051
FY 16	164	$49,623,000	68	54	$543,662,773	$748,647,755	$48,681,998
FY 17	173	$48,053,000	49[3]	54	$78,986,162	$333,830,145	$265,451,911
FY 18[2] (Spend Plan)	172	$53,385,000	70 (estimated)	65 (estimated)	$26,243,545	$714,045,500	$682,413,593

[1] FY 15 collections include the Deutsche Bank's $800 million fine

[2] Cases refer to Litigations Opened and Closed; Cases closed represented in a fiscal year are irrespective of when the case was opened.

[3] This amount includes three Non-Prosecution Agreements entered by the Commission.

[4] Amounts Assessed and Collected through August 9, 2018.

CFTC Pay Scale

23. Mr. Aderholt: Please provide the pay-scale the CFTC currently uses for all grades, ranks, levels and steps. Use the most up to date information available.

Response: The below chart provides the CFTC pay scale and the four CFTC locations with the locality pay adjustment cited for each area.

CT Grade	Minimum	Maximum	Steps[1]
CT-1	$22,902	$32,286	N/A
CT-2	25,747	36,611	N/A
CT-3	28,093	41,264	N/A
CT-4	31,536	46,316	N/A
CT-5	35,285	51,819	N/A
CT-6	39,331	57,769	N/A
CT-7	43,707	64,200	N/A
CT-8	48,405	71,097	N/A
CT-9	53,464	78,529	N/A
CT-10	58,877	86,481	N/A
CT-11	64,686	95,022	N/A
CT-12	77,529	113,877	N/A
CT-13	92,195	135,423	N/A
CT-14	108,946	160,029	N/A
CT-15	128,155	188,233	N/A
CT-16	148,271	217,786	N/A
CT-17[2]	171,551	243,500[2]	N/A
CT-18[2]	$198,484	$243,500[3]	N/A
Locality Percentages			
Washington, DC		28.22%	
Chicago		27.47%	
New York		32.13%	
Kansas City		16.10%	

[1]N/A - Not applicable to CFTC pay scale. CFTC pay system is a pay for performance system and increases are based on the individuals annual performance assessment.

[2]Total pay capped at Vice President's Salary of $243,500 effective January 2018

[3]Since there is no GS equivalents, used Certified SES system salaries and EX Pay Plan

24. Mr. Aderholt: Please provide a table with the number of employees the CFTC currently employs broken down by grade, rank, level, and steps. Please use the most up to date information available.

Response: The below table provides the requested information.

Count of Federal Employees as of August 21, 2018

Pay Plan	Grade	Count
EF*	0	5
EX**	3	1
EX***	4	2
CT	7	6
CT	8	6
CT	9	8
CT	10	3
CT	11	13
CT	12	20
CT	13	69
CT	14	350
CT	15	155
CT	16	40
CT	17	2
CT	18	8
Total		688

*Employee Consultants
**Chairman, EX-3
***Commissioners, EX-4
Includes positions funded by the Consumer Protection Fund

25. Mr. Aderholt: Please provide a table that displays the difference in pay-scale between the CT pay-scale that the CFTC currently uses and the GS pay-scale that is used government-wide (show Washington D.C., Chicago and New York City). The values in this table must show the difference between the CT and GS pay-scale for each and all grades, ranks, levels and steps. Do not just provide a copy of the GS Pay scale and the CT Pay Scale. Use the most up to date information available.

Response: The following tables display the difference between the CFTC CT pay scale used by CFTC and the general schedule (GS) pay scale used government-wide, and the difference between the CT and GS pay scale. Please note that unlike the GS pay scale, the CT scale does not include steps. Movement within a pay band is based upon performance, and is paid as merit pay based on an annual individual's annual performance rating, and not longevity.

Current Base Rate (No locality)
CFTC Pay Scale

CFTC - CT Grades	Band Minimum	Band Maximum	Within Grade Adjustments
CT-01	$22,902	$32,286	N/A*
CT-02	25,747	36,611	N/A*
CT-03	28,093	41,264	N/A*
CT-04	31,536	46,316	N/A*
CT-05	35,285	51,819	N/A*
CT-06	39,331	57,769	N/A*
CT-07	43,707	64,200	N/A*
CT-08	48,405	71,097	N/A*
CT-09	53,464	78,529	N/A*
CT-10	58,877	86,481	N/A*
CT-11	64,686	95,022	N/A*
CT-12	77,529	113,877	N/A*
CT-13	92,195	135,423	N/A*
CT-14	108,946	160,029	N/A*
CT-15	128,155	188,233	N/A*

	Min	Max	
CT-16**	$148,271	$217,786	N/A*
CT-17**	171,551	243,500**	N/A*
CT-18**	198,484	243,500***	N/A*

Current Base Rate (No locality)
General Schedule - Government Wide

General Schedule	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Within Grade Amounts
GS-01	$18,785	$19,414	$20,039	$20,660	$21,285	$21,650	$22,267	$22,891	$22,915	$23,502	VARIES
GS-02	21,121	21,624	22,323	22,915	23,175	23,857	24,539	25,221	25,903	26,585	VARIES
GS-03	23,045	23,813	24,581	25,349	26,117	26,885	27,653	28,421	29,189	29,957	768
GS-04	25,871	26,733	27,595	28,457	29,319	30,181	31,043	31,905	32,767	33,629	862
GS-05	28,945	29,910	30,875	31,840	32,805	33,770	34,735	35,700	36,665	37,630	965
GS-06	32,264	33,339	34,414	35,489	36,564	37,639	38,714	39,789	40,864	41,939	1,075
GS-07	35,854	37,049	38,244	39,439	40,634	41,829	43,024	44,219	45,414	46,609	1,195
GS-08	39,707	41,031	42,355	43,679	45,003	46,327	47,651	48,975	50,299	51,623	1,324
GS-09	43,857	45,319	46,781	48,243	49,705	51,167	52,629	54,091	55,553	57,015	1,462
GS-10	48,297	49,907	51,517	53,127	54,737	56,347	57,957	59,567	61,177	62,787	1,610
GS-11	53,062	54,831	56,600	58,369	60,138	61,907	63,676	65,445	67,214	68,983	1,769
GS-12	63,600	65,720	67,840	69,960	72,080	74,200	76,320	78,440	80,560	82,680	2,120
GS-13	75,628	78,149	80,670	83,191	85,712	88,233	90,754	93,275	95,796	98,317	2,521
GS-14	89,370	92,349	95,328	98,307	101,286	104,265	107,244	110,223	113,202	116,181	2,979
GS-15	105,123	108,627	112,131	115,635	119,139	122,643	126,147	129,651	133,155	136,659	3,504

	Min	Max
SES	126,148	189,600
SES	126,148	189,600
SES	153,800	189,600

* N/A - Not applicable to CFTC Pay Scale. Pay System is a pay for performance system and increases are based on performance assessment.
** Total Pay Capped at Vice President's Salary of $243,500 effective January 2018
***Since there is no GS equivalents, used Certified SES system salaries and EX Pay Plan

Locality Rates Applicable to both CFTC CT and GS Schedules

Washington, DC	28.22%
Chicago	27.47%
New York	32.13%
Kansas City	16.10%

The CT Pay Scale Compared to the GS Pay Scale

CFTC - CT Grades	CT Band Minimum*	General Schedule	GS Step 1*	Difference between the CT and the GS Scales - Minimum Range
CT-01	$22,902	GS -01	$18,785	$4,117
CT-02	25,747	GS-02	21,121	$4,626
CT-03	28,093	GS-03	23,045	$5,048
CT-04	31,536	GS-04	25,871	$5,665
CT-05	35,285	GS-05	28,945	$6,340
CT-06	39,331	GS-06	32,264	$7,067
CT-07	43,707	GS-07	35,854	$7,853
CT-08	48,405	GS-08	39,707	$8,698
CT-09	53,464	GS-09	43,857	$9,607
CT-10	58,877	GS-10	48,297	$10,580
CT-11	64,686	GS-11	53,062	$11,624
CT-12	77,529	GS-12	63,600	$13,929
CT-13	92,195	GS-13	75,628	$16,567
CT-14	108,946	GS-14	89,370	$19,576
CT-15	128,155	GS-15	105,123	$23,032
	CT Band Minimum*	Schedule ***	GS Minimum	Difference between the CT and the GS Scales-Minimum Range
CT-16	$148,271	SES	$126,148	$22,123
CT-17**	171,551	SES	126,148	$45,403
CT-18**	198,484	SES	153,800	$44,684

CFTC - CT Grades	CT Band Maximum*	General Schedule	GS Step 10*	Difference between the CT and the GS Scales - Maximum Range
CT-01	$32,286	GS -01	$23,502	$8,784
CT-02	36,611	GS-02	26,585	$10,026
CT-03	41,264	GS-03	29,957	$11,307
CT-04	46,316	GS-04	33,629	$12,687
CT-05	51,819	GS-05	37,630	$14,189
CT-06	57,769	GS-06	41,939	$15,830
CT-07	64,200	GS-07	46,609	$17,591
CT-08	71,097	GS-08	51,623	$19,474
CT-09	78,529	GS-09	57,015	$21,514
CT-10	86,481	GS-10	62,787	$23,694
CT-11	95,022	GS-11	68,983	$26,039
CT-12	113,877	GS-12	82,680	$31,197
CT-13	135,423	GS-13	98,317	$37,106
CT-14	160,029	GS-14	116,181	$43,848
CT-15	188,233	GS-15	136,659	$51,574
	CT Band Maximum	Schedule ***	Maximum	Difference between the CT and the GS Equivalent-Maximum Range
CT-16	$217,786	SES	$189,600	$28,186
CT-17**	243,500	SES	189,600	$53,900
CT-18**	243,500	SES	189,600	$53,900

* Steps not applicable to CFTC Pay Scale. Pay System is a pay for performance system and increases are based on performance assessment.

** Total Pay Capped at Vice President's Salary of $243,500 effective January 2018

***Since there is no GS equivalents, used Certified SES system salaries and EX Pay Plan

Purchase Cards

26. Mr. Aderholt: Please provide all purchase card account monthly statements for August 2017 to March 2018.

Response: Purchase card account monthly statements for August 2017 to March 2018 are provided as attachment D.

Work with Department of Justice (DOJ)

27. Mr. Aderholt: How many cases were referred to DOJ between fiscal years 2011 thru 2018? Please provide the total, the number per year, and the status.

Response: The CFTC has a robust history of working cooperatively with DOJ on enforcement matters. As part of its cooperative enforcement efforts, the CFTC routinely communicates with and provides information, data and other records on specific matters to DOJ for consideration for criminal investigation and prosecution. Between FY 2011 and FY 2018 (as of August 16, 2018), the CFTC referred a total of 252 matters to DOJ. These referrals resulted in the provision of non-public information by the CFTC to DOJ.

Fiscal Year	Number of CFTC Referrals to the Department of Justice
2011	25
2012	24
2013	22
2014	34
2015	31
2016	38
2017	28
2018 (as of 8/16/18)	50
Total	**252**

Customer Protection Fund (CPF)

28. Mr. Aderholt: What is the current balance of the Customer Protection Fund?

Response: As of July 31, 2018, the balance in the Customer Protection Fund (CPF) was $208,874,658.

29. Mr. Aderholt: What were the total obligations for the CPF in FY 2017 and FY 2018 to date?

Response: Total obligations in the CPF for FY 2017 were $12,177,314 and obligations as of the period ending July 31, 2018 were $34,005,293.

30. Mr. Aderholt: What are the planned obligations of the Fund for the remainder of FY 2018 and FY 2019?

Response: Estimated planned obligations (expenditures) for the fund are provided in the table below, and have been updated from the display in Appendix 5 of the CFTC FY 2019 President's Budget Justification.

FY 2018 estimated planned obligations include approved and distributed whistleblower awards.

FY 2019 estimated planned obligations include awards approved in late FY 2018 pending distribution and anticipated whistleblower award payments based on current cases that are still in process.

Planned Obligations

	FY 2018 Estimate	FY 2019 Estimate
Whistleblower Awards	$30,000,000	$54,000,000
Customer Education Program	$2,734,949	$13,365,000
Whistleblower Admin Program	$3,812,130	$3,654,000

31. Mr. Aderholt: How many FTEs will the CPF use in fiscal years 2018 and 2019?

Response: In FY 2018, 14 FTE are projected to be funded from the Consumer Protection Fund. A total of 25 FTE are projected to be funded in FY 2019.

Leveraging All Resources

32. Mr. Aderholt: Please provide a table showing the budget and staff of the National Futures Association since FY 2012.

Year*	Total Operating Expenses	Average Staffing
2012	$49 million	299
2013	$62 million	330
2014	$69 million	415
2015	$77 million	471
2016	$83 million	482
2017	$92 million	520
2018	$96 million	519

* Fiscal year ending June 30

33. Mr. Aderholt: How many regulatory staff are dedicated to regulatory compliance across the entire Self-Regulatory Structure of the futures, options, and swaps market?

Response: The CME dedicates approximately 222 regulatory surveillance staff. ICE dedicates approximately 30 regulatory surveillance staff. The NFA has a total staff of approximately 520.

Performance Measures

34. Mr. Aderholt: Please provide a table showing CFTC's performance measures and actual performance for the past three years. Also indicate how each of these measures relate to specific outcomes.

Response: Below are the past three years' results for CFTC performance measures. Each measure relates to and falls under one of CFTC's outcomes (labeled as goals and strategic objectives). Below the results is a list of discontinued measures and an explanation for why each was discontinued.

Goal One: Market Integrity and Transparency

Objective 1.1: Markets not readily susceptible to manipulation and other abusive practices		
Performance Indicator 1.1.a: Strive for percentage of high impact contract and rule submissions received by the Commission through the OPERA portal.		
FY 2015	FY 2016	FY 2017
Nearly 96%	99%	100%
Performance Indicator 1.1.b: Strengthen capacity to receive and expeditiously evaluate all trading data and associated information to identify potential violations of the CEA or Commission regulations and the timely response to market emergencies.		
FY 2015	FYs 2016-2017	
No reporting	CFTC is in the early stages of a multi-year effort to develop analytic tools to harmonize data and improve trading data evaluation.	

Objective 1.2: Establishment of an effective self-regulatory framework		
Performance Indicator 1.2.a: Examine compliance by exchanges with the CEA Core Principles and Commission regulations, prioritizing systemically important entities.		
FY 2015	FY 2016	FY 2017
Baseline Year – Commission completed four rule enforcement reviews (RERs) [1] and completed on-site interviews for 3 1/2 of four additional RERs	One DCM Rule Enforcement Review complete and two RERs initiated	Three RERs and a draft report for a fourth RER completed in FY 2017. Also, three formal and three informal RERs initiated in FY 2017.
Performance Indicator 1.2.b: Review exchange and SDR notifications and periodic status updates regarding significant systems disruptions and material planned changes to mission-critical systems or programs of risk analysis and oversight.		
FY 2015	FY 2016	FY 2017

Baseline year – Commission reviewed 100% of notifications and updates during the fiscal year.	100% review	100%
Performance Indicator 1.2.c: Examine compliance by exchanges and SDRs with the system safeguards and cyber security requirements of the CEA Core Principles and Commission regulations, prioritizing systemically important entities.		
FY 2015	FY 2016	FY 2017
Baseline Year – Commission completed SSEs for five systemically important entities.	Five on-site reviews for SSEs conducted	Five on-site reviews for SSEs conducted

[1] Revised to four Rule Enforcement Reviews (RER) from 2015 APR figure of one RER.

Objective 1.3: Availability of market information to the public and for use by authorities		
Performance Indicator 1.3.a: Percentage of derivatives activity covered by regularly published Commission reports.		
FY 2015	FY 2016	FY 2017
90%	98%	98%
Performance Indicator 1.3.b: Publish economic research reports to inform the public about market structure of the derivatives markets.		
FY 2015	FY 2016	FY 2017
Four reports	Five reports	Seven reports

Objective 1.4: Integrate futures and options positions and transactions data		
Performance Indicator 1.4.a: Percentage of derivatives for which trader data can be matched across CFTC datasets.		
FY 2015	FY 2016	FY 2017
Baseline year – Commission made limited progress because CFTC is waiting for Ownership and Control Reporting to begin.	Due to data reporting relief granted through No Action Letter 16-32 (NAL 16-32), CFTC was not in receipt of the data required to make progress on this target in FY 2016.	In order for CFTC to accurately examine swap and futures transactions in detail, by an entity, errors in reporting data need to be addressed.

Goal Two: Financial Integrity and Avoidance of Systemic Risk

Objective 2.1: Avoid disruptions to the system for clearing and settlement of contract obligations		
Performance Indicator 2.1.a: CFTC strives to conduct back testing of DCOs' material product and portfolio initial margin requirements to assess their sufficiency.		
FY 2015	FY 2016	FY 2017
Conducted back testing of products and portfolios of two DCOs	Five DCOs	Conducted back-testing of products and portfolios of 5 DCOs
Performance Indicator 2.1.b: CFTC develops and calculates clearing members' ability to fund variation and initial margin requirements using hypothetical market scenarios.		

FY 2015	FY 2016	FY 2017
Assessed 10% of clearing members	Assessed 10 clearing members (approx. 25% of overall clearing members)	Assessed 24% of clearing members

Performance Indicator 2.1.c: Aggregate cleared swaps, futures, and options positions into a comprehensive risk surveillance process and conduct analysis for each material market participant.		
FY 2015	FY 2016	FY 2017
CFTC aggregated the risk of 25 interest rate swap (IRS) and interest rate (IR) futures accounts.	16 CFTC aggregated the risk of 16 interest rate swap (IRS) and interest rate (IR) futures accounts.	Aggregated the risk of 100 IRS and IR futures accounts.

Performance Indicator 2.1.d: Review Derivatives Clearing Organization (DCO) notifications regarding: hardware or software disruptions, cyber security events or threat events, activation of the DCOs' business continuity or disaster recovery plans, significant planned changes to mission-critical systems, planned changes to the DCOs' programs of risk analysis, and other notifications that potentially impact or could impact the DCOs' ability to process, clear and manage the risk of its business activities.		
FY 2015	FY 2016	FY 2017
Filings reviewed within appropriate timeframe, 75% of the time.	Reviewed 93% of material notifications within 2-5 business days. 80% of non-material notifications reviewed within 30 days.	All eight material notices received were analyzed within 2-5 business days. 35 (56%) of the 63 non-material notices were reviewed within 30 calendar days.

Performance Indicator 2.1.e.1: Strive to examine compliance by DCOs with the Core Principles, including system safeguards and cyber security requirements, of the CEA and Commission regulations, prioritizing systemically important entities.		
FY 2015	FY 2016	FY 2017
100%	100%	Both systemically important DCOs were examined and examination reports have been issued.

Performance Indicator 2.1.e.2: Strive to examine compliance by DCOs with the Core Principles, including system safeguards and cyber security requirements, of the CEA and Commission regulations, prioritizing systemically important entities.		
FY 2015	FY 2016	FY 2017
30%	Completed fieldwork for four exams.	DCR initiated an examination of a non-systemically important DCO and completed all fieldwork within the calendar year.

Objective 2.2: Provide market participants with timely guidance		
Performance Indicator 2.2.a.2: Percent of swap dealer and major swap participants registration documentation completed.		
FY 2015	FY 2016	FY 2017

71% - Commission worked with NFA to develop NFA's capacity to review swap dealer applications effectively.	100%	Activity complete

Objective 2.3: Strong governance and oversight by financial registrants		
Performance Indicator 2.3.a.1: Conduct oversight reviews of Swap Dealers (SDs).		
FY 2015	FY 2016	FY 2017
Three SDs	49 SDs	DSIO completed 10 Volcker Rule Issue horizontal oversight reviews of SDs during FY 2017. DSIO continually assessed the need for additional SD reviews but, due to the decision to delay the SD Capital Rule, no SD examinations beyond the Volcker reviews were planned.
Performance Indicator 2.3.a.2: Conduct oversight reviews of Futures Commission Merchants (FCMs).		
FY 2015	FY 2016	FY 2017
Zero FCMs	55 FCMs	24 FCMs
Performance Indicator 2.3.b: Review Chief Compliance Officer (CCO) annual reports for Swap Dealers (SDs), Major Swap Participants (MSPs), and Futures Commission Merchants (FCMs), and provide feedback to the registrants on governance and compliance oversight.		
FY 2015	FY 2016	FY 2017
49%	96%	60%

Objective 2.4: Market participants maintain sufficient financial resources, risk management procedures, and customer protection practices		
Performance Indicator 2.4.b: Monitor high-risk registrants focusing on Futures Commission Merchants for signs of financial stress.		
FY 2015	FY 2016	FY 2017
100%	100%	100%

Goal Three: Comprehensive Enforcement

Objective 3.1: Strengthen capacity to receive and expeditiously handle high-impact tips, complaints and referrals		
Performance Indicator 3.1.a.1: Strengthen and ensure a coordinated approach to receiving, assessing, and referring tips, complaints and referrals as necessary and appropriate; establish a unit or office dedicated to this function.		
FY 2015	FY 2016	FY 2017

20-hour average time to review tips met	78% of referrals were converted by teams within 18 hours. 80% of referrals lead to an investigation.	Developing new indicators to demonstrate improved performance of handling tips, complaints, and referrals.
Performance Indicator 3.1.b.1: Develop a comprehensive communication strategy, geared for internal and external stakeholders, relating to the role of whistleblowers and the function of the Whistleblower Office (WBO).		
FY 2015	FY 2016	FY 2017
Completed training for 28 new Division of Enforcement staff, including training 13 newly hired division contractors.	Provided individualized training to over 20 employees in home office and regions.	Completed training in the DC office and regions for 15 new Division of Enforcement staff, plus three FBI detailees. Best practices guide in progress.
Performance Indicator 3.1.b.2: Develop a comprehensive communication strategy, geared for internal and external stakeholders, relating to the role of whistleblowers and the function of the Whistleblower Office.		
FY 2015	FY 2016	FY 2017
Participated in 12 public forums and trade shows	Participated in 18 annual public forums and trade shows and launched new website for whistleblower office.	Participated in 16 public forums and trade shows.
Objective 3.2: Execute rigorous and thorough investigations		
Performance Indicator 3.2.a: Percentage of enforcement investigations completed within 18 months of opening, depending on the nature and scope of investigations.		
FY 2015	FY 2016	FY 2017
75%	76%	82%

Goal Four: Broad Outreach on Regulatory Concerns

Objective 4.1: Broad outreach on regulatory concerns		
Performance Indicator 4.1.a: Number and types of opportunities that have been provided for the exchange of views between the Commission and other domestic and international regulators.		
FY 2015	FY 2016	FY 2017
Contextual indicator – no annual result	Contextual indicator – no annual result	Contextual indicator – no annual result
Performance Indicator 4.1.b: Number and types of opportunities that have been provided for the exchange of views between the Commission and the public.		
FY 2015	FY 2016	FY 2017
Contextual indicator – no annual result	Contextual indicator – no annual result	Contextual indicator – no annual result

Objective 4.2: Sound international standards and practices

Performance Indicator 4.2.a: Number and types of projects that have been initiated and/or completed within international regulatory and standard setting groups that promote the CFTC's regulatory policies.		
FY 2015	FY 2016	FY 2017
Contextual indicator – no annual result	Contextual indicator – no annual result	Contextual indicator – no annual result
Performance Indicator 4.2.b: Number of regulatory cooperation and coordination arrangements negotiated with international regulatory authorities to facilitate high-quality derivatives regulation worldwide and the CFTC's supervision of markets and entities that are global in nature.		
FY 2015	FY 2016	FY 2017
See FY 2015 APR for list of arrangements signed that year	Contextual indicator – no annual result	Contextual indicator – no annual result

Objective 4.3: Provide global technical assistance		
Performance Indicator 4.3.a: Number of non-U.S. regulators trained.		
FY 2015	FY 2016	FY 2017
150	113	No annual result

Objective 4.4: Robust Domestic and International Enforcement Cooperation and Coordination		
Performance Indicator 4.4.a: Leverage the impact of its enforcement program through coordination with Self-Regulatory Organizations (SROs) and active participation in domestic and international cooperative enforcement efforts.		
FY 2015	FY 2016	FY 2017
Participated in 11 domestic and international cooperative meetings, task forces, etc.	Participated in more than two dozen domestic/international cooperative enforcement meetings	Participated in 38 domestic and international cooperative enforcement meetings, task forces, etc.

Objective 5.1: A High-performing, diverse, and engaged workforce		
Performance Indicator 5.1.a: Implement operational planning across the Commission.		
FY 2015	FY 2016	FY 2017
Commission developed budget strategy documents that Chairman used to make strategic resource decisions	Two divisions have fully functioning operational plans with active internal processes in place to track priorities and key projects	Completed Strategic Plan Framework capturing Chairman's priorities. Developing CFTC Strategic Plan now that divisions have leadership in place.
Performance Indicator 5.1.b: Implement performance management plans for executives.		
FY 2015	FY 2016	FY 2017
Developed improved template for strategic alignment of executive plans, based on OPM's Executive Core Qualifications.	No reporting	New performance plans were established for new executives coming on board since May of 2017 and for all Chairman direct reports for the 2017-18 performance cycle.

Performance Indicator 5.1.c: Establish and implement an Individual Development Plan (IDP) strategy.		
FY 2015	FY 2016	FY 2017
Baseline year – CFTC completed baseline activities and projects – approximately 10 percent of Commission employees have IDPs.	Over 15% of Commission employees in have Individual Development Plans in place	Approximately 20% Commission employees have IDPs in place.
Performance Indicator 5.1.d: Establish certification programs in executive, supervisory, and one core subject matter function.		
FY 2015	FY 2016	FY 2017
80% of planned FY 2015 activities completed	Finalized a draft curriculum that addresses every level of derivatives education	Finalized a curriculum that addresses supervisory certification and executive education.
Performance Indicator 5.1.e: Increase Employee Viewpoint Survey scores to achieve and maintain a ranking of Top 10 in the Best Places to Work (small agency category).		
FY 2015	FY 2016	FY 2017
60% employee engagement index (EEI) score 25 (CFTC ranking)	65% employee engagement index (EEI) score	67% employee engagement index (EEI) score.

Objective 5.2: Effective stewardship of resources		
Performance Indicator 5.2.a: Improved CFTC customer satisfaction with management programs and services.		
FY 2015	FY 2016	FY 2017
Commission identified programs and services that will be evaluated.	Created two draft customer satisfaction surveys: operations and technology/help desk. Received initial approvals by end of fiscal year.	FY 2017 Actual IT completed help desk survey with 26% response rate.

Objective 5.3: A Robust and Comprehensive Consumer Outreach Program		
Performance Indicator 5.3.b: Finalize and monitor campaign success measures.		
FY 2015	FY 2016	FY 2017
At outset of campaign, CFTC had one annual survey indicator, which has since been dropped.	144% of annual targets for reach, awareness, and engagement.	7.3% of user visits to smartcheck.gov resulted in a "check" action to research a financial professional or firm.

Discontinued Indicators from the CFTC strategic plan published in FY 2015.

Indicator	**Why not Included?**

2.2. a.1 – Review and provide feedback as appropriate on SD and MSP risk-exposure reports.	CFTC discontinued indicator at end of FY 2015 due to challenges encountered in gathering reliable and comprehensive data.
2.2.a.3 – Percent of substantive industry issues addressed in a timely manner.	The Commission determined in FY 2016 that the indicator contains fundamental flaws that cannot be effectively remediated. As a result, CFTC discontinued it.
2.4.a – Conduct limited scope reviews of Swap Dealers (SDs), Major Swap Participants (MSPs), and Futures Commission Merchants (FCMs) risk management and internal control systems and procedures, including controls, processes and procedures over technology risks.	Indicator had no reporting during FY 2015 because Commission determined that indicators 2.3.a.1 and 2.3.a.2 better encapsulate DSIO's activities. Commission discontinued indicator at end of FY 2015.
3.1.a.2 – Strengthen and ensure coordinated approach to receiving, assessing, and referring tips, complaints and referrals; establish a unit or office dedicated to this function.	Enforcement Division established new triage unit in FY 2015 to intake and triage tips and leads from all sources. Indicator was discontinued at the end of FY 2015. Success of campaign is now measured through indicator 3.1.a.1.
5.1.f – Number of diversity-related partnerships and alliances.	Commission met its strategic plan target of 10 new partnerships by end of FY 2016, and moved indicator to completed/discontinued Appendix for FY 2017.
5.3.a – Launch long-term anti-fraud campaign.	Anti-fraud campaign launched in FY 2015. CFTC discontinued indicator at end of FY 2015. Success of campaign is measured through indicator 5.b.3.
5.3.c – Complete Congressional report.	Annual report to Congress on customer initiatives is a routine report and is not a direct measure of CFTC priorities. Therefore, indicator does not merit inclusion in the APR.

35. Mr. Aderholt: In the past, CFTC measured success by the amount of fines and penalties imposed on the private sector. What types of outcome based performance measures does the CFTC plan to put in place that differ from those of the past?

Response: CFTC is developing performance measures that will gauge progress against strategic goals and strategic objectives that are specifically tied to Chairman Giancarlo's priorities. Since his priorities do not include maximizing private sector fines and penalties, under current leadership CFTC will not be creating such performance measures for external reporting of strategic goals and strategic objectives. The Commission will continue to internally track fines and penalties imposed on the private sector.

Bitcoin and Cryptocurrencies

36. Mr. Aderholt: Please provide detail as to what role CFTC plays regarding the regulation of the bitcoin market and what role other agencies have? Please make reference to any statutes and regulations as necessary.

Response: In 2015, the Commission determined that certain virtual currencies, such as Bitcoin, met the definition of "commodity" under the Commodity Exchange Act (CEA). This means that the CFTC's jurisdiction is implicated from an oversight perspective if a commodity-based future or swaps product is offered to the market and from an enforcement perspective if there is fraud or manipulation involving such products or their underlying commodity markets. The CFTC does not, however, have direct oversight authority over the underlying commodity markets. Platforms that permit spot or cash trading in virtual currencies are frequently subject to state licensure laws, usually with respect to money transmission. These platforms are not regulated as exchanges at the federal level.

In December 2017, two CFTC regulated futures exchanges self-certified and launched Bitcoin futures products. Under the CEA and Commission regulations and related guidance, futures exchanges may self-certify new products on twenty-four hour notice prior to trading. This type of framework encourages market-driven innovation and has made America's listed futures markets the envy of the world. Both Chicago Mercantile Exchange (CME) and Chicago Board Options Exchange (CBOE) worked with the CFTC for months before launching Bitcoin futures in December 2017. As detailed in the Chairman's prior Congressional testimony, due to the complexity of issue, the CFTC conducted a "heightened review" of CME's and CBOE's responsibilities.

Chairman Giancarlo has outlined six elements regarding CFTC oversight of the virtual currency-related futures and swaps markets. These elements include: (1) staff competency; (2) consumer education through our Office of Customer Education and Outreach; (3) interagency cooperation including with the SEC, the Department of Treasury's Financial Crimes Enforcement Network known as FinCEN, and through the Financial Services Oversight Council; (4) CFTC exercise of its regulatory oversight authority; (5) strong enforcement efforts to deter and prevent fraud and manipulation; and (6) heightened review of virtual currency-related product self-certifications.

With respect to heightened review, in May of this year, our Division of Market Oversight and Division of Clearing and Risk issued a joint staff advisory that gives exchanges and clearinghouses registered with the CFTC guidance for listing virtual currency derivative products. The advisory highlights key areas that require particular attention in the context of listing a new virtual currency derivatives contract, including: enhanced market surveillance; close coordination with CFTC staff; large trader reporting; outreach to member and market participants; and, Derivatives Clearing Organization risk management and governance.

Commission staff further noted at the time that since the Agency found virtual currencies such as Bitcoin to be commodities in 2015, it has taken action against unregistered Bitcoin futures exchanges; enforced the laws prohibiting wash trading and prearranged trades on a derivatives platform; issued proposed guidance on what is a derivative market and what is a spot market in the virtual currency context through an interpretation of 'actual delivery'; issued warnings about

valuations and volatility in spot virtual currency markets; and, addressed a virtual currency Ponzi scheme.

On the topic of enforcement, it is worth mentioning that the CFTC is working closely with the SEC and other fellow financial enforcement agencies to aggressively prosecute bad actors that engage in fraud and manipulation regarding virtual currencies.

37. Mr. Aderholt: CFTC has enforcement authority "in the underlying markets". Please explain what this means in terms of actually policing the bitcoin markets that exist outside of the futures contracts?

Response: The CFTC has anti-fraud and anti-manipulation authority with respect to transactions in commodities in interstate commerce, including Bitcoin. Except to a very limited extent, the CFTC does not have direct oversight or monitoring capabilities over Bitcoin spot markets. Nevertheless, the Division of Enforcement actively monitors publicly available sources for evidence of wrongdoing in these markets and will evaluate and investigate complaints directed or referred to the CFTC. The CFTC's investigations generally focus on market abuse, manipulation and financial advisor-type frauds such as Ponzi schemes.

38. Mr. Aderholt: Please describe some of CFTC's enforcement cases in the crypto currency markets and how the Commission can be proactive to educate people on the risks of these instruments?

Response: To date, the CFTC's enforcement actions in this area have focused on unauthorized transactions or business dealings in derivatives and outright frauds involving the retail public. Publicly announced litigation or settlements serve to both deter future misconduct by wrong actors and to educate the general public as to the various risks involved in these instruments. In addition, the CFTC has prioritized consumer outreach with respect to the cryptocurrency markets, including, but not limited to, creating a number of educational materials and customer advisories available publicly at www.cftc.gov/bitcoin.

39. Mr. Aderholt: Can CFTC use the CPF to educate people on the risks of the cryptocurrency markets?

Response: Yes, subject to certain limitations. The Commodity Exchange Act provides that the CPF is a fund available to the Commission without fiscal year limitation for "customer education initiatives designed to help customers protect themselves against fraud or other violations of this Act, or the rules and regulations thereunder." 7 U.S.C. § 26(g)(2). Based on the specific language of the CPF, the CFTC believes that it is available to educate customers and members of the public about the specific risks of fraud and/or violations of the Commodity Exchange Act in the cryptocurrency markets.

40. Mr. Aderholt: Recent statements by CFTC Commissioners and the Chairman indicate an interest in the proposal by the Winklevoss twins to have a self-regulatory structure, similar to the futures and options market, for the crypt-currency market. Can you explain this proposal and what would be required to enact the proposal?

Response: Chairman Giancarlo has testified on the current regulatory framework for virtual currencies, and in his formal testimony on February 6, 2018 to the Senate Banking Committee,

he expressed the view that policymakers should explore potential improvements to the existing patchwork approach to regulating spot markets for virtual currencies. Any such effort should be thoughtful and deliberative, however, which means that there is an opportunity for industry participants to develop standards that could inform policy discussions and benefit retail market participants. The Chairman would accordingly view proper, effective and balanced self-regulatory efforts favorably. He has not, however, entertained or supported any current self-regulatory proposals that would require legislative action.

Evaluating the Size of the Swaps Market

41. Mr. Aderholt: Chairman Giancarlo's recent comments regarding the "right-sizing" of the swaps market highlighted some of the same questions Members of this Subcommittee have had about the notional size of the swaps market. His comments were at a speech at a derivative conference in New York. Following the Financial Crisis of 2008, the swaps market became a topic of much debate in the public discourse, and the only number being thrown around was that of notional value. At the time, the number discussed was in excess of $600 trillion. Please explain the difference between notional value and the new metrics CFTC is using and the numbers associated with each?

Response: The new metric is called "Entity-Netted Notionals," or ENNs. The basic idea is i) to adjust the notional amounts of products by their respective risks, and ii) to net the offsetting long and short positions that two counterparties have with each other in the same product.

The Office of the Chief Economist (OCE) at the CFTC published the ENNs methodology for interest rate swaps (IRS) in January 2018[4] and has been updating the results quarterly. As of June 2018, the notional amount outstanding of IRS across all U.S. reporting entities was $228 trillion. Measured in ENNs, however, the amount outstanding was less than $17 trillion.[5]

42. Mr. Aderholt: How does this new metric help or hurt the calculation of risk that CFTC oversees and what effect will it have on any changes in regulation?

Response: The ENNs metric gives insight into the overall size of derivatives markets and into the sizes of various sectors' participations in those markets. The June 2018 report, for example, showed that the hedge fund sector was simultaneously long $800 billion ENNs and short $900 billion.

The most promising use of ENNs in regulation would be in setting risk-based but simple thresholds, above or below which an entity would or would not be subject to various rules. To date, however, no proposed Commission actions use ENNs in this way.

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[4] "Introducing ENNs: A Measure of the Size of Interest Rate Swap Markets," by R. Haynes, J. Roberts, R. Sharma, and B. Tuckman, January 2018. The paper can be accessed at https://www.cftc.gov/About/EconomicAnalysis/ResearchPapers/index.htm

[5] "Update as of June 15, 2018," which can be accessed at the same website.

It should be noted that ENNs is essentially a risk-adjusted measure of size rather than a measure of net market risk, counterparty risk, or operational risk. For monitoring these risks in the financial system, therefore, the CFTC relies on more traditional risk management metrics.

43. Mr. Aderholt: Within this revised estimate of risk, can CFTC break out the various segments of the swaps markets and rank by risk? If so, what would that look like?

Response: As alluded to in the answer to the previous question, the quarterly ENNs report breaks the IRS market down by sectors, i.e., Swap Dealers, Banks, Hedge Funds, Asset Managers, Insurance, Pension Funds, Corporates, and Government or Quasi-Government.

OCE is currently working on expanding the ENNs methodology to measure the size of the credit default swaps and foreign exchange swaps markets. Results for these markets are expected in fall of 2018.

44. Mr. Aderholt: What tools are needed to more accurately determine the size of this market?

Response: Given the vast amount of data that go into the calculations, the biggest challenges in computing ENNs are staff and technology resources. Data quality is also an issue, but continuing global and U.S. efforts along these lines are well underway.

Inter-Affiliate Swaps/Cost-Benefit Analysis

45. Mr. Aderholt: The FY 2018 House Agriculture Appropriation bill carried a provision that would amend the Commodity Exchange Act to require a lower level of margin or capital, known as variation margin, in the transaction of a swap between one party and its affiliate with whom it has some type of shared ownership interest. This is in contrast to the current requirement for a higher amount of capital known as initial margin. Additionally, the bill carries a provision that would require a more stringent analysis of the costs-and benefits of CFTC actions. Please explain why the initial margin requirements were put into place by the prudential regulators but were not initially required by the CFTC, which specializes in regulating swaps and has the knowledge and expertise on these matters?

Response: With respect to adopting margin requirements, CEA Section 4s(e) establishes a jurisdictional separation between the prudential regulators and the CFTC for those swap dealers (SDs) that are banks.

Both the CFTC and the Prudential Regulators issued proposals for initial and variation margin requirements for uncleared swaps in 2011 and 2014. None of these proposals treated affiliated parties that are swap dealers or financial end users differently than other covered counterparties. The CFTC's and Prudential Regulators' 2014 re-proposals did request and receive numerous comments on this issue. Variation margin requirements were kept in place in the final rules.

The final Prudential Regulators' rule limited the interaffiliate requirement from their proposal, keeping only the collection of initial margin from entities that are SDs or financial end users,

after the application of a threshold for each affiliated entity. In the preamble, the Prudential Regulators noted that this approach is consistent with other rules generally requiring banks transact with affiliates on terms comparable to those offered to non-affiliated companies.[6]

The final CFTC rule limited initial margin requirements for interaffiliate transactions, preserving them only to prevent rule evasion via foreign affiliates and when certain conditions related to centralized group risk management were not met. The CFTC rule's preamble explains that the final rule revisions were based on cost and international competitiveness considerations, as highlighted by commenters, as well as to avoid interfering with existing centralized group risk management programs. Furthermore, the preamble notes this approach is consistent with the exemption to the clearing mandate for interaffiliate transactions.[7]

46. Mr. Aderholt: What was the position of prior CFTC Chairmen on this issue and where do the agency's policies differ on this issue?

Response: The 2011 proposal (under CFTC Chairman Gensler) did not address interaffiliate transactions. CFTC Chairman Massad did not comment on this topic in the 2014 re-proposal but the re-proposal had several questions on the issue. In the final rule release, Chairman Massad stated that interaffiliate transactions pose a different cost-benefit balance than market-facing transactions given that many firms operate centralized group risk management programs and that interaffiliate transactions are often integral to the program together with other contractual arrangements. The final 2016 CFTC rule amended the initial margin requirements, preserving them only to prevent rule evasion via foreign affiliates when certain conditions related to centralized group risk management were not met.

CFTC staff understands that the final 2016 Prudential Regulators' rule continues to require the collection of initial margin from entities that are SDs or financial end users, after the application of a threshold for each affiliated entity.

47. Mr. Aderholt: What is the CFTC's position on the Cost-Benefit Analysis requirement?

Response: The Commission has not taken a position on section 202 of H.R. 238 which is enacted into law by section 760 of H.R. 5961. In his speeches and testimony, Chairman Giancarlo has repeatedly stated his support for rigorous cost-benefit analysis including thorough econometric analysis and the need to minimize costs imposed by agency regulation.

48. Mr. Aderholt: The House passed both of these provisions in both the CFTC reauthorization and agriculture appropriations bills. Is the CFTC aware of any opposition either from Congress or in the Administration that would prevent the enactment of these provisions into final law?

Response: There is no bill on the Senate side that is substantially similar to section 202 of H.R. 238. We are not aware of an Administration position on this provision.

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[6] Margin and Capital Requirements for Covered Swap Entities, 80 FR 74846 FN 49 (Nov. 30, 2015).
[7] Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 81 FR 635 (Jan 6, 2016).

Labor Union Negotiations

49. Mr. Aderholt: During the CFTC budget hearing last year, the Subcommittee discussed the situation around CFTC's labor union negotiations. Included in the FY 2018 House Agriculture Appropriations bill is a provision that would allow CFTC to adjust the pay and benefits of employees should furloughs or reductions-in-force occur as a result of these negotiations. This was done because there were reports that the CFTC would have to lay off employees if it did not receive its budget request and a Federal Services Impasse Panel imposed excessive financial burdens on your agency. At the time, it would be difficult to give the CFTC more funding unless this situation was resolved because the money would not be used to invest in the high-priority resources for overseeing the markets the Commission continues to claim it needs. Please provide an update on your labor negotiations for the current fiscal year and future years?

Response: As background, 7 U.S.C. § 2(a)(7) of the Commodity Exchange Act (CEA), 7 U.S.C. § 1 et seq., generally authorizes the Commission to make changes to pay and benefits for Commission employees without regard to chapter 51 or subchapter III of chapter 53 of Title 5 of the U.S. Code. This authority is limited by 5 U.S.C. §§ 7114 and 7117 of the Federal Service Labor-Management Relations Statute (FSLMRS). Specifically, where a union is the exclusive representative of employees of a Federal agency, the FSLMRS imposes upon the agency a general obligation to negotiate in good faith over the conditions of employment of the represented employees. 5 U.S.C. §§ 7114, 7117; *U.S. Merit Sys. Protection Bd. v. FLRA*, 913 F.2d 976, 977 (D.C. Cir. 1990). The U.S. Supreme Court and the Federal Labor Relations Authority (FLRA) have also both opined that when an agency is exempted from the statutorily mandated pay provisions contained in Title 5 of the U.S. Code, the agency is then required to negotiate over pay and benefit issues. See *Fort Stewart Schools. v. FLRA,* 495 U.S. 641 (1990) (Since Congress exempted pay and compensation issues for employees working at schools on military bases, under 20 U.S.C. § 241, the Army was obligated to negotiate with its union over mileage reimbursement, paid leave, and a salary increase for employees of the schools); *SEC and NTEU*, 62 FLRA 432 (2008) (SEC Chairman's implementation of new pay system for all SEC employees without an agreement with NTEU for bargaining unit employees constituted an unfair labor practice under the FSLMRS). Consequently, the Commission is required to negotiate with its union over pay and benefits before making changes to such pay and benefits.

In response to the question regarding the implications of current negotiations on the CFTC's ability to invest increased money in high-priority resources for overseeing the markets, the parties executed a multi-year Memorandum of Understanding (attachment B) that provides for employee compensation and benefits at a constant level for FY 2018, 2019 and 2020, within certain financial constraints and assumes that the Commission continues to be funded at FY 2017 levels. The advantage of a multi-year agreement is transparency around the allocation of any relative increase in funding levels for its duration, as well as a more informed fiscal planning process.

50. Mr. Aderholt: What are the increased costs these negotiations are expected to result in?

Response: The negotiated pay agreement has brought a measure of cost certainty/containment to the Commission's employee compensation system. The three-year agreement puts the CFTC pay increases in line with that of the rest of the government. The agreement provides a two percent (2%) across the board increase annually; this is in place of the January 1 government-wide increase that other government agencies typically receive. The agreement also provides for the merit pay increase at three percent (3%) annually, commensurate with the step increases in the GS pay plan. As noted in question seven, the cost of the pay agreement in FY 2019, for existing staff, is approximately $5.5 million.

51. Mr. Aderholt: What steps has CFTC or the union taken to address the issues raised about putting CFTC employees at risk of furlough or lay-offs as a result of the negotiations?

Response: The multi-year Memorandum of Understanding (attachment B) negotiated by the parties, contains a provision designed to enable CFTC to renegotiate employee compensation and benefits subject to budget limitations. The agreement specifically states, "This Compensation Article is subject to appropriated funding for the Agency and budget limitations. If the Agency determines that it cannot meet its financial obligations set forth in this Article due to a reduction in appropriations from FY 17 levels, the imposition of new congressional mandates on spending, or significant unanticipated events impacting the agency budget, the Agency will notify the Union immediately and the Union can reopen the terms of this Article, and the associated Articles on Telework and Work Schedules."

Administrative Overhead

52. Mr. Aderholt: The House Agriculture Appropriations FY 2018 Committee report addressed issues related to increases in administrative overhead and contractors at the Commission. Between 2014 and 2017 the number of administrative contractors at the Commission tripled in size according to CFTC's responses for the record at last year's hearing. Please explain the purpose of these increases and why such increases while the appropriation remained flat during these years?

Response: Hiring of employees and contracting for support are executive agency decisions under 5 U.S.C. 7106(a). While the ability to hire additional staff, whether government employees or contracted support, is dependent upon the total annual appropriation, it is not the single deciding factor. The decision process includes reviewing types of tasks to be accomplished, the longevity of the tasks, nature of the tasks such as recurring or project-orientation, and budgetary constraints are part of the review prior to a determination being made to contract for support vice hiring a government employee. In many instances, it is more economical and a better business decision to hire a contracted staff.

53. Mr. Aderholt: What types of tasks did these employees perform in the years that followed the increase that were so necessary prior to the increase? In other words, what changed in 2014, except for an increase in the budget that justified the hiring of so many of these administrative employees?

Response: Administrative contractors are not employees of the government. Typical administrative contracted positions at CFTC include executive assistants for Commissioners, Division Directors, and paralegal support for Enforcement attorneys, human resources assistants, budget analysts and travel specialists, internal controls and audit testing assistance, and logistics support. The Office of the Executive Director centrally manages these administrative contractors to ensure consistent, equitable, and economical support to the all divisions. For example, as the Division of Enforcement increased its workload and numbers of attorneys, the number of paralegals to support the effort increased. In some cases, decisions were made to contract support vice hiring a government employee as the costs are more economical and some tasks are of a project-type nature. For instance, contracted staff assisted the Human Resources Office staff to transition to the e-OPF system, consisting of scanning and uploading documents into a centralized portal. Once the transition to the e-OPF system is complete, the contracted support would no longer be required.

Swap Dealer de Minimis

54. Mr. Aderholt: In the FY 2018 House Agriculture Appropriations-passed bill and report, language was included that kept the Swap Dealer de Minimis level at its current level of $8 billion, preventing the automatic drop of 60 percent to $3 billion. Last year, CFTC had delayed the effective date of this reduction and were planning to find a more permanent solution to this regulatory guillotine. Please provide an update of where CFTC is in that process and a timeline of how it plans to move forward?

Response: On June 4, 2018, the Commission proposed to amend the de minimis exception within the swap dealer definition in the Commission's regulations. The proposed amendments include setting the aggregate gross notional amount threshold for the de minimis exception at $8 billion in swap dealing activity entered into by a person over the preceding 12 months.

In his testimony before the House Agriculture Committee on July 25, 2018, Chairman Giancarlo committed to completing a final rule by the end of 2018.

The swap dealer de minimis public comment period closed on August 13, 2018.

Commission staff are currently reviewing the comments and formulating a series of recommendations for the Commission to adopt final rule amendments.

55. Mr. Aderholt: Does CFTC still need statutory authority to make changes or is this something that CFTC can do through the Commission's regular order?

Response: As the Commission noted in the June proposal notice, the proposed rule changes would amend the de minimis exception provision in paragraph (4) of the swap dealer definition, pursuant to the Commission's authority under Commodity Exchange Act section 1a(49), which

requires the Commission to promulgate regulations to establish factors with respect to the making of this determination to exempt a de minimis quantity of swap dealing.[8]

In May 2012, the CFTC and the SEC adopted regulations further defining, among other things, term "swap dealer" in § 1.3 of the CFTC's regulations and providing for a de minimis exception in paragraph (4) therein.[9] As discussed in that joint release, a joint rulemaking is not required with respect to the de minimis exception-related factors.[10]

Information Technology Spending/Cybersecurity

56. Mr. Aderholt: The FY 2019 budget request includes a total of $86.5 million for information technology spending and IT spending was also mentioned in the prepared testimony regarding cyber security. This as a significant threat to not only the market but the CFTC itself. If the government cannot protect proprietary data, then it cannot do its job effectively.

One of the discrepancies in the request shows a reduction in the funding category of development, modernization, and enhancement of IT spending of approximately $6 million over last year while increasing the cost of operations and maintenance by $15 million and the overall amount of spending by $8 million. Please explain this reduction in spending for what would seem like new IT initiatives and the increase for maintenance efforts?

Response: The CFTC's budget request was formulated to enhance mission and cyber security capabilities and to replenish the Commission's base resources (following years of straight-line budgets and successive inflationary increases). This replenishment includes the management and maintenance of existing investments. Restoring the base level of IT funding will help prevent the curtailment of IT services key to enforcement, market oversight, and infrastructure IT contracts; and, it will allow the continuation of important technology/equipment refresh efforts essential to maintaining mission operations.

Investments in Development, Modernization, and Enhancement (DME) eventually transition into sustainment or in other terms, Operations and Maintenance (O&M). This rebalancing of the CFTC's DME/O&M resources is a prudent and necessary step for sustaining and protecting past high-impact, mission enhancing technology investments while, simultaneously, ensuring sustainment of sound and secure IT framework that will more optimally support the agency's current and future needs.

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[8] See De Minimis Exception to the Swap Dealer Definition, 83 FR 27448 (June12, 2018).

[9] Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant" and 'Eligible Contract Participant," 77 FR 30596 (May 23, 2012).

[10] 77 FR at 30634 n.464. ("We do not interpret the joint rulemaking provisions of section 712(d) of the Dodd-Frank Act to require joint rulemaking here, because such an interpretation would read the term "Commission" out of CEA section 1a(49)(D) (and Exchange Act section 3(a)(71)(D)), which themselves were added by the Dodd-Frank Act.").

57. Mr. Aderholt: Are there plans to make any major changes to current contracts and IT spending that will allow the CFTC to make these shifts?

Response: The transition of costs from one subcategory in the IT Portfolio to another occurs through completion of previously contracted efforts based on the project plan for the specific investment and system. This occurs as a normal course of the business cycle for IT projects and does not require additional planning or changes.

58. Mr. Aderholt: Has the agency been able to identify any wasteful or unnecessary spending in its IT investments?

Response: The Commission routinely reviews all IT spending and implemented an Information Technology Investment Review Board in FY 2018. Like other agencies, the review board is intended to balance competing priorities across the Commission as IT resources are in high demand. Continuous change and innovation in the technology sector drives demand for new products and services from throughout the Commission that regularly go unmet due to the fiscally constrained environment of not receiving the Commission's full budget request.

59. Mr. Aderholt: How would this funding apply to cyber security initiatives?

Response: The Commission does not have wasteful or unnecessary spending, and it is committed to meeting its cybersecurity responsibilities. CFTC's risk management strategy requires a commitment in the investment of people, processes, and technology to provide information assurance and computer network defense for our mission essential systems and data. Our ability to achieve our goals depends on our capability to capture, process, manage, analyze, prioritize and share information with our customers and counterparts in the federal IT communities. Managing known risks, added requirements from the cybersecurity legislation and the constantly evolving threat landscape all require significantly more resources to maintain a timely, reliable and accurate risk posture with actionable remedial activities.

GAO Legal Decisions

60. Mr. Aderholt: The Government Accountability Office continues to review CFTC's leasing contracts. These leases are a proverbial tangled web of issues that the GAO is diligently combing through to sort out various legal issues. All of these issues pre-dated Chairman Giancarlo's tenure. GAO recently issued its third legal opinion stating the Commission should report another violation of the Anti-Deficiency Act due to open-ended liabilities that put taxpayers on the hook for unknown amounts of money. While Chairman Giancarlo did not create these problems, the fact remains that they are now under his responsibility. Please provide some insight into what CFTC is doing to address these issues.

Response: The CFTC takes compliance with all applicable fiscal and appropriations laws seriously. The Commission entered into a Memorandum of Understanding with General Services Administration (GSA) in November 2016 that established a relationship to collaborate on the development of a comprehensive real estate portfolio strategy to addresses CFTC's

current leasehold interests and its future leasing needs. The Commission began initial discussions this year with GSA on the replacement leases for three of its four locations that expire between April 2020 and June 2021. The Commission intends to leverage GSA expertise to acquire the replacement facility leases, which mitigates the need for Commission staff to become experts in facility leasing and construction contracting.

Since the initial leasing issues were discovered by GAO, the Commission strengthened its internal controls program, and launched the Enterprise Risk Management Program. The internal controls program expanded management oversight and reporting throughout the agency and implements a programmatic risk-based approach that focuses on financial and operational effectiveness and efficiency, including adherence to laws and regulations. The Commission is anticipating investing in additional Enterprise Risk Management support in FY 2019 to leverage public and private sector best practices, as well as applicable laws and regulations.

61. Mr. Aderholt: Please briefly describe the situation as issued in the most recent legal opinion?

Response: The recent GAO opinion "*Commodity Futures Trading Commission—Liabilities Outside of the Government's Control*", B-328450 was issued on March 6, 2018. The GAO found that some of leases the Commission entered into contained clauses that exposed the government to unlimited and potentially unrecorded liabilities and potentially violated the Antideficiency Act based on these leases. GAO recommended the Commission determine the amount of any potential liability incurred due to these clauses that were outside of the Government's control and were not subject to a fixed limit. The GAO also stated that an agency does not violate the Antideficiency Act when it enters into an uncontrolled liability that has a fixed limit that is ascertainable when it agrees to assume the liability, provided an obligation was recorded at the time the agency entered into the liability. The Commission is also determining which of these clauses fall into this latter category and the amount of the obligation recorded for each instance.

62. Mr. Aderholt: Does CFTC believe another statutory solution will be necessary?

Response: The Commission believes it is premature to discuss whether a statutory solution will be required as the research into the extent of the potential liability is ongoing. As part of this review, the Commission is also determining which of these clauses were supported by a properly recorded obligation at the time of the agency entered into the liability.

Memorandum of Understanding between the National Treasury Employees Union and the Commodity Futures Trading Commission

This memorandum is an interim agreement between the Commodity Futures Trading Commission (CFTC or Agency) and the National Treasury Employees Union (NTEU or Union) (collectively referred to as the parties). This interim agreement applies to all bargaining unit employees represented by NTEU as set forth in the Certification of Representation (Case No. WA-14-0060) issued on November 7, 2014.

1. **Duration**: This agreement shall become effective as of the date of execution by the Chairman and shall terminate at the effective date of a term collective bargaining agreement between the parties, unless the parties agree to modify this agreement.

2. **Governing Law:** The parties acknowledge the rights conferred on unions and management in the Federal Services Labor-Management Relations Statute (FSLMRS), Title VII of the Civil Service Reform Act of 1978.

3. **Designation of Union Officials:** NTEU will promptly notify the CFTC of all persons designated as Union officers or stewards authorized to act on behalf of NTEU and will provide ongoing notice of any changes to these designations.

4. **Official Time:** The Agency agrees to provide Union representatives a reasonable amount of official time to prepare for and to carry out the Union's statutory representational functions. Absent exigent circumstances, the use of official time must be requested by the employee to their supervisor no less than 24 hours in advance. The supervisor will approve the requested time, absent substantial interference with business needs as determined by management. The employee must inform the supervisor as to the best estimate of how much time will be spent on these duties at the time the request is made. The Agency will provide official time for training Union officers and new stewards, not to exceed 20 hours per representative per year.

5. **Dues Withholding**: After processing of the initial dues withholding forms, new requests for dues withholding deductions will be processed in a timely manner, normally within one pay period. The Agency will provide the NTEU National President (or her designee, her current designee being National Field Representative Richard L. Otzel) with a biweekly report of allotments withheld and the amounts.

6. **Notifications:** In matters that pertain to specific individual CFTC employees, which also require notice to the exclusive representative (e.g. individual employee grievances in which the employee has opted for self-representation), CFTC will simultaneously serve notice to the NTEU National President (or her designee, her current designee being Richard L. Otzel) and the specific CFTC employee. In matters requiring notice by the Union to the CFTC, notice shall be provided to the Chief of Workforce Relations. Notice may be by email, fax, or mail.

7. **Access to Facilities and Email**: The Agency will afford NTEU reasonable access to Agency facilities and equipment for the purposes of conducting labor- management activities. Absent substantial interference with business needs as determined by management, the CFTC also will provide the Union with reasonable access to meeting rooms for union business, subject to existing rules for reserving such rooms. The Agency will provide NTEU with an office at the headquarters of the Agency to conduct labor-management activities. The CFTC further will afford access to agency facilities by NTEU national staff representatives. Consistent with law and in conformance with existing email policies, CFTC employees designated by the Union in paragraph 3 above will be permitted use of the CFTC's email system to carry out representational activities.

8. **Formal Meetings**: The CFTC will provide the NTEU National President (or her designee, her current designee being Richard L. Otzel) notice and an opportunity to be represented at any formal meeting or discussion in accordance with 5 U.S.C. § 7114(a)(2).

9. **Changes to Conditions of Employment**

(a) During the term of this Agreement, all current Agency policies, procedures, rules, instructions and past practices will remain in full force and effect.

(b) Subject to paragraph (a) above, before making any changes to conditions of employment, as defined in 5 U.S.C. §7103(a)(14), the Agency will give notice by email to the NTEU National President (or her designee, her current designee being Richard L. Otzel). The union has seven (7) calendar days from receipt of official notice to request a briefing. The union has fifteen (15) calendar days from receipt of the official notice or fifteen (15) calendar days from the date of the briefing to request, in writing, to bargain and submit negotiable written proposals. The union shall submit its bargaining request and negotiable written proposals to the Chief of the Workforce Relations Office. If the union does not submit negotiable written proposals within the 15-calendar day period then the Agency may implement the proposed change(s) in working conditions.

(c) If the Union submits negotiable written proposals prior to the expiration of the notice period, the parties will bargain in accordance with 5 U.S.C. § 7117. Union negotiable written proposals will address only the subject of the proposed change, and will not address unrelated matters. Bargaining under this section shall be subject to the following rules:

(i) Negotiations will take place during the Agency's regular administrative work days and hours.

(ii) Negotiations will take place on the Agency's premises.

(iii) Official time to participate in negotiations will be granted to the same number of negotiators for the Union as the number of negotiators being utilized by the Agency.

(iv) If an agreement is not reached between the parties sixty (60) calendar days after the union's receipt of the Agency's official notice and negotiable proposals are still outstanding then either party may declare impasse and request the services of the Federal Mediation and Conciliation Service. The parties may mutually agree to utilize the services of the Federal Labor Relations' Authority Collaboration and Alternative Dispute Resolution Program (CADRO) or any other mediation service to resolve the dispute. The parties shall equally share the costs of the mediation services. In accordance with 5 USC § 7114 agreements negotiated between the parties will be subject to either Chairman or Commission approval as appropriate.

(d) The Parties may agree in writing to reasonable extensions of time under for the deadlines set forth above.

10. **Grievance Procedure:**

(a) A grievance for purpose of this agreement will be defined as set forth in 5 U.S.C. § 7103(a)(9). Additionally, the matters listed on Appendix 1 are not grievable and are excluded from this grievance process.

(b) Informal Grievance Process

(i) Before an employee may file a formal grievance or NTEU files an institutional grievance, an attempt must be made to informally resolve the concerns with the management official(s) believed responsible for the matter on which the concerns are based. The informal grievance is not a meeting pursuant to 5 USC § 7114. An informal grievance must be submitted in writing or via email to the lowest level supervisor with authority to grant appropriate relief with a copy to the Chief of Workforce Relations. The informal grievance must be submitted no later than fifteen (15) calendar days of the individual(s) becoming aware of the matter which created the basis for the informal grievance. The Human Resources Branch will respond to the informal grievance no later than twenty (20) calendar days after its submission. If the parties cannot resolve the dispute informally then the employee may file a formal step one grievance.

(ii) When the first level official for resolution is the Chairman, or if the first level official has executive responsibilities or is a Division Director or Office Head who reports to the Chairman, the informal grievance will be processed under the formal grievance procedure set forth below.

(c) Formal Grievance Process

(i) Step One: A Step One grievance must be submitted in writing to the Human Resources Branch no later than twenty (20) calendar days from the date the grievant becomes aware of the matter being grieved if not submitted through the informal grievance process or twenty (20) calendar days from receipt of the informal grievance response. The Step One grievance must include a statement of the issue(s), including the date(s), location(s), pertinent fact(s) (which may include any witnesses to the issue(s) or incident(s) described and any supporting documentation), the requested remedy or remedies, and whether a meeting is requested. If a meeting is requested to discuss the grievance, the meeting shall occur with the management official identified by the Human Resources Branch within ten (10) calendar days of the submission of the grievance. The Step One management official will respond with a Step One decision to the Step One grievance no later than thirty (30) calendar days after the grievance has been submitted.

(ii) Step Two: If dissatisfied with the Step One decision, an employee or the Union may file a Step Two grievance. A Step Two grievance must be submitted in writing or via email to the Human Resources Branch no later than fifteen (15) calendar days from the receipt of the Step One grievance response. The Step Two management official must be the Step One management official's supervisor or the supervisor's designee. The Step Two grievance shall not introduce new issues or remedies that were not presented at Step One. The Step Two management official will respond with a Step Two decision to the Step Two grievance no later than thirty (30) calendar days after the Step Two grievance has been submitted.

(d) For any meetings that take place during the formal grievance process, the number of union representatives from the Agency is limited to the number of management representatives and must be mutually agreed upon prior to any such meeting(s).

(e) The CFTC may offer mediation at any time to resolve the matter.

(f) Agency and Union Institutional Grievances

(i) To increase the ability to resolve disputes expeditiously, Institutional Grievances must be raised no later than thirty (30) calendar days after the date the moving party became aware of the incident giving rise to the complaint by sending an Institutional Grievance to the Human Resources Branch if the NTEU is the moving party, or to NTEU National President (or her designee, her current designee being Richard L. Otzel) if CFTC is the moving party.

In an effort to resolve national level disputes in an expeditious manner, the parties will schedule a meeting within thirty (30) calendar days of receiving the Institutional Grievance. Within thirty (30) calendar days of this meeting, a written decision will be provided by the non-moving party to the moving party.

(ii) If not satisfied with the resolution provided by the non-moving party, the moving party may invoke arbitration within thirty (30) calendar days of receipt of the grievance denial.

(g) Arbitration

(i) Consistent with 5 U.S.C. § 7121, binding arbitration is available as a final step in the grievance procedure. If invoked, the Union or the Agency will make a request for binding arbitration in writing within thirty (30) calendar days after the receipt of the Step Two decision.

(ii) The moving party will, within ten (10) calendar days after invocation of arbitration, request a list of seven (7) arbitrators from the Federal Mediation and Conciliation Service (FMCS). As soon as practicable after the list is received from FCMS, the parties will select an arbitrator by alternatively striking names from the list until one name remains. Which party strikes first will be determined by the date the FMCS list is issued. The Union strikes first if the date is an odd number and the Agency strikes first if the date is an even number.

a. Except for the specific exclusions in Appendix 1, and other administrative procedures and exclusions provided by law, the grievance procedure is the exclusive administrative procedure for resolving grievances under this agreement.

b. The parties will share equally the FMCS and arbitrator's costs.

(h) The Parties may agree in writing to reasonable extensions of time under for the deadlines set forth above in the Grievance Procedure.

11. **Bargaining Unit Lists:** Within 30 days of the effective date of this agreement, and

quarterly thereafter, CFTC will provide the NTEU National President (or her designee, the current designee being Richard L. Otzel) a list of all bargaining unit employees, including their names, position title, grade level, organizational component, official duty station (city and state), CFTC e-mail address, and salary.

12. **Precedential Effect:** The terms of this Agreement are not precedential and may not be relied upon by either party as justifying the same or similar terms in any subsequent negotiations.

Colleen M. Kelley
National President
National Treasury Employees Union

1/13/2015
Timothy Massad Date
Chairman
Commodity Futures Trading Commission

Appendix 1: List of Matters Not Subject to the Grievance-Arbitration Provisions

1. The content of published government-wide regulations or CFTC policies on ethics rules and classification matters.

2. The subject of a formal complaint of discrimination which has already been filed as a formal EEO complaint.

3. A decision or action for which a notice of appeal has already been filed with the Merit Systems Protection Board.

4. A preliminary warning or notice of a proposed action that, if effected, would be covered under the grievance system.

5. The termination or expiration of a:

   a. Time-limited excepted appointment;

   b. Temporary or term appointment on or before the date specified on the appropriate appointing SF-52; or

   c. Temporary or term appointment at any other time provided the employee was informed in advance of the temporary nature of the promotion and that he or she was returned to his or her former position or to a different position of equivalent grade and pay.

6. The content of job elements and performance standards that have been established in accordance with 5 U.S.C. § 430.

7. The termination of a probationary, temporary, or trial period employee for unsatisfactory performance or conduct.

8. The return of an employee serving a supervisory or managerial probation period to a nonsupervisory or non-managerial position according to 5 C.P.R. Part 315.

9. A separation or termination of a non-preference eligible from the excepted service before the employee has two years of current continuous service and acquires a right to appeal to the MSPB.

10. Grievances filed prior to the effective date of this agreement.

11. The issuance of performance improvement plans.

12. The non-selection for promotion from a properly ranked and certified list of candidates

13. An action taken in accordance with the terms of a formal agreement voluntarily

entered into by an employee, and reviewed by NTEU for compliance with applicable law or agreements, including agreements which assign an employee from one geographical location to another.

AGREEMENT ON COMPENSATION AND BENEFITS FOR FISCAL YEARS 2018, 2019 AND 2020 between The Commodity Futures Trading Commission and The National Treasury Employees Union

Section 1
Annual Pay Increase

A. In each year of this Agreement, CFTC will increase the pay of each bargaining unit employee by 2.0%. Such adjustment shall be effective no later than the second full pay period of each calendar year.

B. This Compensation Article is subject to appropriated funding for the Agency and budget limitations. If the Agency determines that it cannot meet its financial obligations set forth in this Article due to a reduction in appropriations from FY 17 levels, the imposition of new congressional mandates on spending, or significant unanticipated events impacting the agency budget, the Agency will notify the Union immediately and the Union can reopen the terms of this Article, and the associated Articles on Telework and Work Schedules. If the Union reopens bargaining over compensation, such bargaining will commence within one week and will proceed on an expedited basis. If the Union reopens bargaining on Telework and Work Schedules, the parties will schedule these negotiations on telework and work schedules as soon as practicable, and these will also be conducted on an expedited basis.

Section 2
Merit Pay Increase

In each year of this Agreement, the CFTC will provide funding for merit pay at 3%.

Section 3
Pay Bands

A. CFTC pay band maximums will be increased at 2% on an annual basis, commencing with the 2018 annual pay increase in Section 1 above, and these increases shall be effective no later than the second full pay period of each calendar year.

B. However, the adjusted basic pay (i.e., total annual salary) of CFTC employees will be capped at the U.S. Vice-President's annual pay rate. Therefore, if an employee's annual increase would cause his or her adjusted basic pay to exceed the U.S. Vice-President's annual pay rate, the employee will not receive any compensation in excess of that rate.

C. If an employee's merit increase would cause his or her adjusted basic pay to exceed the pay band maximum of the employee's grade, or the U.S. Vice-President's annual pay rate, the Employer will set the employee's adjusted basic pay at the pay band maximum and will give the employee a lump sum payment equal to 100% of any merit increase remaining above the band maximum.

Section 4
Locality Pay

CFTC shall increase the locality pay rate for each location by an amount equal to any increase in the GS locality pay rate for that location.

Section 5
Performance Management and Pay Reform Committee

A. Within thirty (30) days of the effective date of this agreement, the CFTC will establish a committee to study issues relating to the pay system, the Performance Management system, and the link between performance and pay.

B. The Committee will seek to make recommendations on improvements to these systems no later than six to nine (6-9) months from its first meeting. Determinations on recommendations will be made by consensus among the members of the Committee.

C. The Committee will be comprised of management and employee representatives, as well as subject matter experts and a neutral facilitator with expertise in these areas. At least three (3) NTEU representative members of the Committee will be selected by NTEU, and any other bargaining unit employees serving on the Committee will be also selected by NTEU, consistent with any relevant demographic criteria (e.g., organizational, occupational, geographic, etc.) identified by the Agency.

D. The Committee's study of the CFTC pay system will include consideration of the following issues or components:
   - Pay Equity
   - Internal/External Pay Setting
   - Pay System linkage to Performance (Pay for Performance/Pass Fail)
   - Pay Mechanism
   - General Adjustment, Locality, Bonus
   - Within Band Progression (Merit/Step)
   - Awards and Recognition

E. The Committee's study of Performance Management will include consideration of the following issues or components:

- Performance Plans (Competencies/Objectives)
- Rating Scale (Decimals/Number of Levels/Pass-Fail/etc.)
- Performance Cycle Timing (FY/CY)
- Process (Timing of Reviews/Quarterly or Semi-Annual, etc.)
- Quality and Quantity of Performance Feedback Provided
- Governance (Rating Review Panels/Reports)
- Mandatory Training

F. The Committee may break into subgroups (including NTEU appointees) to work on the various aspects of the issues being studied.

G. Management will make a good faith effort to provide the Committee (and any subgroups) with access to all data that is deemed relevant and necessary by management for discussion of the issues being studied as well as any recommendations, proposals or options already drafted by management. The Committee (and any subgroups) may request approval to gather additional data and/or feedback from managers and non-managers through mechanisms such as surveys, focus groups, conference calls and/or town hall meetings.

H. The Union retains its rights to bargain, to the extent provided by law, over any changes in working conditions relating to the subjects considered by the Committee.

Section 6
Student Loan Repayment Program

In each year of this Agreement, the CFTC will provide no less than $800,000 (eight hundred thousand dollars) in funding as the Agency-wide cap for the Student Loan Repayment Program. The program shall be administered in accordance with current policy.

Section 7
Commuter Transit Subsidies

A. The CFTC will continue to subsidize transit costs incurred by CFTC employees. Employees will be reimbursed for their actual costs each month up to $255 per month or the IRS tax-free limit, whichever is higher. Any amount over the IRS limit will be taxable.

B. The CFTC will provide a pre-tax parking benefit program to offer an income tax benefit to all eligible employees by allowing them to pay for their qualified parking expenses, not to exceed the maximum amount allowed by the IRS, from pre-tax wages. Employees may voluntarily participate in this benefit as well as the public transportation program to the extent allowed by law.

Section 8 – Duration

This article will remain in effect until October 1, 2020.

Shannon W. Schmidt
Chief Negotiator, CFTC

Date: December 26, 2017

Stephen J. Keller
Chief Negotiator, NTEU

Date: December 26, 2017

Approved:

J. Christopher Giancarlo
Chairman
Commodity Futures Trading Commission

Date: December 26, 2017

Anthony M. Reardon
National President
National Treasury Employees Union

Date: December 26, 2017

Memorandum of Understanding between the National Treasury Employees Union and the Commodity Futures Trading Commission

This memorandum is an agreement on compensation and benefits between the Commodity Futures Trading Commission (CFTC) and the National Treasury Employees Union (NTEU) (collectively, the Parties). This agreement applies to all CFTC bargaining unit employees represented by NTEU.

1. Pay:

   a. All employees shall receive an across-the board 1% pay increase effective Pay Period 1, January 2017.

   b. The CFTC will provide funding for merit pay for the 2016-2017 cycle at 3%.

2. Student Loan Repayment Program:

   The CFTC will provide $800,000 (eight hundred thousand dollars) in funding as the Agency-wide cap for the Student Loan Repayment Program in FY 2017.

3. Public Transit Subsidy

   a. The CFTC will reimburse employees for cost of using public transportation for commuting expenses. Employees will be reimbursed for their actual costs each month, up to the Internal Revenue Service tax-free limit.

   b. The CFTC will continue to provide a pre-tax parking benefit program to offer an income tax benefit to all eligible employees by allowing them to pay for their qualified parking expenses, not to exceed the maximum amount allowed by the IRS, from pre-tax wages.

Shannon W. Schmidt
Chief Negotiator
Commodity Futures Trading Commission

May 15, 2017
Date

Kenneth E. Moffett, Jr.
Director of Negotiations
National Treasury Employees Union

May 15, 2017
Date

THURSDAY, MARCH 15, 2018.

U.S. DEPARTMENT OF AGRICULTURE, OFFICE OF THE INSPECTOR GENERAL

WITNESSES

PHYLLIS K. FONG, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF AGRICULTURE

GIL H. HARDEN, ASSISTANT INSPECTOR GENERAL FOR AUDIT, U.S. DEPARTMENT OF AGRICULTURE

ANN COFFEY, ASSISTANT INSPECTOR GENERAL FOR INVESTIGATIONS, U.S. DEPARTMENT OF AGRICULTURE

Mr. ADERHOLT. The subcommittee will come to order. Good afternoon and welcome to the Agriculture Appropriations Subcommittee. This is our second hearing to review the fiscal year 2019 budget request of $87.4 million, which is a decrease of $10.8 million from fiscal year 2017 level of $98.2 million, for the U.S. Department of Agriculture's inspector general.

Ms. Fong, I would like to thank you for being here today with us, and I believe this is your—they tell me your 16th time straight in a row to be at this subcommittee hearing, or something close to that.

Ms. FONG. Something close to that.

Mr. ADERHOLT. And you, of course, in your role as the inspector general for USDA, so we appreciate your continued work in that office. I also want to welcome back to the subcommittee, Gil Harden, the Assistant Inspector General for Audits, and Ann Coffey, the Assistant Inspector General for Investigations. So welcome all of you today.

We certainly acknowledge that we have a deeply experienced team at the OIG, and we always appreciate the opportunity to discuss the challenges that you face in your Department, as well as the progress that is being made to correct any problems, any policies, any practices that may be of concern to your organization.

As we—as I usually do in the past—as I have done in the past, I want to take just an opportunity to outline the goals for this subcommittee as we conduct this oversight responsibility and craft agricultural appropriations.

The first goal for our subcommittee is to bolster prosperity and economic well-being in rural America and the farm economy. The second is to conduct fair and transparent oversight of agency activities and public resources. Third is to promote economic growth through effective and efficient regulation and minimization of regulatory overreach. And the last goal is to protect the health, safety of people, of plants, and animals.

The work you do at the OIG covers so many different aspects of the lives of all Americans, and it ties into the goals of this subcommittee, especially in regard to conducting fair and transparent

oversight of agency activities and public resources. Please know that your job is incredibly important to the integrity and the success of Department of Agriculture.

The U.S. taxpayer should also be supportive of your work due to the risk exposure of USDA's financial activities. USDA touches the lives of most—or I would say every American in one way or the other. As you know, its portfolio includes over $200 billion in assets, $154 billion in annual spending, and more than $100 billion in loans and crop insurance. Yet, for all of this responsibility, the inspector general only has a fraction of the entire USDA's budget to oversee the vast resources and the programs of the Department. Ms. Fong, your work speaks for itself.

Year after year, the total dollar impact of the inspector general's investigations—and that would include in indictments, convictions, arrests, sanctions, and reports with recommendations—had on the efficiencies and the savings of the U.S. Department of Agriculture's programs and funding grew by 83 percent.

Among other things, in our discussion today, I plan to discuss and bring up issues that are related to your audits and investigations ranging from oversight to activities, disaster response, following the Hurricanes Harvey, Irma, and Maria, USDA's nutrition assistance program, purchase cards, agroterrorism, and scientific integrity.

We would like to highlight the fact that you have once again received outstanding recognition for your excellent work among the IG community. I understand that you have received two audit awards for excellence in 2017 for your work in evaluating SNAP administration costs and the operations of the U.S. Meat Animal Research Center. This recognition came from the Council of Inspectors General on Integrity and Efficiency, which encompasses the entirety of the IG community across the Federal Government. The committee extends our congratulations for these achievements.

Before I recognize the ranking member, Mr. Bishop from Georgia, and his opening statement, I just want to remind everyone that we will do our best to strictly abide by the 5 minute rule. And please make sure you hit the talk button before you speak and then hit it again after you speak as well.

So, Mr. Bishop, you are recognized.

Mr. BISHOP. Thank you very much, Mr. Chairman.

I too would like to welcome Ms. Fong, Mr. Harden, and Ms. Coffey back to the committee. Thank you for appearing before us again. This is a very distinguished panel. And judging by the many years that you have collectively served in the USDA Department of Inspector General, it is evident that you find your work rewarding.

The high quality of your work, as the chairman noted, has been repeatedly recognized, most recently, of course, when your IG associates gave you awards for the audit of the SNAP administrative costs and the U.S. Meat Animal Research Center. That will hopefully lead to better treatment of animals at that facility and more transparency. So congratulations to your office for jobs well done.

As I mentioned last week at our CFTC hearing, we are again in an odd situation budgetwise at the moment with the 2018 bills not finished on a disappointing budget request for 2019. But I appre-

ciate our committee's focus, and we always get the job done, and this year will be no exception.

I have an abiding interest in your work and what you do, and we must do everything that we can to root out fraud, waste, and abuse, and mismanagement. In a number of cases, States and local governments actually administer programs on behalf of the Federal Government.

But like their Federal partners, their budgets are tight, and they struggle with staffing and training. We rely on inspectors general to conduct audits and investigations to ensure the programs that we fund are run efficiently and the concerns are addressed in a timely manner. In your fiscal year 2018 annual plan, you state that you have a goal to recruit, develop, and maintain a highly qualified diverse workforce. That is why I am particularly concerned about the proposed 10 percent cut to your office, including 50 staff this year.

In addition to USDA programs, I want to ensure that civil rights issues are given thoughtful and appropriate attention throughout the USDA. I look forward to discussing that with you as well as other important issues, and I thank you, again, Mr. Chairman, for allowing me the time. I look forward to our discussion.

Mr. ADERHOLT. Thank you, Mr. Bishop.

And, Ms. Fong, you may now proceed with your testimony.

Ms. FONG. Thank you, Mr. Chairman, Ranking Member Bishop, and all of the distinguished members who are here today. We are very, very happy to be here and appreciate the invitation to speak with you today about our work. I want to start out by thanking this committee for the support that you have shown our office over the years. You have demonstrated this just in the past year or so by providing us with a good level of funding for fiscal year 2017 and also by including us in the disaster recovery provisions of the Bipartisan Budget Act that was recently passed.

And we hope that, with these funds that you have provided us, that we will be able to give good audit and investigative services to USDA as it rolls out those very important programs to the affected communities. So thank you for your interest in us through that funding mechanism and throughout the year.

I know you are very familiar with our work, and you have my written statement, so I just want to highlight a couple of pieces of work, some reports that we have done that I think are worthy of mentioning, and then we can move right to the questions and answers.

As you know, we continue to do work in food safety inspections. We view that as a very important mission for our office. And we issued three audits last year on various aspects of food safety inspections, looking at equivalency assessments of exporting countries, controls over allergens in product labels, and inspection activities at establishments that handle livestock.

We also spent a good deal of time looking at different aspects of workplace misconduct issues and complaints and how the Department is handling those complaints. We did a survey of perceptions within the Forest Service of the employees in Region 5 on their sense of how allegations of sexual misconduct are being handled,

and we have some ongoing work in those areas that we will be reporting on through the year.

While we continue to devote quite a bit of resources to oversight of SNAP, this year we have also turned our focus to other programs within the nutrition portfolio at FNS. In particular, the summer food summer feeding program, which gives meals to students during the summer when school is not in session. We have reported a number of very significant case results on our investigation side because of bad actors taking advantage of the program, and we have also issued a series of interim audit reports focused on food safety issues that we found this past summer. Again, we are continuing work in this program, and we will be issuing additional reports this year.

I also note that we do reports, as you all know, in the area of the farm loan portfolio, the rural development programs, and crop insurance, and we focus a large portion of our resources on overall management issues affecting the Department as a whole. For example, financial management, cybersecurity, and improper payments continue to be challenges for all of us at the Department. We believe the Department is making progress in those areas, but those areas will require sustained attention as we move forward.

So, in closing, I want to thank this subcommittee for your interest. I think you have brought up a number of very interesting topics in your opening statements, and we look forward to engaging in dialogue on these topics.

[The information follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

STATEMENT OF

THE HONORABLE PHYLLIS K. FONG

INSPECTOR GENERAL

Submitted to

The Subcommittee on Agriculture,
Rural Development,
Food and Drug Administration, and
Related Agencies

Committee on Appropriations

U.S. House of Representatives

March 15, 2018

Good afternoon, Chairman Aderholt, Ranking Member Bishop, and Members of the Subcommittee. Thank you for the opportunity to testify regarding the Office of Inspector General's (OIG) fiscal year (FY) 2019 budget request. My statement will highlight OIG's recent audit and investigative work, illustrating how we further our mission to promote economy, efficiency, effectiveness, and integrity of the Department of Agriculture's (USDA) programs and operations.

In FY 2017 and the first half of FY 2018, OIG conducted audits and investigations to determine if programs functioned as anticipated, if program payments reached intended recipients, and if funds achieved their intended purpose. We not only work to detect and prevent fraud and abuse in USDA's programs and operations; we make recommendations to improve how programs operate in the future. Our audit and investigative work last year resulted in potential monetary results totaling over $388.2 million. We issued 47 audit reports, including 8 interim reports, and made 276 recommendations to strengthen USDA programs and operations, which produced about $95 million in potential results. OIG investigations led to 518 convictions, with potential results totaling over $293.2 million.

Before I discuss our most recent audit and investigative results under our strategic goals, I would like to thank Chairman Aderholt, Ranking Member Bishop, and Members of the Subcommittee for the funding provided to OIG as part of the Disaster Supplemental Bill.[1] This funding will help us perform audit and investigative oversight activities related to Hurricanes Harvey, Irma, and Maria.

Strategic Goal 1—Safety, Security, and Public Health

OIG's highest goal priority is to help strengthen USDA's ability to ensure public health and safety. Our work reflects these endeavors and focuses on issues such as agricultural inspection activities, information technology (IT) security, and employee safety.

[1] Further Additional Supplemental Appropriations for Disaster Relief Requirements Act, 2018, Pub. L. No. 115-123, div. B, subdiv. 1, tit. I.

Food Safety Inspection Activities

As an example of this type of work, OIG recently completed an audit regarding the Food Safety and Inspection Service (FSIS) and its inspection activities at establishments handling livestock. In response to a Congressional request that we review FSIS' controls to ensure adequately trained inspectors were properly performing humane handling activities, OIG incorporated these concerns into a current review of FSIS' response to 47 recommendations from previous audits of livestock handling activities in 2007 and 2008. Those 47 recommendations included suggested improvements to FSIS' oversight of the inspection process, how it collected critical information, and how it scheduled food safety assessments. Overall, in our most recent audit, we found that FSIS had proper procedures in place to ensure trained inspectors met humane handling requirements. We did not find any issues with the safety or wholesomeness of the products FSIS inspected during our review.

However, our current review revealed that FSIS did not always follow the corrective actions it developed to prevent reported conditions from recurring for 14 of the 47 prior recommendations. When these corrective actions did not remedy the identified problems, FSIS officials were either not monitoring the situations effectively or did not hold their staff accountable for errors. We concluded that FSIS must continue its efforts to support a comprehensive, timely, and reliable food safety inspection program. FSIS generally agreed to take corrective actions based on our 18 recommendations from the most recent review.

IT Security

As required by the Federal Information Security Modernization Act of 2014,[2] OIG reviewed USDA's ongoing efforts to improve its IT security program and practices in FY 2017. Although USDA continues to improve its IT security posture, many longstanding weaknesses remain. In FYs 2009-2016, OIG made 67 recommendations for improving the overall security of USDA's systems; however, 26 of the 27 open recommendations are overdue. Moreover, our testing identified that security weaknesses still exist in 5 of the 40 closed recommendations.

[2] Pub. L. No. 113-283, 128 Stat. 3073.

Our testing also identified weaknesses in areas such as risk management, configuration management, identity and access management, security training, and incident response. Due to these difficulties, we continue to report a material weakness in USDA's IT security, which was included in the Department's Federal Managers' Financial Integrity Act report.[3] As a result, OIG concluded that the Department lacks an effective information security program. The Department agreed with our findings and stated it has developed corrective actions and project plans to address prior recommendations.

Investigations

During the last year, we completed a joint investigation with the Animal and Plant Health Inspection Service's Investigative and Enforcement Services. The investigation determined that a father and son duo transported quarantined citrus trees from Florida to Michigan with the intention of selling and distributing the trees for profit through retail sales online. The subjects purchased the citrus trees from a nursery stock supplier in Florida and traveled by vehicle with other family members to take delivery. Upon their return to Michigan, the individuals repackaged the trees and sold them throughout the United States via online sales in violation of the citrus quarantine. The movement of trees from a quarantined area to the rest of the United States, without proper USDA inspection, created the potential to spread citrus-related diseases to other States. In October 2017, the father and son pled guilty and were sentenced and fined.

Office of Data Sciences

In January 2018, OIG's recently established Office of Data Sciences (ODS) published a report entitled *Survey of the Forest Service (FS) Region 5 Regarding Sexual Harassment*. The survey was conducted, independent of other OIG work in this area, in response to concerns over possible sexual harassment in FS. OIG undertook the survey and analysis to help determine whether Region 5 employees perceive the occurrence of sexual harassment in their work environment and, if so, how they perceive it. Key observations from the survey data included

[3] Pub. L. No. 97-452, § 1(12), 96 Stat. 2467, 2468-69 (1983) (previously enacted as the Federal Managers' Financial Integrity Act of 1982, Pub. L. No. 97-255, § 2, 96 Stat. 814).

that: a small number of respondents reported directly experiencing sexual harassment in Region 5, a larger number reported knowing someone who has been harassed in Region 5 or elsewhere in FS, and a noticeable minority of respondents viewed harassment behaviors (both sexual and non-sexual harassment) as problematic in Region 5.

Future Work

In upcoming work related to Goal 1, OIG is reviewing whether FS' actions in response to sexual harassment and sexual misconduct complaints addressed workplace concerns adequately. Although our work is ongoing, we recently issued an interim audit report that found that, while FS has taken significant steps to improve its process of handling such complaints, the process could be further improved. We expect to complete this work in FY 2018. Other upcoming audits for Goal 1 include IT security at select agencies and use of IT resources, USDA agencies' activities related to agroterrorism, and commodity purchases for international food assistance.

Strategic Goal 2—Integrity of Benefits

Another important OIG goal is to help reduce USDA program vulnerabilities and strengthen program integrity in the delivery of USDA benefit and entitlement programs that support nutrition, rural development, and farm production.

Food Assistance

In FY 2017, the Supplemental Nutrition Assistance Program (SNAP) accounted for $78 billion (57 percent) of USDA's spending. Due to this large allocation of funds, OIG devotes a considerable amount of resources to help safeguard program integrity, ensure SNAP is functioning as intended, and confirm that benefits are reaching intended recipients. About 50 percent of OIG's investigative resources were devoted to SNAP-related investigations in FY 2017. These investigations resulted in 380 convictions and monetary results totaling $99.6 million. Our investigations seek to hold SNAP abusers, both recipients and retailers, accountable for their actions.

A recent investigation found that two brothers working at a California gas station engaged in SNAP trafficking. Their father owned the gas station. The brothers were indicted on counts of conspiracy, SNAP fraud, and wire fraud. The indictment alleged that a loss of approximately $12 million was attributed to the trafficking scheme. In March 2017, the brothers were each sentenced to 41 months in prison and ordered to pay approximately $12 million in restitution to USDA. The judge also signed a court order forfeiting their interest in approximately $1.5 million in assets.

Our investigations also pursue fraud in food assistance programs other than SNAP. The Summer Food Service Program (SFSP) is intended to feed low-income children in the summer months, when school is not in session. Based on a referral from the Arkansas Department of Human Services, OIG initiated work on the At-Risk Afterschool Feeding Program, a part of USDA's Child and Adult Care Food Program, and SFSP. To date, our investigation has resulted in 16 convictions and $12.1 million in monetary results. Our investigative work raised questions about how effectively these programs are being administered, so we initiated a series of audits to examine program management. Our audit work on SFSP is ongoing, but in FY 2017 and the start of FY 2018 we published several interim reports describing food safety issues at SFSP sponsor sites in California, Florida, New York, and Texas. We expect to complete this audit work in FY 2018.

Rural and Farm Programs

Our recent audit work also covers rural and farm assistance programs, which accounted for $24 billion, or 18 percent of USDA's budget, in FY 2017.[4] For example, we reviewed whether the Rural Business-Cooperative Service (RBS) had completed corrective actions on the Intermediary Relending Program (IRP) from a past audit and if it effectively eliminated or reduced weaknesses regarding loans and intermediaries.[5] RBS updated its IRP regulations since

[4] USDA reorganized and shifted the Natural Resources Conservation Service (NRCS) into the new Farm Production and Conservation Mission Area. As a result, spending information will be higher in this area than in prior years. We also included the Foreign Agricultural Service (FAS), which is now its own Trade and Foreign Agricultural Affairs Mission Area, in this figure.

[5] An intermediary is the entity requesting or receiving RBS IRP loan funds for establishing a revolving fund and relending to the ultimate recipient.

the prior audit and implemented all of the prior audit's recommendations, but OIG determined that RBS had not resolved all of the reported weaknesses. For example, we found that intermediaries continued not to relend program funds promptly. We also found that weaknesses remain with intermediary compliance regarding the "credit elsewhere" provisions. We concluded that RBS needs additional controls to correct these recurring program weaknesses, and RBS concurred with the majority of our recommendations.

In the first half of FY 2018, OIG also reported on Rural Housing Service's (RHS) Single Family Housing (SFH) Direct Loan program, which assists low-income applicants in obtaining safe, affordable housing in rural areas. OIG evaluated RHS' controls over the program to determine if they are adequately designed and efficiently operating. We found that, in one State, Rural Development officials either did not secure primary lien positions or did not have adequate legal documentation to determine that the agency was the primary lien holder. We also found internal control weaknesses in all four States we reviewed. RHS generally agreed with our findings.

OIG evaluates farm programs in order to help ensure the integrity of farm benefits. Another early FY 2018 audit reviewed the Risk Management Agency's (RMA) use of contracted data mining results. The Agricultural Risk Protection Act of 2000 required the Secretary of Agriculture to use data mining and data warehousing to improve compliance with, and the integrity of, the Federal Crop Insurance Program.[6] To address this requirement, RMA contracted with the Center for Agribusiness Excellence (CAE). Our audit reviewed whether RMA and approved insurance providers used the results of CAE's data mining to administer and enforce crop insurance program compliance and integrity initiatives. We found that RMA needs to make improvements to maximize the use of data mining results to safeguard the integrity of the Federal crop insurance program. We also found that RMA is not obtaining the information necessary to identify and implement controls that mitigate potential problem areas and weaknesses. RMA agreed with our findings and recommendations.

[6] Pub. L. No. 106-224, 114 Stat. 358.

Our investigators also performed work relating to rural and farm programs. In FY 2017, we obtained 56 convictions and $145 million in monetary results.[7] In one investigation, a man acted as a loan broker for his cousin. The cousin received guarantees totaling $6.65 million from RBS and the Small Business Administration on two loans to purchase hotels in Texas. The investigation revealed that financial documentation the broker submitted for both loans contained materially false information pertaining to the cousin's personal assets. Additionally, the investigation determined that the broker had been convicted of embezzlement in a separate matter and was scheduled to report to prison prior to submitting the false information on behalf of his cousin. In January 2017, the cousin was sentenced to 60 months' probation. In March 2017, the man who acted as a broker was sentenced to 78 months in prison and ordered to pay restitution totaling $3.7 million, jointly and severally, with his cousin. He was also ordered to forfeit interest in assets totaling $1 million.

In another investigation, FAS referred two individuals to OIG for investigation following an FAS partial audit of a business participating in the Export Credit Guarantee Program. Both individuals controlled numerous business entities registered as exporters in this program. OIG's investigation revealed that the individuals acquired copies of shipping documents from various sources and thereafter presented false and altered shipping documents to secure loans from U.S. banks. In September 2017, the two individuals were ordered to pay $18.8 million in restitution, with $18.5 million payable to USDA and $305,700 payable to a private bank. The individuals involved in the scheme were sentenced in June 2017 to 15 months and 5 months in prison and were ordered to forfeit $1.5 million and $63,500, respectively.

Future Work

In upcoming work, OIG is reviewing FSA's required implementation of the Agriculture Risk Coverage and Price Loss Coverage Program. We are also reviewing the adequacy of controls over SFSP in the States of California, Florida, New York, and Texas and determining whether selected sponsors and sites in these States are compliant with SFSP program requirements.

[7] These numbers reflect statistical results from OIG investigations involving convictions and monetary results from FSA, RHS, the Rural Utility Service, RBS, RMA, and NRCS programs.

Strategic Goal 3—Management Improvement Initiatives

By conducting audits and investigations that focus on areas such as improved financial management and accountability, OIG helps USDA better manage its assets.

Financial Management

After an absence of sufficient, appropriate audit evidence to provide a basis for an audit opinion in FY 2015, OIG did not express an opinion on USDA's consolidated financial statements. In FY 2016, USDA, along with two component agencies—the Commodity Credit Corporation (CCC) and NRCS—made progress in addressing significant challenges to ensure accurate presentation of their financial statements. CCC's and NRCS' progress in addressing these weaknesses resulted in an unmodified opinion on their balance sheets. Overall, due to these efforts, USDA received an unmodified opinion on its balance sheet for FY 2016.

In FY 2017, though CCC and NRCS improved their presentation of their financial statements, we continued to find weaknesses. The material weaknesses for financial management were due to needed improvements in accounting and internal controls for both agencies. However, both CCC and NRCS received an unmodified opinion on their balance sheets, resulting in an unmodified opinion for USDA again on its balance sheet for FY 2017. We continue to work with the Department and its agencies to improve their controls over financial reporting.

Improper Payments

OIG performs statutorily required work intended to ensure that USDA is reducing its improper payments. We found that USDA did not comply with improper payment requirements as set forth by the Improper Payments Information Act of 2002 (IPIA), as amended,[8] for a sixth consecutive year. USDA reported improper payment information for 18 programs identified as

[8] Pub. L. No. 107-300, 116 Stat. 2350, as amended by the Improper Payments Elimination and Recovery Act of 2010 (Pub. L. No. 111-204, 124 Stat. 2224) and by the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. No. 112-248, 126 Stat. 2390).

susceptible to significant improper payments (thus considered high-risk programs), and complied with 3 of 6 IPIA requirements. However, 9 of the 18 high-risk programs did not comply with 1 or more of the following requirements: publishing an improper payment estimate as required, meeting annual reduction targets, or publishing gross improper payment rates of less than 10 percent. The Department generally agreed with our findings and recommendations.

Office of the Chief Financial Officer Controls over Final Action

OIG reviewed Departmental controls over final action on OIG audit recommendations. We found that the Office of the Chief Financial Officer (OCFO) needed to strengthen its controls over the final action process and its monitoring of pending collection recommendations. Specifically, OCFO did not follow its standard operating procedures and omitted a second-level review of final action determinations, did not maintain current claim balances for some pending collection recommendations, and needed to improve its audit tracking system. OCFO agreed with our findings and recommendations.

Suspension and Debarment

OIG reviewed USDA's implementation of prior audit recommendations and oversight of the Department's suspension and debarment program. We found that while OCFO had implemented a comprehensive set of suspension and debarment tools since a previous audit in 2010, 5 of the 27 recommendations were not implemented effectively and a sixth had yet to reach final action. Additionally, 12 USDA agencies had not fully implemented their suspension and debarment tools. OCFO generally agreed with our findings, and we accepted management decision on all nine recommendations.

Investigations

Under the strategic goal of management improvement, OIG investigates matters involving the alleged personal misconduct of USDA employees. One recent investigation was conducted to determine if a county executive director and a program technician were involved with authorizing approximately $161,604 in fraudulent payments from the FSA's Emergency Conservation Program to family members who were not entitled to such payments. The former director initially pled guilty to the charge of the conspiracy, but later tried to withdraw the plea. Her motion was denied and she was sentenced to 27 months in prison and ordered to pay $146,401 in restitution to FSA. The county executive director's husband also participated in the scheme and, in May 2017, he was sentenced to 46 months in prison and ordered to pay restitution with his wife, jointly and severally.

Conclusion

We would like to thank the Subcommittee for your continuing support and interest in our work. This support enabled us to carry out our mission of identifying potential improvements to USDA's programs and operations.

OIG's appropriations for FYs 2013-2017 totaled approximately $460 million. During this period, the potential dollar impact of OIG's audits and investigations was $3.9 billion, resulting in cost savings and recoveries of approximately $8.43 for every dollar invested. During this same period, OIG made 1,387 total audit recommendations. While some of these recommendations carry no monetary value, they can significantly improve safety, security, and public health. Furthermore, OIG investigations resulted in 3,116 successful convictions in that same 5-year period.

We appreciate your support in continuing to provide funding that will allow us to provide effective oversight and beneficial recommendations to Congress and USDA decision makers.

This concludes my testimony. I would be pleased to answer any questions you may have.

Mr. ADERHOLT. Thank you, Ms. Fong.

I would like if you could give the subcommittee a brief overview of your plans for the upcoming fiscal year under your regular discretionary appropriations under the President's budget request and the recent changes that you have made regarding your agency's operating structure. While you have laid out some of these things in your opening statement and remarks and your budget request, I wanted to ask you to focus a little bit more on your priorities for the year.

Can you just give us maybe your top three priorities for investigations and audits for this upcoming fiscal year?

Ms. FONG. I would be happy to address that question. As I mentioned, for us, one of the very top priorities is any issue that arises that could affect the safety, security, and health of the American public, USDA employees, or animals or plants. And so we do focus quite a bit of work on those issues as they arise. If we have allegations of tampering with the food supply, we will look at that. We also have work going on with FSIS on various aspects of the portfolio.

A second major priority for us is making sure that program assistance is delivered effectively across the full range of USDA programs. So we have ongoing work in FSA. ARC/PLC is one program that we are looking at. We have work in the rural development portfolio on rental housing and other housing programs. You know, we try to provide some level of coverage to all of the major assistance programs, with the overlay of the disaster programs as well.

And then our third major area is overall departmental management. And we have alluded to that with respect to the financial statement audits, which are mandatory every year. We devote a lot of attention to that. Tied to that are the improper payments work and audits that we are required to do to make sure that the Department is dealing with its rate of improper payments to try and get those rates down. And IT security enters into all of that as an overlay. We want to make sure that the Department's data is protected.

Mr. ADERHOLT. We have—it has been referred to, the President's budget request for decrease in your staffing levels about 50 staff years. How does that affect those priorities?

Ms. FONG. Well, those are overall priorities for 2018 and 2019. If the President's request were enacted, we would lose 50 people, as you mentioned, we anticipate. If we spread that evenly between our audit and investigative portfolios, what we are looking at is a significantly decreased level of effort.

For example, we anticipate we would issue 16 percent fewer audit reports and roughly 16 percent fewer investigations, based on a straight projection. Our return on investment, as you noted, ranges. Our average over the past 5 years has been roughly $8 returned for every dollar spent. If our budget is reduced by $10 million, a straight line projection would be a reduction in returns to the government of about $80 million a year.

Mr. ADERHOLT. OK. How has your recent reprograming and the creation of the Office of Data Sciences affected your operational capacity, and how has it improved the outcomes of your work?

Ms. FONG. That is a very good question. The reason we created the Office of Data Sciences was because we recognized that it is critical to be able to analyze and look at the data that resides within the Department, as well as public sources of data, to try and determine, are there indicators there that we can look at, patterns of transactions, indicators of potential fraud? What do we see in the data that can enable us to focus our audit and investigative resources more effectively, to go after bad actors involved with potential fraud?

And we have seen over the last year that there have been significant good results coming out of ODS with respect to our SNAP investigations. ODS has also issued two products this past year. They completed the survey of the Forest Service employees' perceptions of how FS is dealing with misconduct allegations. They also completed a survey of research scientists within USDA that was done in tandem with our audit report on scientific research misconduct.

And, in addition, our ODS staff and our audit staff are leading the IG community in a project to look at purchase card data across the government. We are teaming up with 20 other IGs to look at the data that exists on purchase card transactions to try and figure out, are there indicators of patterns here where perhaps there are some unusual transactions that we should be taking a harder look at? So that is where we see the future of data analytics.

Mr. ADERHOLT. Thank you.

Mr. Bishop.

Mr. BISHOP. Thank you very much, Mr. Chairman.

Ms. Fong, in September 2017, the IG published an audit which evaluated the AMS' controls over approval and oversight of the National Organic Program agreements for international trade and the import of organic products. One aspect of the audit found that AMS was unable to provide reasonable assurance that the National Organic Program required documents for review at U.S. ports of entry to verify that imported agricultural products labeled as organic were from certified organic foreign farms and businesses that produce and sell organic products.

Given the hurdles that our domestic farmers must go through to be labeled organic, it is concerning that farm products could flood the organic market, thus blocking our domestic farmers' products.

Can you discuss your recommendations, specifically the recommendation to sign an MOU with Customs and Border Patrol—Border Protection, rather, whose own resources are currently stretched very thin?

Mr. HARDEN. Yes, sir. We did make that recommendation that they work with CBP to put some protocols in place so they would at least have a go-by as to what AMS expects CBP to look at. As we went in and did the work, they didn't have any guidelines at all, so they weren't looking at anything. And we did get agreement from AMS that those protocols were necessary, and so from what I understand right now, they are working on implementing those recommendations to put those protocols in place. But it will be a prioritization of resources on both sides.

Mr. BISHOP. Thank you.

On the issue of civil rights, I noticed that last time you audited the Office of Civil Rights was in 2012, and we understand they just

recently resolved the recommendations from that audit with your office. The position for Assistant Secretary is currently vacant, and even so, on March 9, USDA proposed a realignment of that office and its functions within USDA.

The request for Office of Civil Rights is a decrease of $1.6 million from the fiscal year 2018 annualized CR level, which their own justification describes as not allowing them to fill critical vacancies. In fiscal year 2017, that office reduced its backlog and indicated it is keeping up with current cases, which must be a challenge, because the caseload increased 6 percent in fiscal year 2017 from the previous year.

Can you talk about the impact the budget reduction would have on their ability to address any backlogs and keep current on cases as they come in? Will you be auditing them again soon? And what is your opinion about the proposal to reorganize the Office of Civil Rights? There was an announcement about a reorganization of the Rural Development's Office of Civil Rights that was released prematurely and then withdrawn in January. Do you know where that stands, and have you looked into that office recently?

Ms. FONG. Well, I will try to address all of those questions and ask my colleagues to comment as well. You are exactly right. Our office has a long history of looking at civil rights issues within the Department and the processing of EEO complaints. We have not looked at it from the audit perspective for a number of years. We are planning to look at that this summer and determine where in our audit plan for the next year it will fall.

So we will be able to get back to you this summer with a decision on that. That is not to say that we haven't been doing work in that area. In the last 2 years or so, we had some complaints that were referred to us by the Office of Special Counsel that dealt with complaint processing within the Office of Civil Rights. And we did quite a bit of work to assess the process at that time, the backlog, how the office was doing. We came up with some findings. I believe the Department has addressed all of those findings at this time. So we will be looking at the issue in that context.

Mr. BISHOP. Has there been some settlements, some monetary settlements, some awards with regard to complaints recently?

Ms. FONG. We aren't normally in the loop on settlement discussions involving EEO complaints unless they involve employees of our own office.

Mr. BISHOP. I see.

Ms. FONG. With respect to the reorganization questions that you asked, we don't have any current work going on to assess reorganizations within USDA. The proposal on the reorganization of OASCR, we understand that that is open for public comment at this point and congressional comment. We are looking at it ourselves in terms of the impact on our office and how that might be affected. So we will be analyzing it from that perspective.

Mr. BISHOP. Can you also analyze it from the perspective of the effectiveness of the reorganization as opposed to the current organization structure?

Ms. FONG. We will.

Mr. BISHOP. Add that to your——

Ms. FONG. We will keep that in mind as we go through that proposal, and that may be an issue that we have to take into account as we develop an audit plan for the next year. I think that might be the appropriate way to approach that, but we are happy to discuss those issues with you further.

Mr. BISHOP. Thank you.

Mr. ADERHOLT. Mr. Yoder.

Mr. YODER. Thank you, Mr. Chairman.

Ms. Fong, welcome back to the committee. As you are well aware, some years ago, Congress passed legislation to create the National Bio and Agro-Defense Facility, NBAF, to be placed in Manhattan, Kansas. Lots of money is being spent on construction and preparation, and the purpose of such facility is to prepare America to defend ourselves from agroterrorism, efforts to poison our food supply, our livestock, both the financial risk, the human risk, the impact that would have on America. And it is a vulnerability, and we are well aware of it, and that is one of the reasons we are so supportive and hopeful that NBAF will prepare us to defend ourselves in a much better fashion.

I want to ask you some questions about a report that you released in March of 2017 related to the USDA's Office of Homeland Security and Emergency Coordination. In that report, you found that the OHSEC had not adequately overseen and coordinated USDA's efforts to prevent and detect and respond to agroterrorism. In particular, your audit indicated that the Department had failed to comply with the Homeland Security Presidential Directive 9.

Could you discuss with the committee the findings in that report, recommendations, and concerns that Congress should have based upon your audit?

Ms. FONG. I will offer a few comments, and then Gil may have some additional comments. You are right: we did issue that audit. We were concerned about whether the Department was implementing HSPD-9 appropriately. And we found that at the very high departmental level, that better coordination needed to happen in order to ensure that the directive was carried out.

As a result of those recommendations, we currently have work ongoing in three of the Department's key agencies for biosecurity. We are looking at APHIS, FSIS, and ARS currently to make sure that they are appropriately implementing. So I wanted to just give you that piece of information as well.

Gil, I am going to——

Mr. HARDEN. Yes, in terms of the compliance with HSPD-9, there was a severe, I would say, a real lack of coordination from OHSEC in terms of how it was coordinating with the departmental agencies and its role. So it really brought into focus for them where they needed to be focusing on coordinating the Department activities. They agreed with the recommendation and are putting together the comprehensive plan to address HSPD-9. Right now, they are in the process of implementing that.

The other effort related to this, which Phyllis referred to, is the work that we have in the three key agencies ongoing at this time where we are looking at their efforts and actions to prevent, detect, and respond to agroterrorism attacks. We are working—late in field work right now, so we hope to have a report out before the

end of the fiscal year. But the documentation that we are seeing in the individual agencies is better than what we saw at the Department level.

Mr. YODER. One of the reasons I bring this particular topic up is because of the risks we face, of course, as Americans, and the impact of agroterrorism. But the NBAF project is such a critical component of this, and there is a proposal in the administration's budget to move NBAF from DHS to USDA. And I am wondering, given the findings of noncompliance on HSPD-9, can you shed any light on whether this transfer would make sense, and how the audit might help guide us as to whether this is a proper transfer.

Mr. HARDEN. I hear your question and let me take that back and think about it. I haven't thought about the transfer in connection with that report, but we will get back to you on that.

Mr. YODER. Yes, certainly. I think this is a major proposal. I think the committee is going to have to take a look at this administration proposal and make sure this is the best move for the American people, for national security. And your audit and the work you have done could really be helpful in helping us understand the deficiencies we have and whether the administration of these programs are properly being done and how that impacts the eventual NBAF project.

Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. ADERHOLT. Ms. Pingree.

Ms. PINGREE. Thank you, Mr. Chair.

Thank you all for being here again and the good work and important work your Department does.

First, I want to associate myself with the remarks of our ranking member. I, too, am deeply concerned about the issues around organic importation. And as the ranking member said, it is a high standard in the United States to meet the organic standard, and it is very discouraging to farmers if they think that the same isn't being done with things that are coming from offshore.

And I guess the one question that I wanted to add on is I am just worried that the NOP is understaffed, underresourced, and can't meet the deadlines that they have talked to you about for the memorandum of understanding and also just to do their work. They receive about $9 million a year. We expect them to watch over an industry that has grown to nearly $80 billion. Do you think that they have the resources and are actually able to do what we are asking them to do?

Ms. FONG. That is a difficult question to assess at this time. I think our recommendations went to process and internal controls, which are the very first things that need to be addressed. Once AMS is able to get those controls into place, then the next question would be, are those being executed effectively? And we would certainly—whenever we go and look at a program, across the board, we look to see if the resources are available, if there are sufficient staff resources, IT resources, financial resources. And if we see issues there, the program points it out to us, and we will also point it out.

Mr. HARDEN. We did have an issue regarding their resources and staff in a prior report a couple years ago which led to different staffing levels and resource levels for the NOP.

Ms. PINGREE. OK. We will certainly be continuing to follow that, and I hope you will, too.

I want to take a different tack and talk about scientific integrity. So, in the most recent OIG report, the Audit of Scientific Integrity at USDA, you surveyed USDA research-grade scientists at four agencies in 2016. And your report has five recommendations, and I just want to ask about two.

Question 54 of the survey was: Do you have any other concerns related to scientific integrity that you want to share with OIG?

481 respondents answered the questions, and your report indicates that over half of those 481 respondents indicated that they had no other concerns. I am wondering about the respondents who did respond to the question with concerns. Do you know what their concerns were, and were there any trends in those responses? I can understand if you don't have this information in front of you.

Ms. FONG. We need to provide that for the record.

Ms. PINGREE. Well, let me go on to my second one, and we will stay in touch and hope that you can provide us that information.

On question 19, the survey asked researchers to identify which research areas have been identified to them as sensitive, controversial, prominent, or high profile. The top three responses to that question were: climate change, pollinator health, and antimicrobial research.

So, of course, those happen to be areas of important concern to me and to my constituents.

There was an additional question on whether the agency supports conducting research on sensitive, controversial, prominent, or high profile topics. Ninety-nine researchers said no. So that raised concerns for me. I am wondering how you plan to follow up on this audit in the future. I know that the agency has agreed to complete your recommendations over the next year or so, But I think it is very concerning if even one scientist at USDA believes that their work has been altered or suppressed, they can't share their research with the public, and so on. So I think we need to be diligent about this.

Do you have any plans to conduct a similar survey among USDA researchers after the USDA has completed the recommendation?

Ms. FONG. At the current time, we have not engaged in planning that far into the future. I think you do raise a really valid point that many of the respondents who express concerns also indicated a concern that, if they surfaced their issues, that there would be a potential for retaliation or reprisal, and we think that that issue should be addressed as well. We want to be keeping an eye on that.

Ms. PINGREE. Well, again, I appreciate your response to that. I hope there will be followup, and I am glad you concur with me that that is a serious concern. We expect scientific research conducted by the government to be fair, that the scientists to be operating without any fear of retaliation if they say something that they see as true or they are not allowed to speak out on what they know their research shows them. That is deeply troubling and particularly in the areas that we are talking about, which can be politi-

cally sensitive but are very important to people that I and others represent and certainly to Americans in general.

Thank you. I yield back.

Mr. ADERHOLT. Mr. Rooney.

Mr. ROONEY. Thank you, Mr. Chairman.

Ms. Fong, in the latest disaster supplemental bill we passed earlier this year, we gave your office $2.5 million to conduct oversight over the USDA disaster assistance programs funded in the bill. You clearly have experience, given your work in this area after Hurricane Sandy. So I have a couple of questions that I am going to ask all at once, and then we can go from there.

I would like to know what role, if any, your office has or could have in conducting proactive oversight over the $2.3 billion Congress provided to the Office of the Secretary for the purposes of providing disaster relief to producers who suffered hurricane-related crop losses in 2017.

Then you could you please explain what your role will be in helping to ensure that the Secretary's administration of that $2.3 billion in direct payments for crop losses is done so in a timely, effective, and appropriate manner?

Ms. FONG. Well, there are a lot of questions there for us to address. Thank you for the question on disaster oversight. We have, as you mentioned, done quite a bit of it, particularly I am thinking of our experience with the Recovery Act in 2009, where billions of dollars were rolled out very quickly, and then the Sandy situation, as you mentioned.

In 2009, we spent a lot of time proactively looking at each program that received money from the Recovery Act, sitting down with the sub-Cabinet members who are responsible for those programs, saying, "These are the internal controls in your area that you should be paying attention to," and then watching to make sure that the controls were there and then, as the money went out, that the money was going to the right people for the right purposes. So we did extensive oversight of that. We had extensive resources to do that oversight.

This time around, we have been looking at the programs that have received the money. We recognize that these programs, for the most part, are current programs. They have been operating for a number of years. We know what the controls are, and so we are looking not so much to be going in at the front end on the controls issues but to be really watching the money as it rolls out to make sure it is being distributed to eligible people for eligible purposes. So that is our current focus.

Now, we are engaged in discussions with the Department to just be aware of what their current plans are and timetable. We have briefed the Deputy Secretary on the fact that we have these responsibilities, and I think we are looking forward to a good working relationship on that.

Mr. HARDEN. In addition to the $2.3 billion, we are also talking to FSA and NRCS on the big programs that they have. They haven't gotten money out the door yet, but we are trying to work with them to know when and where that is going to go so we can monitor it in the same way. The program that we will probably get into first is the nutrition assistance program for Puerto Rico. It got

a huge amount of money, and it is money that is already going out the door. So we expect to start an assignment on that this fiscal year and have other assignments starting in 2019 related to the other disaster programs.

Mr. ROONEY. Thank you, Mr. Chairman. Thank you.

Mr. ADERHOLT. Mr. Pocan.

Mr. POCAN. Thank you very much, Mr. Chairman.

Thank you for being here. Let me just say first off, I wanted to thank you, Inspector General, and specifically Gil Harden, for meeting with my office and accepting our request, along with Representative Fitzpatrick, for a new audit of the USDA's Animal Plant Health Inspection Services Animal Care unit's enforcement of the Animal Welfare Act for commercial breeders. So we look forward to working with you on that. So thank you very much.

As you know, the Food Safety Inspection Service had proposed a rule entitled Modernization of Swine Slaughter Inspection. The new inspection model being proposed is based on a pilot project called HIMP that the agent has been conducting since the late 1990s. In May of 2013, your office published an audit report entitled "Food and Safety Inspection Service Inspection and Enforcement Activities at Swine Slaughter Plants." Your office was especially critical of the number of regulatory violations found in some of the plants participating in the HIMP pilot and the fact that the agency has never conducted an evaluation of the pilot to determine whether it was meeting food safety objectives.

In November 2014, the Food and Safety Inspection Service published an evaluation of the HIMP pilot in market hog slaughter. The agency is claiming that the evaluation report and the proposed rule addresses all of the concerns raised in your May 2013 report. Do you agree that the agency is correct in that analysis?

Mr. HARDEN. Actually, at this time, that rule is out for comment, and so I have members that were on those teams doing those audits, looking at the rule, and from that work and other work that we have done to see if we have any comments on that.

Mr. POCAN. So when is that comment period?

Mr. HARDEN. I would have to get back to you. I just know that we recently got it so we could provide comments.

Mr. POCAN. Appreciate it. Thank you. A number of consumer, food safety, worker safety, animal welfare, and public health organizations have requested that the Food Safety Inspection Service extend the comment period for the Modernization of Swine Slaughter Inspection proposed rule for as long as necessary to allow the pending external peer review of their assessment of the rule's impact.

Originally, the comment period was 60 days and extended to 90 days, which is still insufficient, particularly since the peer review is not complete. By comparison, I think the similar report on an uncontroversial proposed rule to amend egg products inspection was 120 days, just as a comparison.

I was just wondering if you agree that an extended time period is needed to make sure the peer—until the peer review is complete and that the public has adequate time to consider that?

Ms. FONG. Well, I think you make some very good points. That decision most likely rests with the program agency and the Office

of General Counsel in terms of how they go about doing the comment process and receiving comments and evaluating them. So those may be the offices to take up that particular issue with.

Mr. POCAN. Thank you.

On the budget, there is an $8.2 million decrease in your budget. I am most concerned about animal welfare enforcement. With the President's budget, what oversight projects would have to be skipped, and specifically around animal fighting, how efforts around that issue would be addressed with the cut? If you could just talk about that for a second.

Ms. FONG. I will offer a few comments, and then I think Ann might have some. We have done quite a bit of work in animal fighting over the years, and they tend to rise—those issues tend to arise in the context of investigations, allegations that there may be some illegal fighting going on, and we then look at them. And so, because of the nature of how we plan our investigative work, we will react to allegations as they come in, prioritize them depending on what is involved, other felonies, level of dollars involved.

But let me just let Ann comment.

Mr. POCAN. Sure.

Ms. COFFEY. Yes. As Phyllis mentioned, we typically look at—we are sort of a little bit more reactive than proactive on the audit side. So it is hard for us to say specifically what that impact will be. It is really based on the allegations and referrals we receive. We are working closely with the Department of Justice on their initiative on animal welfare, and so, you know, we partner with them, and we partner with State agencies to try to maximize the coverage, even when maybe resources won't allow us to work on a particular matter.

But at this point, I can't say exactly. I mean, obviously, a decrease in funding, a decrease in personnel means that we aren't going to be able to do as many of those types of investigations.

Mr. POCAN. Thank you. I yield back, Mr. Chairman.

Mr. ADERHOLT. Mr. Valadao.

Mr. VALADAO. Thank you, Chairman.

Thank you, Ms. Fong, and both our guests, all three of our guests, for being here today. I do want to follow up a little bit, just a quick comment on the fraudulently labeled imported organic products. I appreciate my colleagues asking these questions. I think that is something important we have got to really focus on. There is a huge investment on the behalf of farmers to get into the organic business, and to have someone come in and undercut it is, obviously, very frustrating and something that has a huge impact on our local economies.

I want to change topics just a little bit to one that I have a feeling no one else wanted to bring up. Inspector General, in September 2017, your office released a memo outlining misuse of USDA's information technology networks. Specifically, the memo says that, since 2015, the USDA's Office of Chief Information identified 229 instances of USDA employees and contractors using government equipment to access pornography. What I find the most concerning is that the memo also found that USDA employees had access to child pornography on government equipment.

My question to you is whether or not any of the individuals involved in the 229 notices of accessing graphic websites are still at work for the USDA. Additionally, were the instances of viewing child pornography referred to law enforcement agencies for potential criminal prosecution?

Ms. FONG. I will offer a few comments, and then Ann has more detail. You raise a very good point. The way we work with the Department on these issues is that when the Department's software identifies potential improper use, they refer it directly to our office for investigative evaluation. And we did see a significant rise in the level of referrals over the past few years.

Child pornography, as you know, is a felony and a criminal violation, and so when we receive those kinds of allegations that look like there is something to them, we make that a priority.

So, Ann.

Ms. COFFEY. So, as noted, we did see a significant increase in the cases that we received related to pornography. And, yes, in some cases, they were, of those 229 that were referred, we have about 32 cases which involve child pornography. That is really kind of the catalyst that led us to send that memorandum forward, because that is very troubling for us. And we actually work those investigations. We don't refer them to another law enforcement agency. We actually do those investigations ourselves. We may consult with the FBI, the Federal Bureau of Investigation, on those.

The individuals who we have who work for our technical crimes division, they are, sad to say, experts—they come from the FBI in many instances—in identifying that. One of the challenges I think we have with those types of cases is that you don't always know that it is child pornography right off the bat. So we will get the referral. Then we have to do analysis to determine exactly what we are looking at and if it rises to the level that we are going to be able to prosecute.

With respect to your question about whether or not those individuals who were reviewing the pornography are still employed,—I would have to—check—we usually refer those back, if they are strictly pornography, to the agencies, to take administrative action against those individuals. And, obviously, we follow through on the cases that are, specific to child pornography. We just had a very significant case where we had a contractor who was removed from his—well, he left his position, but he had actually obtained another position. He was a foster parent, had obtained a position with the Department of Defense, and had been sent to Iraq. Our agent worked, I would say tirelessly, to have that person extradited back to the United States. He is going to be serving 25 years in prison. So we take those very, very seriously.

Mr. VALADAO. Have any of the websites been blocked?

Ms. COFFEY. Yes, they have. As a matter of fact, I would also say that, as a basis for the memorandum, we have seen a significant decrease in the referrals we have received from the Department on those matters. So, yes, the Department is blocking those websites now.

Mr. VALADAO. All right.

I am going to change the topic to something a little bit cleaner. Oversight on USDA restructuring–no, no, no. I am sorry; you already hit that one, too.

High-risk list. Every 2 years, the Government Accountability Office puts together a high-risk list which calls the attention to agencies and programs that are high risk due to vulnerabilities to fraud, waste, and abuse, mismanagement, and those that are in need of transformation.

Is your office able—if they were to create a list today, which USDA agencies and programs would be at the top of that list, and why?

Ms. FONG. Well, you bring up a good point. We, as an IG office, do a similar kind of report every year. We call it the top management challenges facing the Department. And, this year, we identified seven challenges. Many of them are things we have been talking about this afternoon—for example, food safety inspections, FNS oversight of SNAP, IT security, financial management within the Department, improper payments, that kind of thing.

We would be happy to provide you that report.

Mr. VALADAO. I would like that, yes. And my time is up, and thanks again.

Chairman, I yield back.

Mr. ADERHOLT. Mr. Young.

Mr. YOUNG. Thank you, Mr. Chairman.

Welcome, everybody.

The Federal Information Security Modernization Act of 2014—does that ring a bell to you?—required the OIG, you folks, to review USDA's IT security program and practices.

There are a lot of nefarious characters out there trying to steal people's identity and their personal financial information.

It is my understanding that you all have established a Research Aggregated Data Analysis Repository system, RADAR—true?

Ms. FONG. Yes.

Mr. YOUNG. OK—that collects, stores, and organizes USDA information, including information from program participants, recipients, borrowers, grantees, contractors, employees, as well as personally identifiable information, personal data, work-related data, geolocation data, financial data.

How is the USDA mitigating the privacy and security risks of the RADAR system?

How many different systems are there in terms of, kind of, computer systems within the USDA? Are they all integrated? Do they all work fluidly together? I know that other agencies and departments, such as the IRS, they have about 13 different kind of systems.

Ms. FONG. Let me just comment on a very high level.

Within the Department, as you know, there are 30 different agencies and offices.

Mr. YOUNG. Right.

Ms. FONG. Each agency and office has its own systems, maintains their own data for their own program and management purposes. And OIG is one of those offices. We have our own systems as well.

And when we do the FISMA work to look at IT security, we are looking at how the Department is doing overall, each of its agencies as well as the Department overall. And we also do a similar review of our own internal systems to make sure we are holding ourselves to those same standards of security.

The RADAR system that you mentioned in your question is an OIG system——

Mr. YOUNG. Okay.

Ms. FONG [continuing]. Not a department——

Mr. YOUNG. Not a department-wide system.

Ms. FONG. Exactly.

Mr. YOUNG. I am assuming that there are folks out there who are trying to hack every day into the USDA. Do you get reports on the frequency and when breaches are successful unfortunately?

Mr. HARDEN. We do get notification of those incidents. And as part of the FISMA work, those are followed up to see how the Department handles those.

Mr. YOUNG. So have there been instances where there have been breaches and the personal information of farmers, producers who are receiving maybe payments and have financial information, personal identifiable information, that their information is stolen and taken?

Mr. HARDEN. I understand the question. I don't have an example right off the top of my head, but let me get back to you.

Mr. YOUNG. It seems that would be pretty serious, if there was a breach and——

Mr. HARDEN. Right.

Mr. YOUNG [continuing]. The information within the USDA of producers and grantees were downloaded and taken.

Ms. FONG. We do have a very good working relationship with the Department's Office of the Chief Information Officer, which is the primary office that would manage the Department's programs and is aware of potential breaches. And they have a group there, the ASOC group, that will work very closely with us when it appears that there may be a breach.

And their relationship with us is through our investigations side, so Ann might have——

Ms. COFFEY. Yes. I mean, we will get referrals if there is—obviously, a potentially criminal matter, if someone is hacking or breaching. The FBI actually has primary jurisdiction over that type of investigation, but we will get notified incidentally in case we need to do coordination for the followup investigation.

But I am not aware—at this time, I have not gotten any information indicating that there were breaches.

Mr. YOUNG. So you are confident in saying that you are hackproof and there have not been breaches?

Ms. COFFEY. I would not say that. I would turn it over to my colleague who does the assessments on the IT security systems. We get notification if something happens——

Mr. YOUNG. Well, let me just ask you this. Let's say there have been hacks and breaches. What are the protocols to let people know that, that their information has been compromised, their personal identification number, their banking account numbers? Are there protocols in place to let them know that?

Ms. FONG. Yes, there are. There are government-wide policies. OMB implements them.

But let me just comment to give sort of a big picture on this. The Department's IT security posture can be better. That is what our FISMA work basically says. We are looking at it, and we are concluding—and the CIO agrees with us—that the Department needs to really strengthen its IT security. There is the potential for hacking. The potential is always there. And we know, as you mentioned, that people are trying.

Now, what we are saying is that, when some of these attempts can occur, we are usually notified by the CIO's office to let us know that there is a situation that needs to be looked at. We will coordinate with the appropriate organizations, law enforcement entities, whoever.

If there has been a material breach of privacy information, there are protocols in place to notify affected individuals, and those would come into play. Fortunately, I don't believe USDA has had any situation like that that I am aware of.

Mr. YOUNG. But you would be aware if there were. You should, at least, be.

Ms. FONG. We should be.

Mr. YOUNG. What if you are not?

Ms. FONG. Well, ultimately, the——

Mr. YOUNG. That is another report.

Ms. FONG. Ultimately, the Department is——

Mr. YOUNG. But it is serious.

Ms. FONG [continuing]. The responsible organization for managing the program and making the notifications.

Mr. YOUNG. Thank you.

Mr. Chairman, I went over my time, and I apologize.

Mr. ADERHOLT. Mr. Palazzo.

Mr. PALAZZO. Thank you, Mr. Chairman.

And thank you all for being here today.

In your testimony, you said half of your investigative resources were devoted to SNAP-related investigations in fiscal year 2017.

I saw an article out of Memphis just this morning where seven people were arrested for exchanging their SNAP EBT cards for drugs. We also know trafficking happens when a retailer is willing to exchange SNAP benefits for cash or other ineligible items.

Based on your experience, would you say SNAP trafficking has increased, decreased, or remained flat over the past 3 years?

Ms. FONG. You raise some very good questions about the level of SNAP trafficking. We, at this time, don't have a way to quantitatively assess that. I will say that, in terms of our investigative portfolio, we have a very steady stream of casework there. We haven't seen the casework disappear in any way. We always have many cases involving traffickers and retailers.

On the audit side, we did issue a report in the last year or so that is intended to help FNS address ways to identify potential trafficking. And we made some, I think, very good recommendations to FNS, which they are in the process of implementing. So, hopefully, that will proactively get to that problem.

Mr. PALAZZO. OK. So, I mean, are you seeing stacks on your employees' desk increasing and they are looking at the clock Friday

at 5 o'clock saying, "I am never going to get through this?" Or is it just a steady tempo? I mean, you should be able to say it has increased, it hasn't, or it is about the same.

Ms. COFFEY. I would say, in terms what we have seen historically when we look at the, kind of, trends in our SNAP work for investigations, our work tends to mirror, the size of the allocation for that particular program is.

So what we have seen within the last—I think last year, our SNAP percentage of time was about 57 percent. This year, it is at 50 percent. It doesn't necessarily mean there is a decrease in the trafficking, but what it shows is that, you know, we do have, as Phyllis mentioned, a steady stream of work in that particular area.

But the cases, you know, they are there—unfortunately, I would say it is probably consistent, the trafficking is consistent. You are going to have fewer people engaging in it if you don't have as many people participating in the program, I think is kind of the way I would characterize it.

Mr. PALAZZO. Do you feel like you are going to continue to see 50 percent or more of your resources going toward SNAP investigations, like, in 2018, 2019, and beyond?

Ms. COFFEY. I mean, I would say probably yes, only because our cases do tend to take a little bit of time from the initiation to when it is actually completed. So some of the work that you are seeing now that is coming to fruition that we report out on were cases that were actually initiated in prior years.

So I think you probably will see that trend. And I think there are probably other factors relative to the program that may impact that in the future years.

Mr. PALAZZO. Do you feel like you have the tools necessary to do good investigations and have successful outcomes in prosecuting the people who are cheating in the SNAP program?

Ms. COFFEY. I would say our agents do a very, very, very good job. We have about a 99-percent conviction rate for our SNAP investigations. So, if our agents are working those cases, they are doing a very good job at doing that.

You know, I think probably resources are always something that everyone struggles with. So that is, you know, something we have to think about and factor in when we are figuring out how we are going to move forward over the next few years.

Mr. PALAZZO. Because you are probably much more familiar with how these people traffic in the SNAP benefits than the normal person would be, and maybe even within the agency, because of your investigations.

Do you ever provide back to your colleagues, hey, you know, if we could just do this or enact this, we could probably reduce the amount of fraud in the program? And is that well-received? And do you share that information with others?

Ms. COFFEY. We absolutely do. If we find a particular fraud scheme that we think is of concern, we will absolutely share that information with FNS.

And FNS is very receptive to—you know, I think a lot of times we have to sort of work through, kind of, maybe challenges to implementation, but they are always very receptive if we make recommendations to them about how we can improve the program.

Mr. PALAZZO. Would you say the fraud is just pretty much geographically spread across the United States, across the same demographics? Or is it more rural versus urban? Or is it just everywhere?

Ms. COFFEY. So I think there is a little bit everywhere. But I think, historically, just looking at the analysis that we have done, we do see trends on the eastern seaboard more so, some in California, in that area, and then in Texas are kind of the areas where we see—most of our casework is focused.

Mr. PALAZZO. I see my time is almost up. One last question. What is the most outrageous thing that you have seen in the trafficking for SNAP benefits?

Ms. COFFEY. Oh, gosh.

Mr. PALAZZO. Lobster? Steak? Other——

Ms. COFFEY. I mean, we have seen some——

Mr. PALAZZO. People buying puppies?

Ms. COFFEY. I think I actually—yeah, I mean, I would have to think about that a little bit more and get back to you, but we have seen some pretty unusual things purchased with SNAP benefits.

Mr. PALAZZO. All right. You do not have to submit that for the record.

Ms. COFFEY. OK. Thank you, sir.

Mr. PALAZZO. I yield back, Mr. Chairman.

Mr. ADERHOLT. Thank you.

I want to talk a little bit more about SNAP.

In the past, we have discussed the OIG's report on the SNAP quality control process used to determine error rates. The report raised some serious concerns that call into question some of the methods that States have used to achieve low error rates in the program. I know FNS has taken the report seriously, and I am pleased that the agency is working to implement much-needed changes to ensure accountability and integrity in SNAP.

Since the Food and Nutrition Service could not validate that State data was accurate, FNS was unable to calculate a national error rate for fiscal year 2015. A national payment error rate for fiscal year 2016 was not released since FNS is working with States to implement changes to the system.

Since the Food and Nutrition Service hasn't released its national error rate for SNAP for fiscal year 2015 or fiscal year 2016, how does this affect the Department's overall error rate?

Ms. FONG. Well, that is a good question. I don't believe they issued a rate in fiscal year 2017 either. They are anticipating a rate to be issued in fiscal year 2018, so that would be the first in several years. Mathematically, I am not sure how that would work.

Gil?

Mr. HARDEN. Yes, I mean, it is just not included—there is not a number included for it in the improper payment rate.

Ms. FONG. So the improper payment rates are calculated based on the programs that do have rates that are high-risk.

Mr. HARDEN. Right.

Ms. FONG. Yes.

Mr. ADERHOLT. For some programs like SNAP, the error rate threshold increases each year based on inflation. And I am aware this happens in other Federal agencies as well.

Do you think that having the error rate indexed to each year still provides an accurate assessment for improper payments, or are we just sweeping errors under the rug?

Mr. HARDEN. I know that they changed how that factored in recently. So when we go back—and I know we will go back and do followup work in the QC arena—I would have to take that as part of the question, to see how that impacted it.

I know that when they changed the threshold with the Recovery Act from what had been $25 to $50, that errors wouldn't be reported, then, yes, a lot of the errors were just not reported because they didn't reach the threshold.

The new threshold brings it back to somewhere in the $35 range, if I am remembering the number right. And then, yes, it can be indexed, but we would have to see how that works over time.

Mr. ADERHOLT. OK.

In your testimony, you mentioned that USDA did not comply with improper payment requirements set forth by the Improper Payments Information Act for a sixth consecutive year. Is the Department making progress in correcting improper payments? Are you finding the same problems year after year?

Mr. HARDEN. The compliance report has noted the same three errors for 6 years running. So, in terms of being able to meet those compliance requirements, you know, they are making strides but they haven't gotten there yet.

There is another indicator that would say that they are making improvements on whether they are having significant improper payments, and that is a report we do—have done separately in the past that is now part of the improper compliance work on high-dollar overpayments.

This one, they have made progress in making sure they were accurately and more timely reporting information about those improper payments. And the number of payments, if memory serves right, has gone down over time.

Ms. FONG. Yes. I would note that I think there are arguments to be made on both sides of that issue, because it appears that the Department's improper payment rate for fiscal year 2017 has gone up——

Mr. ADERHOLT. Yes.

Ms. FONG [continuing]. Overall. So you have that on the one hand. And then, on the other hand, you see progress being made on the high-dollar payments. So it is a mixed bag.

Mr. ADERHOLT. To reduce improper payments, do you think it is a matter of having good management in place and following the laws and rules already on the books? Or do you think there needs to be to some changes made to programs and the regulations?

Mr. HARDEN. I would want them to get a good handle on what they have to do currently before changing it.

Mr. ADERHOLT. OK.

Ms. FONG. Yes. And I think what we are seeing is that individual agencies, the ones with the high-risk programs, are the ones who need to be focusing in specifically on their programs to identify the root causes of their improper payments, which will probably vary agency by agency. But that is where the effort needs to be put in, at the individual agency program level.

Mr. ADERHOLT. OK.

Mr. Bishop.

Mr. BISHOP. Thank you very much.

I, too, want to talk about SNAP.

In December 2017, your office published an audit on the States' compliance with SNAP requirements for participating State agencies, and it looked at five States, one of them being Georgia. Four of the States, including Georgia, did not comply with nondiscrimination requirements, including failures to send decision letters regarding complaints. Others SNAP regulations that the States didn't always comply with include the prisoner verification system, deceased matching system, the income eligibility verification system.

Now, we understand that the Food and Nutrition Service has concurred with your recommendations, and I think you have talked about some of what they are doing.

The administration now has proposed a radical new approach to SNAP that has come under a great deal of criticism. They want to provide the harvest food boxes in place of money on an EBT card. They claim that this will reduce fraud, waste, and abuse.

Much of your investigative work is dedicated to ensuring the integrity of SNAP. I would like to know if you have looked at this proposal, thought about this proposal. And if so, what opportunities do you see for fraud, waste, and abuse in it?

I heard someone recently suggest that leaving harvest boxes on the front step would probably mean that they wouldn't stay there very long in the neighborhoods where the recipients would probably be looking to get them.

Ms. FONG. You raise some very good questions. We have been watching this proposal and initiative with great interest, because SNAP is such a big part of the Department's portfolio. And I think, at this stage of the game, we are watching it because we want to get a better understanding of the specifics on how the new program, if it were enacted, would be delivered. And I think it appears that there is still a lot of discussion going on around that.

In the past, when we have looked at SNAP and delivery of SNAP, we look at, overall, FNS's responsibilities, and we also look at the States and the State and local responsibilities. Because, as you mentioned in your opening remarks, there is a lot of responsibility that is given to local communities to actually deliver, and I think we would want to keep an eye on that as well, how the responsibilities are divided up.

Mr. BISHOP. It seems as if there would be a lot more moving parts and a lot more opportunities for fraud, waste, and abuse and criminal activity.

Ms. FONG. We are watching it with great interest.

Mr. BISHOP. Thank you, Mr. Chairman. I will yield whatever time I have to Ms. DeLauro.

Mr. ADERHOLT. OK. Well, let me go to Mr. Harris.

Mr. HARRIS. Thank you very much.

Two quick questions.

One, to follow up, Ms. Fong, last year, I asked you about what steps were being taken to address the lack of response to identified cost-reduction measures in the SNAP program, specifically con-

cerning the per-case administrative costs. And can you follow up with me and, you know, at this point discuss what progress has been made since we last spoke to address that high variance in SNAP administrative costs?

Mr. HARDEN. Unfortunately, I don't know that I have a lot to add. I mean, we made that recommendation to FNS, and so they have would have to go out and figure out how they were going to do those cost-reduction strategies. And so we would need to engage with them to see where they are at this point. That is not stuff that they would traditionally just report to us voluntarily.

Mr. HARRIS. And when will you follow up with them to see if they have, in fact, addressed this variance in administrative costs?

Mr. HARDEN. I will commit to taking that up as part of our planning process this year as we build the 2019 plan. Normally, we give agencies a couple of years after they have gotten everything implemented so it can be put in place and it is functioning before we go in and look again. But we can look and see if we can do that sooner than later.

Mr. HARRIS. OK. Thank you very much.

The other question I have is in response to a report or concerning a report dated this month about the use of purchase or credit cards in the Department. And, you know, according to the report, I think the Department has over 12,000 cardholders, $145 million worth of transactions just in the first half of fiscal year 2017.

And I understand that purchase cards have to be used, but what I don't understand, is unusual here, is that it is a fairly high number and that there are a high number of, quote, you know, the high-risk transactions, ones where we haven't taken—obviously, if you are using a purchase card, you are probably not taking advantage of, you know, the buying power of the Federal Government, our ability to contract at lower prices, things like that.

Can you speak to some of the issues? Because I think the report says 58 percent of the transactions had at least one issue with them. Can you speak to the kind of issues that you found?

Mr. HARDEN. Yes, sir.

And one of the first things I want to point out is that we did not identify any transactions that we thought were fraudulent that would need to be referred to investigations.

And so, yes, the 58 with errors in our 100 sample fit in about 4 major categories. One of them you have mentioned, that they were not using required sources. That was 34 of them. So those were purchasing things that they needed to purchase or were correct to purchase, but they just weren't probably doing it at the best price, because they weren't using what the Federal Government had put in place.

The other big number that is in there is ones with missing documentation. There were a total of 28 that had some form of missing documentation. It wasn't that they had all the documentation missing; it was just it had pieces. So it doesn't break down as big as it sounds, in some ways.

The other two areas, one was seven hadn't paid sales tax—or had paid sales tax when the government should not be paying sales tax. And the last one, which is probably the riskiest of the four that we looked at in USDA, were split transactions, where there were eight

split transactions where they were trying to buy it in multiple things under a cap.

Another thing I would say for this work, this is work, as Phyllis referred to earlier, that we are leading in the IG community. We have 20 different IGs that have done the same type of data analytics and gone out and looking at what were considered high-risk transactions. And we are working on that summary report to go out to OMB hopefully this spring.

Mr. HARRIS. Well, when you look at that versus other departments, is your perception that the USDA has less of a problem, about the same problem, these are common problems among departments?

Mr. HARDEN. I would say it is common among departments. And one of the other things that we found through the work we did with the 20 is that none of the transactions that the 20 IGs looked at were fraudulent transactions that needed referring.

Mr. HARRIS. OK. Thank you very much.

And thank you, Mr. Chairman. I yield back the time.

Mr. ADERHOLT. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman. And sorry to be late. There are many, many hearings today.

Ms. Fong, it is a pleasure to see you again. Thank you.

I have a couple questions here. But in your written testimony, you mention the integrity of Federal safety net programs, specifically note that, quote, "a considerable amount of resources are devoted to SNAP."

I think it is important for us to consider the broader context of other programs under USDA's jurisdiction. In 2017, the average SNAP recipient received about $126 a month or about $1,500 a year. In contrast, according to the most recent USDA data, of those receiving government payments, the average farm received $9,925 in agricultural subsidies.

I know there has been a lot of conversation, at least I have heard, about SNAP and improper payments and so forth. I believe this comes from a December 2017 document that you all produced. This is "Appendix C: Summary of Monetary Results." And it talks about the findings and potential for improper payments identified during site visits to each State. There are about five States listed here, and the total amount was $29,574. I will put that number up against any dollar in any agency that we have with regard to fraud, waste, and abuse in this system.

But let me move on. I am concerned about your recent reports which have shown shortcomings of the Risk Management Agency's oversight of the Federal crop insurance program. In December, you found that the RMA is not effectively reviewing crop insurance agents and loss adjustors with abnormal claims.

Just last month, another audit report found that four of five producer claim files from a crop insurance provider did not contain the required evidence to support indemnity payouts, resulting in questionable payments totaling $7.7 million just for producers.

Five States, $29,754.

In light of the findings, is it possible that fraudulent claims and improper payments associated with the Federal crop insurance program are more widespread than previously believed? And what rec-

ommendations has OIG made to further address crop insurance fraud?

If you can answer, because I would love to get one more question in, and I know I was late to this hearing, so——

Mr. HARDEN. In terms of the crop insurance, that is something that they have been analyzing, those——

Ms. DELAURO. Hit the button.

Mr. HARDEN. Oh. I apologize.

That list that they have created, they have been creating that list since 2001. So, yes, we looked at them to see what type of—how are you using the analytics that you are using.

One of the things we found, that the AIPs, the insurance providers, were being given a part of the list to track down, and they really weren't coming back to RMA with good, solid information. They would just say something was corrected or something was——

Ms. DELAURO. Yes.

Mr. HARDEN [continuing]. Completed.

Ms. DELAURO. Yes.

Mr. HARDEN. I do know from other work that we did as part of that, a part of the list is given to the Farm Service Agency to follow up with, and they have found significant problems with what is being found.

Ms. DELAURO. So I am presuming the answer to the question is that the Federal crop insurance program, there is more widespread improper payments than is currently believed.

I have asked the question, and if you can't answer it now—what I want to know from you—from 2001, 2018, let us know what recommendations OIG is making to further address crop insurance fraud and how we do in crop insurance fraud. I would like to get that report, and I would like to get it fast, as we go into discussions about a farm bill and crop insurance and SNAP and other kinds of programs.

Mr. Chairman, I don't know. I have 36 seconds left. Is it possible to ask another question?

Mr. ADERHOLT. I will tell you what. We are going to come back around.

Ms. DELAURO. That is perfect. I will take it. That is great. Thank you.

Mr. ADERHOLT. OK. Let's go over to Ms. Pingree.

Ms. PINGREE. Thank you, Mr. Chair.

I think I have a relatively short question. And I think you have heard from all of us today that we greatly appreciate the work that you do. And it is vitally important for this committee to have oversight, and we are always grateful when you are willing to go in and do some more for us.

But I have this question about OIG workplace environment. So, every year, the Partnership for Public Service and Deloitte produce rankings on the best places to work in the Federal Government. Federal agencies receive an index score that measures employee engagement, which is defined as the satisfaction and commitment of the workforce and the willingness of employees to put forth discretionary effort to achieve results.

For 2017, the USDA's overall index score increased by 2.8 percent compared to the previous year. But for the same year, OIG's index score decreased by 9.8 compared to the previously year.

So, given your important role at the USDA, it is concerning that employee satisfaction and commitment seem to have dropped last year. Do you have some thoughts about why that happened? And, also, just what you are doing to make sure there is plenty of commitment and satisfaction in the workplace.

Ms. FONG. This is an issue that is very important to us. And I think if you go back a year, you may have noticed that for the FEVS results not for last year but the year before, we were the highest within the Department of Agriculture.

Ms. PINGREE. I did see that, yes.

Ms. FONG. Yes.

Last year, we were looking at—OPM started to use a lot of different scales. We are very focused on those numbers. And it is important to me personally that we have that commitment.

One of the things that we are doing this year, because we want to keep an eye on our profile, our workplace satisfaction, in response to the ranking member's question as well, is we have engaged a contractor to come in and help us do an analysis to see whether there are any barriers within our current practices and procedures that are standing in the way of us really getting to the next level in terms of diversity and workplace satisfaction.

So we are very engaged in that work right now. We should have some recommendations from them in the next few months to move forward.

Ms. PINGREE. So I guess it wasn't clear to you what was causing the change in the numbers, what employees were feeling, but what you are saying is you have a contractor helping to determine what the dissatisfaction is?

Ms. FONG. We do. And we are working on that.

We also are engaging with our workforce to get their thoughts on what we can do better. We have that initiative actively going on as well.

Ms. PINGREE. Great. Well, thank you for that. And I hope you will report back to us, just to give us a better sense of where you go with that. Thank you very much.

Mr. ADERHOLT. Mr. Young.

Mr. YOUNG. Thank you, Mr. Chairman.

Some questions about the Rural Utilities Service's broadband loan program. I know that you have had some reports done on that in 2005. I think 2009 was probably the last report? OK.

Some are critical of the program, and based upon a lot of questions that we have raised up here on Capitol Hill. A well-intended program. Want to make sure that we get broadband out to those areas that don't have it.

But it appears that there have been some grants or loans made to areas where there has already been broadband build-out, so you are kind of piggybacking on another network there. And it is kind of competing against the taxpayer or private entities out there. As well as that they are not always going to unserved or underserved areas.

Have you seen a shift where these grants and loans are going to more unserved areas where it is really needed?

Mr. HARDEN. That is an issue that we did see when we did the Recovery Act work from 2012 through 2015 or so, where you still had some of those questions of are we getting out to the ones that are most needing the service.

And as part of this year's plan, we also have a proposal to look at broadband, to go back in to kind of see what changes they have made, where they are going, have they improved in those areas. Because, as you said, we have had findings where, you know, they are going into places where there is already service, it doesn't seem to be meeting the most rural need. So we want to see what progress they are making in those areas.

Mr. YOUNG. Yes.

Are we all missing something? I mean, it seems to me that, if there is service somewhere, OK, they have service, we shouldn't go there. If they don't have service other places, that is where we need to be.

Do we need to be so explicit in maybe some authorization language where we have to really spell that out to folks at the USDA and the RUS service, that where there is not service, that is where we should go? And why piggyback where there is service already? Because no one is really being served in that capacity. It is a waste of money.

Mr. HARDEN. I hear your question, and we have had the same——

Mr. YOUNG. I know. I am not venting at you, Gil. I like you. You are a good guy. But it is—to me, it gets goofy to me.

Mr. HARDEN. Yes. We have had the same type of discussions with them, and it doesn't yield great answers.

Mr. YOUNG. It sounds like a future meeting before this committee or maybe just in my office. But thank you.

I yield back.

Mr. ADERHOLT. OK. I think we need another round. So we will quickly—you know what? Let me go ahead and recognize Ms. DeLauro.

Go ahead.

Ms. DELAURO. Thank you very much, Mr. Chairman.

As you are aware, farmers are able to receive subsidies through both a traditional farm subsidy program like ARC or the Price Loss Coverage program, PLC, as well as subsidized crop insurance. Together, farm subsidies represent a huge taxpayer investment every year, often with the largest amount of farm subsidies going to the largest, most successful farm businesses.

In addition, the Agriculture Risk Coverage program in Title I and the federally subsidized crop insurance program in Title XI, they are similar in nature, raising the question about duplicative payments going to farmers.

How much money is USDA paying through farm subsidies to pay farmers twice for the same loss?

Mr. HARDEN. We currently are wrapping up an assignment on the ARC/PLC program. As part of that work, I can't talk about the specific findings right now because they are not ready to be public. But we did have conversations with RMA concerning some of their

programs as they relate to FSA programs—or to the ARC/PLC program specifically.

Ms. DELAURO. OK.

Mr. HARDEN. So I think we will have something to talk about——

Ms. DELAURO. How soon will we have that?

Mr. HARDEN. I hope in the next couple of months.

Ms. DELAURO. OK. Thank you.

It is my understanding that the nonpartisan Congressional Budget Office estimates that—there was a bill introduced by Congressman Duncan and Senator Flake to end the duplicative payments and, in fact, that that would save—this is CBO—save taxpayers more than $60 billion over 10 years.

So I will be very anxious to see the report that you are doing. Because when you want to take a look at significant savings, these are the places where we need to look.

In October 2017, you published an audit report entitled "Evaluation of Food Safety and Inspection Service's Equivalency Assessments of Exporting Countries." You made a number of recommendations. "FSIS needs to strengthen its oversight of the equivalence process." You found that FSIS auditors were inconsistent in conducting, completing, and documenting audit procedures. FSIS had approved individual sanitary measures for exporting countries that were inconsistent with domestic food safety standards. FSIS needed to establish a policy on foreign plant delistments.

Your office and the agency did not reach management decisions on all the issues raised.

FSIS's procedures for conducting ongoing verification audits did not include corrective actions recommended in previous audits. You made some specific recommendations to address this finding, and the agency's response, if this is accurate, did not satisfy your office.

In light of your findings, to what extent does your office believe that FSIS has improved its oversight of the ongoing equivalence verification audit process since your previous audits on this issue?

To follow on, do you believe the agency needs to develop a procedure to revoke the equivalency for a country that has had numerous suspensions of exports due to food safety concerns or where the verification audits show that a country has failed to implement corrective actions from previous audits?

What has FSIS done? Do you believe they have improved its oversight of ongoing equivalence verification?

Mr. HARDEN. The positive thing is, since we issued that report, we have gotten an agreement on all the recommendations. So they do have plans in place now to make the program better and address the weaknesses that we identified.

Ms. DELAURO. What kind of timeframe is on that?

Mr. HARDEN. I don't have that. I will get that date for you, but——

Ms. DELAURO. Please.

Mr. HARDEN. OK.

Ms. DELAURO. I would like that.

And then the other question is, do we need to develop a procedure to revoke the equivalency for a country that has had numer-

ous suspensions of exports due to food safety concerns or the verifications audits show a country has failed to implement the corrective actions from previous audits?

Mr. HARDEN. It is my understanding—and understand that I have done audits of this particular program at USDA multiple times myself and led the teams. I do believe they have the authority that you are talking about to do that now.

Ms. DELAURO. So there is a procedure in place now—and if that is the case, I would really like to see where the authority comes from—to revoke equivalency from a country that has not met the standards.

Mr. HARDEN. I will go back and find that, because——

Ms. DELAURO. That would be great.

Mr. HARDEN [continuing]. I am working off memory of my experience——

Ms. DELAURO. OK. Appreciate it very, very much.

Thank you very much, Mr. Chairman.

Mr. ADERHOLT. OK. Thank you, Ms. DeLauro.

Ms. Fong, Ms. Coffey, Mr. Harden, thank you all, all three, for being here today, for your testimony. I know there is a few things that you are going to get back with us on the record. There may be some members that also have some questions they would like to submit for the record, and that will be forwarded to you.

So, again, thank you for your being here again this year. And we look forward to working with you as we continue the fiscal year 2019 ag appropriations process.

The committee is adjourned.

UNITED STATES DEPARTMENT OF AGRICULTURE OFFICE OF THE INSPECTOR GENERAL (OIG) QUESTIONS FOR THE RECORD
HOUSE AGRICULTURE APPROPRIATIONS SUBCOMMITTEE HEARING MARCH 15, 2018

QUESTIONS SUBMITTED BY CHAIRMAN ROBERT ADERHOLT

Staffing Levels at OIG

1. Please include a table showing the staffing levels (both actual on-board employees and FTEs) for every year since 1978 to present.

Response: The information requested follows:

Fiscal Year	FTE Level	Staffing Level[1]
2018 EST	482	445[2]
2017	480	454
2016	531	500
2015	525	503
2014	525	494
2013	560	514
2012	577	558
2011	600	608
2010	623	593
2009	586	550
2008	600	576
2007	615	588
2006	639	595
2005	721	579
2004	721	597
2003	721	621
2002	723	642
2001	723	650
2000	753	670
1999	753	701
1998	750	737
1997	754	742
1996	811	754
1995	831	777

[1] All staffing level data includes full-time, part-time, permanent, and temporary staff.
[2] Staffing level as of May 26, 2018.

Fiscal Year	FTE Level	Staffing Level[3]
1994	850	821
1993	850	862
1992	850	876
1991	870	817
1990	860	834
1989	850	860
1988	818	835
1987	850	818
1986	880	820
1985	891	851
1984	902	879
1983	902	897
1982	901	872
1981	950	900
1980	1001	936
1979	955	988
1978	N/A[4]	894

2. Please provide the funding level for each year going back to 1978 to present for personnel compensation and benefits as defined by OMB object class.

Response: The information requested follows:

Fiscal Year	Labor Costs (thousands)	Fiscal Year	Labor Costs (thousands)
2018 EST	$ 73,095	1997	$ 52,000
2017	$ 73,094	1996	$ 52,000
2016	$ 74,587	1995	$ 52,000
2015	$ 74,405	1994	$ 51,651
2014	$ 72,632	1993	$ 50,938
2013	$ 70,619	1992	$ 49,751
2012	$ 75,292	1991	$ 43,353
2011	$ 76,000	1990	$ 40,193
2010	$ 78,000	1989	$ 38,644
2009	$ 83,000	1988	$ 36,090
2008	$ 72,000	1987	$ 33,586
2007	$ 66,000	1986	$ 31,893
2006	$ 67,000	1985	$ 32,272
2005	$ 64,000	1984	$ 31,919
2004	$ 60,000	1983	$ 31,241
2003	$ 59,000	1982	$ 28,672
2002	$ 60,000	1981	$ 27,017
2001	$ 63,000	1980	$ 25,100
2000	$ 56,000	1979	$ 23,159
1999	$ 54,000	1978	$ 20,531
1998	$ 54,000		

[3] All staffing level data includes full-time, part-time, permanent, and temporary staff.
[4] Historic staff ceiling level is unknown for FY 1978.

3. Please provide a table showing OIG's rate of attrition each fiscal year from 2013 to 2017 and projected for fiscal year 2018.

Response: The information requested follows:

	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	***FY 2018 (Projected)***
Agency Transfer - Out	5	7	6	10	12	*5*
Separation from Federal Civil Service	28	28	30	23	38	*28*
Separation - All	33	35	36	33	50	*33*
Annual OnBoard (Actuals)	514	494	503	500	454	*445*
Annual Attrition Rate	6.42	7.09	7.16	6.60	11.01	*7.41*

OIG Priorities, Concerns and Recommendations

4. What are OIG's top management and programmatic challenges as well as priorities? From the IG's perspective, does the rest of USDA view these management and programmatic challenges and priorities to the same extent as OIG views them? Please explain any possible deviations between the two sets of priorities.

Response: We plan our work by prioritizing work that is critical to accomplishing our Strategic Goals:

Strategic Goal	
Goal 1:	Strengthen USDA's ability to implement and improve safety and security measures to protect the public health, as well as agricultural and Departmental resources.
Goal 2:	Detect and reduce USDA program vulnerabilities and deficiencies to strengthen the integrity of the Department's programs.
Goal 3:	Provide USDA with oversight to help it achieve results-oriented performance.

We also plan our audit work to review areas that we have identified as challenges within the Department. In 2017, we reported seven Management Challenges that identified and consolidated broad issues that challenge the Department as a whole, as well as the unique challenges specific to certain programs.[5] This is consistent with challenges reported since 2015.

See the table below for a summary of the current top Management Challenges.

Management Challenge	
Challenge 1: USDA Needs to Improve Oversight and Accountability for its Programs	USDA, much like other agencies and departments throughout the Government, faces challenges in overseeing its many programs. USDA employs nearly 100,000 employees in 17 agencies and 18 staff offices; in total, these employees operate approximately 300 programs responsible for delivering about $143 billion in public services annually. Overseeing these programs so every dollar spent accomplishes the intended results poses significant challenges to USDA program managers.
Challenge 2: Information Technology Security Needs Continuous Improvement	Despite actions to improve information technology (IT) security, USDA continues to display weaknesses in planning, management, and oversight of its cybersecurity initiatives that affect the

[5] *USDA Management Challenges*, Office of the Inspector General, USDA, September 2017.

	Department's compliance with standards for safeguarding IT systems as directed in the Federal Information Security Modernization Act of 2014 (FISMA). The degree to which USDA complies with FISMA and other security guidance directly correlates to the security posture of each agency and office. USDA senior management needs to make sure agencies and offices understand how implementation of IT security directly affects USDA's overall security posture. For USDA to attain a security posture that is secure and sustainable, all 35 of its agencies and offices must consistently implement Departmental policy based on a standard methodology. When every agency and office is in compliance with USDA's policies, USDA as a whole will be compliant with FISMA and, more importantly, have a sustainable security posture.
Challenge 3: USDA Needs to Strengthen Program Performance and Performance Measures	Designing, developing, and implementing programs that reliably achieve their intended results has been a recurring challenge for the Department. OIG has found that agencies do not have adequate reviews or controls in place to supply the metrics necessary to evaluate program performance. In some programs, the strategy for measuring performance is missing altogether. As a result, some agencies are using inaccurate or unreliable data in program performance reports.
Challenge 4: USDA Needs to Strengthen Controls over Improper Payments and Financial Management	USDA continues to be noncompliant with Federal requirements for improper payments. In addition, USDA needs to address internal control deficiencies to resolve ongoing problems with financial management and reporting.
Challenge 5: USDA Needs to Improve Outreach Efforts	USDA has emphasized its efforts to improve outreach to new and beginning farmers and ranchers, local and regional food producers, minorities, women, and veterans. As part of those efforts, the Department has stressed the importance of civil rights, highlighting that significant progress needs to be made in working with communities when addressing past civil rights issues. Due to a history of public

	attention concerning how USDA has treated members of socially disadvantaged groups, the Department faces challenges in earning those groups' trust.
Challenge 6: Food Safety Inspections Need Improved Controls	The Food Safety and Inspection Service (FSIS) has taken action to improve food safety and the humane handling of animals at the plants FSIS inspects. However, we have found that FSIS continues to face challenges gathering reliable data to ensure safety verification tasks are completed, effective, and consistent. FSIS also continues to face challenges in training, documenting and tracking, overseeing, testing, and verifying that the Nation's commercial supply of meat, poultry, and egg products complies with regulatory requirements.
Challenge 7: Food and Nutrition Service (FNS) Needs to Strengthen SNAP Management Controls	Although FNS has endeavored to improve management controls for the Supplemental Nutrition Assistance Program (SNAP), weaknesses continue to exist in controls over administrative tasks, benefit distribution, and quality control (QC) processes. The potential exists for billions of dollars of taxpayer-funded assistance not to be delivered or used as intended.

Finally, Departmental officials have expressed agreement with the management and programmatic challenges we have identified. We believe that USDA views them as priorities based on the tracking performed by the Office of the Chief Financial Officer to gauge agencies' actions and progress to address the challenges.

5. What USDA programs, functions, or agencies are of most concern to you? Please explain why the OIG holds such concerns.

Response: Because OIG's mission is to identify and eliminate fraud, waste, and abuse, any USDA program with identified weaknesses and vulnerabilities is of significant concern to us. However, as referenced in OIG's past semiannual reports to Congress and annual reports on Management Challenges facing USDA, the programs and functions of most concern are those relating to food safety and security, information technology security, and improper payments in agency programs. Our work has also shown that these programs would benefit from the implementation of strong, integrated internal control systems. USDA managers need to make use of available tools to ensure high program performance and integrity.

Below are some examples of programs, functions, or agencies that are of most concern:

Food Safety and Security: We view food safety inspection as a continuing concern because food-borne pathogens and food contamination can put consumer health in jeopardy. In FY 2017, we issued 3 audits related to food safety and security.

Our audit of FSIS' equivalency assessments of exporting countries' food safety systems found that

equivalent countries were not consistently audited in compliance with agency policies.[6] We also found that policies and procedures did not contain sufficient guidance for conducting ongoing equivalence verification audits. In addition, FSIS procedures for conducting ongoing equivalence verification audits did not include corrective actions in response to prior audit recommendations. We recommended that FSIS strengthen its oversight of the equivalence process and revise its guidance and management control manual for conducting ongoing equivalence verification audits. FSIS generally agreed to take corrective actions based on our recommendations.

Another audit found that FSIS could improve its current approach to the disclosure of allergens on product labels as required by the Federal, Meat, Poultry, and Egg Inspection Acts.[7] For example, FSIS could more thoroughly address the possibilities of cross-contact between products on the same production floor and better document how they control data from complaints of undisclosed allergens. We recommended that FSIS collaborate with stakeholders to develop a more robust approach to preventing food allergen illness. We also made recommendations to help FSIS improve how it currently verifies that labels accurately disclose allergen presence in food products. Again, FSIS generally agreed with our findings and recommendations.

Further, as a follow-up on 2007 and 2008 audit initiatives, we evaluated the corrective actions taken by FSIS to implement 47 prior OIG audit recommendations regarding pre-slaughter activities and risk-based inspection in processing establishments.[8] We found that FSIS had procedures in place to ensure trained inspectors were completing humane handling requirements. However, FSIS did not always follow corrective actions it designed to prevent reported conditions from reoccurring for 14 of our prior audit recommendations. FSIS officials were either not effectively monitoring or did not hold its staff accountable when the actions did not correct the problems identified. As a result, those deficiencies related to humane handling and access to the Public Health Information System continue to exist. FSIS generally agreed to take corrective actions based on our recommendations.

Information Technology (IT) Management and Security: IT management and security has been a longstanding concern for USDA. We have consistently recommended that the Office of the Chief Information Officer (OCIO) work in collaboration with USDA agencies to achieve an improved security posture. USDA senior management needs to continue its efforts in making sure each agency and office understands that how well it implements IT security directly influences USDA's overall security posture and FISMA score. The degree to which USDA, as a whole, complies with FISMA and other security guidance has a direct correlation to the security posture of each agency and office. For USDA to attain a secure and sustainable security posture, all 36 agencies and offices must consistently implement Departmental policy based on a standard methodology. When every agency and office complies with USDA's policies, USDA, as a whole, will be FISMA compliant and, more importantly, will have a sustainable security posture.

Improper Payments: In FY 2017, USDA reported that its 10 high-risk programs collectively made approximately $3.3 billion in improper payments, which is a 9.93 percent improper payment rate. Per OMB Circular A-123,[9] USDA is required annually to report its high-risk programs as part of its Agency Financial Report. USDA also reported 56 high-dollar overpayments totaling over $9.3 million. This total represents no change from the 56 overpayments reported for FY 2016, but is a reduction in the amount from the $11.9 million in FY 2016.

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[6] Audit Report 24601-0002-21, *Evaluation of Food Safety and Inspection Service's Equivalency Assessments of Exporting Countries*, Sept. 2017.
[7] Audit Report 24601-0005-31, *Food Safety and Inspection Service's Controls Over Declaring Allergens on Product Labels*, June 2017.
[8] Audit Report 24016-0001-23, *Food Safety and Inspection Service Followup on the 2007 and 2008 Audit Initiatives*, June 2017.
[9] OMB Circular A-123, Appendix C, *Requirements for Effective Estimation and Remediation of Improper Payments* (Oct. 20, 2014).

Our FY 2017 Improper Payment Requirements review found that the Department did not comply with the Improper Payments Elimination and Recovery Act of 2010 (IPERA) for a seventh consecutive year.[10] Specifically, 6 of USDA's 10 high-risk programs did not comply with one or more of the following requirements: (a) publishing an improper payment estimate as required, (b) meeting annual reduction targets, or (c) publishing gross improper payment rates of less than 10 percent. Our FY 2017 review of high-dollar overpayments found that USDA maintained the quality of its high-dollar overpayments reports, with no overall declines in the accuracy, completeness, and timeliness of the Department's reporting.

6. Is OIG aware of hacking into USDA computers by foreign governments? If so, please answer in general terms as to avoid the release of any sensitive information. Has USDA's OIG taken steps to address these issues?

Response: OIG is in continuous communication with OCIO and is notified about any possible hacking incidents of USDA computers. USDA tracks all unauthorized access incidents regarding USDA-related computers and systems, including cybersecurity incidents potentially involving foreign governments, and reports all incidents to the United States Computer Emergency Readiness Team (US-CERT) at the Department of Homeland Security. US-CERT then works with the Federal Bureau of Investigation (FBI), the entity that handles hacking of computers by foreign governments. Due to the sensitivity of this topic, any further Committee interest would best be addressed through a request for briefings.

7. Is OIG aware of any recent cases of economic espionage by foreign governments? If so, is USDA sufficiently addressing the threats?

Response: OIG is not aware of any recent economic espionage against USDA systems. The FBI is the entity that handles such matters. Due to the sensitivity of this topic, any further Committee interest would best be addressed through a request for a briefing.

SNAP Fraud Detection

8. Please provide a table that shows how much of OIG's budget is spent on monitoring SNAP to reflect fiscal years 2012 through 2017 and estimated for fiscal years 2018 and 2019.

Response: The following table reflects the cost of direct investigation staff time spent on SNAP investigations during FYs 2012 through 2018 (as of May 31, 2018). The chart also includes an estimate for FY 2019.

SNAP INVESTIGATIONS

Fiscal Year	**Percent of Direct Investigations Time Spent on SNAP Investigations**	**Cost** ***(in millions)***
FY 2012 (actual)	52.35%	$22.8
FY 2013 (actual)	54.52%	$22.8

[10] IPERA, Public Law 111-204 (July 22, 2010).

Fiscal Year	Percent of Direct Investigations Time Spent on SNAP Investigations	Cost *(in millions)*
FY 2014 (actual)	58.32%	$25.1
FY 2015 (actual)	58.60%	$28.4
FY 2016 (actual)	55.80%	$27.0
FY 2017 (actual)	50.37%	$24.6
FY 2018 (actual thru 5/31/18)	42.62%	$21.3
FY 2019 (estimate)	41.50%	$18.7

9. Please provide a table showing the number of SNAP-related cases that were investigated, the number referred to the Department of Justice, and the number accepted by the Department of Justice, for fiscal years 2012 through 2017 and fiscal year 2018 to date.

Response: The information requested follows:

	Opened	Referred to DOJ	Accepted by DOJ	Referred to State or Local Prosecutors	Accepted by State or Local Prosecutors
FY 2012	201	123	88	47	30
FY 2013	195	137	109	41	36
FY 2014	207	138	64	58	36
FY 2015	181	114	47	52	28
FY 2016	208	112	72	60	44
FY 2017	157	109	69	61	32
FY 2018 (thru 5/31/18)	64	55	33	42	33
Total	1,213	788	482*	361	239

*The period of time to obtain court action varies widely, therefore the number of cases accepted by DOJ, as well as State and local prosecutors, does not necessarily correlate to the total number of cases resulting in convictions during these Fiscal Years.

10. Please provide a table showing the number of SNAP-related cases that were successfully prosecuted for fiscal years 2012 through 2017 and fiscal year 2018 to date. Please note any monetary penalties associated with these cases.

Response: The information requested follows:

	Number of SNAP Cases Resulting in Convictions from DOJ, State, and Local Prosecutions	**Monetary Results of SNAP cases**
FY 2012	141	**$57,681,053**
FY 2013	149	**$49,855,920**
FY 2014	174	**$77,691,816**
FY 2015	190	**$122,716,634**
FY 2016	176	**$95,638,737**
FY 2017	173	**$99,671,338**
FY 2018 (thru 5/31/18)	108	**$51,451,749**
Total	1,111	**$554,707,247**

SNAP Fraud Trafficking

11. In the prepared testimony, the IG said half of its investigative resources were devoted to SNAP-related investigations in FY 2017. A recent article out of Memphis showed where 7 people were arrested for exchanging their SNAP EBT cards for drugs. It is common knowledge that trafficking happens when a retailer is willing to exchange SNAP benefits for cash or ineligible items. Based on the IG's experience, has SNAP trafficking increased, decreased, or remained flat over the past 3 years?

Response: There is no evidence to indicate that SNAP trafficking has decreased or will decrease at this time.

12. Is half of the IG's investigative resources being used for SNAP-related investigations in FY 2018 and is that anticipated to continue in FY 2019?

Response: For FY 2017, 50% of OIG's investigative resources were being used for SNAP-related investigations. Thus far, in FY 2018, the level has dropped to 42.1%. Since SNAP investigations are typically multi-year, we anticipate that our investigative resources devoted to SNAP will remain constant in FY 2019.

13. Does the IG have the tools needed to be successful in these investigations or is there anything specific that could be more helpful to its work – not just related to SNAP investigations but any investigation it might be undertaking?

Response: OIG has a number of ongoing investigations involving SNAP, and other USDA-related programs. Given the limited amount of agency personnel available to conduct investigations, USDA OIG would benefit from increased use of data analytics. The use of data analytic risk models is a known tool that can have significant impacts on the success of investigations. Not only do the tools help identify the highest risk for potential individual fraud to maximize resource allocation but they can also assist in identifying potential fraud rings which, once identified, can significantly impact the overall success of investigations. In addition, risk models can assist in uncovering additional anomalies that may give insight into other forms of potential fraud that were not previously known. Developing these models takes time and resources to not only identify and acquire data but to engage data science expertise to model and ensure that data representations/visualizations are developed in order to best aid the investigators. Such expertise and tools must be procured and can represent a sizable investment, but successes within the IG community have proven to have a significant return on investment. The ODS has the fundamental expertise and tools to support the initial risk model development and maintenance efforts and, if augmented by additional data science expertise and proven visualization tools, the incorporation of this type of data analysis can provide long term impact to the success of investigations.

Reporting Hotline

OIG has an 800-number hotline where individuals may report potential fraud. In fact, this Subcommittee directed the Food and Nutrition Service ensure the hotline number is printed on SNAP EBT cards as well as the WIC food instruments.

14. On average, how many calls and/or reports does OIG receive on SNAP and WIC fraud per month?

    Response: In FY 2018, from October 1, 2017 through May 31, 2018, the OIG Hotline received, on average, 1,034 calls and/or reports per month related to SNAP and WIC fraud. This information includes complaints received via phone, e-mail, fax, and mail.

15. Besides SNAP and WIC, what other programs are the basis of OIG hotline calls?

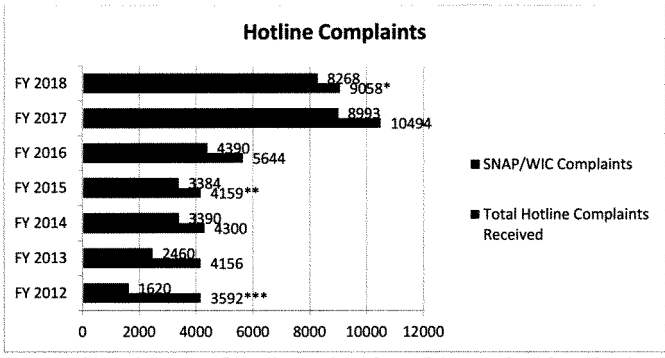
    Response: The OIG Hotline receives complaints involving all programs within USDA, with the majority of the calls and/or reports involving SNAP fraud. Most other complaints involve employee misconduct; Child and Adult Care Food Program fraud; National School Lunch Program fraud; health/safety issues to include food safety complaints; crop insurance and farm loan fraud; and mismanagement of USDA programs.

16. Does USDA receive reports regarding farm program payment or related fraud / abuse? If so, what types of reports come into USDA?

    Response: The OIG Hotline receives complaints regarding farm program payment and related fraud. The complaints typically involve allegations of entities falsifying information in order to receive farm program payments, the forging of signatures on contracts and other documents, and misuse of farm program funds.

17. Has OIG seen an increase in the number of hotline calls over the years? Please update the charts to include fiscal years 2012 through 2017 and fiscal year 2018 to date.

Response: As reflected in the chart below, OIG has seen an increase in the number of complaints received. The Food and Nutrition Service (FNS) added a reporting feature to its website, which has resulted in a dramatic increase in complaint reporting to OIG.



* For FY 2018, the chart reflects the number of complaints received from October 1, 2017, through May 31, 2018.
** In FY 2015, the Hotline complaints did not decrease as it appears; OIG Hotline received over 3,200 contacts related to the welfare of a circus elephant; all 3,200 contacts were reported under one Hotline number, as they were very similar in nature.
***Please note that the total number of hotline complaints received in FY 2012 is 3,592. It was incorrectly noted as 4,156 on the previous year's submission.

18. Does the OIG believe that the hotline will continue to be a valuable tool for combatting fraud and abuse in SNAP and WIC? What might be some alternative forms of communications by which the public can help the agency identify and investigate illegal activities with these programs and/or any other USDA program?

Response: Yes, OIG believes that the OIG Hotline will continue to be a valuable tool for individuals to report allegations of fraud, waste, and abuse in USDA programs. Analysis of Hotline complaint patterns and trends allows OIG to identify larger issues for audit or investigative focus within SNAP and WIC. Additionally, a large percentage of our contacts include allegations of SNAP recipient fraud. OIG forwards information obtained from these complainants directly to FNS, which refers it to the appropriate State entity for investigation and action. Most States have contact numbers where nutrition assistance fraud can be reported directly to the applicable State(s). The OIG Hotline serves as a conduit for information to assist with combatting fraud in the SNAP and WIC programs.

In addition, the public presently can report fraud, waste, and abuse by methods other than the 800 number,such as using our Online Hotline complaint form, or by submitting a complaint via mail or by fax. OIG does not believe that any additional/alternative forms of communicating with our Hotline are warranted at this time. Lastly, as mentioned in the response to Question #17, FNS added

a reporting feature to its website, which has resulted in a dramatic increase in complaint reporting to OIG.

19. What program or area do most of the complaints relate to?

Response: The overwhelming percentage of complaints relate to potential SNAP fraud. Out of a total of 9,058 complaints received by the OIG Hotline so far in FY 2018 (October 1, 2017 through May 31, 2018), there have been 8,237 SNAP complaints, which is 90% of the total number of complaints filed with the Hotline.

Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

20. Previously I asked if the OIG been able to assess the status and work of the National Program Integrity Monitoring Branch that FNS began operating in April 2015. Can you please tell me if OIG will be reviewing the WIC program integrity branch?

Response: OIG has an ongoing audit to evaluate the activities and effectiveness of the WIC National Program Integrity and Monitoring Branch (PIMB). As the PIMB was created in FY 2014, the audit will cover FY 2014 to the present. The final report is expected in Spring 2019.

School Meals

21. Please provide an update regarding the National School Lunch and School Breakfast Program error rates. Last year there was some progress in lowering the error rates. Has that progress continued?

Response: The improper payment error rates for the National School Lunch and School Breakfast Program have remained relatively the same from FY 2016 at 15.17% and 22.48% to FY 2017 at 15.30% and 22.75%, respectively.

OIG Audits, Investigations and General Information Requests

22. Please update the table from the fiscal year 2018 questions for the record (QFR) showing the financial statement audits OIG contracts for and those conducted in-house, as well as the cost of each audit for fiscal years 2011 through 2017.

Response: See table below:

Audited Agency	Method of Performance	FY 2011 Actual Cost	FY 2012 Actual Cost	FY 2013 Actual Cost	FY 2014 Actual Cost	FY 2015 Actual Cost	FY 2016 Actual Cost	FY 2017 Actual Cost
Federal Crop Insurance Corporation*	**In-House**	$416,235	$342,501	$313,003	$433,856	$1,521,728	$1,204,335	$1,386,576
Commodity Credit Corporation	Contract	$1,872,158	$1,910,229	$1,935,520	$1,859,293	$2,018,971	$1,577,921	$1,454.350
Food Nutrition Service	**In-House**	$1,097,324	$1,129,030	$1,063,129	$952,203	$1.732,214	$1,109,403	$1,251,169
Rural Development **	**In-House**	$2,368,598	$1,723,854	$1,513,150	$1,325,696	$1,612,851	$1,790,182	$1,799,601
Natural Resources Conservation Service	Contract	$2,291,408	$1,675,767	$1,475,407	$1,424,991	$1,410,364	$1,463,320	$1,446,031
USDA Consolidated	**In-House**	$2,089,368	$2,184,386	$1,909,983	$2,170,507	$3,307,354	$3,226,852	$3,242,935

*Starting in FY 2015, FCIC's financial statement audit was performed in-house and the estimation insurance claims methodology section of the audit was performed under contract.

** The audit was performed by OIG; however, the credit reform review was performed under contract.

23. Please update the table from the fiscal year 2018 QFRs showing the amount of funds expended for public accountants hired under contract for fiscal years 2011 through 2017.

Response: See table below:

Audited Agency	Method of Performance	FY 2011 Actual Cost	FY 2012 Actual Cost	FY 2013 Actual Cost	FY 2014 Actual Cost	FY 2015 Actual Cost	FY 2016 Actual Cost	FY 2017 Actual Cost
Type of work the independent public accounting firm performs: • FCIC: Starting with FY 2015, FCIC's financial statements audit was performed in-house and the estimation insurance claims methodology section of the audit was performed under contract. • CCC: The entire financial statement audit was performed under contract. • RD: the financial statement audit was performed by OIG; however, the credit reform review was performed under contract. • NRCS: The entire financial statement audit was performed under contract.								
Federal Crop Insurance Corporation	**In-House**	$380,942	$297,162	$277,594	$397,148	$229,716	$191,449	$195,319
Commodity Credit Corporation	Contract	$1,823,830	$1,855,111	$1,898,000	$1,810,993	$1,892,481	$1,474,264	$1,360,078
Rural Development	**In-House**	$890,400	$253,079	$238,157	$245,830	$237,218	$243,917	$225,640
Natural Resources Conservation Service	Contract	$2,248,258	$1,607,314	$1,440,349	$1,389,249	$1,362,955	$1,394,735	$1,396,064
Type of work the independent public accounting firm performs: OIG contracted with public accountants to perform attestation engagements in accordance with Government auditing standards.								
Food and Nutrition Service	Contract	NA	NA	NA	NA	NA	$691,098	$488,595
Office of the Chief Financial Officer	Contract	NA	NA	NA	NA	$205,228	$283,090	$291,482
Type of work the IT consultant performs: OIG contracted with an IT consultant to do process management for the USDA implementation of the Government-wide Continuing Diagnostic and Monitoring Project headed by the Department of Homeland Security.								
Office of the Chief Information Officer	Contract		NA	NA	NA	NA	$451,794	$403,139

24. What was OIG's cost of performing audits of Commodity Credit Corporation (CCC) financial statements in fiscal year 2017? What was the reimbursement from CCC?

Response: CCC's financial statements audit was contracted out in Fiscal Year 2017. However, OIG monitored the audit in accordance with GAO/PCIE[11] Financial Audit Manual Section 650 to ensure that the audit was performed by an audit firm that is independent, objective, and possesses the required

[11] The President's Council of Integrity and Efficiency (PCIE) was the predecessor organization for the Council of the Inspectors General on Integrity and Efficiency (CIGIE).

qualifications. This monitoring also ensured that the audit was performed in accordance with generally accepted auditing standards in the United States. OIG's cost of performing the monitoring for FY 2017 was $94,273. OIG did not receive reimbursement from CCC for this service. CCC paid the contractor cost of $1,360,078 for FY 2017.

25. Please update the status report included in the fiscal year 2018 QFRs on all current findings of material weakness since 2009. Specifically, please list the finding, OIG's recommendation and the current status.

Response: See table below.

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
FY 2009 Consolidated Financial Statements Audit, Assignment No. 50401-67-FM	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Provide additional oversight to ensure agencies (1) properly monitor and review obligation balances, (2) provide valid certifications based on complete and accurate reviews as required by Departmental Regulation 2230-001, and (3) understand the importance of responding to requests for bills or additional information in a timely manner.	Yes
Finding 2: Improvements are needed in Information Technology, Security and Controls. **Recommendation:** (1) Create a plan of action and milestones to correct deficiencies in both System Security Plans and Contingency and Disaster Recovery Plans, (2) revise Cyber Security Assessment and Management and/or system documentation to reflect consistent and accurate information, and (3) institute policy and procedures to ensure review and signature of all parties bound by Interconnection Security Agreements.	Yes
FY 2010 Consolidated Financial Statements Audit, Assignment No. 50401-70-FM	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Provide additional oversight to ensure that agencies are properly reviewing, researching, and timely implementing action to correct abnormal balances.	Yes
Finding 2: Improvements are needed in Information Technology, Security, and Controls. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2011 Consolidated Financial Statements Audit, Assignment No. 50401-0001-11	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** (1) Provide additional oversight of the accounting functions at FAS to ensure that the objectives of the internal control over financial reporting are maintained, (2) provide additional oversight and training to ensure agencies are following Departmental policy in identifying and reconciling intradepartmental transactions.	Yes
Finding 2: Improvements are needed in Information Technology Security and Controls. **Recommendation:** Because of recommendations made in our annual	N/A

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
FISMA audits, we are making no further recommendations.	
FY 2012 Consolidated Financial Statements Audit, Assignment No. 50401-0003-11	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Because of recommendations already made to CCC and NRCS in other reports, we are making no further recommendations in this report.	N/A
Finding 2: Improvements are needed in Information Technology Security and Controls. **Recommendation:** Because of recommendations made in our annual FISMA audits, we are making no further recommendations.	N/A
FY 2013 Consolidated Financial Statements Audit, Assignment No. 50401-0005-11	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Because of recommendations already made to NRCS, CCC, and FCIC in other reports, we are making no further recommendations in this report.	N/A
Finding 2: Improvements are needed in overall Information Technology Security Program. **Recommendation:** Because of recommendations made in our prior FISMA audits, we are making no further recommendations.	N/A
FY 2014 Consolidated Financial Statements Audit, Assignment No. 50401-0007-11	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Because of recommendations already made to NRCS, CCC, and FCIC in other reports, we are making no further recommendations in this report.	N/A
Finding 2: Improvements are needed in overall Information Technology Security Program. **Recommendation:** Because of recommendations made in our prior FISMA audits, we are making no further recommendations.	N/A
FY 2015 Consolidated Financial Statements Audit, Assignment No. 50401-0009-11	
Finding 1: Improvements are Needed in Overall Financial Management **Recommendation:** Because USDA has actions planned and in progress, we are making no further recommendations herein.	N/A
Finding 2: Improvements are Needed in Overall Information Technology Security Program **Recommendation:** Because of recommendations made in our FISMA audits, we are making no further recommendations in this report.	N/A
FY 2016 USDA Balance Sheet Audit, Assignment No. 50401-0011-11	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Because USDA has actions planned and in progress, we are making no further recommendations herein.	N/A
Finding 2: Improvements are needed in overall Information Technology Security Program. **Recommendation:** Because of recommendations made in our prior FISMA audits, we are making no further recommendations.	N/A
FY 2017 USDA Balance Sheet Audit, Assignment No. 50401-0013-11	

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Since USDA has actions planned and in progress, we are making no further recommendations herein.	N/A
Finding 2: Improvements are needed in overall Information Technology Security Program. **Recommendation:** No new recommendations were made as the prior FISMA reports addressed the security weaknesses noted this year. As a result, we are making no further recommendations.	N/A
Finding 3: Controls over unliquidated obligations (ULO) can be strengthened. **Recommendation:** Provide additional oversight to ensure that financial reporting controls over ULOs are strengthened and maintained.	Yes
FY 2009 CCC Financial Statements Audit, Assignment No. 06401-24-FM	
Finding 1: Improvements are needed in financial management system's functionality. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2010 CCC Financial Statements Audit, Assignment No. 06401-25-FM	
Finding 1: Improvements are needed in financial management system's functionality. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2011 CCC Financial Statements Audit, Assignment No. 06401-0001-11	
Finding 1: Improvements are needed in financial management system's functionality. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2012 CCC Financial Statements Audit, Assignment No. 06401-0002-11	
Finding 1: Improvements are needed in funds control. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2013 CCC Financial Statements Audit, Assignment No. 06401-0003-11	
Finding 1: Improvements are needed in funds control. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2014 CCC Financial Statements Audit, Assignment No. 06401-0004-11	
Finding 1: Improvements are needed in funds control. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2015 CCC Financial Statements Audit, Assignment No. 06401-0005-11	
Finding 1: Improvements are Needed in Financial Reporting **Recommendations:** (1) Design and implement processes, procedures, and effective controls related to significant accounting estimates. (2) Develop effective information and communication processes to ensure that policies	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
and procedures related to programs or events that may give rise to the recognition of accounting transactions are consistently communicated and applied throughout the agency and that technical accounting issues are identified, analyzed, and resolved in a timely manner. (3) Accumulate relevant, sufficient, and reliable data on which to base accounting estimates. (4) Ensure accounting estimates are prepared by qualified personnel with a full understanding of the underlying generally accepted accounting principles (GAAP) requirements. (5) Ensure there is an adequate review and approval of the estimates by appropriate levels of management, including review of sources of relevant factors, development of assumptions, and reasonableness of assumptions and resulting estimates. (6) Implement processes, procedures, and effective controls to enable the timely preparation of financial statements and sufficient evidential matter to support accounting transactions. (7) Design and implement policies, procedures, and controls to accept, track, and monitor agreements entered into with other agencies (customers) and link the goods/services provided and the transactions entered into the respective funding agreement to produce a population of unfulfilled customer orders (UFCO) by customer, which reconciles to the general ledger. (8) Design and implement policies, procedures, and controls to review UFCOs balances to determine whether they should still be open (on an agreement-by-agreement basis) or whether the funding should be returned to the ordering agency before the period of availability or the funding appropriation ends. (9) Design and implement Due Care policies, procedures, and controls to identify, and investigate known and potential sites. (10) Develop a complete inventory of sites potentially needing review and their status and disposition. (11) Continue to refine the precision of each site's estimate and maintain adequate supporting documentation that is readily available.	
Finding 2: Improvements are Needed in the Accounting for Parent/Child Transactions **Recommendations:** (1) Implement processes, procedures, and controls to assess and periodically reassess methodologies used to account for parent/child activity. (2) With the assistance of the child agency, conduct a detailed review of the transactions and balances reported in the general ledger to ensure that CCC maintains a complete set of supporting documentation for transactions and balances reported in the general ledger.	Yes
Finding 3: Improvements are Needed in the Accounting for Budgetary Transactions **Recommendations:** (1) Design and implement policies and procedures to require communication and collaboration between the decentralized groups involved in the review of undelivered orders. (2) Modify the policies and procedures related to the review of stale obligations by developing detailed, written procedures to facilitate adequate and consistent review across the various groups performing the reviews. Also, include expanded criteria to review the validity of undelivered orders to correspond to the nature of the agency and its programs. (3) Implement the necessary functionality within	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
the financial management systems to automatically deobligate undelivered orders at the time of payment. (4) Conduct a detailed review of the transactions and balances reported in the general ledger to ensure that CCC maintains adequate supporting documentation for transactions and balances reported in the general ledger and that the supporting documentation is readily available. (5) Continue the implementation of automated funds control of all obligations and expenditures at the transaction level within the core financial system. Further, implement necessary compensating controls until such automated controls are fully implemented.	
FY 2016 CCC Balance Sheet Audit, Assignment No. 06401-0006-11	
Finding 1: Improvements are needed with accounting estimates. **Recommendations:** (1) Design and implement processes, procedures, and controls to ensure data used in its accounting estimates are complete and accurate; (2) Ensure that accounting estimates are prepared by qualified personnel with a full understanding of the underlying accounting requirements; (3) Ensure there is an adequate supervisory review and approval of the estimates, by appropriate levels of management, including review of the sources of relevant factors, development of assumptions, and reasonableness of assumptions and resulting estimates. These reviews should be at a sufficient level of precision, to detect errors in the estimates that would be material to the financial statements	Yes
Finding 2: Improvements are needed with maintenance of accounting records. **Recommendations:** (1) Continue the implementation of processes, procedures, and controls to improve the accuracy and timeliness of the Fund Balance with Treasury (FBWT) reconciliation, including reconciliations of related child agency FBWT accounts. (2) Ensure that month-end reconciliations of all accounts are performed timely, and reviewed at appropriate precision levels through the implementation of thresholds that are monitored by management. Reconciling differences identified should be timely corrected in the subsidiary or general ledgers.	Yes
FY 2017 CCC Balance Sheet Audit, Assignment No. 06401-0008-11	
Finding 1: Improvements are needed with accounting for budgetary transactions. **Recommendations:** (1) Develop and implement necessary policies, procedures, and controls at the appropriate level of precision to record, monitor, and validate Undelivered Orders (UDOs) balances periodically, and, when necessary, deobligate UDOs in a timely manner (appropriate fiscal year) at the individual producer and/or transaction level; (2) Develop policies and procedures to ensure that its accounting positions appropriately identify the accounting issue, assess all aspects of U.S. GAAP, and effectively implement positions that are in accordance with GAAP. In those instances where a prior period error is identified, appropriately correct such errors retrospectively; (3) Continue to evaluate all budgetary general and subsidiary ledgers, to ensure that they reflect the appropriate accounting and reporting	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
guidance provided by OMB and the U.S. Department of Treasury.	
Finding 2: Improvements are needed with accounting estimates. **Recommendations:** (1) Develop policies and procedures to ensure that accounting positions appropriately identify the accounting issue, assess all aspects of GAAP, and effectively implement positions that are in accordance with GAAP; (2) Design and implement processes, procedures, and controls to ensure that data used in its accounting estimates are complete and accurate; (3) Ensure there is an adequate supervisory review and approval of the estimates, by appropriate levels of management, including review of the sources of relevant factors, development of assumptions, and reasonableness of assumptions and resulting estimates. These reviews should be at a sufficient level of precision, to detect errors in the estimates that would be material to the financial statements. In addition, these reviews should also include an evaluation of adjusting entries recorded as a result of the executed methodology.	Yes
FY 2009 NRCS Financial Statements Audit, Assignment No. 10401-03-FM	
Finding 1: Improved accounting and controls needed over undelivered orders. **Recommendation:** Continue to train budget and program personnel to review open obligation balances and monitor compliance.	Yes
Finding 2: Improved accounting and controls needed over the revenue and unfilled customer order process. **Recommendation:** Develop and implement policies and procedures for reimbursable agreements, accounts receivable, and unfilled customer orders.	Yes
Finding 3: Improved accounting and controls needed over accrued expenses. **Recommendation:** Provide additional training to field personnel regarding the policy and procedures for recording accruals.	Yes
Finding 4: Improved controls needed over financial reporting. **Recommendation:** Obtain and use the United States Government Standard General Ledger posting models for conservation easements, travel advances to others, cumulative results of operations for non-appropriated funds, recoveries of prior year obligations, and accounts receivable with the public.	Yes
Finding 5: Improved accounting and controls needed for property, plant, and equipment. **Recommendation:** Establish a policy that outlines the proper procedures for identifying and tracking the appropriate costs related to the development of new applications through the various stages of the development process.	Yes
FY 2010 NRCS Financial Statements Audit, Assignment No. 10401-03-FM	
Finding 1: Improved accounting and controls needed over undelivered orders. **Recommendation:** Review the current policies are compliant with Title 31 of the U.S. Code and GAO's Redbook, The Principles of Federal Appropriations Law.	Yes
Finding 2: Improved accounting and controls needed over the revenue and	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
unfilled customer order process. **Recommendation:** Develop a systematic methodology for calculating the allowance for uncollectible accounts, which considers historical data, estimates losses on an individual and aggregate account basis, and considers other risk factors that may have an impact on NRCS' ability to collect amounts due.	
Finding 3: Improved accounting and controls needed over accrued expenses. **Recommendation:** Perform quality assurance procedures to determine if accrued expenses are complete, accurate, and exist at quarter and year end.	Yes
Finding 4: Improved controls needed over financial reporting. **Recommendation:** Establish a more robust internal control identification and evaluation process to identify all significant control deficiencies.	Yes
Finding 5: Improved accounting and controls needed for property, plant, and equipment. **Recommendation:** Reinforce segregation of duties responsibilities for inventory taking, reminding Accountable Property Officers that the inventory taker should not also have the authority to purchase Property, Plant and Equipment (PP&E).	Yes
Finding 6: Improved general and application access controls needed. **Recommendation:** Establish a process to actively review and document its review of application, active directory, and virtual private network (VPN) access to determine whether it is appropriate based on the employee's role.	Yes
Finding 7: Improved controls needed over purchase and fleet card transactions. **Recommendation:** NRCS management immediately reviews all cardholders to determine whether they are current NRCS employees and should have access to a purchase card.	Yes
FY 2011 NRCS Financial Statements Audit, Assignment No. 10401-0001-11	
Finding 1: Improved accounting and controls needed over undelivered orders. **Recommendation:** (1) Provide additional training to field personnel related to the identification and recording of advances and disbursements, (2) provide guidance and policy to field personnel relating to the monitoring and validation of the obligation's period of performance prior to payment.	Yes
Finding 2: Improved accounting and controls needed over accrued expenses. **Recommendation:** (1) Perform quality assurance procedures to determine if accrued expenses are complete, accurate, and exist at quarter and year end, (2) reduce the number of standard voucher and year end accruals required by configuring systems to record accruals when goods/services are receipted in the application, where there is a cost benefit; (3) enhance monitoring internal controls over obligations and payment approvals to determine whether appropriate documentation is provided to support the obligation and disbursement; (4) utilize transaction codes in the Foundation Financial Information System (FFIS) to record accruals that do not reverse for direct entry obligations; and (5) provide guidance on the Prompt Payment Act	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
related to the entry of acceptance dates and determine if additional interest is due to vendors or whether the vendor was overpaid as a result of any errors.	
Finding 3: Improved controls are needed over financial reporting. **Recommendation:** Enforce NRCS' Circular 21 to ensure condition assessment policies and procedures are compliant with Statements of Federal Financial Accounting Standards (SFFAS) No. 29.	Yes
Finding 4: Improved accounting and controls needed for property, plant and equipment. **Recommendation:** Develop in coordination with the Department Chief Information Officer a reconciliation process for State offices to utilize to reconcile between the International Technology Services (ITS) property report and State inventory reports.	Yes
Finding 5: Improved general and application access controls are needed. **Recommendation:** Establish controls to monitor the control environment at the International Technology Services (ITS) and mitigate the identified weaknesses.	Yes
FY 2012 NRCS Financial Statements Audit, Assignment No. 10401-0002-11	
Finding 1: Improved controls are needed over general accounting operations. **Recommendation:** (1) Focus on strengthening the internal control environment and ensuring that system components are fully operational; (2) identify the underlying impediments causing errors in the Accounts Receivable billing module, proper liquidation of advances, and posting of depreciation/amortization; (3) continue to implement procedures over the FBWT process, to include procedures for ensuring that unprocessed items are cleared from the suspense account in a timely manner; and (4) complete a thorough review of the FBWT suspense account to identify older reconciling items, and take the appropriate actions to clear these items.	Yes
Finding 2: Improved controls are needed over financial reporting. **Recommendation:** (1) Continue to implement a comprehensive financial management system strategy to ensure compliance with Federal financial management systems requirements; (2) enforce accounting entries that are consistent with those prescribed by the United States General Ledger; (3) develop policies to ensure all relevant Federal accounting standards are followed; (4) improve the communication and implementation of policies and procedures regarding the preparation of financial statements; Management's Discussion and Analysis, footnote disclosures, and Required Supplementary Information; (5) ensure all qualitative information reported in footnote disclosures, including supplementary information, is accurate and current; and (6) continue to develop remediation plans to address FMFIA and FFMIA noncompliance.	Yes
Finding 3: Improved controls are needed over property, plant and equipment (PP&E). **Recommendation:** (1) Complete the PP&E remediation efforts as soon as possible to ensure that real property and personal property information is	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
provided in a timely manner. Remediation efforts should include completion of real property and personal property physical inventories, and review of budget object codes currently assigned to personal property; and (2) finalize efforts to implement the "Methodology for Condition Assessment Surveys and Determining Deferred Maintenance" to track deferred maintenance, and suggest that NRCS continue to develop and implement effective steps and related policies and procedures to track improvements to leased and owned assets.	
Finding 4: Improved controls are needed over accrued expenses. **Recommendation**: (1) Finalize and implement steps to regularly review the accounts payable accrual methodology, and grants and agreements accrual methodology against actual results to validate their predictive reliability; (2) develop a process for accruals and disbursements, including Intragovernmental Payment and Collection transactions, to properly documents that the related accrual or disbursement is appropriate; and (3) research and remediate current debit vendor balances.	Yes
Finding 5: Improved controls are needed over reimbursable agreements. **Recommendation**: (1) Continue to implement sustainable internal controls to verify the completeness and accuracy of UFCOs for future years; (2) continue to conduct analysis of current UFCO balances to determine if they are complete;. (3) continue to review open UFCO balances for validity and accuracy; (4) continue to provide comprehensive training, instruction, and support to personnel responsible for recording and monitoring Reimbursable Agreements (RA); (5) continuously monitor the effectiveness of RA controls; and (6) confirm the accurate conversion of UFCO balances for beginning balances FY 2013.	Yes
FY 2013 NRCS Financial Statements Audit, Assignment No. 10401-0003-11	
Finding 1: Improved accounting and controls are needed over undelivered orders. **Recommendation**: (1) Continue to monitor activity in U.S. General Standard Ledger (USSGL) accounts 4801, 4871, and 4881 to ensure that invalid upward and downward adjustments are identified and negated in a timely manner and that balances are appropriate; (2) continue to monitor open obligations to ensure that upward and downward adjustments are recorded in the appropriate period and liquidated timely; and, (3) provide adequate training to personnel related to the documentation requirements for support.	Yes
Finding 2: Improved controls are needed over financial reporting. **Recommendation:** (1) Identify and document transactions that, when required, are recorded in accordance with the guidance found in SFFAS No. 21; (2) implement procedures to reduce the need to record a large volume of misstatements at year end; (3) establish policies/guidelines that assist accounting personnel in properly determining the type of sufficient supporting documentation for journal entries and deferred maintenance; and (4) enhance the management review of journal entries to include use of appropriate posting models obtaining and inspecting supporting	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
documentation.	
Finding 3: Improved accounting and controls are needed over expenses. **Recommendation:** (1) Provide guidance and/or training to employees on policies and procedures to ensure purchase transactions have adequate supporting documentation to determine if they are accurate and exist; (2) enhance monitoring controls over payment approvals to determine whether appropriate documentation is provided to support the disbursement; and (3) enhance procedures to determine if accrued expenses are complete, accurate, and exist at quarter-ends and are properly supported.	Yes
Finding 4: Improved accounting and controls are needed over revenue and accounts receivable. **Recommendation:** (1) Continue to improve documentation that will support revenue, accounts receivable, and unfilled customer orders transactions in accordance with OMB Circular No. A-123; and (2) review and liquidate invalid unfilled customer orders.	Yes
FY 2014 NRCS Financial Statements Audit, Assignment No. 10401-0004-11	
Finding 1: Improved accounting and controls are needed over obligations and undelivered orders. **Recommendations**: Develop comprehensive policies and procedures to monitor the GRP program and confirm transactions are accurate, adequately supported and recorded in the proper fiscal year. (1) Continue to monitor activity in USSGL accounts 4871, and 4881 to ensure that invalid upward and downward adjustments are identified and corrected in a timely manner and that balances are appropriate; (2) continue to monitor open obligations (USSGL accounts 4801 and 4802) to ensure that they are recorded in the appropriate period and liquidated timely; and, (3) provide adequate training to personnel related to the documentation requirements for support.	Yes
Finding 2: Improved controls are needed over financial operations. **Recommendations:** Review and evaluate options to reference accruals to the appropriate undelivered orders so that these amounts can be incorporated in the balances. (1) Identify and document transactions that, when required, are recorded in accordance with the guidance found in SFFAS No. 21; (2) implement procedures to reduce the need to record a large volume of misstatements at year end; (3) establish policies/guidelines that assist accounting personnel in properly determining the type of sufficient supporting documentation for journal entries and deferred maintenance; and (4) enhance the management review of journal entries to include use of appropriate posting models obtaining and inspecting supporting documentation.	Yes
Finding 3: Improved accounting and controls are needed over expenses. **Recommendation:** (1) Provide guidance and/or training to employees on policies and procedures to ensure purchase transactions have adequate supporting documentation to determine if they are accurate and exist; (2) enhance procedures to determine if accrued expenses are complete, accurate,	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
and exist at quarter-ends and are properly supported; and (3) enhance monitoring controls over payment approvals to determine whether appropriate documentation is provided to support the disbursement.	
FY 2015 NRCS Financial Statements Audit, Assignment No. 10401-0005-11	
Finding 1: Improved Accounting and Controls are Needed Over Obligations and Undelivered Orders (Repeat Condition). **Recommendations**: As noted in recommendation 1A, 1B and 1C of Audit Report No. 10401-0003-11, December 2013, we continue to recognize the need for NRCS management to: (1) Monitor activity in U.S. Standard General Ledger (USSGL) 4871 and 4881 to ensure that invalid upward and downward adjustments are identified and corrected in a timely manner and that balances are appropriate; (2) Monitor open obligations (USSGL accounts 4801 and 4802) to ensure that they are recorded in the appropriate period and liquidated timely; and (3) Provide adequate training to personnel related to the documentation requirements for support.	Yes
Finding 2: Improved Accounting and Controls are Needed Over Financial Operations (Repeat Condition). **Recommendations:** Establish policies and procedures that: (1) Assist personnel producing data extracts to determine the completeness and accuracy of such extracts; (2) Ensure data extracts are reviewed by process owners regularly for errors; and (3) Establish a closing schedule for period 13 transactions in order to avoid any delays in producing such extracts. We continue to recognize the need for management of the NRCS to: (1) Establish policies/guidelines that assist accounting personnel in properly determining the type of sufficient supporting documentation; and (2) Continue to develop and implement internal controls and policies and procedures to correct or mitigate the risks and potential misstatements within the agency. We also recommend that management of the NRCS: (1) Enhance policy and control procedures for the accuracy and consistent application of period end accruals; and (2) Provide adequate training to personnel relating to the new accrual policy.	Yes
Finding 3: Improved Accounting and Controls are Needed Over Transactions Related to the Grassland Reserve Program **Recommendation:** We recommend that management of the NRCS: (1) Implement management's plan to develop a new process for administering the remaining funds for the GRP in FY 2016; (2) Request and obtain supporting documentation for prior services rendered by FSA to NRCS; (3) Review and reconcile the supporting documentation to determine and mutually agree upon the amount of services that have been rendered by FSA to NRCS; (4) Make and record any necessary corresponding adjustments to fund balance with Treasury, accounts receivables, accounts payable, and cumulative results of operations balances; and (5) Obtain sufficient supporting documentation for the remaining GRP obligations recorded in the general ledger at the end of FY 2015.	Yes
FY 2016 NRCS Balance Sheet Audit, Assignment No. 11401-0007-11	

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
Finding 1: Improved Accounting and Controls are Needed Over Obligations and Undelivered Orders (Repeat Condition). **Recommendations:** Because of recommendations already made, there are no new recommendations.	N/A
Finding 2: Improved Accounting and Controls are Needed Over Expenses (Repeat Condition). **Recommendations:** Because of recommendations already made, there are no new recommendations.	N/A
FY 2017 NRCS Balance Sheet Audit, Assignment No. 11401-0009-11	
Finding 1: Improved Accounting and Controls are Needed Over Obligations and Undelivered Orders (Repeat Condition). **Recommendations:** (1) Monitor open obligations to ensure that they are recorded in the appropriate period and liquidated timely and (2) provide adequate training to personnel related to the documentation requirements for support.	Yes
Finding 2: Improved Accounting and Controls are Needed Over Expenses (Repeat Condition). **Recommendations:** (1) Identify and document transactions that, when required, are recorded in accordance with the guidance found in SFFAS No. 21: Reporting Correction of Errors and Changes in Accounting Principles, Amendment of SFFAS 7, Accounting for Revenue and Other Financing Sources; and (2) enhance procedures to determine if accrued expenses are complete, accurate, and exist at quarter end and are properly supported.	Yes
Finding 3: Improved Accounting and Controls are Needed Over the Monitoring of Service Organizations. **Recommendations:** Management should appropriately align knowledgeable resources to evaluate the roles of service organizations, assess controls at those service organizations, and identify and assess the complementary end user controls (CUECs) of those service organizations.	Yes
FY 2013 FCIC/RMA Financial Statements Audit, Assignment No. 05401-0003-11	
Finding 1: Improvement needed in controls over estimated losses on insurance claims calculation. **Recommendation:** (1) Implement procedures to ensure that manual processes of the indemnity projection model are performed and subsequently reviewed by independent individuals within management to ensure the review process over calculation is adequate and limits the risk of material misstatements in the liability for estimated losses on insurance claims at year-end; (2) consider performing an Independent Verification and Validation review of the indemnity projection model every year in which a new model is implemented, or when a model has been substantially enhanced; (3) consider the need to save documentation to provide an audit trail of all relevant computations; (4) consider performing additional risk assessments on the indemnity calculation aimed at the processes that have the greater risks of errors in the calculations.	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
FY 2014 FCIC/RMA Financial Statements Audit, Assignment No. 05401-0004-11	
Finding 1: Improvement needed in controls over estimated losses on insurance claims calculation. **Recommendations:** Design and implement policies and procedures to include the following: when evaluating the need to change estimation methodologies, particularly as it relates to significant financial statement balances, management should consider: availability of support for assumptions, comparability with prior years methods and computations, potential effect on balances and the effect on the consistency of financial statements, and, changes or enhancements to estimation methodologies that are in accordance with US GAAP. The following were identified in the prior year audit and should be considered when developing the corrective action plan: (1) implement actions to ensure that changes to the indemnity projection methodology are performed and subsequently reviewed by independent individuals within FCIC/RMA management to ensure that the changes to the calculation are appropriate and verifiable to limit the risk of material misstatements in the liability for estimated losses on insurance claims at year-end; (2) consider performing an Independent Verification and Validation (IV&V) review of the indemnity methodology every year in which a new methodology is implemented or when the indemnity model has been substantially enhanced; (3) consider the need to save supporting documentation to provide an audit trail of all relevant estimate computations; and, (4) consider performing additional risk assessments on the indemnity calculation aimed at the processes that have the greater risks of errors in the calculations. The magnitude of potential errors should be viewed in terms of financial statement line items and the financial statements as a whole, in order to ensure that management limits the risk of material misstatements on the financial statements.	Yes
FY 2015 FCIC/RMA Financial Statements Audit, Assignment No. 05401-0005-11	
Finding 1: Improvements Are Needed in the Review of the Estimated Loss Calculations **Recommendations:** Develop control procedures over the program code to ensure that all variables are input correctly and calculating properly.	Yes
FY 2017 FCIC/RMA Financial Statements Audit, Assignment No. 05401-0009-11	
Finding 1: Improvements Are Needed in RMA's Information Technology General Controls **Recommendations:** (1) Establish an effective disaster recovery program, failover system and alternate processing facility; (2) perform annual testing of the contingency plan; (3) develop and implement an effective process for the timely maintenance, monitoring and reporting of Plan of Action and Milestones (POA&Ms); and (4) develop and implement a process to verify that vulnerabilities that continue to exist over 30 days are entered as POA&Ms, approved and remediated timely.	Yes

FY 2009 through FY 2017 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
FY 2015 RD Financial Statements Audit, Assignment No. 85401-0005-11	
Finding 1: Subsidy Model Design and Review Needs Improvement **Recommendation 1:** Develop and implement a formal review and evaluation process to assess results from the current models, explaining and documenting any adjustments needed in the methodology.	Yes
FY 2017 RD Financial Statements Audit, Assignment No. 85401-0007-11	
Finding 1: Subsidy Model Design and Review Needs Improvement **Recommendation 1:** RD's assessment of internal controls over financial reporting and OIG's audit report 11601-0001-22, USDA's 2017 Compliance with the DATA Act, resulted in recommendations to address the noncompliance with the DATA Act. Therefore, we made no further recommendations.	N/A

26. Please update the table from the fiscal year 2018 QFRs showing the amount spent for confidential operational activities for fiscal years 2011 through 2017.

Response: The information requested follows:

Fiscal Year	Available	Spent
2011	$125,000	$92,835
2012	$125,000	$96,979
2013	$125,000	$83,061
2014	$125,000	$76,408
2015	$125,000	$78,089
2016	$125,000	$64,145
2017	$125,000	$83,443

27. Please provide a summary of complaints from the OIG Hotline for fiscal year 2017.

Response: The below chart summarizes OIG Hotline complaints received during FY 2017.

Hotline Complaints Summary	
FY 2017 Hotline Complaints received	
Total No. of Complaints Received	**10494**
Employee Misconduct	517
Participant Fraud*	9512
Waste Mismanagement	312
Health/Safety Problem	27
Opinion/Information	119
Bribery	4
Reprisal	3

*This category encompasses various forms of fraud. In FY 2017, of the total 10,494 complaints, there were 8,950 complaints involving SNAP fraud that were directly referred to FNS for action.

28. Please provide a table showing the number of audit reports, investigative reports, indictments, convictions, and lawsuits filed for fiscal year 2017.

Response: The requested information for FY 2017 follows:

Audit Reports—Final	47
Audit Reports--Interim	8
Investigative Reports	292
Indictments	498
Convictions	518
Lawsuits Filed	10

29. How were the indictments resolved, and what percent led to convictions? Please report for the latest data available.

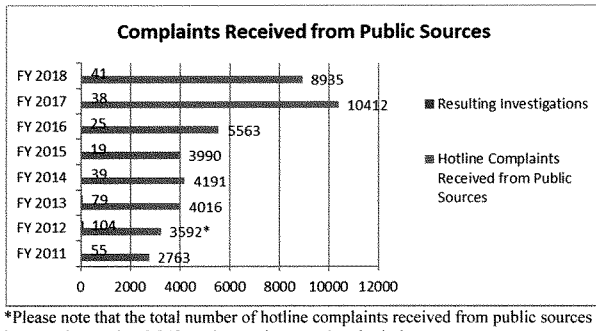
Response: In FY 2017, the conviction rate was 94.6%. As of May 31, 2018, the conviction rate is 99% for FY 2018. The period of time to obtain court action on an indictment varies widely; therefore, indictments claimed in a time period do not necessarily correspond to the convictions claimed in that same time period.

30. Please update the description from the fiscal year 2018 QFRs of the work the IG is doing in regard to federal, state or industry employee whistleblowers. How many open investigations and reviews are related to whistleblower complaints?

Response: OIG receives complaints from many sources including, but not limited to, Federal and State employees, and the public. Any individual who contacts OIG to report an allegation of fraud, waste, or abuse is considered a potential whistleblower. Each Hotline complaint received is reviewed with a determination made whether the matter should be addressed by OIG; referred to the appropriate USDA agency for review, response, and appropriate action; or referred to the appropriate Federal government agency for any action if deemed appropriate. This fiscal year, as of May 31, 2018, OIG opened 22 investigations and initiated 3 audits resulting from complaints received through the OIG Hotline. There are an additional 29 complaints currently being evaluated by Investigations and 5 currently being evaluated by Audit.

31. How many complaints did OIG receive from outside groups that are not whistleblower complaints in fiscal years 2011 through 2017? How many did OIG consider worthy of further investigation?

Response: We consider all complaints received to be potential whistleblower complaints. OIG tracked complaints received from public sources through the OIG Hotline from October 1, 2010, through May 31, 2018, as follows:



*Please note that the total number of hotline complaints received from public sources in FY 2012 is 3,592. It was incorrectly noted as 3,243 on the previous year's submission.

32. Please provide for the record the amounts transferred to OIG from the Department of Justice Assets Forfeiture fund for fiscal years 2011 through 2018 to date. Provide an explanation of the use of these funds by OIG.

Response: As a participating member of the Department of Justice (DOJ) Assets Forfeiture Fund, OIG receives funds pursuant to annual allocation requests and pursuant to petitions for remission or mitigation. Under DOJ's annual allocations, funds can be requested for program operations expenses and investigative expenses. Investigative expenses incurred by OIG involve mainly the equipping of conveyances when the DOJ annual allocation allows. Program operations expenses include the following: case related expenses; joint law enforcement operations; special contract services; contracts to identify assets; and training. Funds received as a result of petitions for remission or mitigation are utilized for law enforcement activities authorized under the Inspector General Act.

Department of Justice			
Fiscal Year	Petitions	Annual Allocations	Totals
2011	$11,663	$1,683,000	$1,694,663
2012	$40,190	$1,725,000	$1,765,190
2013	$0	$1,614,000	$1,614,000
2014	$818,495	$1,647,000	$2,465,495
2015	$72,570	$1,680,000	$1,752,570
2016	$128,970	$1,555,000	$1,683,970
2017	$2,299,556	$1,402,000	$3,701,556
2018 EST*	$274,104	$1,313,000	$1,587,104

*Information as of 5/31/18.

33. Please provide for the record amounts transferred to OIG from the Department of Treasury Forfeiture Fund for fiscal years 2011 through 2017. Provide an explanation of the use of these funds by OIG.

Response: The amounts below represent funds received from petitions for remission or mitigation from the Department of Treasury Forfeiture Funds. OIG does not receive a separate annual allocation from the

Department of Treasury.

Receipt of Petition Funds	
Fiscal Year	Department of Treasury
2011	$0
2012	$52,033
2013	$135,205
2014	$1,124,225
2015	$576,090
2016	$184,547
2017	$1,530,094

Amounts transferred to OIG are utilized for law enforcement activities authorized under the Inspector General Act. Such uses for law enforcement activities have included law enforcement equipment and investigative/law enforcement supplies.

34. Please provide for the record amounts transferred to OIG through the granting of a Petition for Remission or Mitigation for fiscal years 2011 through 2017.

Response: The amounts below represent the total asset forfeiture funds received on granted petitions for remission or mitigation:

Receipt of Petition Funds			
Fiscal Year	Department of Treasury	Department of Justice	Totals
2011	$0	$11,663	$11,663
2012	$52,033	$40,190	$92,223
2013	$135,205	$0	$135,205
2014	$1,124,225	$818,495	$1,942,720
2015	$576,090	$72,570	$648,660
2016	$184,547	$128,970	$313,517
2017	$1,530,094	$2,299,556	$3,829,650

35. Please describe the pay scale for OIG employees. How many are entitled to Law Enforcement Officer, Pay? How many receive Law Enforcement Availability Pay?

Response: OIG employees are either on the GS or ES pay scale. However, pursuant to law and OPM regulations, 131 of OIG's criminal investigators (GS 1811) are entitled to an additional 25% in Law Enforcement Availability Pay (LEAP), a premium pay that is paid to Federal law enforcement officers. Due to the nature of their work, criminal investigators are required to work, or be available to work, substantial amounts of "unscheduled duty." Availability pay is generally an entitlement that an agency must provide if the required conditions are met. OIG uses the Federal locality pay scale authorized by OPM for all other employees within the Federal Government.

36. Please provide for the record a table showing OIG-owned firearms. Also, please make note of the size and general purpose of the firearms.

Response: The information requested follows:

OIG Owned Firearms *(Inventory as of 06/08/18)*		
Type of Firearms	**Number**	**General Purpose**
.40 cal. semiautomatic pistols (includes Glock models 23 and 27)	266	Assigned to each Special Agent and carried while carrying out their law enforcement authorities.
MP-5s	83	Carried during the execution of high-risk arrest and search warrant operations.
UMP	85	Procured to replace the MP-5s. Currently under evaluation, these have not been placed into a duty carry status.
.357 cal. Revolvers	4	Used in undercover operations.
.38 cal. Revolvers	2	Used in undercover operations.
12-gauge shotguns	89	Carried during the execution of high-risk arrest and search warrant operations.
Miscellaneous weapons maintained for training purposes	120	These are semi-automatic pistols, MP-5s, and shotguns, which are the firearms OIG agents carry as described above. However, they are unable to fire live rounds. The weapons are used only for training.
Total	**649**	

37. Please update the table from the fiscal year 2018 hearing QFRs showing the allocation of OIG's resources and the percent of each that went towards investigations and audits of each USDA agency for fiscal year 2010 through estimates for fiscal year 2018.

Response: The information requested follows:

FY 2010 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,300	29	$2,800	3%	18	3%
FSA	10,000	67	6,200	7%	40	7%
FAS	500	3	500	1%	3	1%
FNS-SNAP	18,900	123	16,300	19%	105	18%
FNCS-OTHER	8,500	56	5,700	6%	36	6%
AMS	1,600	11	800	1%	5	1%
APHIS	4,200	28	3,400	4%	22	4%
GIPSA	50	0	40	0%	0	0%
FSIS	4,000	27	2,200	3%	15	3%
ARS	600	5	500	1%	4	1%
NIFA	100	0	50	0%	0	0%
RD	1,200	8	0	0%	0	0%
RBS	1,700	12	100	0%	1	0%
RHS	6,900	47	2,100	2%	14	2%
RUS	1,300	9	300	0%	2	0%
FS	8,800	60	2,000	2%	13	2%
NRCS	3,000	21	1,000	1%	6	1%
OO	40	0	40	0%	0	0%
OCFO	800	6	100	0%	2	0%
OCIO	500	3	0	0%	0	0%
OIG (internal)	6,400	44	700	1%	4	0%
Multi-Agency	4,797	34	91	0%	0	0%
OCRE	80	0	80	0%	0	0%
SEC	30	0	30	0%	0	0%
Total	**$88,297**	**593**	**$45,031**	**51%**	**290**	**49%**

FY 2010 Audit						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Audit Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Audit Staff Years*	*Percentage of OIG Staff Years per Agency*
RMA	$4,300	29	$1,600	5%	11	2%
FSA	10,000	67	3,800	4%	27	5%
FAS	500	3	0	0%	0	0%
FNS-SNAP	18,900	123	2,600	3%	18	3%
FNCS-OTHER	8,500	56	2,800	3%	20	3%
AMS	1,600	11	900	1%	6	1%
APHIS	4,200	28	800	1%	5	1%
GIPSA	50	0	0	0%	0	0%
FSIS	4,000	27	1,700	2%	12	2%
ARS	600	5	80	0%	0	0%
NIFA	100	0	40	0%	0	0%
RD	1,200	8	1,200	1%	8	1%
RBS	1,700	12	1,600	1%	11	1%
RHS	6,900	47	4,700	5%	33	6%
RUS	1,300	9	1,000	1%	7	1%
FS	8,800	60	6,800	7%	48	8%
NRCS	3,000	21	2,100	2%	15	2%
OO	40	0	0	0%	0	0%
OCFO	800	6	700	1%	6	1%
OCIO	500	3	500	1%	3	1%
OIG (internal)	6,400	44	5,700	6%	40	7%
Multi-Agency	4,797	34	4,646	6%	33	6%
OCRE	80	0	0	0%	0	0%
SEC	30	0	0	0%	0	0%
Total	**$88,297**	**593**	**$43,266**	**49%**	**303**	**51%**

FY 2011 Investigations						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Investigation Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Investigation Staff Years*	*Percentage of OIG Staff Years per Agency*
RMA	$3,300	22	$2,400	3%	16	3%
FSA	7,500	51	4,400	5%	29	5%
FAS	700	5	500	1%	3	0%
FNS-SNAP	22,700	151	20,700	24%	137	23%
FNCS-OTHER	8,400	57	6,000	7%	39	6%
AMS	2,100	15	700	1%	5	1%
APHIS	3,600	25	2,100	2%	14	2%
GIPSA	200	2	200	0%	2	0%
FSIS	4,700	32	2,400	3%	16	3%
ARS	600	4	300	0%	2	0%
NIFA	120	1	100	0%	1	0%
RD	1,500	10	0	0%	0	0%
NASS	20	0	20	0%	0	0%
RBS	1,500	10	300	0%	2	0%
RHS	5,900	41	1,800	2%	12	2%
RUS	1,100	8	200	0%	1	0%
FS	6,900	49	1,300	1%	8	1%
NRCS	3,600	25	700	1%	4	1%
CR	400	3	0	0%	0	0%
OO	20	0	20	0%	0	0%
OCFO	700	5	0	0%	0	0%
OCIO	700	6	0	0%	0	0%
OGC	30	0	30	0%	0	0%
OIG (internal)	6,800	48	600	1%	4	2%
OHCM	10	0	0	0%	0	0%
Multi-Agency	5,009	36	4	1%	1	0%

FY 2011 Investigations						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Investigation Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Investigation Staff Years*	*Percentage of OIG Staff Years per Agency*
OCRE	200	1	200	0%	1	0%
SEC	130	1	130	0%	1	0%
Total	**$88,439**	**608**	**$45,104**	**51%**	**298**	**49%**

FY 2011 Audit						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Audit Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Audit Staff Years*	*Percentage of OIG Staff Years per Agency*
RMA	$3,300	22	$1,000	1%	7	1%
FSA	7,500	51	3,100	2%	22	4%
FAS	700	5	300	2%	2	0%
FNS-SNAP	22,700	151	2,000	2%	14	2%
FNCS-OTHER	8,400	57	2,400	3%	17	3%
AMS	2,100	15	1,400	2%	10	3%
APHIS	3,600	25	1,500	2%	11	2%
GIPSA	200	2	0	0%	0	0%
FSIS	4,700	32	2,300	3%	16	3%
ARS	600	4	300	0%	2	0%
NIFA	120	1	20	0%	0	0%
RD	1,500	10	1,400	2%	10	2%
NASS	20	0	0	0%	0	0%
RBS	1,500	10	1,100	1%	8	1%
RHS	5,900	41	4,000	4%	29	6%
RUS	1,100	8	900	1%	6	1%
FS	6,900	49	5,600	6%	40	7%
NRCS	3,600	25	2,900	3%	21	3%
CR	400	3	400	0%	3	0%

FY 2011 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
OO	20	0	0	0%	0	0%
OCFO	700	5	700	1%	5	1%
OCIO	700	6	700	1%	5	1%
OGC	30	0	0	0%	0	0%
OIG (internal)	6,800	48	6200	7%	45	6%
OHCM	10	0	10	0%	0	0%
Multi-Agency	5,009	36	5105	3%	37	5%
OCRE	200	1	0	0%	0	0%
SEC	130	1	0	0%	0	0%
Total	**$88,439**	**608**	**$43,335**	**49%**	**310**	**51%**

FY 2012 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$2,986	19	$1,993	2%	12	2%
FSA	6,016	38	4,349	5%	27	5%
FAS	1,177	8	451	1%	3	1%
FNS-SNAP	26,546	164	22,847	27%	140	26%
FNCS-OTHER	3,955	25	2,826	3%	17	3%
AMS	1,599	10	569	1%	3	1%
APHIS	2,689	17	1,271	1%	8	1%
GIPSA	369	2	369	0%	2	0%
FSIS	4,622	29	2,304	3%	14	3%
ARS	677	4	219	0%	1	0%
NIFA	34	0	33	0%	0	0%

FY 2012 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
ERS	10	0	10	0%	0	0%
NASS	20	0	20	0%	0	0%
RD	1,351	9	0	0%	0	0%
RBS	1,897	12	761	1%	5	1%
RHS	4,476	29	2,202	3%	13	2%
RUS	2,716	18	412	0%	3	1%
FS	5,661	37	1,333	2%	8	1%
NRCS	2,566	17	271	0%	2	0%
CR	258	2	0	0%	0	0%
OO	2	0	3	0%	0	0%
OCFO	1,039	7	16	0%	0	0%
OCIO	219	1	23	0%	0	0%
OHCM	14	0	3	0%	0	0%
OIG (internal)	6,269	41	578	1%	4	1%
Multi-Agency	6,196	41	98	1%	1	1%
OGC	1,116	7	0	0%	0	0%
OCRE	72	0	72	0%	0	0%
DM	320	3	0	0%	0	0%
OMS	93	1	0	0%	0	0%
SEC	608	4	608	0%	4	0%
Total	**$85,573**	**545**	**$43,641**	**51%**	**267**	**49%**

FY 2012 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$2,986	19	$992	1%	7	1%

FY 2012 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
FSA	6,016	38	1,666	2%	11	2%
FAS	1,177	8	725	1%	5	1%
FNS-SNAP	26,546	164	3,699	4%	25	5%
FNCS-OTHER	3,955	25	1,129	1%	7	1%
AMS	1,599	10	1,030	1%	7	1%
APHIS	2,689	17	1,419	2%	9	2%
GIPSA	369	2	0	0%	0	0%
FSIS	4,622	29	2,318	3%	15	3%
ARS	677	4	457	1%	3	1%
NIFA	34	0	2	0%	0	0%
ERS	10	0	0	0%	0	0%
NASS	20	0	0	0%	0	0%
RD	1,351	9	1,351	2%	9	2%
RBS	1,897	12	1,136	1%	8	1%
RHS	4,476	29	2,273	3%	15	3%
RUS	2,716	18	2,304	3%	15	3%
FS	5,661	37	4,328	5%	29	5%
NRCS	2,566	17	2,295	3%	15	3%
CR	258	2	258	0%	2	0%
OO	2	0	0	0%	0	0%
OCFO	1,039	7	1,023	1%	7	1%
OCIO	219	1	197	0%	1	0%
OHCM	14	0	11	0%	0	0%
OIG (internal)	6,269	41	5,690	7%	38	7%
Multi-Agency	6,196	41	6,099	7%	40	8%
OGC	1,116	7	1,116	1%	7	1%

FY 2012 Audit						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Audit Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Audit Staff Years*	*Percentage of OIG Staff Years per Agency*
OCRE	72	0	0	0%	0	0%
DM	320	3	320	0%	2	0%
OMS	93	1	93	0%	1	0%
SEC	608	4	0	0%	0	0%
Total	**$85,573**	**545**	**$41,931**	**49%**	**278**	**51%**

FY 2013 Investigations						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Investigation Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Investigation Staff Years*	*Percentage of OIG Staff Years per Agency*
RMA	$3,066	19	$2,192	3%	13	1%
FSA	6,696	42	4,120	5%	25	5%
FAS	1224	8	307	0%	2	0%
FNS-SNAP	26,409	161	22,792	28%	138	28%
FNCS-OTHER	5,374	34	2,894	4%	18	4%
AMS	916	6	252	0%	2	0%
APHIS	3,214	20	1,677	2%	10	2%
GIPSA	180	1	180	0%	1	0%
FSIS	3,820	24	1,702	2%	10	2%
ARS	703	4	329	0%	2	0%
NIFA	73	0	71	0%	0	0%
ERS	78	0	78	0%	0	0%
RD	1,242	8	0	0%	0	0%
NASS	266	2	0	0%	0	0%
RBS	1,389	9	807	2%	5	1%
RHS	2,991	19	1,997	2%	13	3%

FY 2013 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RUS	2,115	14	553	1%	3	1%
FS	2,017	13	708	1%	4	1%
NRCS	1,795	12	174	0%	1	0%
OPPM	568	4	0	0%	0	0%
OO	2	0	3	0%	0	0%
OCFO	1,451	9	40	0%	0	0%
OCIO	510	3	71	0%	0	0%
OGC	1384	9	3	0%	0	0%
OIG (internal)	6,438	41	500	1%	3	1%
OHCM	11	0	0	0%	0	0%
Multi-Agency	5,729	37	31	0%	0	0%
OCRE	3	0	3	0%	0	0%
OHSEC	358	2	0	0%	0	0%
OMS	99	1	0	0%	0	0%
SEC	317	2	317	0%	2	0%
DM	1,525	10	0	0%	0	0%
Total	**$81,963**	**514**	**$41,801**	**51%**	**252**	**49%**

FY 2013 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$3,066	19	$874	1%	6	1%
FSA	6,696	42	2,574	3%	17	3%
FAS	1224	8	916	1%	6	1%
FNS-SNAP	26,409	161	3,617	4%	24	5%

FY 2013 Audit						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Audit Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Audit Staff Years*	*Percentage of OIG Staff Years per Agency*
FNCS-OTHER	5,374	34	2,480	3%	16	3%
AMS	916	6	664	1%	4	1%
APHIS	3,214	20	1,538	2%	10	2%
GIPSA	180	1	0	0%	0	0%
FSIS	3,820	24	2,118	3%	14	3%
ARS	703	4	374	0%	2	0%
NIFA	73	0	2	0%	0	0%
ERS	78	0	0	0%	0	0%
RD	1,242	8	1242	2%	8	2%
NASS	266	2	266	0%	2	0%
RBS	1,389	9	582	1%	4	1%
RHS	2,991	19	995	1%	6	1%
RUS	2,115	14	1,561	2%	10	25%
FS	2,017	13	1,310	2%	9	2%
NRCS	1,795	12	1,621	2%	11	2%
OPPM	568	4	568	1%	4	1%
OO	2	0	0	0%	0	0%
OCFO	1,451	9	1,411	2%	9	2%
OCIO	510	3	439	1%	3	1%
OGC	1384	9	1,381	2%	9	2%
OIG (internal)	6,438	41	5,938	7%	38	7%
OHCM	11	0	11	0%	0	0%
Multi-Agency	5,729	37	5,698	6%	37	7%
OCRE	3	0	0	0%	0	0%
OHSEC	358	2	358	0%	2	0%
OMS	99	1	99	0%	1	0%

FY 2013 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
SEC	317	2	0	0%	0	0%
DM	1,525	10	1,525	2%	10	2%
Total	**$81,963**	**514**	**$40,162**	**49%**	**262**	**51%**

FY 2014 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,301	25	$2,322	3%	13	3%
FSA	7,541	44	3,624	4%	20	4%
FAS	841	5	316	0%	2	0%
FNS-SNAP	26,792	150	25,148	31%	141	30%
FNCS-OTHER	5,773	33	3,598	5%	20	4%
AMS	1,127	7	130	0%	1	0%
APHIS	2,547	15	1,247	1%	7	1%
GIPSA	93	1	93	0%	1	0%
FSIS	3,480	20	1,712	2%	10	2%
ARS	936	6	149	0%	1	0%
NIFA	91	1	89	0%	1	0%
RD	1,226	7	0	0%	0	0%
ERS	26	0	26	0%	0	0%
NASS	15	0	0	0%	0	0%
RBS	896	5	644	1%	4	0%
RHS	2,320	13	1,727	2%	10	1%
RUS	638	4	618	1%	3	2%
FS	2,132	13	871	1%	5	1%
NRCS	2,592	16	138	0%	1	1%

FY 2014 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
CR	0	0	0	0%	0	0%
OGC	107	1	0	0%	0	0%
OPPM	439	3	0	0%	0	0%
OCFO	1,305	8	22	0%	0	0%
OCIO	43	0	11	0%	0	0%
NAD	78	0	78	0%	2	0%
OIG (internal)	9,331	57	327	0%	0	0%
OHCM	15	0	15	0%	0	0%
Multi-Agency	8,723	53	30	0%	0	0%
OTHER	7	0	9	0%	0	0%
OCRE	167	1	167	0%	0	0%
DM	957	6	0	0%	0	0%
SEC	7	0	7	0%	0	0%
Total	**$84,546**	**494**	**$43,118**	**51%**	**242**	**49%**

FY 2014 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,301	25	$1,979	2%	12	2%
FSA	7,541	44	3,915	5%	24	5%
FAS	841	5	524	1%	3	1%
FNS-SNAP	26,792	150	1,644	2%	10	2%
FNCS-OTHER	5,773	33	2,174	3%	13	3%
AMS	1,127	7	997	1%	6	1%
APHIS	2,547	15	1,302	2%	8	2%

FY 2014 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
GIPSA	93	1	0	0%	0	0%
FSIS	3,480	20	1,768	2%	11	2%
ARS	936	6	786	1%	5	1%
NIFA	91	1	2	0%	0	0%
RD	1,226	7	1,226	0%	0	0%
ERS	26	0	0	1%	7	1%
NASS	15	0	15	0%	0	0%
RBS	896	5	252	0%	2	0%
RHS	2,320	13	593	1%	4	1%
RUS	638	4	19	0%	0	0%
FS	2,132	13	1,262	1%	8	2%
NRCS	2,592	16	2,454	3%	15	3%
CR	0	0	0	0%	3	0%
OGC	107	1	107	0%	0	0%
OPPM	439	3	439	1%	8	1%
OCFO	1,305	8	1,283	2%	0	2%
OCIO	43	0	32	0%	1	0%
NAD	78	0	0	0%	0	0%
OIG (internal)	9,331	57	9,005	10%	53	12%
OHCM	15	0	0	0%	0	0%
Multi-Agency	8,723	53	8,693	10%	53	11%
OTHER	7	0	0	0%	0	0%
OCRE	167	1	0	0%	0	0%
DM	957	6	957	1%	6	1%
SEC	7	0	0	0%	0	0%
Total	**$84,546**	**494**	**$41,428**	**49%**	**252**	**51%**

FY 2015 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$5,023	27	$2,722	3%	14	3%
FSA	6,438	34	4,620	5%	24	5%
FAS	1,039	6	413	0%	2	0%
FNS-SNAP	29,139	152	27,701	31%	145	29%
FNCS-OTHER	8,176	45	4,747	5%	25	6%
AMS	1,982	11	404	0%	2	0%
APHIS	2,090	11	944	1%	5	1%
GIPSA	47	0	47	0%	0	0%
FSIS	6,407	36	1,536	2%	8	2%
ARS	1,798	10	140	0%	1	0%
NIFA	178	1	81	0%	0	0%
ERS	102	1	0	0%	0	0%
NASS	0	0	0	0%	0	0%
RD	1,486	8	0	0%	0	0%
RBS	1,933	11	761	2%	4	1%
RHS	2,091	11	1,183	1%	6	1%
RUS	790	4	391	0%	2	0%
FS	3,990	22	1,140	1%	6	1%
NRCS	2,337	13	276	0%	1	0%
OPPM	301	2	0	0%	0	0%
OCFO	512	3	4	0%	1	0%
OIG (internal)	7,012	40	64	0%	0	0%

FY 2015 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
OHCM	17	0	17	0%	0	0%
Multi-Agency	9,672	55	4	0%	0	0%
OTHER	51	0	51	0%	0	0%
OCRE	26	0	26	0%	0	0%
DM	79	0	0	0%	0	0%
SEC	26	0	26	0%	0	0%
Total	**$92,742**	**503**	**$47,298**	**51%**	**246**	**49%**

FY 2015 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$5,023	27	$2,301	2%	13	3%
FSA	6,438	34	1,818	2%	10	2%
FAS	1,039	6	626	1%	4	1%
FNS-SNAP	29,139	152	1,438	2%	8	2%
FNCS-OTHER	8,176	45	3,429	4%	19	4%
AMS	1,982	11	1,578	2%	9	2%
APHIS	2,090	11	1,147	1%	6	1%
GIPSA	47	0	0	0%	0	0%
FSIS	6,407	36	4,872	5%	28	5%
ARS	1,798	10	1,657	2%	9	2%
NIFA	178	1	97	0%	1	0%

FY 2015 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
ERS	102	1	102	0%	1	0%
NASS	0	0	0	0%	0	0%
RD	1,486	8	1,486	3%	8	2%
RBS	1,933	11	1,172	1%	7	1%
RHS	2,091	11	909	1%	5	1%
RUS	790	4	398	0%	2	0%
FS	3,990	22	2,850	3%	16	3%
NRCS	2,337	13	2,061	2%	12	2%
OPPM	301	2	301	0%	2	0%
OCFO	512	3	508	1%	3	1%
OIG (internal)	7,012	40	6,948	7%	39	8%
OHCM	17	0	0	0%	0	0%
Multi-Agency	9,672	55	9,667	10%	55	11%
OTHER	51	0	0	0%	0	0%
OCRE	26	0	0	0%	0	0%
DM	79	0	79	0%	0	0%
SEC	26	0	0	0%	0	0%
Total	**$92,742**	**503**	**$45,444**	**49%**	**257**	**51%**

FY 2016 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,479	24	$2,257	2%	11	2%
FSA	5,423	28	5,264	6%	27	5%
FAS	497	3	118	0%	1	0%
FNS-SNAP	29,921	152	26,946	29%	137	28%
FNCS-OTHER	5,398	28	3,991	5%	20	5%
AMS	1,260	7	539	1%	3	1%
APHIS	3,230	17	2,609	3%	13	3%
GIPSA	76	0	77	0%	0	0%
FSIS	7,025	37	1,495	2%	8	2%
ARS	717	4	247	0%	1	0%
NIFA	1,251	7	134	0%	1	0%
RD	2,507	14	0	0%	0	0%
RBS	1,070	6	713	1%	4	1%
RHS	2,334	12	1,179	1%	6	1%
RUS	1,065	6	458	0%	2	0%
FS	7,024	38	1,414	1%	7	1%
NRCS	1,388	7	372	0%	2	0%
OPPM	50	0	0	0%	0	0%
CR	75	0	0	0%	0	0%
OCFO	1,750	10	24	0%	0	0%
OCIO	134	1	134	0%	0	0%
OIG (internal)	7,569	42	8	0%	1	0%

FY 2016 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
OHSEC	1,639	9	0	0%	0	0%
Multi-Agency	8,495	47	0	0%	0	0%
Disaster Mgmt	235	1	235	0%	1	0%
OCRE	53	0	53	0%	0	0%
SEC	24	0	24	0%	0	0%
Total	**$94,689**	**500**	**$48,291**	**51%**	**245**	**49%**

FY 2016 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,479	24	$2,222	2%	12	2%
FSA	5,423	28	160	0%	1	0%
FAS	497	3	379	0%	2	0%
FNS-SNAP	29,921	152	2,976	3%	16	3%
FNCS-OTHER	5,398	28	1,407	1%	8	2%
AMS	1,260	7	721	1%	4	1%
APHIS	3,230	17	621	1%	3	1%
GIPSA	76	0	0	0%	0	0%
FSIS	7,025	37	5,530	6%	30	6%
ARS	717	4	469	0%	3	1%
NIFA	1,251	7	1,117	1%	6	1%
RD	2,507	14	2,507	3%	14	3%

FY 2016 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RBS	1,070	6	357	0%	2	0%
RHS	2,334	12	1,155	1%	6	1%
RUS	1,065	6	606	1%	3	1%
FS	7,024	38	5,610	7%	31	6%
NRCS	1,388	7	1,015	1%	6	1%
OPPM	50	0	50	0%	0	0%
CR	75	0	75	0%	0	0%
OCFO	1,750	10	1,726	2%	9	2%
OCIO	134	1	0	0%	0	0%
OIG (internal)	7,569	42	7,560	8%	43	9%
OHSEC	1,639	9	1,639	2%	9	2%
Multi-Agency	8,495	47	8,496	9%	47	9%
Disaster Mgmt	235	1	0	0%	0	0%
OCRE	53	0	0	0%	0	0%
SEC	24	0	0	0%	0	0%
Total	**$94,689**	**500**	**$46,398**	**49%**	**255**	**51%**

FY 2017 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,929	25	$1,751	2%	9	2%
FSA	7,628	37	5,980	6%	29	6%
FAS	306	1	273	0%	1	0%

FY 2017 Investigations						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
FNS-SNAP	24,642	118	24,454	26%	117	25%
FNCS-OTHER	11,966	60	5,721	6%	27	6%
AMS	1,298	6	784	1%	4	1%
APHIS	4,281	21	3,233	3%	16	3%
GIPSA	781	4	264	0%	1	0%
FSIS	3,301	17	1,316	1%	6	1%
ARS	520	3	511	1%	2	1%
NIFA	1,347	7	128	0%	1	0%
RD	2,215	11	0	0%	0	0%
RBS	613	3	575	1%	3	1%
RHS	2,318	12	1,112	1%	5	1%
RUS	60	0	38	0%	0	0%
FS	7,246	37	1,333	1%	6	1%
NRCS	2,290	12	405	1%	2	1%
OPPM	51	0	0	0%	0	0%
CR	127	1	0	0%	0	0%
OCFO	3,573	18	17	0%	0	0%
OCIO	85	0	85	0%	1	0%
OIG (internal)	4,503	23	34	0%	0	0%
OHSEC	167	1	13	0%	0	0%
Multi-Agency	10,760	55	47	0%	0	0%
OTHER	490	2	490	1%	2	0%
Disaster Mgmt.	247	1	247	0%	1	0%
OCRE	13	0	13	0%	0	0%
SEC	25	0	25	0%	0	0%
Total	**$95,782**	**475**	**$48,849**	**51%**	**233**	**49%**

FY 2017 Audit						
Agency	*Total OIG Dollars in Thousands*	*OIG Staff Years*	*Audit Dollars in Thousands*	*Percentage of OIG Dollars per Agency*	*Audit Staff Years*	*Percentage of OIG Staff Years per Agency*
RMA	$4,929	25	$3,178	3%	17	4%
FSA	7,628	37	1,647	2%	9	2%
FAS	306	1	33	0%	0	0%
FNS-SNAP	24,642	118	188	0%	1	0%
FNCS-OTHER	11,966	60	6,245	7%	32	7%
AMS	1,298	6	515	1%	3	1%
APHIS	4,281	21	1,049	1%	5	1%
GIPSA	781	4	517	1%	3	1%
FSIS	3,301	17	1,985	2%	10	2%
ARS	520	3	8	0%	0	0%
NIFA	1,347	7	1,219	1%	6	1%
RD	2,215	11	2,215	2%	11	2%
RBS	613	3	38	0%	0	0%
RHS	2,318	12	1,206	1%	6	1%
RUS	60	0	20	0%	0	0%
FS	7,246	37	5,913	6%	31	6%
NRCS	2,290	12	1,886	2%	10	2%
OPPM	51	0	51	0%	0	0%
CR	127	1	127	0%	1	0%
OCFO	3,573	18	3,556	4%	18	4%
OCIO	85	0	0	0%	0	0%
OIG (internal)	4,503	23	4,468	5%	23	5%
OHSEC	167	1	155	0%	1	0%
Multi-Agency	10,760	55	10,714	11%	55	12%
OTHER	490	2	0	0%	0	0%

FY 2017 Audit						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
Disaster Mgmt.	247	1	0	0%	0	0%
OCRE	13	0	0	0%	0	0%
SEC	25	0	0	0%	0	0%
Total	**$95,782**	**475**	**$46,933**	**49%**	**242**	**51%**

FY 2018 Investigations - Estimated[12]						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,929	25	$1,751	2%	9	2%
FSA	7,628	37	5,980	6%	29	6%
FAS	306	1	273	0%	1	0%
FNS-SNAP	24,642	118	24,454	26%	117	25%
FNCS-OTHER	11,966	60	5,721	6%	27	6%
AMS	1,298	6	784	1%	4	1%
APHIS	4,281	21	3,233	3%	16	3%
GIPSA	781	4	264	0%	1	0%
FSIS	3,301	17	1,316	1%	6	1%
ARS	520	3	511	1%	2	1%
NIFA	1,347	7	128	0%	1	0%
RD	2,215	11	0	0%	0	0%
RBS	613	3	575	1%	3	1%
RHS	2,318	12	1,112	1%	5	1%
RUS	60	0	38	0%	0	0%

[12] FY 2018 estimates are based on FY 2017 actuals because FY 2018 data will not be available until after the end of the current fiscal year.

FY 2018 Investigations - Estimated[12]						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Investigation Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Investigation Staff Years***	***Percentage of OIG Staff Years per Agency***
FS	7,246	37	1,333	1%	6	1%
NRCS	2,290	12	405	1%	2	1%
OPPM	51	0	0	0%	0	0%
CR	127	1	0	0%	0	0%
OCFO	3,573	18	17	0%	0	0%
OCIO	85	0	85	0%	1	0%
OIG (internal)	4,503	23	34	0%	0	0%
OHSEC	167	1	13	0%	0	0%
Multi-Agency	10,760	55	47	0%	0	0%
OTHER	490	2	490	1%	2	0%
Disaster Mgmt.	247	1	247	0%	1	0%
OCRE	13	0	13	0%	0	0%
SEC	25	0	25	0%	0	0%
Total	**$95,782**	**475**	**$48,849**	**51%**	**233**	**49%**

FY 2018 Audit - Estimated[13]						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
RMA	$4,929	25	$3,178	3%	17	4%
FSA	7,628	37	1,647	2%	9	2%
FAS	306	1	33	0%	0	0%
FNS-SNAP	24,642	118	188	0%	1	0%
FNCS-OTHER	11,966	60	6,245	7%	32	7%

[13] FY 2018 estimates based on FY 2017 actuals because FY 2018 data will not be available until after the end of the current fiscal year.

FY 2018 Audit - Estimated[13]						
Agency	***Total OIG Dollars in Thousands***	***OIG Staff Years***	***Audit Dollars in Thousands***	***Percentage of OIG Dollars per Agency***	***Audit Staff Years***	***Percentage of OIG Staff Years per Agency***
AMS	1,298	6	515	1%	3	1%
APHIS	4,281	21	1,049	1%	5	1%
GIPSA	781	4	517	1%	3	1%
FSIS	3,301	17	1,985	2%	10	2%
ARS	520	3	8	0%	0	0%
NIFA	1,347	7	1,219	1%	6	1%
RD	2,215	11	2,215	2%	11	2%
RBS	613	3	38	0%	0	0%
RHS	2,318	12	1,206	1%	6	1%
RUS	60	0	20	0%	0	0%
FS	7,246	37	5,913	6%	31	6%
NRCS	2,290	12	1,886	2%	10	2%
OPPM	51	0	51	0%	0	0%
CR	127	1	127	0%	1	0%
OCFO	3,573	18	3,556	4%	18	4%
OCIO	85	0	0	0%	0	0%
OIG (internal)	4,503	23	4,468	5%	23	5%
OHSEC	167	1	155	0%	1	0%
Multi-Agency	10,760	55	10,714	11%	55	12%
OTHER	490	2	0	0%	0	0%
Disaster Mgmt.	247	1	0	0%	0	0%
OCRE	13	0	0	0%	0	0%
SEC	25	0	0	0%	0	0%
Total	**$95,782**	**475**	**$46,933**	**49%**	**242**	**51%**

Top Three Priorities and Budget Request

38. Please provide the Subcommittee with the IG's plans for the upcoming fiscal year under the regular discretionary appropriations, under the President's Budget request, and with the recent changes made regarding the IG's operating structure.

Response: At this time, OIG is in the early stages of its planning process for fiscal year 2019. Discretionary appropriations that are provided through the President's Budget request will be used to perform the work we are required to annually perform regarding financial statements, improper payments, and IT security. The remainder of funding will be applied to high impact and critical risk areas associated with our strategic goals (e.g., safety and security, program integrity, and results-oriented performance) and the Management Challenges we have identified at the Department. Finally, we will also take into account requests received from Congress and the Administration. Using our Oversight Plan of USDA Disaster Funding, we will use the additional funding provided to perform oversight of the Department's disaster programs (see response to Question 42).

In September 2017, the Inspector General notified this Committee of a reorganization of the Office of Audit. The reorganization utilized existing OIG resources, took into account changes to our work environment and available technologies, and sought to ensure the best use of our resources. In summary, this reorganization (1) updated support for Audit executive leadership, (2) established a dedicated, centralized work unit to oversee audit business operations, and (3) established an additional work unit to perform performance audits. In fiscal year 2018, the Office of Audit began implementing the reorganization by filling the leadership and staff positions associated with the two new work units. The audit plan of work for the new units is consistent with our established approach for developing our audit plan. For example, this unit has already initiated a review of AMS' oversight of the Farmers' Market and Local Food Promotion Program. To focus on areas of high impact and critical risk, our plan considers the Management Challenges for the Department, our strategic goals, and other risk factors to identify areas for review.

The Office of Investigations plans to continue its work to strengthen USDA's ability to protect public health, as well as animal and plant health, by conducting investigations involving the National Organics Program, animal fighting, and matters involving the inspection of meat and poultry for human consumption. Additionally, to ensure program integrity, Investigations plans to allocate its resources to focus on investigations involving disaster funding provided by USDA and a continued emphasis on investigations involving areas such as farm fraud, crop insurance fraud, and fraud identified in various feeding programs under FNS. Investigations will work with ODS to utilize data analytics to assist in identifying potential fraud in these programs. To improve management effectiveness, Investigations will also focus on investigating allegations of senior-level misconduct in addition to conducting investigations involving alleged whistleblower retaliation, which are mandated by statute.

The Office of Data Sciences (ODS), in addition to supporting audit and investigations work utilizing the advanced capabilities of data analytics, will be focusing on developing models and tools to identify anomalies and trends which may indicate program vulnerabilities, potential weaknesses in program operations and controls, and potential fraud. For example, ODS will be concentrating on data mining techniques to better visualize USDA program payments in order to better identify trends that could indicate improper payment root causes or patterns of potential fraudulent activity.

39. Please provide the IG's "top three" priorities for investigations and audits for the upcoming fiscal year?

Response: OIG's top priority is to strengthen USDA's ability to implement and improve safety and security measures to protect the public health, as well as agricultural and Departmental resources. OIG works to provide audits and investigations to help USDA and the American people meet critical challenges in safety, security, and public health. Our work focuses on issues such as the ongoing challenges of agricultural inspection activities, the safety of the food supply, homeland security, and IT security and management.

OIG's second major priority is detecting and reducing USDA program vulnerabilities and deficiencies to strengthen the integrity of the Department's programs. OIG conducts audits and investigations to help ensure or restore integrity in various USDA benefit and entitlement programs, including a variety of programs that provide payments directly and indirectly to individuals or entities. Some of the programs are among the largest in the Federal Government and support nutrition, farm production, and rural development. OIG attempts to provide coverage to the major assistance programs while also assessing risks associated with and providing oversight of the disaster assistance programs.

OIG's third major priority is providing USDA with oversight to help USDA achieve results-oriented performance. OIG conducts audits and investigations that focus on areas such as improved financial management and accountability, research, real property management, employee integrity, and performance management. Considerable resources are devoted to the annual mandatory financial statement audits, which includes IT work related to financial reporting. Tied to that is the mandatory work on the Department's compliance with improper payment reporting requirements.

40. How would the President's Budget request to decrease staffing levels by 50 staff years affect these priorities?

Response: OIG would spread this decrease in staffing evenly between our audit and investigative portfolios. This would result in a significantly decreased level of effort. For example, we anticipate we would issue 16 percent fewer audit reports and roughly 16 percent fewer investigations based on a straight line projection. Our average return on investment over the past five years has been roughly $8 returned for every dollar spent. If our budget is reduced by $10 million, a straight line projection could result in a reduction in returns to the government of about $80 million a year.

41. How has the IG's recent reprogramming and the creation of the Office of Data Sciences affected its operational capacity and improved the outcomes of its work?

Response: ODS was created to support the OIG's efforts to detect and prevent fraud, waste, and abuse in USDA programs. The OIG recognizes that data, which resides within the Department, as well as other Government and public sources, can provide us with a wide variety of insights into program operations. Data analysis allows us to better identify and assess spending patterns and trends in support of audits and investigations. We can also analyze data utilizing known indicators to focus our resources more effectively on those areas indicating a high risk of fraud, waste, and abuse. ODS can also provide the OIG with insights to promote internal data driven decision making.

Over the last year, ODS provided data analytics support for our SNAP investigations and summer feeding program investigations, and provided statistical sampling and projections for many of our audits. This work has yielded positive results. In addition, ODS issued two survey products in FY 2018. The first was completed in tandem with our audit report on scientific research misconduct, and the second surveyed Forest Service Region 5 employees regarding perceptions of sexual misconduct and

how allegations are handled.

OIG continues to incorporate and leverage ODS expertise and capabilities into the work of our mission areas. ODS work assisting the identification of patterns, trends, and anomalies provides a valuable contribution to improved operational capacity and outcomes.

Oversight of Disaster Funding for Hurricane Relief

42. Congress provided OIG with $2.5 million for oversight of USDA's disaster response to Hurricanes Harvey, Irma, and Maria. The Subcommittee wants USDA to respond as quickly as possible when disaster strikes, but at the same time, USDA needs to have proper protocols in place to control fraud, waste and abuse. It's no easy task to balance the need of helping those who are suffering with the need to be good stewards of taxpayer resources, and that is where OIG comes in. Please tell the Subcommittee how OIG plans to go about the task of auditing and investigating USDA's response to the Hurricanes, and when might this work begin if it hasn't already?

Response: Congress provided USDA with more than $5.7 billion for necessary expenses related to agricultural losses, nutrition and rural assistance, and wildfires from Hurricanes Harvey, Irma, Maria, wildfires, and other declared major disasters and emergencies occurring in calendar year 2017. OIG appreciates the additional funds provided by the Subcommittee for oversight of USDA's disaster assistance activities. To ensure that we use these funds as effectively as possible, we are updating our Oversight Plan of USDA Disaster Funding based on risk and other factors. We are engaged with the Department to obtain relevant information about the program agencies' current plans and timetable for using this funding. For example, we have been coordinating with FSA and NRCS to determine when it would be appropriate to start work with respect to FSA's Emergency Conservation Program and NRCS' Emergency Watershed Protection Program. As part of our FY19 audit plan, we plan to initiate work to provide oversight of these 2 programs. We will continue to monitor the distribution of these program funds and other related USDA programs to consider other prospective audits.

In April 2018, we started audit work to review FNS' disaster relief efforts to provide nutrition assistance to Puerto Rico due to Hurricanes Irma and Maria. In FY 2018, we also plan to start work to look at Forest Service's controls over its 2018 supplemental disaster appropriations and to review FSA's 2017 Hurricane Relief Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP). Audits of these programs are appropriate at this time due to the amount of funds already distributed. We are also working to gain an understanding of how the $2.36 billion appropriated to the Office of the Secretary for disaster relief will be used and distributed under the new Wildfires and Hurricanes Indemnity Program in order to plan future audit coverage.

In FY19, OIG will coordinate with Federal, State, and local partners to provide assistance in investigative efforts. In an effort to provide direct support, Investigations is reviewing the practicality of hiring additional law enforcement personnel to a two-year temporary position to supplement investigative efforts where no investigative personnel are available. The implementation of our disaster work relies on the distribution of assistance. Based upon previous disaster work, there may be a period of time between when the disaster occurred and when the fraud schemes emerge. Addtionally we will leverage assistance from ODS to take a more proactive approach to identifying potential fraud.

43. Will OIG only be looking at USDA's response to the Hurricanes or will it also encompass the response to the wildfires in California, ad-hoc disaster funding, the Disaster Supplemental Nutrition Assistance Program in Puerto Rico, the Emergency Watershed Protection Program, the Emergency Conservation Program, and

the other recent changes to mandatory disaster programs, including the cotton and dairy provisions?

Response: As noted in response to Question 42, the disaster assistance funding is related to agricultural losses, nutrition and rural assistance, and wildfires. OIG will use its updated Oversight Plan of USDA Disaster Funding to guide our oversight planning. OIG will focus its efforts on the areas of highest risk and will not be limiting our disaster audits to USDA's response to the Hurricanes. As noted above, we have plans in FY 2018 to not only review FNS's disaster relief efforts to provide nutrition assistance to Puerto Rico due to Hurricanes Irma and Maria but to also look into Forest Service's controls over its 2018 supplemental disaster appropriation and to review FSA's 2017 Hurricane Relief ELAP.

44. Will your reviews be pro-active in nature, for example a look at the requests that have already come in for funding and their validity, or will the review be retroactive once funding has already been obligated?

Response: In order to appropriately prioritize OIG's efforts, OIG will conduct a risk analysis of the USDA programs that provide disaster assistance to identify those programs which warrant coverage. The reviews will be designed to pro-actively bring forward critical findings once identified so that the needed corrective measures can be taken as programs are implemented. Reviews will also have a retroactive aspect to ensure that the funds obligated were used appropriately.

Improper Payments and Error Rates

45. In the past the Subcommittee has discussed the OIG's report on the SNAP quality control process used for determining error rates. The report raised some serious concerns that call into question some of the methods that States have used to achieve low error rates in the program. FNS has taken the report seriously and is working to implement much needed changes to ensure accountability and integrity in SNAP. Since the Food and Nutrition Service (FNS) could not validate the State data was accurate, FNS was unable to calculate a national error rate for FY15. A national payment error rate for FY16 was not released since FNS is working with States to implement changes to the system. Since FNS hasn't released this national error rate for SNAP in FY15 or FY16, how does this affect the Department's overall error rate?

Response: As reported in the Department's Agency Financial Reports (AFR), USDA's improper payment rate for its high-risk programs rose from 5.70 percent for FY 2015 to 8.86 percent for FY 2016 and from 8.86 percent for FY 2016 to 9.93 percent for FY 2017. In its FY 2017 AFR, the Department explained that this is because FNS programs with historically higher error rates now comprise a larger percentage of the total high-risk program outlays for FY 2017. Additionally, OIG notes that FNS' SNAP did not report an error rate for FYs 2016 and 2017; therefore, the computation of the Department's overall error rate did not include SNAP error rates and outlays. Outlays ($ in millions) in FY 2015 were $110,332.78 (which included SNAP outlays of $70,022.00) compared to outlays of $37,827.57 in FY 2016 and $32,655.25 in FY 2017 (which excluded SNAP outlays). Higher numbers of errors compared to lower outlays for the high-risk programs reporting error rates resulted in the increase of USDA's improper payment percentage.

46. For some programs, like SNAP, the error rate threshold is indexed each year based on inflation, and this happens in other Federal programs as well. With the error rate indexed each year, does this mean it is possible that a greater amount of errors would no longer be considered an improper payment? Do you think an indexed error rate provides an accurate assessment of the amount of improper payments, or is this a way to sweep more errors and improper payments under the rug?

Response: Our office has not specifically reviewed how the SNAP error rate threshold is indexed. Our reviews have focused on whether the agencies use an approved methodology and whether FNS enforces

policies to ensure error rates are accurate and determined in compliance with regulations. However, we do note that errors below the threshold are not considered as part of the error rate.

47. In the prepared testimony, the IG mentioned that USDA did not comply with improper payment requirements set forth by the Improper Payments Information Act for a sixth consecutive year. Is the Department making progress in correcting improper payments or is the IG finding the same problems year after year?

Response: In its May 2018 report, OIG reported that USDA did not comply with improper payment requirements as set forth by the Improper Payments Information Act of 2002, as amended, for a seventh consecutive year (Audit Report 50024-0013-11). However, OIG notes the following progress by the Department:

- The number of USDA high-risk programs was reduced from 18 to 10 because OMB granted relief for programs under the reporting threshold.
- FSA's Loan Deficiency Payments and Livestock Forage Disaster Programs were non-compliant with IPERA in FY 2016; however, for FY 2017 all requirements were met and those programs were considered compliant.
- USDA expanded its use of the Do Not Pay portal by onboarding additional agencies to verify eligibility and post payment reviews.

48. To reduce improper payments, is it simply a matter of having good management in place and following the laws and rules already on the books, or do does there need to be some changes made to the programs and regulations?

Response: OIG notes that many USDA programs have highly decentralized structures that often rely on State and local organizations and self-reporting. Some of these organizations do not have sufficient accountability processes and management controls. In addition, legislation limits USDA's ability to act due to concerns about potential barriers to participation in the National School Lunch Program (NSLP) and School Breakfast Program (SBP). We have issued audit recommendations to FNS to propose statutory changes to its programs. For example, in 2017, we recommended to FNS that it should submit to Congress proposed statutory changes to bring NSLP, SBP, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and the Child and Adult Care Food Program (CACFP) into compliance.[14] However, FNS has yet to obtain statutory changes to bring these programs into compliance, and has chosen other methods to improve its programs. To reduce improper payments without making changes to the programs and regulations, OIG notes the following actions need to be taken:

- Correct State errors and program methodologies to estimate improper payments.
- Seek ways to increase accountability within the limits of legislation to balance the mandated goal of simplifying access to benefits with the goal of reducing improper and erroneous payments.
- Continue to seek opportunities to expand data mining resources available to check eligibility.

OCFO Controls Over Final OIG Actions

49. The Office of the Chief Financial Officer (OCFO) is responsible for ensuring that recommendations made by OIG audits are implemented by the respective agencies. So it was concerning that the OCFO needed to strengthen its controls over the final action process on OIG audit recommendations. It is troubling that OCFO is not following its standard operating procedures. The IG's written testimony states OCFO has agreed with your findings and recommendations. Please provide the Subcommittee with a description of how long OCFO has not been following the proper procedures.

[14] Audit Report 50024-0011-11, *USDA's Fiscal Year 2016 Compliance with Improper Payment Requirements*, May 2017.

Response: OCFO has not been following its standard operating procedures since 2013. Specifically, OCFO stopped the second level review for final action, that was required by their standard operating procedures, in 2013. OCFO's rationale for discontinuing the second level review was the belief that the desk officers should be held accountable for their own final action determinations; however, we found that OCFO did not always have sufficient documentation to support final action. In response to our finding and recommendation, OCFO reinstituted the second level review.

50. What is the best way to ensure OCFO has followed the IG's recommendations? Has OIG had any discussions with the USDA OCFO regarding the need for OCFO to add a scorecard to its website of agency performance in closing or not closing recommendations? If so, why or why not?

Response: USDA's OCFO is responsible for closing audit recommendations. This includes reviewing and approving agency requests for closure (final action) and tracking the closure status of audit recommendations. We have not had any discussions with OCFO about adding a scorecard to its website of agency performance in closing or not closing recommendations.

As an alternative, in FY 2018, OIG is piloting a final action verification review of selected audits to determine whether the documentation that agencies provided to OCFO was sufficient to close the recommendations. We plan to complete a final action verification review on the recommendations to OCFO to monitor controls over the final action process.

51. The Subcommittee has repeatedly called upon the Department, and some agencies more than others, to implement suspension and debarment tools. Again, it's concerning that 12 agencies have not fully taken these actions. Which agencies have not implemented suspension and debarment tools and how can the Subcommittee help encourage these agencies to get these tools into place?

Response: Of the 12 agencies that did not fully comply with one or more of the requirements for suspension and debarment, we found that 3 agencies did not consider suspension and debarment action for known program violators. Those agencies were AMS, FNS, and FSIS. The remaining nine agencies did not comply with specific suspension and debarment requirements such as no agency specific guidance, no training plan, or training was not completed (see table below).

In September 2017, we completed an audit of USDA's suspension and debarment tools,[15] and OCFO took immediate corrective action by issuing a memo to all USDA agencies to address the lack of enforcement power by OCFO. The memo stated that OCFO would elevate any agencies that do not fully comply with suspension and debarment guidelines to the applicable offices of the Mission Area Under Secretaries. Additionally, OCFO directed each Under Secretary to designate a representative to join the USDA Suspension and Debarment Council to ensure each agency is fully compliant with suspension and debarment regulations. Furthermore, OCFO directed agencies to develop action plans detailing specific suspension and debarment internal control components to achieve USDA's suspension and debarment program objectives. We expect that the additional measures put into place by OCFO should enhance the ability of agencies to become compliant with suspension and debarment requirements and meet USDA's suspension and debarment program objectives.

[15] Audit Report 50016-0001-23, *Implementation of Suspension and Debarment Tools in the U.S. Department of Agriculture*, Sept. 2017.

Agencies Reviewed	No Agency-Specific Guidance[16]	Did Not Take Action on Known Program Violators	Did Not Provide All Activity Reports to OCFO	No Training Plan	Responsible Officials Did Not Complete Training
AMS		X		X	X
APHIS					X
FNS	X	X	X	X	X
FS				X	
FSA				X	
FSIS		X	X		X
RD				X	X
FAS	X				
GIPSA	X*				
NRCS	X				
OAO	X*				
OCE	X*				

* In response to our audit, OCFO allowed three agencies (OCE, OAO, & GIPSA) to use the Departmental Regulation as their agency guidance. This was due to the limited staff and activity of those agencies.

Scientific Integrity

52. Last year there were some reports of USDA scientists, specifically Agricultural Research Service (ARS) scientists being asked to alter or suppress findings from their research. Needless to say reports such as this are alarming and people immediately begin to question the merits of ARS research and the negative perception that can tarnish the critically important research being completed by ARS. It is important the integrity of the science within government research is preserved. These questions focus on the Inspector General's recently completed report on scientific integrity at the Department. Please share the major findings of the report and comment on the methodologies used to complete the review and what agencies were reviewed— for example, in press reports involving ARS— did the IG also review other areas such as the Economic Research Service or Natural Resource Conservation Service?

Response: OIG conducted an audit to assess employees' perceptions and the Department's efforts to support scientific integrity.[17] The audit included a survey questionnaire that was sent to 2,212 research-grade scientists at 4 USDA agencies: ARS, FS, ERS, and NRCS. We developed the questions for the survey for the purpose of determining the scientists' perception of research integrity within USDA. The survey was initiated by sending emails to all of the scientists, which contained a link to SurveyMonkey, which allowed us to receive anonymous responses via the Internet. Publishing research is a part of research-grade scientists' evaluation criteria, which ties into the audit objectives of communicating research without

[16] We also found an additional five USDA agencies that did not provide their suspension and debarment guidance to OCFO. These five agencies were not a part of the seven agencies in our selected sample and included Foreign Agricultural Service, Grain Inspection, Packers and Stockyards Administration, Natural Resources Conservation Service, Office of Advocacy and Outreach, and Office of the Chief Economist.

[17] Audit Report 50601-0006-31, *Reviewing the Integrity of USDA's Scientific Research Program*, Feb. 2018.

undue interference. Based on the timing of the audit, part of the survey focused on the 2013 Scientific Integrity Policy. Our audit resulted in two findings: one related to employees' perceptions of scientific integrity and one related to scientists' awareness and knowledge of the Scientific Integrity Policy.

About 83 percent of the survey respondents said they feel that their agencies "strongly" or "somewhat" promote a culture of scientific integrity. However, we found there were survey respondents who indicated a perception that their research findings had been altered or suppressed for reasons other than technical merit. Even a perception of such activity could have a negative effect on the credibility of Department-sponsored research.

Our survey also showed that the Department's primary tool for promoting and ensuring scientific integrity, the Scientific Integrity Policy, had limited perceived impact on USDA scientists and their work. Additionally, ambiguities in the 2013 Scientific Integrity Policy could have misinformed scientists on key aspects of the policy. Although the Scientific Integrity Policy and other resources were improved in November 2016, this knowledge gap could cause researchers to misinterpret responsibilities, which places them at risk to either intentionally or unintentionally commit a scientific integrity violation in their research.

53. As a result of the audit can the IG comment on whether or not researchers have the unhindered ability to conduct and report their research?

Response: As reported in Finding 1, we concluded that a large majority of researchers believe they have the unhindered ability to conduct and report their research. Because a small percentage had a perception that problems existed, we recommended that the Office of the Chief Scientist coordinate with the four agencies with research grade scientists to try to determine why these perceptions existed and work to correct the situations. Our specific recommendations were as follows:

- Recommendation 1: The Office of the Chief Scientist should coordinate with each agency to determine the best method to identify why some scientists perceive that there are inappropriate influences that might hinder them from performing all elements of their research.
- Recommendation 2: Based on the responses to Recommendation 1, the Office of the Chief Scientist should coordinate with each agency to share with other agencies any recognized potential issues or hindrances dealing with scientific integrity, identify any common or systemic problems, and work to develop resolutions that can be implemented across all agencies.
- Recommendation 3: The Office of the Chief Scientist should coordinate with each agency to determine a methodology of outreach that best communicates the importance of supervisors and agencies emphasizing and promoting a culture of scientific integrity.

54. As a result of the report, will there be any changes the Department will make to the 'Scientific Integrity Policy' the primary guiding document on scientific integrity?

Response: When OIG began its fieldwork, the 2013 Scientific Integrity Policy was the governing document in place. Therefore, we based our audit work and the survey questionnaire on this policy. Our auditors did identify concerns related to this 2013 policy, which were discussed with the Office of the Chief Scientist during the audit. Based on these discussions and prior to report issuance, the Office of the Chief Scientist updated the Scientific Integrity Policy in November 2016. This updated policy addressed all of the concerns that our auditors had identified during the audit. At this point, OIG is not aware of any pending changes to the Scientific Integrity Policy.

55. Does the IG intend to conduct any follow up work on this topic?

Response: Currently, OIG does not have follow up work planned on this topic.

Purchase Card Controls

56. According to a report dated March 2018, the Department has over 12,000 cardholders totaling more than $145 million worth of transactions in just the first half of fiscal year 2017. It is nothing new that purchase cards are used to procure needed supplies and services. However two items that stuck out were the finding on the number of 'high risk' transactions and an inability to achieve cost savings by leveraging its purchasing power through certain programs. Not utilizing those programs ultimately costs more as we are paying more for products when we have an agreed upon lower price with other vendors. In the report, it states 58% of the transactions in the sample had at least one issue with it. Please speak to the types of issues with the card transactions and about the purchase control policies in place at USDA.

Response: OIG found four types of issues as follows:

1. Not using required sources, resulting in the inability to leverage purchasing power;
2. Missing requisition and receiving documents, which increases the risk that potentially illegal, improper, or erroneous transactions could occur without detection;
3. Paid sales tax and did not document why it was paid or whether USDA recovered those payments, resulting in unnecessary expenses that make it difficult for supervisors to determine if payments were legitimate or repaid; and
4. Splitting purchases into multiple charges, which increases the risk that USDA is not procuring services and goods at the best value available to the government.

USDA's management control policies over the purchase card program include several levels of control to assist in preventing or detecting illegal, improper, or erroneous transactions. For example, the approving officials, who are often the cardholders' supervisors, are the first line of control over the purchasing activity of cardholders in their units. An approving official's duties include verifying that purchases are necessary, the receipt of supplies and services, and reviewing cardholders' documentation. He or she must also approve the cardholder's transactions and recommend disciplinary action for misuse of the purchase card. Additionally, Local Agency Program Coordinators must review 25% of transactions each quarter in the online system, review documentation, and certify compliance. Finally, in response to an OIG recommendation from a 2015 audit report over purchase cards, Agency Program Coordinators must review and certify 25% of cardholder accounts each quarter (100% of cardholders each year).

57. What has the Department done or intend to do to remedy the issues with the purchase card program

Response: The Department has implemented or committed to five actions to address the types of issues we found. The first action was in response to OIG's 2015 report, while the other four are a result of our report issued in 2018.

1. USDA has implemented a policy where the Agency Program Coordinator quarterly certifies cardholder accounts as described above. However, this action was not fully implemented at the time of our 2018 audit. This control should aid in reducing the frequency of transactions which are missing documentation.

2. USDA planned to establish requirements by March 31, 2018 for documenting the use of non-required sources for approval by approving officials. This control will serve to document the reasons for deviating from policy requiring purchases from required sources.

3. USDA planned to establish, by March 31, 2018, a requirement to document sales taxes paid, including attempts to recover any State and local sales taxes paid, and explain when recovery was attempted but not

achieved in order to reduce the amount of times sales taxes were improperly paid.

4. USDA planned to establish, by March 31, 2018, guidance to identify what constitutes a split purchase, including examples. Actions 4 and 5 both relate to deterring or remedying the occurrence of split purchases.

5. USDA has determined that the four split transactions identified by OIG were unauthorized, and has agreed to require the agencies either to ratify the purchases, or seek reimbursement from the approving officials. The Department anticipates this action will be completed by December 31, 2018.

58. This audit may have been part of a government-wide initiative under the Council of the Inspectors General on Integrity and Efficiency Information Technology. How did the results of the USDA compared to other Federal agencies?

Response: The purchase card audit is part of the government-wide CIGIE initiative. USDA OIG took the lead on consolidating the results of 20 participating OIGs who conducted varying levels of review of their agencies' purchase card program.

The consolidated report identified 501 transactions, of 1,255 tested, that did not comply with applicable policies. These transactions were most widespread in six categories:

Type of Issue	Number of OIGs reporting issue (out of 20 participant OIGs)	USDA reporting issue
Not Using Required Sources	14	Yes
Weekend and Holiday Transactions	14	No
Paid Sales Tax	13	Yes
Splitting Purchases	13	Yes
Prohibited Merchants	11	No
Questionable Merchants	8	No

Agroterrorism- National Bio and Agro-defense Facility (NBAF)

In a report released March 2017, the IG focused on the Department's Office of Homeland Security. What the IG found in the audit is that the Office of Homeland Security had not "adequately overseen and coordinated USDA's effort to prevent, detect, and respond to agro- terrorism." The audit indicates the Department failed to comply with Homeland Security Presidential Directive (HSPD-9). The Subcommittee raises this audit because of the Fiscal Year 2019 proposal to begin transitioning the NBAF from DHS to USDA. This is a significant proposal.

59. Given the findings on non-compliance with HSPD-9, what are the IG's thoughts on the proposed transfer and USDA's ability to effectively operate and manage NBAF?

Response: Our audit focused on the Department's actions to oversee and coordinate USDA's agroterrorism efforts, including whether it was implementing HSPD-9 appropriately. We found USDA's Office of Homeland Security was unable to demonstrate Departmental compliance with the HSPD-9 directive. This office had not developed a documented annual oversight process to obtain, evaluate, and validate HSPD-9

activities from all USDA's agencies. Our audit's finding about Office of Homeland Security's oversight of HSPD-9 compliance at USDA may not have a direct bearing on the issue of whether USDA should operate the NBAF. The audit finding focused on the Office of Homeland Security's actions to ensure USDA was in compliance with HSPD-9 requirements; it did not evaluate agencies' capabilities related to agroterrorism prevention, detection, and response. The Office of Homeland Security agreed with the recommendations in our audit report and is putting together a comprehensive plan to address HSPD-9 and developing improved procedures to more effectively oversee USDA's agroterrorism preparedness, including HSPD-9 compliance. As a result of the audit's recommendations, we currently have another audit ongoing in three of the Department's key agencies for biosecurity: APHIS, FSIS, and ARS. We are looking at their efforts and actions to prevent, detect, and respond to agroterrorism attacks. Fieldwork is currently ongoing, and we plan to issue the report by the end of the fiscal year. However, this current audit is not evaluating laboratory oversight, operations, or security as part of its scope.

60. What has the Department done in response to the report to become compliant with HSPD-9?

Response: In response to recommendations from our audit, the Office of Homeland Security is in the process of developing improved procedures to more effectively oversee USDA's agroterrorism preparedness, including HSPD-9 compliance.

Oversight of USDA Restructuring

61. Given the Administration's recent restructuring of agencies within the Department, what issues will you be evaluating to assure a smooth transition? In particular, (a) the creation of the Farm Production and Conservation mission area, (b) eliminating the confirmed position of Under Secretary for Rural Development, (c) creating the Undersecretary for Trade and Foreign Agricultural Affairs, and (d) reorienting information management within the farm programs area that has been long-criticized for lack of progress.

Response: Currently, we do not have work planned to evaluate the recent restructuring and reorganizations that are taking place within the Department. However, we are obtaining an understanding of the Department's restructuring to assess any impact the changes may have on our office (e.g., liaison activities with the restructured agencies). As we plan our work for future years, we will keep these topics in mind and propose work to address areas of critical risks or weaknesses in program delivery, as appropriate.

High Risk List

62. Every two years the Government Accountability Office (GAO) puts together a "High Risk List" which calls attention to agencies and program areas that are high risk due to their vulnerabilities to fraud, waste, abuse, mismanagement, or those that are in need of a transformation. If the IG were to create a High Risk List today, which USDA agencies and programs would be at the top of the list? Why?

Response: As an IG office, we do a similar report every year, identifying the top Management Challenges facing the Department and its agencies. OIG's Top Management Challenges report focuses on agency programs or management functions with vulnerability to waste, fraud, abuse, and mismanagement, where a failure to perform well could seriously affect the ability of USDA or the Federal Government to achieve its mission or goals. Since 2015, OIG has reported on seven major challenges that represent broad issues for the Department as well as challenges unique to specific programs. These challenges remain unchanged, as it is our view that they continue to be critical challenges for the Department. The seven current Management Challenges are: oversight and accountability for USDA programs; IT security; program

performance and performance measures; improper payments and financial management; outreach efforts; food safety inspections; and oversight of SNAP. (See Question 4 for more details on each Management Challenge.)

QUESTIONS SUBMITTED BY CONGRESSWOMAN CHELLIE PINGREE

Scientific Integrity

63. OIG recently completed an audit on scientific integrity at USDA. As part of this audit, OIG surveyed USDA research-grade scientists at four USDA agencies in 2016. Question 54 of that survey was "Do you have any other concerns related to scientific integrity that you want to share with OIG?" 481 respondents answered the question and your report indicates that over half of those 481 respondents indicated they had no other concerns. Regarding the respondents who did respond to that question with concerns, please provide a list of their concerns. Additionally, will OIG conduct another survey among USDA researchers after USDA has completed OIG's recommendations?

Response: ODS conducted a survey of USDA research-grade scientists in support of the OIG audit, Reviewing the Integrity of USDA's Scientific Research Program, issued March 5, 2018. The survey result tables were published in the appendix of the audit. A companion product, Survey of USDA Scientists Regarding Scientific Integrity, was issued on the same date by ODS. The document provided details on the methodology, analysis, and results of the survey.

The above-referenced ODS companion product included information about concerns, based upon text analysis of the open-ended response, as follows:

Scientists were concerned about:

- Broad censorship, poor efficiency of the publication process, and improperly applied authorship (credit being given when not earned, or removal of authorship for inappropriate reasons);
- Emphasis on the quantity of published reports instead of the quality of reports;
- Procedures for dealing with sensitive topics tended to slow down the publication process;
- Censorship of sensitive topics, such as not being allowed to discuss the results of research on these topics;
- That only viewpoints that are positive towards the agency were supported, and concerns about the lack of general agency support on sensitive research topics;
- A fear of politically driven budget restrictions that could affect conducting research and traveling; and
- That the SIP complicated the publishing and communication process.

Scientists also expressed concerns about the reporting of scientific integrity incidents because some:

- Felt that problems that came from management could not be reported to the same management; and
- Expressed fear of retaliation, reprisal, and reprimand.

In addition:

- One scientist shared concerns about outside pressure on USDA to conduct research on controversial subjects, stating that researchers' work got promoted only if there was such pressure, and if not, the research was not supported. Scientists mentioned concerns about how the change in media interest might affect how they should present results; and

- A few respondents mentioned they had observed or experienced inequitable management or unfair treatment.

OIG has no current plans for follow-up work. However as we plan for future audits, we will take into account program risk assessments to ensure resources are targeted to high risk areas.

Workplace Environment

64. Every year, the Partnership for Public Service and Deloitte produce rankings on the Best Places to Work in the Federal Government. Federal agencies receive an index score that measures employee engagement, which is defined as the "satisfaction and commitment of the workforce and the willingness of employees to put forth discretionary effort to achieve results." For 2017, USDA's overall index score increased by 2.8% compared to the previous year. For the same year, the OIG's index score *decreased* by 9.8% compared to the previous year. What factors contributed to OIG receiving a lower score in the Best Places to Work in the Federal Government ranking this year? How is OIG ensuring that its employees are satisfied and committed?

Response: OIG is fully committed to ensuring that we have a workplace where employees are engaged and committed to the organization and give their best efforts to accomplish their work each day. The Partnership for Public Service (PPS) determines it rankings in part by using data collected by the Office of Personnel Management's Federal Employee Viewpoint Survey (FEVS). While PPS uses FEVS as one of its data sources, the PPS utilizes a different formula for calculating its overall scores than the one utilized by FEVS. We note that for FY 2017, OIG's FEVS Employment Engagement Index was 71%, and OIG's FEVS Global Satisfaction Index Score was 69%, both of which are higher than USDA's FEVS scores in this area, which are 68% and 67% respectively. Our senior management team has reviewed the 2017 FEVS results, and has determined that the 3 areas in which we received the lowest scores were pay increases, performance management, and availability of resources. Further assessment will be needed to determine the factors that contributed to our lower score.

Each year OIG assesses the FEVS results and identifies key areas to focus on where we could enhance ongoing efforts involving employee engagement. For example, in response to our 2016 FEVS results, OIG established several teams to look at employee flexibilities, awards, and communications. These teams made recommendations to OIG management about ways to improve or enhance OIG's policies and practices in these areas, based upon feedback received in the FEVS. We are engaging in similar actions with respect to the 2017 FEVS results. As part of this effort, our Employee Advisory Council (EAC), an employee group created to engage employees in strategic OIG initiatives and to further encourage an alternate avenue for employees to raise issues of importance in the workforce, will be assisting in analyzing our 2017 FEVS results. Working with the EAC, OIG senior management will consider appropriate steps for addressing the areas that we identify to focus on. Through such review and analysis, we will be better positioned to determine the factors that led to the lower FEVS 2017 score. We remain committed to always striving to best ensure an engaged and committed work force.

Organic Import

65. In September 2017 OIG completed an audit on the National Organic Program's international trade arrangements and agreements. In the audit report, OIG made nine recommendations and NOP agreed to complete all of them by July 2018. After July 2018, will OIG follow up with NOP to 1) make sure the agency has completed all of the recommendations and 2) determine if the agency has the resources it needs to fulfill its oversight role?

Response: The National Organic Program's international trade arrangements and agreements audit did not address if NOP had sufficient resources to fulfill its oversight role. Instead, our recommendations addressed process and internal controls, which are the first priority. Specifically, we recommended that NOP develop a plan of action for tracking and verifying import certificates. Once AMS is able to get those controls into place, then we will assess if the controls are being executed effectively. The agency has indicated that they are on track to implement corrective actions on all of the prior audit recommendations by July 31, 2018. In initial discussions with the agency, they stated that NOP lacks sufficient resources to fulfill their oversight role; however, Congress did give an incremental increase of $3 million to their budget in FY 2018. The agency also referenced a recent American National Standards Institute Peer Review of the NOP that identified two findings supporting that view, stating: the NOP does not have sufficient auditors for certifier oversight, and the program does not have sufficient compliance officers to process and investigate incoming complaints. OIG will consider a follow-up audit of NOP in the future once relevant final actions have been implemented for a sufficient time to test their effectiveness—usually 18-24 months after implementation.

TUESDAY, APRIL 17, 2018.

FY 2019 BUDGET—FOOD AND DRUG ADMINISTRATION

WITNESS

SCOTT GOTTLIEB, M.D., COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION

OPENING STATEMENT—MR. ADERHOLT

Mr. ADERHOLT. The subcommittee will come to order.

Good afternoon, everyone. I want to welcome all of you to today's hearing. Our primary goal this afternoon is to examine the Food and Drug Administration's fiscal year 2019 budget, while also reviewing the use of funds past and present.

Our witness today is the Commissioner for the Food and Drug Administration, Dr. Scott Gottlieb.

Welcome to the subcommittee, and good to have you here. Welcome.

Commissioner Gottlieb, you have not quite reached, I think, your first-year anniversary, but are getting close. But you have already accomplished or made progress in a number of high priority public health initiatives, from the record number of generic drug approvals to a first-time gene therapy for cancer to new strategies in combatting addictions.

While myself and my colleagues will not always agree with you 100 percent of the time on the agency's regulatory actions, you have overwhelmingly gained bipartisan support for the way you have handled difficult policy matters. So congratulations on that.

This is a real feat in Washington, as you know, these days. So I want to commend you for your leadership in that area.

You lead an agency that touches the lives of every single American every day and millions of consumers, not only in the United States, but around the globe, whether it is through human and animal foods, human and animal drugs, medical devices, vaccines, and cosmetics.

And we appreciate you and your folks on the front lines in the public health. As noted, we may not always agree on FDA's level of regulatory enforcement, but I want to recognize your actions and efforts toward providing flexibility in a number of regulatory actions.

As you may have seen many times in the past, FDA employees can sometimes become a bit too zealous and inflexible in their development and the implementation of the rules, and you have wisely recognized the negative impacts of rigid regulations, and a number of times this past year have allowed regulated industries more time to comply with these rules.

As long as you do not sacrifice safety and public health, which I trust that you will not, I encourage you to continue to provide

regulatory relief where feasible for the sake of a small and medium size business, as well as maintaining jobs in and bringing jobs back to the United States.

FDA's budget and workforce continues to grow substantially despite what some people claim. It is difficult to say with certainty what the right size is. We will need to deliberate on this matter as we develop the fiscal year 2019 appropriations.

We do know the reasons for growth vary. First, the cost of paying, training, and supporting scientific and medical experts is on the rise.

Second, FDA is a regulator of products sourced all over the world in the complex nature of an international workplace in resourcing intensively.

Thirdly, Congress continues to place more requirements and responsibility on the agency, sometimes too much.

And lastly, Congress and the private sector continue to invest more in medical research and development.

This Congress added $3 billion to NIH research last year alone, with a total of $37 billion in NIH research for fiscal year 2018. We will eventually see medical breakthroughs, which need to go through FDA before they can reach the marketplace.

To put FDA's growth in context, when you last worked at FDA back in 2007, Congress funded FDA at $1.79 billion. FDA's fiscal year 2019 budget request before us today stands at $5.8 billion.

The Trump administration's fiscal year 2019 budget request for FDA is likely to be the boldest and largest funding request in recent memory and maybe ever. There appears to be nine different funding initiatives, plus request for agency infrastructure.

The discretionary budget seeks to increase in excess of $400 million, or approximately a 16 percent increase.

When Secretary Perdue appears before this subcommittee, which is scheduled for tomorrow, he may wish he was in your position to be asking for such an increase when the administration proposes a comparable level of decrease.

The wide assortment of medical product initiatives goes beyond FDA's typical regulatory boundaries. For example, FDA seeks $12 million for an initiative entitled "Bring Tech Med Manufacturing Home: Advanced medical device manufacturing and quality." The agency requests $100 million alone for the new Medical Data Enterprise.

One more example involves the promoting of domestic manufacturing for $58 million. This latter initiative involves the concept of continuous manufacturing, a production process that could be revolutionary if adopted by medical product companies on a large scale.

While FDA's narrative seeks to address real world problems, this committee must make some major decisions on whether or not to invest these initiatives and, if so, at what cost should we do them.

I also hope to touch upon the funding and the policy decisions included in the fiscal year 2018 omnibus bill enacted last month. The members of this subcommittee were key players in an appropriation which targeted increases to several of the Nation's highest priorities: food safety, drug compounding, the Oncology Center of Excellence, and the opioid epidemic impacting every community across the Nation.

The opioid increase of $94 million should help FDA go after illegal and counterfeit drugs entering this country through the international mail facilities. We hope to hear from you today and over the second half of this fiscal year on FDA's performance with these new resources.

I am also aware that you have unveiled a nutrition innovative strategy that included issues of interest to this subcommittee, such as standards of identity for food products, providing nutritional information to consumers, and recommendation for sodium levels.

We look forward to discussing these items, as well as the continual implementation of the Food Safety Modernization Act.

As we conduct our oversight responsibilities and craft the agriculture and FDA appropriations bill for fiscal year 2019, I want to outline just briefly our goals for this subcommittee.

First of all, the first goal is to bolster prosperity and economic wellbeing in rural America and the farm economy.

Second is to conduct fair and transparent oversight of agency activities and public resources.

Number 3, to promote economic growth through and efficient regulation and minimization of regulatory overreach.

And the last goal is to protect the health and safety of peoples, plants, and animals.

As we move forward, we will use these goals to guide us as we consider the budget request and adequately fund critical programs. The aforementioned items just scratch the surface of the issues to discuss today and in the months ahead.

As a committee, we analyze these requests and focus on allocating funds using the goals that I have outlined to target the most effective and the highest priority programs.

Again, thank you, Dr. Gottlieb, for your being here today and for your presence, and we look forward to your testimony.

And at this time, I would like to recognize the distinguished ranking member of this subcommittee, Mr. Bishop, for any opening remarks that he may have.

OPENING STATEMENT—MR. BISHOP

Mr. BISHOP. Well, thank you very kindly, Mr. Chairman, and welcome, Commissioner Gottlieb.

Mr. Chairman, I am pleased to be here again today as we have our subcommittee's third hearing on the administration's budget for fiscal year 2019.

It also gives me great pleasure to welcome Commissioner Gottlieb before our subcommittee once again.

Commissioner, you have been accessible to me and to other members on a consistent basis, and I am very grateful for that. When we met last year, we were dealing with a disastrous budget proposal that sought to replace all of the discretionary budget authority that funded medical product reviews with user fees, which would have reduced FDA's discretionary spending by $769 million.

It also cut $174 million mostly from food safety. What a difference a year makes. With the agreement on discretionary spending caps for fiscal year 2018, 2019, our 2018 bill was $980 million over the administration's request for FDA and $41 million of fiscal year 2017.

Continuing on that path, the fiscal year 2019 budget proposes an increase of $372 million over 2018, a 13 percent increase. It includes some welcome proposals, such as modernizing how generic drug applications are handled at FDA and spurring work on rare disease treatments.

But I would be remiss, Mr. Commissioner, if I did not note two major shortfalls in the budget, two things that really seriously concern me.

First, there is no increase for work on opioids. This is surprising given the President's stated commitment to solve this epidemic and his declaration of the opioid epidemic as a national public health emergency.

We have all seen the numbers, and we have all heard the news reports. In 2016, opioid related overdoses killed more than 42,000 Americans. That is an average of 115 deaths every single day. This is a problem that will require the full force of the Federal Government to solve, and individual agencies with different jurisdictions will all have to play a part.

As the agency that oversees the approval of these drugs, FDA has a unique responsibility. I understand FDA is considering new ways to facilitate appropriate prescribing practices, and I look forward to hearing more about that.

Secondly, I am also stunned that you only have a token increase of $10 million for food safety. The FDA, along with this subcommittee, has spent lots of time and invested many, many resources into the implementation of the Food Safety and Modernization Act. I know you understand that food safety compliance on the farmers is a huge issue and it has to be done well, partnering with the States, counties and the farmers themselves.

To get the medium and the small farms ready, I expected to see a significant increase in outreach, education, and training, and there is nothing. So this is a disappointment to me.

On a more promising note, you have mentioned that, quote, "We need to envision a world where cigarettes lose their addictive potential through reduced nicotine levels and a world where less harmful alternative forms efficiently delivering satisfying levels of nicotine are available for those adults who need or want them," end of quote.

I agree. This is an area where innovation can have a big influence.

I want to thank you for delaying product review application deadlines on e-cigarettes until 2022. As I mentioned before, vapor products offer a promising path for harm reduction for those who are seeking to quit or limit their smoking.

The Cole-Bishop legislation finds common ground on this issue. It allows users to transition from regular cigarettes while at the same time addressing concerns of the public health community, such as keeping it out of the reach of children and establishing strict advertising and labeling rules.

As you can see, Mr. Commissioner, we have a lot to discuss. I look forward to continuing to work with you on all of these important issues, the issues that this subcommittee faces to ensure that FDA can adequately fulfill its mission of protecting the public health by ensuring the safety, efficacy and security of human and

veterinary drugs, biological products, and medical devices, and by ensuring the safety of our Nation's food supply, cosmetics, and products that emit radiation.

Mr. Chairman, thank you for the opportunity to welcome the Commissioner and share my concerns, and with that, I yield back.

Mr. ADERHOLT. Thank you, Mr. Bishop.

At this time, I would also like to recognize the ranking member of the full Committee of Appropriations, Mrs. Lowey, if you have any opening comments that you would like to make.

OPENING STATEMENT—MRS. LOWEY

Mrs. LOWEY. Thank you very much, Chairman Aderholt and Ranking Member Bishop, for holding this hearing.

Commissioner Gottlieb, it is a pleasure to welcome you back before this subcommittee.

The FDA regulates more than $2.4 trillion worth of products consumed by Americans, including food, cosmetics, prescription drugs, medical devices, and tobacco. That amounts to Americans spending about 20 cents of every dollar on FDA regulated goods.

In short, you have an enormous responsibility to the American public. Unfortunately, while the fiscal year 2019 amended budget request contains a significant increase for FDA of $372 million above the fiscal year 2018 omnibus levels, I have concerns that it is not adequate to fully meet the needs of FDA, American families, and businesses which rely on its success.

Given FDA's responsibility to regulate roughly 75 percent of the food supply and implement the new Food Safety Modernization Act rules, a $10 million increase in fiscal year 2019, which would not even keep up with inflation, seems insufficient.

In addition, while I am pleased by proposals to modernize and invest in medical products, bring generics to market, and encourage product development for rare diseases, a vision for FDA's ability to combat the opioid epidemic is glaringly missing from this budget request. Every level of government must do all it can to combat the opioid epidemic.

Lastly, as you know, I am deeply concerned by tobacco use. I will repeat that sentence again because it is so important. I am deeply concerned by tobacco use by youth, in particular, the prevalence of e-cigarettes. I commend your leadership to reduce the levels of nicotine in cigarettes and truly believe that if we are able to accomplish this goal, it would be a game changer for our public health and save thousands of lives.

However, at the same time that FDA is focusing on nicotine, its delay in regulating e-cigarettes could very well open Pandora's box, and I am sincerely worried that FDA will replace one addiction with another, and that FDA's silence of e-cigarettes could open the gates to the next public health emergency.

I do want to discuss this with you further during my questions. I am very concerned whether it is a high school in my district. I was talking with a group of youngsters in East Hampton, New York. Sixty percent of the students are using e-cigarettes, and we will discuss that further, because they have these gadgets. Thankfully, their parents in many instances and the teachers do not even know what they are doing.

So I am concerned about the deaths. I am concerned about the addiction to nicotine, and I do hope that we can have adequate time later on during questions to discuss this.

So thank you again, Commissioner Gottlieb. Thank you for joining us. I look forward to your testimony.

And thank you, Mr. Chairman.

Mr. ADERHOLT. Thank you.

And, Commissioner Gottlieb, let me just say without objection, your entire written testimony will be included in the record.

[The information follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT
OF
SCOTT GOTTLIEB, M.D.

COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

UNITED STATES HOUSE OF REPRESENTATIVES

April 17, 2018

Good afternoon Chairman Aderholt, Ranking Member Bishop, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to discuss the President's Fiscal Year (FY) 2019 Budget request for FDA.

First, I would like to thank the Committee for your continued support of the Agency. FDA has received strong bipartisan support throughout the appropriations process in recent years and FY 2018 was no different. I believe this support reflects our shared commitment to the vital role FDA has protecting and promoting the public health. The funding this Subcommittee provides is essential to the Agency fulfilling its mission. The professional staff of FDA is grateful for the support of their work and the funding increases the Subcommittee provided FDA in FY 2018.

Last year was a record year for medical products at FDA in several ways: novel drug approvals, generic drug approvals, and novel medical device approvals. The record number of approvals in 2017 reflects the remarkable opportunities we have at this critical inflection point in science and technology. Advances in medicine and science are providing opportunities that can fundamentally change health in America and the outlook for many patients with life threatening and chronic diseases. At the same time that we have many new opportunities offered by advanced medical technologies; we cannot lose sight of our commitment to the public health basics – reducing smoking rates, preventing kids from initiating use of tobacco products, supporting healthy food choices that can lead to better nutrition and reduced risk of disease, and increasing vaccination rates. FDA is committed to all of these and other public health goals. With your continued support, we have more opportunity to deliver on the promises of science than at any other time in the past.

The funding provided in the President's FY 2019 Budget (Budget) will allow the Agency to sustain its current work—protecting the safety of the food and medical products consumers use every day—and build on these efforts by requesting additional resources to make significant progress on several important fronts; including, fostering innovation and competition to bring better and more

affordable products to market, combatting the opioid epidemic, and implementing the 21st Century Cures Act (Cures).

Overall, the Budget requests $5.8 billion in total resources for FDA—which is an increase of $663 million or 13 percent above the FY 2018 Annualized Continuing Resolution. At this total level, the Budget includes an increase of $473 million in budget authority and an increase of $190 million in user fees. The Budget requests considerable new resources for FDA and makes significant new investments in advancing critical areas of science, domestic technology, and public health.

As the regulatory Agency responsible for ensuring the safety and effectiveness of more than $2.4 trillion worth of products used by consumers, I remain steadfast that these funds are critical investments in our public health agency. They will allow us to more efficiently advance safe and effective new opportunities to Americans.

I. FY 2019 Initiatives

The Budget includes an increase of approximately $400 million in additional resources to advance initiatives to promote public health and spur growth in the domestic economy. These new initiatives provide a renewed focus to some of the Agency's most intensely followed issues—facilitating regulatory pathways to increase patients' access to safe and effective drugs, biologics, and medical devices, and access to higher quality compounded drugs for the patients who need them; better informing patients and providers about pre-and post-market safety of medical products; and, increasing competition among generic drugs in order to lower the cost of generic drugs.

I believe that these new efforts represent discrete areas where targeted additional resources can help the Agency make a meaningful difference for American consumers. A few examples of the new initiatives are described below.

A. Advancing Modern Drug and Biological Product Manufacturing Technologies, Through the Development of Efficient Regulatory Pathways

Advanced manufacturing technologies, such as continuous manufacturing, can improve the agility, flexibility, cost and robustness of drug and biologic manufacturing processes. These technologies have great potential to accelerate new, more targeted therapies, enhance product quality and bolster stability in the U.S. drug supply to meet patient needs. For example, continuous manufacturing has the potential to help address and eliminate drug shortages and reduce recalls related to problems with product or facility quality. Further, with continuous manufacturing platforms for biologics, vaccine manufacturing could be ramped up on short notice, and vaccines themselves adapted over a shorter time period to address infectious diseases, such as the flu. This would help address the challenge we face annually with the flu season. As a result of the long manufacturing cycle required when using traditional egg based manufacturing technologies, manufacturers must select the flu strain six months prior to the flu season. By reducing the amount of time it takes to ramp up manufacturing, we can start manufacturing closer to the start of flu season to minimize or eliminate the matching issues we face, to varying degrees, each year and increase the efficacy of the flu vaccine. Advances in manufacturing could provide a more certain, and nearer-term opportunity to address challenges with flu vaccine supply and effectiveness while we continue to work on longer term, newer vaccine technology such as a universal vaccine.

Despite the promise of these manufacturing improvements, industry remains reluctant to invest in these platforms. Additional regulatory principles and tools to help manufacturers implement and assess these platforms could accelerate their adoption. It would give manufacturers greater certainty that products developed through continuous manufacturing can be efficiently reviewed and gain market entry.

In these ways, FDA can encourage industry to utilize these new technologies by developing a science-based framework that includes the regulatory tools and guidance for how products developed

in these systems will be evaluated. As an additional benefit, these small-footprint, high-technology manufacturing platforms are likely to be domiciled in the U.S. As a result, their adoption could return more product manufacturing to domestic sites, which could help public health, enhance our national security, and foster job creation. The Budget requests $58 million in FY 2019 for advancing this initiative.

B. Establishing the Outsourcing Facility Sector as a Robust and Reliable Source of Compounded Products

Since Congress passed the Drug Quality and Security Act in 2013 (DQSA), patient access to better quality compounded drugs has been a chief concern for the Agency, physicians, and patients alike. Outsourcing facilities have the ability to produce and distribute larger amounts of compounded products to meet the needs of individual patients for whom such drugs are appropriate, including by making office stock that is used by hospitals and clinics. Outsourcing facilities are an important component to our health system and the Agency is committed to clarifying and appropriately tailoring policies so they can continue to provide drugs, based on the clinical need for a compounded medicine, so patients have access to the products they need.

The Budget proposes the creation of a "Center of Excellence on Compounding for Outsourcing Facilities" and expanded FDA engagement with outsourcing facilities and states to help the pharmacy outsourcing industry grow to meet its intended function and adhere to good manufacturing practices (GMPs) to protect patient health. We see an opportunity to make investments in regulatory policy and personnel that could help more compounding pharmacies become outsourcing facilities. This, in turn, would allow these pharmacies to grow and serve more patient needs, including through the provision of office stock compounded under GMP standards, promoting access to better quality compounded drugs for patients who have medical needs that otherwise cannot be met by an FDA approved drug. These new outsourcing facilities would

represent a largely domestic industry and a new area of growth in the healthcare sector. The Budget requests $25 million in FY 2019 for this initiative.

C. Bring MedTech Manufacturing Home: Advance Medical Device Manufacturing and Quality

The Budget proposes to establish a voluntary program for device manufacturers to receive certification for meeting objective manufacturing and product quality criteria. This would make the process for introducing innovations in how medical devices are manufactured more efficient and predictable. In turn, this program would encourage device manufacturers to make investments to re-tool their manufacturing processes in ways that can facilitate manufacturing innovation, encourage investment in new production methods and materials, and lead to better medical products.

This more modern and nimble framework would make it more efficient for device developers to innovate manufacturing processes in ways that can allow devices to better meet the needs of patients and the expectations of providers – such as through intelligent, automated processes that monitor and record manufacturing quality metrics, incorporating features and technological characteristics that can contribute to better options and higher quality that achieves their clinical purpose. Implementing this framework would help increase manufacturing innovation, accelerate availability of high-quality devices to patients and foster a competitive marketplace around device quality similar to other industries, such as automotive and aerospace, that could advance device innovations, reduce manufacturing costs and improve the quality and safety of medical devices. As medical devices become more complex – and given the frequent modifications made to devices – spurring advanced manufacturing and creating a competitive marketplace for device quality is critical for both driving technological innovations and assuring patient safety. The Budget requests $12 million in FY 2019 for this initiative.

D. Create a New Medical Data Enterprise

Advances in technology have the potential to improve the availability and utility of real world evidence (RWE) and real world data[1] (RWD). This data provides researchers the opportunity to answer questions about treatment effects and outcomes more efficiently, saving time and money, while yielding answers more relevant to broader populations of patients than might be possible in a specialized research environment. This data can also help streamline clinical development and inform the safe and effective use of medical products.

The Budget proposes to advance the use of this real-world experience to better inform patient care and provide more efficient, robust and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. The Budget requests funding to establish a new capability, including the development of data and analytical tools, to conduct near-real-time evidence evaluation down to the level of individual electronic health records for at least 10 million individuals in a broad range of U.S. healthcare settings.

Expanding the FDA's capacity to use RWE to evaluate medical products would generate processes that could improve the efficiency of the regulatory process, better inform patients and providers about pre-and post-market safety, reduce some of the burdens that drive up the time and cost required to bring beneficial innovations to the market, and address barriers that can make certain important safety and effectiveness information around the real-world use of products hard to collect and evaluate. Harnessing the power and potential of RWE is especially critical for finding treatments and cures for rare disease. Establishing a strong understanding of each disease and completing clinical trials is especially challenging; however, RWE holds enormous promise for improving

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[1] Examples of RWD include data derived from electronic health records (EHRs), claims and billing data, data from product and disease registries, patient-generated data including in-home use settings, and data gathered from other sources such as mobile devices that can provide information about health status.

understanding of disease and thus, development of treatments and cures. Funding in this area will allow FDA to develop regulatory standards for use of RWE to support medical product applications. The Budget requests $100 million in FY 2019 for this initiative.

E. Facilitate Growth and Spur Transformation of the Digital Health Technology Industry by Shifting Regulation to an Efficient and Novel Framework for Reliable Post-Market Oversight

Digital health products are at the forefront of helping us diagnose and treat our society's increasingly complex medical needs. Health care providers use the latest technological tools to help them screen, detect and treat diseases ranging from cancers to neurological conditions like Alzheimer's. Patients utilize mobile medical applications to manage conditions like diabetes and treat substance use disorder. However, the current regulatory framework is not well-suited for these modern technologies. Every single day, these technologies are helping patients and doctors make health care decisions.

As part of our efforts to support timely access to safe and effective digital health products, the FDA is working collaboratively with industry, patients and providers to establish a new paradigm for digital health technologies under which a company could market lower-risk products without FDA premarket review and market higher-risk products following a streamlined FDA premarket review if the company receives a prior third-party certification for engaging in high-quality software design and testing (validation) and ongoing maintenance. This regulatory model would be fully proven and expanded from its current pilot status to a broader program. For low-risk products, rather than evaluate each individual digital health product before the product comes to market, the FDA would instead focus its resources on validating the quality of a firm's software design and the firm's methods for certifying the quality and reliability of its underlying software performance. The agency would further reduce the time and cost of market entry of digital health technologies while assuring appropriate patient safeguards by relying on postmarket collection of real-world data to support new

and evolving product functions. The Budget also proposes the creation of and resources for a Center of Excellence on Digital Health to establish this regulatory paradigm, build new capacity to evaluate and recognize third-party certifiers, and support an internal cybersecurity unit and an external public-private partnership of experts to complement the advances in software-based devices. Implementing these regulatory innovations and information technology improvements are essential for advancing technologies to improve the health and quality of life of patients while assuring critical safeguards. The Budget requests $70 million in FY 2019 for this initiative.

F. Modernize Generic Drug Development and Review

Increasing patients' access to more affordable prescription drugs is a top issue for Americans and one that I am personally dedicated to addressing during my tenure as Commissioner. Last May, in one of my first actions as Commissioner, I announced FDA's Drug Competition Action Plan. The plan has three overarching principals: eliminate gaming by branded companies that can delay generic drug entry; resolving scientific and regulatory obstacles that can make it difficult to earn approval of generic versions of certain complex drugs; and improving the efficiency and predictability of FDA's generic review process to reduce the time it takes to get a new generic drug approved and lessen the number of review cycles undergone by generic applications before approval. As part of this process, we also prioritized review for certain generic applications where there was a lack of competition, a situation under which consumers could face high prices for some very old medicines.

The Budget builds on this plan by proposing to establish a new review platform to modernize generic drug review and support efforts to update generics labels. This investment will foster greater use of lower-cost generics as a way to improve patient access and create competition in order to lower drug costs. For example, too many generic labels remain out-of-date because there is no longer a sponsor involved that is able to update the labels with new information about safe and effective new uses for these medicines. If we incorporate into generic drug labels all of the current

information about their safe and effective use, it could promote more prescribing of generic drugs, reducing overall healthcare costs. The Budget requests $38 million in FY 2019 for this initiative.

II. Opioids

One of my highest priorities as FDA Commissioner is combatting the ongoing crisis of opioid addiction. As part of this commitment, we are reexamining the Agency's authorities and policies in this area and working to ensure that FDA has the proper tools and resources to address this epidemic as it continues to evolve.

Thanks to the support of this Subcommittee, FDA received a total of $94 million in the FY 2018 Consolidated Omnibus Appropriations Act (P.L. 115-141) signed into law last month to address the interdiction of illegal drugs, including narcotics, through our work in the international mail facilities. Recognizing the Agency's responsibility in helping to curb the flow of these counterfeit and illegal drugs from entering our communities, and the critical public health obligation that the FDA was entrusted with through these additional resources, I am pleased to report the Agency will start to invest this new funding in purchasing equipment and assessing additional technologies we might deploy before the end of this fiscal year.

But FDA's efforts related to addressing the opioid crisis are broad, and there are many new programs we would like to pursue in this mission. The Budget requests an additional $10 million to provide technical assistance related to clinical study design related to medication-assisted treatments, and to also accelerate the development of non-opioid treatments, devices to treat chronic pain, and generic versions of opioid drug products with abuse deterrent formulations. One way FDA will use the resources is funding studies to identify additional tools and methodologies that can be used to evaluate whether differences in formulations impact abuse deterrence. These are small steps, but collectively, over time I am confident they can work together, along with the efforts of so many other of our federal, state, and local partners to make a difference.

III. Cures

Implementation of Cures has been another top priority of the Agency over the past 16 months. Cures includes provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The new law complements many efforts underway at FDA. All of these efforts are aimed at transforming the way we support product development and maintaining FDA's gold standard for safety and effectiveness. Toward these efforts, last June, the Agency published our required work plan for implementing Cures, which includes details of how the Agency will utilize the $500 million in authorized new funds over nine years. For FY 2019, the Budget requests a total of $70 million to support our implementation work.

I want to thank you for your support on this vital work so far. I look forward to working with you on supporting the Agency's implementation efforts in the future.

VI. Conclusion

The last year was historic for the Agency. We are diligently working on a number of fronts and the vital work we do provides Americans with better ways to improve their health and welfare, and empowers consumers to make informed choices about the products they use and the foods they feed to their families. The Budget will help FDA maintain and complement our current efforts, as well as provide a renewed focus and investment in some of the Agency's and the nation's top public health priorities. I look forward to answering your questions today and to working with all of you going forward.

Mr. ADERHOLT. And before I recognize you for your comments, let me mention the White House has set up a briefing this afternoon. I do not know if you consider this fortunate or unfortunate. So we are going to have to adjourn here probably shortly after 2:30. So if you could keep your comments to a minimum.

Also, in order to accommodate all of the members, we are actually reducing our time down to 4 minutes per member so that everyone will have a chance to ask questions.

But at this point, let me turn it over to you, commissioner, and we look forward to your testimony.

OPENING STATEMENT—DR. GOTTLIEB

Dr. GOTTLIEB. Thanks a lot, Chairman Aderholt. Thank you, Ranking Member Bishop and members of the subcommittee.

I would like to thank the Committee for your commitment to FDA. We have been fortunate to receive strong bipartisan support in recent years, and the 2018 budget was no different. With your support, we have more opportunities to deliver on our public health mission than at any time.

The President's 2019 budget request builds on these goals. Overall, it requests $5.8 billion in total resources for FDA, and at this level, the budget includes an increase of $473 million in budget authority and $190 million in user fees.

The budget requests new resources for FDA to make significant investments in advancing critical areas of science, domestic technology, and public health. I would like to highlight one of those initiatives for the Committee today in particular, and it is our efforts to build a knowledge management platform as part of our Medical Product Review Programs.

This platform would enable us to store/manage the collected experience of our medical review staff, to have a way to identify how decisions are made across different functions, the scientific precedents we establish in the course of our review process, and the knowledge we develop.

Right now, if you ask me how we made a particular review decision in the past, I would begin by asking our review staff if they have confronted a similar clinical circumstance and how it was decided and why.

We have limited options to query or review decisions to extract how we reached certain conclusions. We cannot store or interrogate our own scientific precedent.

This sort of knowledge management system is key to how we are modernizing our Medical Product Review Programs. Among other things, our new efforts are aimed at bringing a more team-based approach to medical product review to facilitate the easier sharing of information across scientific disciplines and to bring more consistency to decision making across different disease products and disease areas.

As part of these new steps, we will set up a policy office inside our Drug Center's Office of New Drugs that will distill and align regulatory, clinical, and scientific reasoning of review divisions to promote policy transparency and consistency. And we will be converting more of that information into hundreds of new disease-focused guidance documents once these efforts are fully engaged.

We will also take new steps to make sure that these drug policy documents stay up to date.

These guidances will outline clear, concise, and up to date development guidelines as a way to foster innovation. Among some of the many areas we are working on right now are new guidances to lay out modern criteria for the development of drugs targeted to ulcerative colitis, rare pediatric cancers, pediatric HIV, and serious, life-threatening and non-cancer blood disorders like aplastic anemia.

These guidance documents will aim to apply modern principles to make drug development more efficient by focusing on the most effective ways to prove safety and efficacy.

For example, the guidance on blood disorders will allow drug developers to reduce the use of animal testing and will outline ways to measure benefit that may permit more efficient development programs and earlier approvals.

There is a common theme here. One aim is to focus more guidance on laying out the pathway for developing drugs targeted to less common and serious conditions where there is a lack of available therapy, and drug development pathways can be more challenging.

But bringing more alignment and shared learnings and more consistency to how we evaluate scientific principles and make decisions requires us to have more than just up to date guidance documents. It also means we need to have better tools for capturing and sharing what we learn so that we can develop the rigorous principles that inform these guidances.

And that is where the new knowledge management system becomes a critical element of our efforts. Let me give you one tangible example of the connection between the knowledge system and how we can advance better and safer medicines.

In the late 1990s and early 2000s, several drugs were discovered after approval to carry a risk of sudden cardiac death leading to their withdrawal. To identify drugs with this pro-arrhythmic potential, a new clinical study requirement was introduced as a preapproval obligation for all new drugs.

These study requirements looked at something called QT prolongation, where the heart's beat becomes elongated. But doing these QT studies is very costly, and the results are imperfect. The studies can flag drugs as having a risk when none really exists and can miss drugs that carry the danger.

Recently, we have improved on this approach by developing cell-based assays that can better discriminate the medicines that are likely to have this side effect. We have done these things using a data warehouse that we have built by collecting knowledge and information over many years and across many different drug reviews and evaluating the differences between drugs that do and do not have this risk.

This new assay is being introduced across all drug programs and all FDA divisions right now. It will replace the old QT study requirements, and this sort of innovation, how we assess risk and benefit, we can make more routine with better capability for curating knowledge gleaned across our Drug Review Programs.

This is the sort of innovation that improves drug development and efficiency, lowering costs while improving our predictive accuracy. It is with better regulatory tools, better management of our process, and your continued support that we will continue to fulfill our critical consumer protection role and advance opportunities for Americans to improve their health.

Thank you.

Mr. ADERHOLT. Thank you, Dr. Gottlieb.

And I will start out with the questioning and, again, like I said, we are going to reduce it down to 4 minutes, and I am usually pretty lenient on our time, but because of our restrictive nature today, we are going to try to stick by 4 minutes and keep it at that, certainly including myself.

FY 2019 PRIORITIES

As I noted in my opening statement, FDA is requesting the most discretionary dollars in its history, without the typical budget gimmicks. It is tempting to tell us that everything in the budget is equally important.

On the surface, it is challenging to say that new drug development might be a more impactful investment than an equally important initiative, which may advance medical devices.

You may be so vested in these issues that it feels like I am asking you to pick a favorite child. However, like you and your agency, we have to make hard decisions.

First, I want to dive into a particular funding initiative that intrigues me and, I think, also intrigues a lot of members of this subcommittee. Then I want to get a bigger picture of the funding issue.

Back in 2011, just a few years ago, Dr. Woodcock was quoted in saying that manufacturing experts from the 1950s would easily recognize the pharmaceutical manufacturing process of today. What my question would be: is this still true 7 years later after Dr. Woodcock's comments?

And if it is, would you provide us a real-world example of how this might work and what role FDA plays and what might be reasonable outcome from this effort?

Dr. GOTTLIEB. I think there is still some truth in that, Congressman. I appreciate the question. I think we have made improvements in terms of trying to bring the pharmaceutical sector towards more modern manufacturing, but there is still a long way to go.

And the fundamental issue is that drug companies are reluctant to innovate and introduce a lot of new technology for the fear that it is going to introduce uncertainty as well because they are not sure how FDA is going to embrace changes in manufacturing.

But we know that there are a lot of technologies that would allow manufacturing to happen in a way that is higher quality, that could be safer, less prone to shortages, and I will give you one tangible example.

We have talked about continuous manufacturing, and there is a proposal in the budget for $58 million to help FDA support a transition to continuous manufacturing on the new drug side. In the biologics context, right now we manufacture flu vaccines in eggs.

It is 6-month process. It takes a very long lead-up time, as you know, and is prone to problems.

If you had a continuous manufacturing platform manufacturing flu vaccine, you could quite literally manufacture in a cell-based environment a recombinant vaccine basically using a gene cassette, and it would allow you to basically change the flu vaccine that you were producing by just changing the gene cassette, which is something that could happen in a matter of weeks.

So you could scale up much more quickly and you could convert to different kinds of vaccine if you saw changes in the contours of the resistance patterns over the course of a season.

That is just one very tangible example, but on the whole, we know that this technology could lead to a better public health outcome but for our ability, we believe, to put out guidance to train our review staff on it, to train our inspectorate on it, and to try to work in public-private partnerships with the industry to help them convert over to these new technologies. It is going to be a very slow migration.

ADMINISTRATION'S PRIORITIES

Mr. ADERHOLT. Again, my time is coming to a close, but I want to get back to a bigger picture briefly with the administration's priorities.

There may be eight or nine funding issues in the budget request or there are that many, but can you just pick out a top couple of initiatives that you think have potential to deliver the greatest public health impact?

Dr. GOTTLIEB. Well, you are talking about picking out a favorite child. So I have three children. So I will pick out three, if that is okay?

I think that the ones that I would point to are the ones that I think can be the most fundamentally transformational for the FDA, and it would be what we are doing on continuous manufacturing; the efforts with respect to evidence, to try to move towards more real time monitoring for safety in the post-market right now. Even with what we do with Fentanyl, it is retrospective. It is looking at claims data. We want to move towards more real time monitoring where we are looking at data in electronic health records and have an active surveillance system. That is going to take an investment to do that.

And then what I talked about with respect to the knowledge management system across the whole continuum of medical products, being able to capture and query our own precedent, these can be transformational types of infrastructure changes, if you will, for the agency on a data side and on a qualitative side.

But I think it is going to take an initial up-front investment to make these happen, and I think we have an opportunity now to do that.

There will be dividends in terms of more innovation; I think lower costs as well.

Mr. ADERHOLT. All right. Mr. Bishop.

E-CIGARETTES

Mr. BISHOP. Thank you very much.

Commissioner, at last year's fiscal year 2018 budget hearing, I mentioned that Public Health England and the Royal College of Physicians both concluded that e-vapor products are 95 percent less harmful than combustible cigarettes; that these products effectively move people off regular cigarettes; and that, in fact, many of my constituents have been referred by their physicians to e-vapor products to stop smoking.

Since that time, the American Cancer Society has added its voice in support of e-cigarettes as a more healthy alternative to combustible tobacco.

I mentioned that the Cole-Bishop legislation finds common ground by helping people quit smoking, but also establishes a variety of requirements and restrictions that address public health groups' concerns, such as keeping these products out of the reach of children.

That is why I am concerned about reports that indicate that under-age use of vapor products is increasing. A majority of vaping consumers are adults. What is FDA doing to ensure that these products are not being accessed by youth?

And specifically, what are the steps being taken to enforce against secondary marketing platforms, such as eBay and others that may not age-verify their consumers?

Regarding the e-vapor products as a whole, last year you mentioned you were still working through this unit; that you wanted to make sure you were fully grounded in the facts before beginning a policy discussion with career officials inside the Tobacco Center. You assured us that whatever you did in this area would be science based.

A year later, can you comment on that?

PREMIUM CIGARS

And finally, last month the Food and Drug Administration announced that it was reconsidering its premium cigar regulations. The comment period for the public to voice their opinions on issues is open until June 25.

You are looking for comments on a lot of different topics: use patterns, public health considerations, standards regarding consumer perceptions, and studies on whether any applicable manufacturing, marketing, sales, distribution, advertising, labeling and/or packaging requirement restrictions should be applied.

I am a strong advocate for getting it right the first time. Is 90 days enough?

Dr. GOTTLIEB. Thank you for the question, Congressman.

As you know, we have engaged in a comprehensive policy with respect to tobacco to really put nicotine at the center of our regulatory efforts, and at the same time that we move to regulate nicotine and combustible cigarettes to render them minimally or non-addictive, provide opportunity for products that might present less risk than combusting tobacco to be available for adults who still want to have access to satisfying levels of nicotine, and these are the electronic cigarettes and things like Electronic Nicotine Delivery Systems (ENDS), and there are other technologies available that are coming onto the market or being put forward.

We need to make sure we have the right regulations in place to properly evaluate these products and put them through an appropriate series of regulatory gates to make sure that they actually can help smokers transition off of combustible tobacco.

We are engaged in that policy right now. We are going forward on the rulemaking with respect to the nicotine in the combustible cigarettes, and we are also exploring the issues of flavors of cigarettes and whether the flavors continue to create a lot of youth initiation and whether or not the agency should take action with respect to flavors in cigarettes, including menthol.

With respect to the youth use, I will say that we are deeply concerned about this. Whereas we see the potential for some opportunity for the ENDS and the e-cigarettes to provide a viable alternative for adults that potentially poses less risk than combusting tobacco, we also recognize that that opportunity is not going to be available if the youth use continues to increase at the rate at which it is. It is simply unsustainable. It is not going to be tenable. Congress is going to step in. We are going to have to step in.

So we are going to have to address what we are seeing on the youth side. We cannot just addict a whole generation of young people on nicotine with e-cigarettes and consider that a public health advance.

So I will tell you that we will be taking some very vigorous enforcement steps in the coming weeks, starting in the coming weeks, and we will continue that action to try to address what we perceive as inappropriate utilization by youth, and so we see the agency stepping into this fight very soon.

Mr. BISHOP. I believe my time has expired.

Mr. ADERHOLT. Okay. Thank you.

We have the former chairman of the committee, Mr. Rogers, here today, and I would like to recognize him.

OPIOID EPIDEMIC

Mr. ROGERS. Thank you, Mr. Chairman.

Commissioner, FDA is the traffic cop for prescription pills, and frankly, when this epidemic burst upon the scene 15 years ago, FDA was asleep at the switch, and the opioid epidemic has flared like a wildfire.

Now it is at amazing heights. We are losing 60,000 people a year in the country to opioid abuse and overdoses.

You were kind enough to come to the summit that we had in Atlanta a couple of weeks ago with the heads of NIH, CDC, the Surgeon General, and so on and forth gathered, 3,300 people representing all walks of life on the fight against opioid abuse. Your testimony there, your speech there was well received and encouraged the rest of us greatly by the actions that you are taking.

So I commend you for making opioid abuse high on your list, as it should be.

I want to ask you briefly about two or three of the actions which you have taken, which I salute. For example, you started in May 2017. You announced an opioid policy steering committee to examine mandatory pain management education for health care professionals and revamping your risk management responsibilities. That is a great step.

You took Opana off the market after a review of data showed significant potential for abuse and misuse.

You announced that you would implement a risk evaluation and mitigation strategy, REMS, for the prescribing of immediate release opioids to ensure that the benefits of how these drugs are prescribed continue to outweigh the risks of misuse, abuse, addiction, overdose, and death.

That is the first time to extend the same regulatory requirements to the manufacturers of immediate release opioids, and it is significant because 90 percent of opioids prescribed today are immediate release.

I could go on about the things that you are undertaking that are in great measure the reason why for the first time we are now seeing actually a reduction in prescription pill overdoses, sad to say being supplanted by heroin laced with fentanyl.

Can you tell us what you plan to do with the REMS plan that you already are underway with?

Dr. GOTTLIEB. Well, thank you for the comments, Congressman. I appreciate it very much and the recognition of what the staff has done at FDA over the last couple of years to try to confront this epidemic.

I will just say what we are looking at right now with respect to risk management is whether or not we can move towards a system where we try to develop evidence around what the appropriate dispensing should be by indication.

You know, we believe we have an important role to play with respect to new addiction, people who still become medically addicted to opioids. Upwards of 50 percent of people who become addicted, their first exposure will be from a lawful prescription.

So people are still becoming addicted from a prescription, although for more and more people, their first exposure is increasingly a street drug, which is increasingly the low-cost alternative.

But what we want to do is put in place more measures that could help rationalize prescribing and make sure that when pills are dispensed it is for an appropriate duration. So the idea that we would build in place evidence-based guidelines that could be used perhaps in labeling, and perhaps by providers and health systems to better adjust what gets dispensed, and we are working through that right now, how we can develop such a system.

PAIN MANAGEMENT MEDICATION

Mr. ROGERS. The miracle drug hopefully that comes along is an effective pain management pill that is not addictive. NIH and CDC are working heavily to make that happen.

Have you any thoughts on that?

Dr. GOTTLIEB. We certainly see drugs in early development that look like they could be effective at treating pain and might not have all of the addictive effects that opioids have.

I will say that within this category, when it comes to chronic administration of any drug for the treatment of pain, there has been no free lunch. All of the drugs have had some liability associated with them, whether there are safety issues with chronic administration, or abuse potential.

So we would need to look at this very carefully, but we do see some promise in the early pipeline.

Mr. ROGERS. I salute you on taking on the opioid problem.

Dr. GOTTLIEB. Thank you.

Mr. ADERHOLT. Mrs. Lowey.

E-CIGARETTES

Mrs. LOWEY. Thank you, Mr. Chairman.

And, Commissioner Gottlieb, what does this look like to you?

Dr. GOTTLIEB. I know exactly what it is, but it looks like a USB key.

Mrs. LOWEY. It looks like a JUUL.

Dr. GOTTLIEB. Well, that is what it is.

Mrs. LOWEY. I am glad you are familiar with JUUL because it seems most kids are, but most parents are not.

And this is a JUUL, which is now among the most popular e-cigarettes on the market. It resembles a flash drive, can be charged in the USB port of a computer, and offer ten kid-friendly flavors like mango, cool mint, and fruit medley. It delivers nicotine at a higher level than most e-cigarettes. In fact, one JUUL pod like this contains as much nicotine as an entire pack of cigarettes, one pod.

And, frankly, I have been all over my district. I have heard from teachers, parents, superintendents, and even students that JUULs are all over our schools, and worse, people are assuming they are safe.

According to JUUL's own social media post, its highly popular mango and cool cucumber flavors were not, frankly, there until 2017 when they were first introduced to the market.

This appears to be a violation of FDA's "deeming rule," which prohibits new e-cigarettes and other newly deemed tobacco products from entering the market after August 8, 2016, without going through an FDA pre-market review.

Did JUUL submit a pre-market application to FDA for its mango and cool cucumber flavors? Did they?

Dr. GOTTLIEB. Well, Congresswoman, I do not want to telegraph coming enforcement action.

Mrs. LOWEY. Well, do me a favor then. I will finish my discussion of it, and then you could say yes or no because I do not want to take advantage of the time.

If yes, has FDA reviewed the application, issued a marketing order allowing the flavors to enter the market?

And if not, why is FDA not using its enforcement authority to remove these flavors from the market pending an FDA review?

And then you could ask me; perhaps you can suggest. I would like to know if these products are safe. I think they should be off the market, period. So if you could respond with the application and what you have done with it, I would be most appreciative.

Dr. GOTTLIEB. Well, I can comment briefly. I appreciate the question.

As you know, when all of the requirements for regulation on the newly deemed product, including e-cigarettes, went into effect last year, we have authorities over these products to go and inspect and impose Current Good Manufacturing Practices (CGMP) standards and enforce age restrictions.

I think you are going to see us stepping into this fight in a vigorous way in the coming weeks. I look forward to coming back to you and briefing you on what we are doing. We are going to be taking some action to address these concerns.

I share your concerns. This is top of my mind and top of mind for a lot of people in the Agency because, as I said to Congressman Bishop, I do think that there is some potential opportunity from these products to help adult smokers, but not if all they end up doing is hooking a whole generation of young people on nicotine. That is not tolerable for me, and we will be addressing this.

Mrs. LOWEY. Well, I really appreciate your response because in the seven seconds I have left, I think it is important that our colleagues know that in these high schools, 60 percent of the kids are smoking this stuff, and half of the teachers do not even know what it is, and their parents certainly do not.

So whether it is cucumber mint or mango, I think we have got to do something about it, and I thank you very, very much. And every physician I have spoken to says this is a gateway to addiction.

So I appreciate what you are doing with cigarettes, and I appreciate you taking first, important action on these. Thank you very much.

Thank you, Mr. Chairman.

Mr. ADERHOLT. Mr. Yoder.

TOBACCO CONTROL ACT RULEMAKING

Mr. YODER. Thank you, Mr. Chairman.

Commissioner, thank you for coming back to the committee, and I think whether it is Mr. Bishop's questions or Mrs. Lowey's questions, I think the committee and the country stands unified that we do not want these products in the hands of children, and so we appreciate your work.

I think there are some themes you are going to hear from many of us that your work under the Tobacco Control Act is critical to make sure that these rules and regulations and laws are enforced uniformly, with lots of clarity and information, so that the public as well as the regulated industries, we very clearly target what matters most, and we are hitting those things in a predictable manner.

I know last July you made some announcements in regards to rethinking the way FDA regulates these products to go in that direction so that we have clarity. And some of the challenges we have had are lack of clarity, uncertainty, unpredictability.

One of the items you mentioned was the need for foundational rulemakings, including a proposed substantial equivalence rule. In recent public statements, CTP Director Mitch Zeller has indicated the proposed SE rule, when issued, will be identical to the one issued and withdrawn on the same day during the last administration.

As I understand it, that draft rule did not include key definitions or provide clarity as to the FDA's expectations for what should be in an SE application.

When FDA proposes such a rule, will you commit that the proposed rule will provide clarity, transparency and predictability for

both the agency and the regulated industry, including defining the same characteristics and different questions of public health as outlined in the Tobacco Control Act?

Dr. GOTTLIEB. I appreciate the question. We are working through that draft rule right now that is inside the Agency. I can assure you it is not a carbon copy of the rule that was displayed briefly in the last administration.

We have learned a lot since that rule was originally drafted, and we have also announced a lot of policy, and that needs to be accommodated in how we approach the regulatory process and how we approach that rule.

I think we will be in a position in the coming month or two to submit that rule for review with the Department, and Office of Management and Budget (OMB). We are nearing the end of that process, and I am hopeful that will provide the kind of clarity that you are suggesting.

I do not want to comment on specific elements of the rule, if I may, here, but the point is well taken that the industry does need certainty and clarity around these provisions, and we need to get in place these foundational regulations.

Mr. YODER. Do you believe, Commissioner, that we can have a definition of same characteristics as part of this?

Dr. GOTTLIEB. I think it is possible to clarify that either in regulation or guidance. I am not sure where the appropriate place would be, but we would need to address that.

Mr. YODER. As well as different questions of public health.

Dr. GOTTLIEB. That is a fundamental question that we would want to address in some fashion.

Mr. YODER. You believe that will be addressed in the rule?

Dr. GOTTLIEB. I do not want to commit to where we would address it, but we certainly need to address these kinds of considerations. These are the considerations that are elements of the review process itself.

PREMIUM CIGARS

Mr. YODER. OK. Along the same vein, as the FDA looks at considering making changes to its approach regarding premium cigars, something that former chairman has spoken of very eloquently, there is concern the FDA would continue to enforce existing cost requirements that might hurt small businesses when it very well may amend how those categories are regulated.

Can you speak to that?

Dr. GOTTLIEB. Well, as you know, we pushed off the application deadline, which I think was the most costly requirement. A lot of the other requirements relate to things like making sure there are adequate warnings on products and making sure that they are not being sold to minors.

You know, if, in fact, and I am speculating here, which is always dangerous, if, in fact, we end up going through a regulatory process and we determine that premium cigars raise different questions of public health and, therefore, should be regulated differently, that does not necessarily mean that they should be exempt from all regulation.

Certainly, there would be things I think people might agree on that might be good things to continue to require, like restrictions on sales to minors, and so this would need to be determined in regulation.

Mr. YODER. I appreciate your measured approach there, and I appreciate your candid answers.

Thank you, Mr. Chairman.

Mr. ADERHOLT. Ms. DeLauro.

DRUG AND MEDICAL DEVICE SAFETY

Ms. DELAURO. Thank you very much, Mr. Chairman.

Commissioner Gottlieb, let me start with what I believe to be at least alarming to me, the theme throughout your written testimony and the budget.

You refer to new regulatory pathways for pharmaceuticals, third party certifiers for certain medical devices, and voluntary programs for device manufacturers.

With regard to medical devices, I would like to point out that research from the National Center for Health Research has found that in a recent year, half a billion medical devices were recalled as, quote, "high risk" recalls because of the potential for death or very serious injury.

I do have a copy of your action plan, but nevertheless, item number two, explore regulatory options to streamline and modernize timely implementation of post-market mitigations, quite frankly, surprises me or alarms me, not surprises. It is alarming.

The policies you propose do not sound like they have the best interest of consumer safety and public health. It really sounds like the Commerce Department or a business community.

You are the Commissioner of a regulatory agency. I am really concerned about the ways in which you propose to modify FDA's oversight in the name of efficiency and not public health, in my view.

The changes have a potential for disastrous impacts on drug and medical device safety. I am just going to make that statement and move on to a question in the interest of time. This is a question with regard to drug approvals.

Again, alarmed by the recent media reports regarding the drug Nuplazid. Nuplazid received expedited FDA approval for the treatment of Parkinson's disease psychosis, hit the market in June of 2016. Since then, 1,000 adverse effects have been reported to the FDA, the number of reported deaths rising to greater than 700, a staggering amount of reports for a new drug that is unprecedented.

And just as concerning is the drug manufacturer is moving forward with clinical trials to get the drug approved for a larger patient population, dementia related psychosis.

In October the FDA granted breakthrough designation for this possible use, and thus, the drug will again go through a similar expedited review process. Shocking to me that this is going to be made available to an even larger patient population. I do not know why it should stay on the market, especially when the FDA has not determined it to be safe, and while the number of adverse events continues to soar.

You tell me what does it take for a drug like this to be taken off the market? How many more adverse events do we have to have reported? And how many people, quite frankly, have to die?

Why does the industry always take precedence over public health and safety, Dr. Gottlieb?

Dr. GOTTLIEB. Well, I appreciate the question, Congresswoman. We had a very similar exchange last year with respect to a medical device, as I recall, and two weeks ago we took action to make that medical device, a restricted medical device, conditioned sale on some stringent post market requirements.

Ms. DELAURO. That is Essure.

Dr. GOTTLIEB. Right. That is Essure.

Ms. DELAURO. And I appreciate that and spoke about that, but you know, we have had this conversation over and over again. I still do not know why it is on the market in this country when it has been taken off the market in other countries.

Dr. GOTTLIEB. I just want to, if I may, just address the medical device issue more generally.

You know, we are looking for additional ways that we could put in place additional pre-market controls, as well as better data collection in the post market so that when we do learn of a safety problem post approval, we could take action more quickly.

I think that along with seeing a lot of innovation in material science, science and technology, it is allowing us to have better medical devices that can address fundamentally new matters of public health.

I think our expectation should be that those same advances also lead to devices that are safer, and that is the recurring theme in the report we put out today. It is trying to create pathways to help build in a better assurance of safety in devices pre-approval, and in the post market when we do discover problems, discover them more quickly and have the tools to take action more quickly, as well.

That is what we are trying to pursue. It is a balance we are trying to strike.

With respect to the product that you are talking about on the drug side, I would rather not, if I can, get into a product-specific discussion other than to say that there is great care taken across the medical product continuum trying to balance risk and benefit relative to the medical condition, which we are trying to address.

And when you get into issues of unmet medical needs, it is the case that there sometimes is a higher tolerance for risk so long as the patient is properly informed of what those risks are.

But that is a very difficult balance to decide on a case-by-case basis. I will examine the product that you are talking about in particular. I am familiar with it, but I will go back and take another look at it.

Ms. DELAURO. Thank you, Dr. Gottlieb.

Seven hundred people have died. I think that that is a pretty startling event, and with regard overall to devices, we need to take a very hard look at what we are going to do about making a process efficient that leads to adverse outcomes.

Mr. ADERHOLT. Dr. Harris.

SODIUM

Mr. HARRIS. Thank you very much.

And I will try to yield back a little time, if possible, so other members can ask as well.

Thanks again, Dr. Gottlieb, for being in front of the subcommittee.

Just on some issues, and you can get back to me, and maybe we will submit questions for the record. On the salt issue, I am still a little worried that it looks like there is going to be this population-wide recommendation when we are actually going to individualize medicine, and you know, whether or not we differentiate that there are people for whom a low salt intake is actually not good now. It is probably a minority of the American population, but it is true.

So I hope when we come up with the guidelines that we take into account that individualized medicine is the future, and population-wide restrictions maybe are not good for some people.

FOOD GUIDANCES

With regard to the FDA guidance, there is a long list of FDA guidance that is necessary for food providers now to meet FDA regulatory deadlines. They include the new labeling requirements, small packaging issue, and the format requirements, the new dietary fiber definition, added sugars, listeria.

But in general, given the short timelines for compliance, particularly when a product reformulation is necessary, I hope the FDA will provide some enforcement discretion for food providers who act in good faith frequently. They want to comply, but in essence, specially when reformulation is necessary, hopefully there is enforcement discretion so that the people trying to comply with the regulations are not caught up in it.

TOBACCO

Just with regard to tobacco, I do want to thank you because the FDA Center for Tobacco Product recently has issued the do not sell order to rolling paper manufacturers regarding youth-related merchandise, and I know that was something that your administration accomplished, and that is important because obviously protecting children is a high priority for all of us.

With regard to the product approval process for cigars, especially the premium cigars, I know the FDA recently announced a change through the provisional substantial equivalence process, and my question is: will the FDA take a similar approach for newly deemed products under the regular SE process and prioritize products under that regular SE process that are, quote, less likely to raise different questions of public health, which is my understanding one of the changes in the provisional process.

So that is really the only question I am going to leave you with to answer today, and then I am going to yield back my time. We are going to do some QFRs later for the other issues.

Dr. GOTTLIEB. Thank you for the question.

You stated it correctly, Congressman, with respect to what we did on the provisionals in terms of not requiring some of the

provisionals to undergo any additional review in making a determination that they are less likely to raise significant questions of public health.

We did do that on the basis of a risk-based assessment in terms of how dissimilar they were to the predicate that they were referencing in the application, and we were able to make that determination.

We would take a risk-based approach across a continuum of tobacco products. So it would certainly be the case that in terms of how we would treat a regular application, as well. The level of regulatory touch would be adjusted based on the novelty of the product and how likely it is to raise new questions of public health.

I think one of the critical things to point out is that as we are working into this process, and this is a relatively new program, agencies never had this authority before. We are learning a lot of new things about how to make these scientific assessments, and that is allowing us to make easier calls.

So, for example, with the provisionals, we were able to exempt the cigarettes that had the new fire-resistant paper because we made the determination that the existence of that paper alone is not likely to change the characteristics of the cigarette in a way that is going to be more harmful to the consumer.

That is something that it took time for us to figure out that basic scientific principle as we got more familiar with the paper and the nature of the cigarettes themselves.

So we are able to make determinations in a more efficient way as we get smarter about the science.

Mr. HARRIS. Thank you very much, Doctor.

I yield back.

Mr. ADERHOLT. Ms. Pingree.

ADDED SUGARS

Ms. PINGREE. Thank you very much, Mr. Chair.

Thank you, Commissioner Gottlieb, for being with us today and for your work on a whole variety of things. We have had topics here, obviously, ranging from food safety to addictive substances, all critically important.

I want to address something slightly different since we have a limited amount of time, and I have a variety of other questions that I will certainly be glad to submit for the record, but I do appreciate you have been very responsive to our questions in the past and are willing to pick up the phone any time, and that is very helpful.

I want to talk a little bit about added sugars, and while I am very supportive of the work you are doing on the nutrition innovation strategy, I think that is really great that you have taken that on, and I know it can be controversial at times, but moving head on, and I think people totally deserve to understand exactly what is in the food that they eat.

I am a little concerned about the added sugar standard, and while I am happy to have added sugar as a labeling issue, in most products I think about it from the side of the small to medium size farmer, farmers generally, and how it is impacting maple syrup and honey.

I learned, I think, last year in the committee that you make your own maple syrup. So that is very impressive. I know you know the product well, but in Maine, maple syrup contributes about $30 million to the Maine economy. We are third in the Nation in maple syrup production, and we actually are proud to say we have the highest maple syrup yield per tap. Maybe that will change as the climate changes, but so far, we are in a good place.

I brought you a little bottle from Kenny's Sugarhouse in Maine in case you are running out of your own supply, but just so you can taste how delicious it is.

In the guidance in February on added sugars, the guidance shows that honey and maple syrup, which are obviously single ingredient products, must label their sugars "added sugar." There is, I know, a provision, and you and I have talked about it a little bit, that you can put an obelisk on there and then some added information.

I guess what I am saying is I think it is going to be very confusing for the consumer, and it is particularly confusing I would say in the honey side because there is so much fraudulent honey. I do not have the numbers, but I think it is one of the highest likely to be fraudulent products where just sugar water or other products are used and sold as honey.

So you have already got some confusion about is the honey real or not. Then you say "added sugar." Then somebody is wondering is that just really sugar or what is going on?

So anyway, we may not resolve this today, but I just want to make it really clear that I think calling a sweetener product something with added sugar in it has the potential to raise a lot of concerns in a time when consumers are very concerned about their food.

And for us, looking at it as a State where we produced a lot of honey and maple syrup, I think we just want to understand what was your rationale to do that on a sweetener product, while it is particularly appropriate on anything that literally does add sugar.

Dr. GOTTLIEB. Yes, Congresswoman, part of our rationale or a lot of our rationale is driven by the statute, and the statute itself is prescriptive in certain places, and so we are interpreting the law and the regulations as they exist.

We recognize that there are concerns, and you have expressed them well here today, about the potential for confusion here. The guidance that articulates our approach to this with the obelisk is out for public comment. We recently, I think, on Friday extended the comment period another 90 days.

So we are certainly going to take into consideration this kind of feedback, which we have been getting, and reconsider or take into consideration this perspective in what we ultimately choose to do here.

But the point is well taken, and you know, I have heard the concerns, and we will try to see what we can do to address them.

Ms. PINGREE. Great. Well, thank you for extending the comment period. I am sure anyone from our State or other maple syrup and honey producing regions will want to weigh in, and we will look forward to having further conversations about it.

And please enjoy your Maine maple syrup.

Dr. GOTTLIEB. Thank you.
Mr. ADERHOLT. Mr. Young.
Mr. YOUNG. Thank you, Mr. Chairman.
Nice to see you again, Doctor.
Dr. GOTTLIEB. Good to see you.

MEDICAL MARIJUANA

Mr. YOUNG. I have got about 15 questions, and I am not going to get through them all. So I will be submitting some for the record, Mr. Chairman.

But I want to talk about the opioid crisis and alternatives to treating chronic pain. Medical marijuana is talked about a lot. States are doing their own things.

Do you see any kind of derivative or form within marijuana to be helpful to ease chronic pain?

Dr. GOTTLIEB. Well, we see derivatives of medical marijuana both being approved as drugs in certain clinical situations, as well as in development right now. In fact, this week we are having an Advisory Committee with respect to one product that is a Cannabidiol (CBD) as a derivative of marijuana for the treatment of rare forms of epilepsy.

So there is potential that the active ingredients in marijuana might serve to be useful therapeutics in certain situations. They need to be put through an appropriate regulatory process and a scientific process that evaluates them for those purposes. FDA is very open to considering those opportunities and those applications.

Mr. YOUNG. To be put through the regulatory process, you need a lot of research out there to see what can be done with the plant and what is effective, maybe not effective. That research comes about more prominently and easily by moving it from a Schedule 1 to a Schedule 2 drug, I would imagine, or Schedule 3.

Do you have any thoughts on that? Has the administration come down with any statement of an administration policy regarding moving marijuana from a 1 to a 2 or a 3?

Dr. GOTTLIEB. I am not aware of any position the administration has taken on moving marijuana out of Schedule 1. It is certainly something Congress could take up if Congress chose to do it.

As you know, there is a pathway to evaluating even Schedule 1 drugs and studying them, and there is a supply that is available for companies that do want to study botanical marijuana or the derivatives of marijuana, despite the fact that it is a Schedule 1 product.

Mr. YOUNG. Because the train has left the station on this issue. You see a lot of what States are doing, and overseas as well, with studies and research. I was just wondering your general thoughts on it. I will not ask you your personal thoughts.

Dr. GOTTLIEB. Well, my general thoughts on it are that——

Mr. YOUNG. Unless you want to give them.

Dr. GOTTLIEB. Well, I will give you my general thoughts, and I am not going to duck the question. My general thoughts are that the best way to deliver an active pharmaceutical ingredient is in a measured dose in a form where you can purify the ingredient and you know what you are getting, and you can demonstrate a dose effect, and you can provide a reliable treatment to a patient.

And that generally is probably not going to come from something that is smoked. Rolling something up in a piece of paper and lighting it on fire and smoking it is not the most efficient way to deliver an active pharmaceutical ingredient. I cannot think of another drug that we deliver that way at least therapeutically.

Obviously, recreationally people take drugs that way, but you want to make sure the patient is getting a reliable dose and a reliable effect with each administration.

And also the lung itself is not a very efficient drug delivery platform. We generally would prefer not to deliver drugs through the lung unless we were treating the lung in some fashion.

Mr. YOUNG. I appreciate you clarifying that because I think there are some misnomers out there that inhaling or smoking is the best way to get any kind of benefits from the plant.

RARE DISEASE THERAPIES

One last quick question. Drug development for rare disease therapies can be especially complex because of small population sizes that make traditional clinical trials infeasible. FDA has helped develop novel approaches to review treatments for a number of rare diseases, including cystic fibrosis, a rare genetic disease that causes progressive lung damage and life-threatening lung infections.

Only 30,000 people in the U.S. have cystic fibrosis. Can you speak to the agency's current thinking about how he can ensure treatments are safe and effective as clinical trial designs are updated to accommodate in this new paradigm?

Dr. GOTTLIEB. I can speak more generally to just how we develop drugs in a paradigm where you are targeting drugs to very small populations, and there are a number of measures that we have taken with respect to clinical trial design, but one of them is in the budget, and one of them is the new initiatives that we are highlighting today and asking for resources around, and that is to try to develop natural history models to model the behavior of patients who have a rare disease.

So, for example, if you think of a patient with a Duchenne muscular dystrophy or myotonic dystrophy, generally they have a predictable course in terms of their decline in function. We ought to be able to model that and use that model as a placebo arm in trials to make the trials and the development process more efficient.

Sorry, Mr. Chairman. I heard. I am sorry.

Mr. YOUNG. I will have some questions for the record.

Mr. ADERHOLT. Yes, and I apologize, too. It is out of our control.

Mr. Pocan.

DRUG DEVELOPMENT

Mr. POCAN. Thank you, Mr. Chairman.

And thank you, Commissioner. I want to echo our ranking member's comments about your accessibility. I do really appreciate that.

In fact, over the break, we had a sit-down with a bunch of biotech life science companies, Kevin Conroy and others—I know you know Kevin—had helped put together.

You know, in Madison, Wisconsin, there are not a lot of Trump Administration officials that are especially popular. Among almost

all of the companies that work with the FDA, we have had really good feedback. So I just want to let you know that almost to the company, they are really appreciative.

The one issue that did come up though is a lot of the companies I am dealing with are a lot smaller, and just the amount of money that it takes to go through the regulatory process and keep floating while they are going through that has become a burden for some companies.

I was just wondering your reaction about what we can do to help some of those smaller companies that are trying to stay afloat while that process takes as long as it does, what we might be able to do to help streamline that process.

Dr. GOTTLIEB. I appreciate the question. I think it is underappreciated what the true cost of drug development is. We think about the cost of drug development as the cost of doing the clinical trial, but if you are trying to finance a drug development program, as many of you know, I was on the other side of this working with a venture capital firm before I came into this position.

The biggest cost when you model out what your costs are going to be is the time cost of capital and the risk because you have to adjust your model for what the degree of risk is in the drug development program in terms of trying to think of what your costs are and what your expected return needs to be.

And I think FDA is uniquely positioned to try to address those two issues because to the extent we can provide more clarity, more certainty about what the objective measures are going to be on which we assess risk and benefit, we can help reduce not only the time cost of capital, the time it takes to do the programs, but the risk inherent in the programs.

You are not shooting at a moving target. You know the target you are shooting at.

What I talked about at the outset in my oral comments today, trying to get more disease specific guidance, is directly on point to try and address these issues, and I think if I was to point to one thing I think we can do it is to try to get out more guidance about what the objective measures are so we can reduce the cost and reduce the uncertainty.

KRATOM

Mr. POCAN. All right. Thank you. I just want to make a quick comment. I know we have talked about alternatives for pain management, which everyone is talking about opioids now again. We had talked about the issue of kratom, the worry that it could get to Schedule 1, and whether or not there is going to be research or not.

Interestingly, when Dr. Volkow from the National Institute of Drug Abuse was before another subcommittee, they kept referring to kratom as a synthetic, and as you know, it is a plant. It is not a synthetic, which I think is part of the problem, why people have been looking at it, because it is used in some synthetic forms of heroin.

So it is kind of like if you took every ingredient in something and looked at it wrong. So I hope that we can continue that conversation. I appreciate the advice you gave me, and we are going to pur-

sue that through the appropriations process, but I just want to state that.

GENERIC DRUGS

The last area, if I can, in the minute and 15 seconds left, prescription drug prices, specifically some insulin. There is a product called Humalog, which has had big, big increases in insulin cost. Yet we have had a hard time finding generic equivalents.

And there are some questions about if we are aware if there are any applications for substitute generic insulins that are pending with the FDA and what that status might be.

Are you aware of any generic companies having difficulty obtaining samples needed to show that a generic product works the same as a brand name insulin?

I think I saw your agency said you had about 150 inquiries on sample locking by brand name companies, and if you could just talk about the priority because I know you have talked about it to me personally, about trying to make sure we are getting generics to the market faster, but specifically in this area.

Dr. GOTTLIEB. We are aware of companies, generic companies, having problems getting access to the samples they need and the doses they need in order to run the studies that are required for FDA approval of a generic drug, and that is a big concern of ours because I think the system is dependent upon their ability to run those studies.

With respect to the insulins more generally and not to comment on this specific drug, but just generally speaking, they are regulated as drugs. We are trying to put more guidance on how to genericize these complex drugs.

These insulins are going to be moving to the biosimilar pathway, and we are also going to be putting out very soon a suite of policies that address how to bring on biosimilars to the market as well.

So this is something we are acutely focused on as one element of how we are bringing more competition to the market.

Mr. POCAN. All right. I thank you.

Mr. ADERHOLT. Thank you, Dr. Gottlieb, for being here, and I apologize for the schedule today and apologize to the other members of the subcommittee.

Like I said, this was out of our control and came at the last minute, but the administration has a briefing on Syria, of course, and I know a lot of members are very interested in that, and certainly it is an important issue that we are dealing with.

So thank you for your time being here today. I know a lot of members will submit questions for the record, and we appreciate your diligence in getting responses back to them.

So with that, the subcommittee is adjourned.

QUESTIONS FOR THE RECORD
FOOD AND DRUG ADMINISTRATION
FY 2019 BUDGET HEARING
APRIL 17, 2018

QUESTIONS SUBMITTED BY CHAIRMAN ROBERT B. ADERHOLT
FDA Priorities in the New Administration

1. Please inform the Committee of FDA's top five most pressing issues or priorities in fiscal year 2018 and fiscal year 2019.

Response: The Agency has been busy on many fronts and FDA expects that to continue into fiscal year (FY) 2019. FDA's top five most pressing issues or priorities in FY 2018 and FY 2019 include:

I. Reducing the burden of addiction crises that are threatening American families: both tobacco and the opioid crisis.
II. Leveraging innovation and competition to improve and broaden access to healthcare and advance public health goals.
III. Empowering consumers to make better and more informed decisions about their diets and health and expanding opportunities to use nutrition to reduce morbidity and mortality from disease.
IV. Implementing the 21st Century Cures Act (Cures), which has been a top priority of the Agency the past 16 months.
V. Strengthening FDA's scientific workforce and its tools for efficient risk management.

Opioids
One of the Administration's highest priorities is combatting the ongoing crisis of opioid addiction. As part of this commitment, FDA is reexamining the Agency's authorities and policies in this area and working to ensure that FDA has the proper tools and resources to address this epidemic as it continues to evolve.

As part of the FY 2019 Budget, the Administration is requesting resources to address the opioid addiction crisis, including $10 million for FDA activities. These resources would support, among other things, investment in FDA regulatory science activities to develop tools to stem the misuse and abuse of opioids. These resources also would enable FDA to provide technical assistance related to clinical study design related to medication-assisted treatments.

Drug Competition Action Plan
In May 2017, FDA announced the Drug Competition Action Plan. Increasing patients' access to more affordable prescription drugs is a top priority for Americans and one that the Administration is dedicated to addressing. The plan has three overarching principals: eliminating gaming by branded companies that can delay generic drug entry; resolving scientific and regulatory obstacles that can make it difficult to obtain approval of generic versions of certain complex drugs; and improving the efficiency and predictability of FDA's generic review

process to reduce the time it takes to get a new generic drug approved and lessen the number of review cycles undergone by generic applications before they can be approved.

Foods (Nutrition Strategy and implementation of the FDA Food Safety Modernization Act (FSMA))
FDA is diligently working on number of fronts, and the vital work FDA does provides Americans with better ways to improve their health and welfare and empowers consumers to make informed choices about the products they use and the foods they feed to their families. The Budget will help FDA maintain and complement our current efforts, as well as provide a renewed focus and investment in some of the Agency's and the nation's top public health priorities.

FSMA implementation is well underway. The effective dates for six of the seven foundational FSMA rules have gone into effect for some portion of covered industry. The exception is the final rule entitled, "Mitigation Strategies to Protect Food Against Intentional Adulteration," which has an initial compliance date for the largest businesses of July 2019. Inspections are ongoing under most FSMA rules except, in certain cases, where FDA has postponed them to give industry more time to prepare and receive additional outreach and assistance from FDA.

Medical Product Innovation (Cures, New Initiatives)
Implementation of Cures has been another top priority of the Agency over the past 16 months. Cures includes provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The new law complements many efforts underway at FDA. All of these efforts are aimed at transforming the way FDA supports product development and marketing authorization and maintaining FDA's gold standard for safety and effectiveness.

The Budget includes an increase of approximately $400 million in additional resources to advance initiatives to promote public health and spur growth in the domestic economy. These new initiatives provide a renewed focus to some of the Agency's most intensely followed issues—facilitating regulatory pathways to increase patients' access to safe and effective drugs, biologics, and medical devices, and access to higher quality compounded drugs for the patients who need them; better informing patients and providers about pre-and post-market safety of medical products; and, increasing competition among generic drugs in order to lower the cost of generic drugs.

FDA's FY 2019 Funding Initiatives and FY 2018 Funding Initiative Status

As I noted in my opening statement, FDA is requesting the most discretionary dollars in its history without the typical budget gimmicks. It is tempting to tell us that everything in the budget request is equally important. On the surface, it is challenging to say that new drug development might be a more impactful investment than an equally important initiative which may advance medical devices.

2. Back in 2011, Dr. Woodcock was quoted as saying that "manufacturing experts from the 1950's would easily recognize the pharmaceutical manufacturing processes of today." Is this

still true seven years later? If so, please provide us a real world example of how this might work, what role does FDA play, and what might be a measurable outcome from this effort.

Response: To a large extent the statement still remains true; however, FDA is also seeing examples of companies adopting innovations in pharmaceutical manufacturing. A first step to improving manufacturing processes is for a company to commit to ensuring quality and recognizing that quality-focused efforts can be both cost-effective and beneficial to patients. As one step, a company can start to use process capability and other quality indicators as measures of quality, something the pharmaceutical industry has widely adopted over the past several years. Another powerful step is committing to a culture of quality and continuous improvement, which can include embracing innovative manufacturing technologies.

For our part, regulators need to create an environment that appropriately balances risks with regulatory expectations, as well as to serve as a facilitator to help industry with its development and implementation of new technologies. FDA's Center for Drug Evaluation and Research created the Emerging Technology Program to promote the adoption of innovative approaches to pharmaceutical product design and manufacturing that have the potential to make a significant contribution to enhancing product quality and ensuring availability of medicines to patients who need them. The program includes early face-to-face meetings to discuss technical and regulatory challenges related to development of the technology (even before the drug molecules or candidates are identified), and allows FDA staff and industry to work together early to gain experience with the technology prior to a regulatory submission. The Emerging Technology Team (ETT) has considered a wide range of innovative technologies, such as continuous manufacturing, 3D-printed drugs, isolator technology, advanced process control technologies, and novel analytical testing methods. The ETT's work depends on submissions from industry as well as the particular technologies being proposed, which makes it difficult to assign a particular performance metric; however, FDA has received positive feedback from participants in the program and there have been observable outcomes demonstrating the success of the program.

As an example from just one of the technologies that ETT has considered, FDA has approved four applications using continuous manufacturing processes. Assessment of the applications benefitted from the companies' early engagement with ETT, and in some cases the applications were reviewed using an expedited program (as products that received breakthrough therapy designation) and the approvals occurred well before the respective user fee goal date.
With respect to complex biological products, the use of continuous manufacturing and other innovative manufacturing technologies has recently begun to be explored. Improvement in cell lines and expression systems, combined with application of continuous manufacturing, could potentially be transformational, facilitating increased agility for the development and improved availability of products such as vaccines and gene therapies. Research regarding the application of advanced manufacturing technologies to these complex biological products is necessary to help develop and make technologies accessible to industry in the near term, and to help bridge the gap between discoveries in academia or industry and implementation by industry. To support these goals, FDA's Center for Biologics Evaluation and Research is supporting research involving the application of novel technologies for advanced manufacturing of complex biologic products, and innovative analytical approaches to improve product manufacturing and quality.

3. In terms of the bigger picture and the Administration's priorities amongst the ten funding initiatives in the budget request, please provide a ranking in terms of the initiatives that have the potential to deliver the greatest public health impact?

Response: The FY 2019 Budget includes $400 million for initiatives aimed at supporting new and ongoing efforts to foster more investment and innovation in the development of therapeutics and diagnostics that target unmet medical needs; advance drug and device competition; stand up new domestic industries – such as pharmacy outsourcing facilities; and create more modern, domestically-based manufacturing, including continuous manufacturing of drugs and biological products, including vaccines. These manufacturing platforms can bring more businesses back to the U.S., help lower drug and device development costs, and reduce the risk of shortages. Investing in these initiatives will help the FDA advance goals that we all share: improved treatment and diagnostic options for patients; lower healthcare costs; the development of new industries that will lead to U.S.-based jobs; and manufacturing advances that are more reliable, lower cost, and high quality.

As the Agency that regulates $2.4 trillion of consumer products, FDA can think of no better place to make an impact with taxpayer funds. While each of the proposed FY 2019 initiatives are important, FDA would highlight those that the Agency believes could be the most fundamentally transformational for FDA:

Continuous Manufacturing
The FY 2019 Budget Request for FDA includes $58.2 million to promote domestic manufacturing, including continuous manufacturing. These technologies have great potential to accelerate new, more targeted therapies, enhance product quality, and bolster stability in the U.S. drug supply to meet domestic and global needs. These new manufacturing platforms may be especially important in the development of personalized medicines and innovations in cell- and gene-based therapies and vaccines.

New Medical Data Enterprise
The FY 2019 Budget includes $100 million to advance the use of real-world experience to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. Expanding FDA's capacity to utilize real-world evidence to evaluate the pre- and post-market safety and effectiveness of medical products will generate processes that could improve the efficiency of the regulatory process, better inform patients and providers about pre-and post-market safety, reduce some of the burdens that drive up the time and cost required to bring beneficial innovations to the market, and address barriers that can make certain important safety and effectiveness information around the real-world use of products hard to collect and evaluate.

Knowledge Management System for New Drug Development
The FY 2019 budget includes $57.5 million to build a knowledge management system and portal to existing and developing information on drug development and previous regulatory decisions. This platform would enable FDA to store and manage the collective experience of our medical review staff to identify how decisions are made across different functions, the scientific precedents established in the course of the review process, and the knowledge FDA develops.

4. Please provide a detailed breakdown of the cost drivers for the following initiatives: "Create a New Medical Data Enterprise", "New Platform for Drug Development" and "Promote Domestic Manufacturing". The cost drivers should include the cost of personnel and benefits, contractual services, acquisition of assets, and other categories.

Response:

	Costs				
	FTE Costs	Support Contracts	Capital Expenditure	Other	Total
New Medical Data Enterpise	**$3,996,874**	**$95,653,126**	**$350,000**	**$0**	**$100,000,000**
CDER (non-add)	*$568,874*	*$22,431,126*	*$0*	*$0*	*$23,000,000*
CBER (non-add)	*$1,068,000*	*$21,932,000*	*$0*	*$0*	*$23,000,000*
CVM (non-add)	*$980,000*	*$6,670,000*	*$350,000*		*$8,000,000*
CDRH (non-add)	*$1,380,000*	*$44,620,000*	*$0*		*$46,000,000*
New Platform for Drug Development	**$5,374,185**	**$72,125,815**	**$0**	**$0**	**$77,500,000**
CDER (non-add)	*$1,422,185*	*$56,077,815*	*$0*		*$57,500,000*
HQ (non-add)	*$3,952,000*	*$16,048,000*	*$0*	*$0*	*$20,000,000*
Promote Domestic Manufacturing	**$2,852,874**	**$43,757,126**	**$11,620,000**	**$0**	**$58,230,000**
CDER (non-add)	*$568,874*	*$34,431,126*	*$0*		*$35,000,000*
CBER (non-add)	*$1,068,000*	*$2,312,000*	*$11,620,000*	*$0*	*$15,000,000*
NCTR (non-add)	*$0*	*$2,230,000*	*$0*		*$2,230,000*
HQ (non-add)	*$1,216,000*	*$4,784,000*	*$0*	*$0*	*$6,000,000*

5. Please provide a list and status of all funding increases in the fiscal year 2018 Omnibus.

Response: The fiscal year (FY) 2018 bill provides a total program level of $5.4 billion. The FY 2018 total funding includes $3.0 billion in budget authority and $2.4 billion in user fees. The budget authority reflects an increase of $164.7 million over FY 2017, which includes increases of $12.3 million for Food Safety, and $152.4 million for Medical Product Safety, including an increase of $40.0 million in no-year funding for the 21st Century Cures Act Innovation Account, and $94.0 million in one-time funding to process opioids and other imports through International Mail Facilities (IMFs). The bill provides $2.4 billion in user fees, including medical product user fee funding levels consistent with the Food and Drug Administration Reauthorization Act.

Key Initiative Increases:

Food Safety – an increase of $12.3 million for Food Safety compared to FY 2017

- +$0.5 million for botanical dietary supplements research
- +$2.8 million for fish decomposition study
- -$1.5 million for consumer education and outreach regarding biotechnology (was $3.0 million in FY 2017)
- +$10.5 million for Food Safety Modernization Act Cooperative Agreements supporting produce safety

Medical Product Safety – an increase of $152.4 million for Medical Product Safety compared to FY 2017

- +$0.5 million for botanical drug and interaction research
- +$0.4 million to support the Critical Path Initiative
- +$2.5 million to help facilitate 503B Bulks compounding work (one-time, annual funding)
- +$0.3 million to help expedite the clearance at ports and distribution hubs of medical products
- +$9.7 million for animal drugs and feeds program to manage increased workloads
- +$15.0 million for the Oncology Center of Excellence
- +$94.0 million in one-time funding for processing opioids and other articles imported or offered for import through IMFs to remain available until expended.
- +$40.0 million increase for the 21st Century Cures Act Innovation Account in no-year funding for a total of $60.0 million.
- -$10.0 million for Emerging Health Threats

FDA submitted the FY 2018 Omnibus Operating Plan and Narrative, as required, to the Appropriations Committees on May 2, 2018 and is working to obligate the funding increases.

FDA's Sodium Policy & Ongoing National Academy of Science Study

I am deeply concerned about the future issuance of sodium guidance and recommendations. The National Academies is currently conducting a Dietary Reference Intake review of sodium and potassium which will have a long-term effect on federal nutrition policy. Based upon some of your comments last month, FDA has already made up its mind. I also worry that the conclusions of this review have already been baked. There is definite bias amongst members of the review panel, which lead all of the Majority Members of this Subcommittee and most of the Majority Members on the Labor-HHS Subcommittee to send a letter to the Academies asking for a more balanced panel. They responded by adding members with very little to no experience in the subject matter. Two of the panelists published an opinion piece on sodium in the March 7th Journal of the American Medical Association.

6. How is it not a complete conflict of interest to publish such an article when both authors are currently sitting on the panel that is supposed to be objective in determining proper sodium intake levels?

I admit that I'm not a medical doctor or researcher, but it's obvious this is not an objective process that will be open to properly considering all of the science. I am disappointed the Academies did not listen to Members of Congress and establish a more balanced panel. So I am concerned that you are also moving ahead with a sodium reduction agenda. I acknowledge too much of anything can be a bad thing, but the science is emerging and some studies show severe decreases in sodium can cause more harm than good. As this process continues, I would hope FDA as a sponsoring agency of the DRI would want to ensure the objectivity of the committee panel and that all scientific evidence is being considered.

Response: For over 70 years, the National Academies has served as independent advisors to the U.S. Government in the development of nutrient reference values, including the Dietary Reference Intakes, or DRIs. Evidence-based nutrient reference values are critical in assisting FDA and other federal agencies to develop scientifically sound nutrition policy. The Academies have robust policies and procedures to ensure proper composition and balance of its committees, as well as requirements under the Federal Advisory Committee Act to ensure the scientific integrity and independence of the committee process and allow for public input into committee activities. Furthermore, consensus committee reports undergo an external peer review process. Our agency relies on the Academies and supports them in carrying out these requirements in a manner that ensures the DRIs can be used for public health policy needs.

7. Why is FDA making statements about its plans to move forward with sodium reduction policies, rather than utilizing its oversight role as a DRI committee sponsor to ensure that balance is restored to the committee?

Response: The Academies have robust policies and procedures to ensure proper composition and balance of its committees, as well as requirements under the Federal Advisory Committee Act, to ensure the scientific integrity and independence of the committee process and allow for public input into committee activities. Furthermore, consensus committee reports undergo an external peer review process. Our agency relies on the Academies and supports them in carrying out these requirements in a manner that ensures FDA can use the DRIs for our public health policy needs. If any changes to the current DRI for sodium are made, FDA would adjust our targets accordingly.

8. You have said FDA will update the short-term sodium targets in 2019. Do you anticipate issuing a new draft short-term guidance document for comment or will the agency move to finalize the guidance from the Obama Administration?

Response: FDA is committed to advancing short-term voluntary sodium targets. There remains no single more effective public health action related to nutrition than the reduction of sodium in the diet. Researchers have estimated that reducing sodium intake by one-half teaspoon a day could prevent nearly 100,000 premature deaths a year, as well as up to 120,000 new cases of coronary heart disease, 66,000 strokes and 99,000 heart attacks. FDA's draft voluntary short-term targets are aimed at helping to support reducing average sodium consumption from 3,400 to 3,000 mg per day – which is still well above the current federally recommended limit of 2,300 mg per day. FDA is currently carefully reviewing all public comments in response to draft guidance relevant to the short-term targets. Major food manufacturers, such as Mars Inc., Nestlé,

and Unilever, are reducing sodium in their products and have expressed support for FDA's efforts in their comments on the draft sodium reduction targets. FDA is a co-sponsor of the National Academies' sodium and potassium Dietary Reference Intakes update, along with USDA, CDC and NIH. FDA will consider the findings of the updated report, as well as comments on the draft guidance, in determining next steps on sodium.

Food Safety Recalls & the HHS IG Report

With the recent recall of over 200 million eggs for salmonella contamination, I wanted to take a minute to discuss food recall initiation processes at the FDA. Given the size of the recall and the producers operation, it was good to see the producer promptly recall the eggs voluntarily therefore limiting the number of salmonella infections. This recall provides an opportunity to revisit FDA's food recall initiation process. I am sure you are familiar with a previously issued HHS Inspector General report indicating FDA did not have an 'efficient and effective' food recall initiation process. Having an adequate food recall process is imperative towards helping ensure the safety of our food supply and failure to have an effective food recall system in place potentially exposes consumers to hazardous products or foods.

9. In dealing with potentially hazardous product recalls, timeliness is critical. The IG report determined that FDA could not always ensure that firms initiated recalls promptly and did not always evaluate health hazards fast enough. What is the FDA doing to improve the timeliness of recalls and what role has the establishment of the Strategic Coordinated Oversight of Recall Execution (or SCORE team) played in improving timeliness?

Response: FDA and food establishments have an affirmative obligation to act quickly to keep people from getting sick or being harmed when food in the marketplace may be unsafe. FDA is committed to continuously improving its practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to protect consumers. FDA's Strategic Coordinated Oversight of Recall Execution (SCORE) team is charged with reviewing complex or unusual food safety situations and determining the proper action. In the cases brought to the team, SCORE has helped determine an appropriate course of action and shorten recall timeframes, helping to get the products off the market faster. SCORE also has helped improve tactical planning, leading to additional inspections and sampling assignments, and to getting the word out to more consumers about potentially dangerous products.

FDA has taken several other steps to help improve recall timeliness and effectiveness. As part of the FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule, where a hazard analysis identifies the need for a preventive control, the facility must have a written recall plan that includes procedures to notify consignees, to notify the public when necessary, to conduct recall effectiveness checks, and to appropriately dispose of recalled product.

Within FDA, field recall coordinators in the Office of Regulatory Affairs now specialize in specific FDA-regulated product areas. The Agency also has committed to improving how it provides information for the public, including expanding the type of information provided for certain recalls, such as retail locations where recalled food was sold.

10. Is the FDA working to improve recall communications, including but not limited to, establishing timeframes for a voluntary recall with firms to make sure they proactively take appropriate action to protect public health?

Response: FDA is focused on improving recall communications to consumers in several ways. For example, the Agency now publicizes recalls in the FDA weekly enforcement report prior to classification, which makes information about the recall available to consumers sooner. Also, FDA recently released a draft guidance that clarifies and updates information related to the use, content, and circumstances for issuing public warning and notification for recalls. Finally, earlier this year, the Commissioner announced that FDA will identify ways to share additional information with consumers during recalls, such as identifying specific stores where recalled food may have been sold. Regarding recall timeframes, on a case-by-case basis, FDA may establish timeframes for companies to initiate recalls voluntarily, because a voluntary action is often the quickest and most effective way to protect public health.

10a. The report also identified concerns with the system FDA uses to monitor recall activities. Specifically, the monitoring system RES, does not properly track the date FDA identities a product as potentially hazardous. Therefore FDA cannot adequately track the time between identification of a potentially hazardous product and actual recall. What is the FDA doing to improve the data system used for tracking recall information?

Response: The Recall Enterprise System (RES) is the internal database specifically designed to oversee FDA monitored recalls. FDA recently made several improvements to RES to allow for more complete evaluation of recall timelines. Specifically, the Agency added important monitoring fields, including the Recall Determination Date, the Recall Audit Check Assignment Date, and the Recall Audit Check Completion Date. These additional fields enhance the ability to monitor open recalls to ensure that a recall is completed and terminated promptly.

In addition to the improvements above, FDA performed a baseline audit of recalls and identified 14 critical control points in managing recalls. FDA is now actively monitoring both the dates and data in this system related to the 14 critical control points to identify recalls that may need additional resources or support to remain on track.

FDA is committed to continuously improving our policies and practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to best protect consumers.

Opioids Policies & Actions

According to several media outlets in my home state, Alabama has four cities that rank in the top 15 in the Nation with the highest rates of opioid abuse – in fact, four out of the top 11. I have one of those cities in my district and two very close to my district. While we are fortunate that we are not one of the states with the highest drug overdose rates, the abuse is a real concern to the communities in my state and across the country. Your budget seeks a $10 million increase to help accelerate the development of non-opioid treatments, devices to treat chronic pain instead of prescriptions and generic versions of abuse deterrent formulations.

11. Dr. Gottlieb, please give me an overview of FDA's ongoing efforts to help reduce the number of opioid prescriptions and how this funding request may help to reduce opioid abuse in general?

Response: FDA is actively seeking to promote and foster innovation that could lead to non-opioid treatment options and options that reduce the risk of opioid abuse. In the last 5 years, FDA has cleared, granted or approved more than 200 510(k), de novo, and premarket approval (PMA) devices related to the treatment or management of pain, including 10 new or novel technologies. These devices are indicated for the treatment or management of moderate to severe chronic intractable low-back, limb, or trunk pain, osteoarthritis pain or chronic or episodic migraine, or as an adjunctive treatment for post-surgical and post-trauma acute pain, or pain associated with arthritis.

FDA is also working to promote the development of opioids that are harder to manipulate and abuse. FDA has approved 10 opioids with labeling describing abuse-deterrent properties and released final Guidance for Industry: General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products in November 2017 to assist sponsors planning to develop and submit an abbreviated new drug application (ANDA) to seek approval of a generic version of a solid oral opioid drug product that references an opioid drug product with abuse-deterrent properties described in its labeling. FDA intends to review any ANDAs for an abuse-deterrent formulation consistent with the recommendations set forth in the final guidance.

In addition, FDA will take steps to reduce the incidence of new addiction that's derived from the medical use of prescription opioids by encouraging evidence-based guidelines for appropriate dose and duration for some common procedures to promote the use of sensible prescribing.

12. As it relates to the funding Congress appropriated in FY 2018, your testimony mentions that the Agency plans to purchase new equipment and deploy the resources at or near the International Mail Facilities by the end of the year. How quickly do you expect to see results?

Response: FDA has begun the additional hiring in support of the International Mail Facilities (IMFs) utilizing the no-year opioids funding provided in the FY 2018 Omnibus Bill, but some hires will be dependent on securing additional space. In the interim, FDA is looking at bringing more staff on board, but locating them near the International Mail Facilities (IMFs), while the Agency works out additional space in the IMFs.

FDA expects to hire and train additional IMF-related staff, as necessary, and have them on board before the end of FY 2019. FDA will work closely with Customs and Border Protection (CBP) and the U.S. Postal Service (USPS) to secure additional space and infrastructure at the IMF facilities to accommodate the additional staff. Once additional staff are on board and they have successfully completed the requisite training, the Agency expects to increase annual mail examinations to 100,000 parcels.

FDA will deploy to the IMF facilities additional rapid screening tools to help identify products containing undeclared and/or non-permitted drug ingredients. Further, FDA is evaluating an enhanced version of a screening tool that identifies potential counterfeit products. The Agency expects to have additional screening tools, including the enhanced counterfeit screening tools, at each IMF facility by the end of FY 2018.

13. Please provide FDA's total resources – dollars and FTE – spent on the opioid epidemic for fiscal years 2016 and 2017 as well as planned expenditures for fiscal years 2018 and 2019?

Response: FDA allocated approximately $23.6 million / 96 FTE for FY 2016 and $42.6 million / 168 FTE for FY 2017 for opioid related activities. These activities include regulatory and technical review, policy and guidance development, research, compliance activities, education and outreach, and associated administrative support activities. These estimates do not include rent and infrastructure costs. FDA's existing opioid related activities are projected to be approximately $44.4 million / 173 FTE for FY 2018 and $43.8 million / 173 FTE for FY 2019. In addition, FDA will be obligating the majority of the $94.0 million appropriated for the Opioids-IMF Initiative in FY 2018 with the remainder in FY 2019 and beyond.

Bulk Drug Compounding Guidance

Just last month, FDA issued new draft guidance that addresses the clinical need for bulk drug substances by outsourcing facilities. This guidance represents an important step to enforcing the Food, Drug, and Cosmetic Act's restrictions on these substances. As the draft guidance explains, the use of bulk drug substances poses additional risks to patients, undermines the drug approval system, and it also disadvantages those facilities that are doing the right thing by compounding from FDA-approved drugs. But there remains a great deal of confusion among customers about what outsourcers are using, and what the additional risks are for patients.

14. I understand that the process described in the draft guidance may take time to complete. In the meantime, what is FDA doing now to make sure the market understands what you told the Energy & Commerce Committee back in January: that bulk drug substances may only be used when a patient needs a drug that cannot be compounded from an FDA-approved product?

Response: In March 2018, FDA issued a draft guidance, *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, to describe its proposed policy for evaluating substances nominated for inclusion on the list of bulk drug substances that outsourcing facilities can use in compounding ("bulks list"). If the guidance is finalized as written, one of the factors that FDA would consider when deciding whether to include a nominated bulk drug substance on the bulks list is whether there is a basis to conclude that the drug product proposed to be compounded needs to be produced using a bulk drug substance.

While the process of developing the 503B bulk drug substances list is underway, another provision of section 503B helps to mitigate concerns about outsourcing facilities compounding drug products when an approved drug is available to meet patients' medical needs. Specifically,

under section 503B(a)(5) of the Federal Food, Drug, and Cosmetic Act, an outsourcing facility cannot compound a drug that is essentially a copy of one or more approved drugs. FDA issued a final guidance, *Compounded Drug Products that are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, describing its policies with respect to that provision.

15. In the FY18 Statement of Managers accompanying the Omnibus, this Committee instructed FDA "to prohibit outsourcing facilities from compounding drug products from bulk ingredients when outsourcing facilities could otherwise be compounding from an FDA approved drug product," which is consistent with your own statements about what the law requires. While the new draft guidance is an important step toward establishing a process to evaluate bulk substances, what steps will FDA take to ensure the law is being adhered to as instructed by Congress?

Response: In March 2018, FDA issued a draft guidance, *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, to describe its proposed policy for evaluating substances nominated for inclusion on the list of bulk drug substances that outsourcing facilities can use in compounding ("bulks list"). If the guidance is finalized as written, one of the factors that FDA would consider when deciding whether to include a nominated bulk drug substance on the bulks list is whether there is a basis to conclude that the drug product proposed to be compounded needs to be produced using a bulk drug substance. Under the policy proposed in the draft guidance, if FDA determines, after reviewing public comment, that there is not a basis to draw such a conclusion, FDA would not include the bulk drug substance on the 503B bulks list.

While the process of developing the 503B bulks list is underway, another provision of section 503B helps to mitigate concerns about outsourcing facilities compounding drug products when an approved drug is available to meet patients' medical needs. Specifically, under section 503B(a)(5) of the Federal Food, Drug, and Cosmetic Act, an outsourcing facility cannot compound a drug that is essentially a copy of one or more approved drugs. FDA issued a final guidance, *Compounded Drug Products that are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, describing its policies with respect to that provision.

New Tobacco Initiatives – Regulations & Policy

Commissioner Gottlieb, I want to raise a topic with you that has been a heated issue on this Subcommittee, and that comes directly under your purview- tobacco policy.
First, I want to acknowledge and commend you for your actions to propose a comprehensive plan for a balanced approach to tobacco regulation last summer.

Secondly, I want to discuss where we go from here. In your own words during a recent statement on the announcement of a rulemaking for flavors in tobacco products, you stated that "we need to take every effort to prevent kids from getting hooked on nicotine" while simultaneously looking for ways to "help currently addicted adult smokers switch to potentially less harmful forms of nicotine-containing tobacco products".

News reports of a very concerning surge in youth usage of certain electronic nicotine delivery systems highlight the need for action to prevent this. At the same time, there needs to be certainty and flexibility for the small and medium sized businesses in this same industry to provide less harmful alternatives for adult smokers and prevent a complete consolidation of the marketplace.

16. Can you provide a brief update on the status of all the announced notices of proposed rulemakings related to your comprehensive plan for tobacco regulation that came out last summer?

Response: On March 16, 2018, FDA published an Advance Notice of Proposed Rulemaking (ANPRM) to obtain information to explore a potential tobacco product standard to set the maximum nicotine level in combusted cigarettes to minimally or non-addictive levels, including seeking input on the potential public health benefits and any possible adverse effects. Reviewing the science and hearing from stakeholders will help FDA determine whether and how it should take regulatory action. The comment period closes on June 14, 2018.

On March 21, 2018, FDA published an ANPRM to seek input on information relating to the role flavors play in tobacco products, including how flavors in tobacco products appeal to youth and the potential role that some flavors may play in helping some adult users transition away from cigarettes and how FDA should assess and balance these potential risks and benefits.

FDA will use the information received in response to the ANPRM, as well as relevant scientific research, to build on our past efforts to gather public input and the best available information as FDA explores all possible regulatory actions to address the public health concerns raised by flavored tobacco products. The comment period closes on June 19, 2018.

In March 26, 2018, FDA published an ANPRM to provide interested parties an opportunity to submit new or different information or data related to the definition of premium cigars and patterns of use of and resulting public health impacts from premium cigars. FDA will explore any new and different questions raised, and carefully consider any additional data submitted that could inform FDA's regulation of premium cigars.

Once the public has the opportunity to submit information and data, FDA will carefully consider any new and different questions raised that could inform FDA's regulation of premium cigars. FDA is seeking comments, data, research results, and other information that address the definition of premium cigars, the use patterns for premium cigars, and the public health considerations associated with premium cigars, which could inform FDA's thinking about the regulatory treatment of premium cigars. The comment period closes on June 25, 2018.
In addition, FDA is continuing to work on the proposed rule for the Substantial Equivalence pathway as well as the final guidance for Electronic Nicotine Delivery Systems (ENDS) under the Premarket Tobacco Product Application (PMTA) pathway.

17. What tools do you have at your disposal or can this Subcommittee provide to prevent and deter youth from accessing these new tobacco products that are sweeping our nation?

Response: FDA continues to use its authorities to prevent a new generation of youth from becoming addicted to tobacco products, including electronic nicotine delivery system (ENDS) products and other deemed products. FDA has several tools to address the issue in multiple ways, such as taking enforcement action, educating the public, and exploring potential rulemaking.

FDA continues to vigorously enforce youth access rules by conducting inspections to determine if retailers are checking identification and if they are selling tobacco products to minors. As of March 31, 2018, FDA has issued over 12,000 Warning Letters to brick and mortar and online retailers for selling deemed tobacco products (e.g., e-cigarettes, e-liquids and cigars) to minors.

On April 24, 2018, FDA announced several enforcement actions as part of a new Youth Tobacco Prevention Plan to stop youth use of – and access to – JUUL and other e-cigarettes. These actions include:

- issuing warning letters to 40 retailers for violations related to youth sales of JUUL e-cigarettes;
- conducting a large-scale, undercover nationwide blitz of retail establishments;
- sending an official request for information to JUUL Labs requiring the company to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of these products; and
- taking steps to foreclose online sales of JUUL and similar products to minors.

In October 2017, FDA expanded its national youth tobacco prevention campaign, "The Real Cost," to include messages about the potential dangers of using ENDS in adolescence. The initial digital ad educates youth ages 12-17 that using ENDS containing nicotine can "rewire" their brains to crave more nicotine. This effort is part of the Agency's comprehensive plan for tobacco and nicotine regulation, as well as ongoing efforts to educate youth about the risks of using tobacco products. FDA plans to launch a full-scale youth ENDS prevention effort under "The Real Cost" brand umbrella in September 2018. This advertising will run in highly-targeted, teen-relevant digital channels such as YouTube, Spotify, and Xbox. The messages will also be supported by new ENDS-focused content on "The Real Cost" website as well as content delivered through the campaign's teen-targeted social media channels.

FDA is also examining the use of flavors in tobacco products and the role they play in attracting youth. On March 21, 2018, the Agency published an Advance Notice of Proposed Rulemaking (ANPRM) to seek comment on the role that tobacco product flavors, including menthol, play in attracting youth, as well as the role they may play in helping some adult smokers switch to potentially less harmful forms of nicotine delivery. The information received in response to the ANPRM, as well as relevant scientific research, will build on FDA's past efforts to gather public input and the best available information as FDA explores all possible regulatory actions to address the public health concerns raised by flavored tobacco products.

18. How can we help to ensure that small and medium sized-businesses that provide harm reducing alternatives to adult smokers are able to cope with the regulatory costs associated with FDA regulations for these new products- specifically would some form of product

standards, a risk-based approach to the Pre-market Tobacco Approval process for new tobacco products, or a small business exemption and limitation for regulatory costs be a viable solution?

Response: On July 28, 2017, the Agency announced a new comprehensive plan and regulatory framework that includes: 1) exploring the reduction of the addictiveness of combustible cigarettes while 2) recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. Several steps and components make up each part, and to be successful, all these measures must be pursued together to allow FDA to address known harms while establishing a framework for sustainable regulation of all products going forward, including by encouraging innovations that have the potential to help smokers quit cigarettes.

To encourage innovations that have the potential to make a notable public health difference and to put foundational rules in place to provide increased clarity and efficiency for industry, the Agency has extended the premarket application compliance dates described in the deeming rule preamble for certain products. This additional time will especially benefit small and medium-sized businesses.

Specifically, FDA has announced its intent to defer enforcement of the premarket review requirements for certain new, newly regulated tobacco products:

- Compliance date for applications for combustible products on the market as of August 8, 2016 is August 8, 2021.
- Compliance date for applications for non-combustible products on the market as of August 8, 2016 is August 8, 2022.

The new revised timelines will allow the Agency time to explore clear and meaningful measures to make tobacco products less toxic, appealing, and addictive, as well as to develop potential product standards or other regulations to protect against known risks such as ENDS battery issues and concerns about children's exposure to liquid nicotine. The revised timelines also provide FDA the time to put key foundational rules in place and to undertake a series of internal improvements to make the product review process more efficient, predictable, and transparent, while upholding the Agency's public health mission. Each of these steps is critically important to achieving our goals, and must be approached as an overall, integrated plan to be successful.

FDA announced on April 5, 2018, that FDA is removing about 1,500 provisional Substantial Equivalence (SE) applications from review. The Agency did so after concluding that these products are less likely to raise different questions of public health. Therefore, the products will not undergo any further review and can continue to be legally marketed so long as they do not undergo further changes or so long as they do not fall under a few other exceptions that would cause FDA to pull them back into review. Along with this significant action, FDA continues to work towards finalizing the SE rule, which FDA noted as a priority in our July 2017 comprehensive plan announcement. Together, the removal of approximately 1,500 provisional SE applications from review and the SE rule itself, will be very helpful to small and medium-sized businesses.

Premarket review is one of FDA's most important consumer protection responsibilities. Consistent with our public health mission, it's important for the Agency to continue work on important foundational rules and to explore continued improvements and refinements to the product review program.

FSMA Projected Results of Investments & Implementation

The Government Accountability Office released a report in January of this year entitled "Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities." The report documents spending and shows a steady increase in spending for food safety due in part to Congressional spending increases. FDA has spent over a billion dollars a year since 2011. With increases of $36 million in FY 2017 and $10.5 million in FY 2018, FDA will likely spend $9.5 billion on food safety over these eight years. A majority of this spending relates to activities surrounding the Food Safety Modernization Act development and implementation activities.

With this level of funding on the Federal side and billions more invested by the private sector, Congress and the American people need to see results in terms of reduced illnesses, hospitalizations and deaths.

At the end of last month, Dr. Ostroff was quoted as saying at the Grocery Manufacturers Association annual science forum: "If the trends are going in sort of funny directions because of different types of diagnostics, it makes it really difficult for us to be able to monitor what the ultimate impact is as a result of the work we're doing with FSMA."

19. Dr. Gottlieb, how can we be in year six of the FSMA implementation and we are talking about different types of diagnostics as a reason why we can't determine the impact of all of this food safety work?

Response: FDA is developing and implementing performance measures for monitoring implementation of FSMA. Among these, FDA will evaluate the number of reported outbreaks and estimated illnesses in the U.S. population as measures of the effectiveness of the specific rules.

One of the most significant challenges in evaluating impacts on the incidence of foodborne disease is the dramatically increasing use of new, rapid diagnostic tests. These tools result in the identification of many infections that previously went undiagnosed or unidentified. Likewise, the use of whole genome sequencing may increase the number of illnesses and outbreaks detected, with increased attribution, from the ability to link sporadic cases of foodborne illness to contaminated food. These paradigm shifts in clinical diagnostics and laboratory methods are occurring at the same time as the implementation of FSMA. As a result, the numbers of detected foodborne illnesses may rise even as the actual risk of foodborne illness is decreasing. Nevertheless, FDA is working through these challenges to quantify changes in the numbers of illnesses and outbreaks that can be ascribed to foods covered by the FSMA rules. For example, separate analyses of FDA's final juice Hazard Analysis Critical Control Point (HACCP) rule and

proposed shell egg rule each looked at 10 years of illness data (Minor and Parrett 2016, 2017) to estimate the benefits of these rules in reducing foodborne illness. Likewise, an analysis of U.S. Department of Agriculture Food Safety and Inspection Service's implementation of HACCP for meat and poultry required 14 years of hospitalization data (Chui et al. 2009). FSMA is likely to be more complicated to evaluate than these other policies, due in part to staggered FSMA compliance dates, which extend to 2022 for some farms subject to the Produce Safety Rule. In the meantime, FDA will look at interim measures that will help show progress towards the success of FSMA.

20. Can you tell me one way or another whether or not the FSMA investments of time, money and process change will have a direct tie to reduced illnesses or deaths? If not, how do we know if we are making a difference?

Response: FDA estimates that a significant number of foodborne illnesses and outbreaks will be prevented once the FSMA foundational rules are fully implemented. FDA will evaluate the number of reported outbreaks and estimated illnesses in the U.S. population as measures of the effectiveness of the attributed to specific FSMA rules.

There are several challenges with predicting when reductions in foodborne illness may be observed because the number of foodborne illnesses and outbreaks is subject to many factors beyond the scope of the FSMA rules. In particular, advances in disease surveillance and laboratory methods—such as whole genome sequencing—could significantly increase the number of illnesses detected and linked to outbreaks in the near future, even if other factors are held constant.

To track intermediate progress that is expected to result in reduced illnesses and outbreaks, FDA will monitor training, compliance, and implementation of the FSMA rules through a combination of program and outcome measures. The first performance measures to be implemented for this purpose will be for Preventive Controls for Human Food and Preventive Controls for Animal Food, which has the earliest compliance dates. A set of these measures will be published in 2018 via FDA's Agency-wide performance management system, FDA-TRACK.

FDA would be happy to keep you updated about the publication of FSMA-related performance measures.

21. Please provide the Committee an update on the milestones and dates for each of the foundational rules.

Response: FDA has been working diligently to meet the challenges of implementing FSMA. FDA has finalized all seven of the FSMA foundational rules, which establish the broad, preventive framework envisioned by Congress, and has been actively releasing guidance documents and other resources to assist industry in complying with the requirements in the rules. Below, please find a summary of the compliance dates that have passed and major guidances or milestones for each of the foundational rules.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food – published September 17, 2015

- Compliance dates:
  - For businesses that are not small or very small: September 19, 2016.k
  - For small businesses: September 18, 2017.
- FDA has been releasing draft chapters of this multi-chapter guidance since August 2016. As of April 17, 2018, FDA has released 7 of 16 draft chapters.
- FDA also released a Food Safety Plan Builder tool to assist companies in creating a food safety plan.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals – published September 17, 2015

- Compliance dates:
  - For Current Good Manufacturing Practices (CGMPs)
    - For businesses that are not small or very small: September 19, 2016.
    - For small businesses: September 18, 2017.
  - For Preventive Controls
    - For businesses that are not small or very small: September 18, 2017.
- FDA published a final guidance on current good manufacturing practice requirements for food for animals in October 2017.
- FDA published draft guidance on hazard analysis and risk-based preventive controls for food for animals in January 2018.

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption – published November 27, 2015

- Compliance dates:
  - For covered activities involving sprouts:
    - For businesses that are not small or very small: January 26, 2017.
    - For small businesses: January 26, 2018.
  - For activities involving all other covered produce:
    - For businesses that are not small or very small: January 26, 2018.
- FDA published draft guidance for the sprouts industry in January 2017 and a small entity compliance guide in September 2017.
- FDA intends to publish a draft Compliance and Implementation Guidance for the Produce Safety Rule soon.

Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals – published November 27, 2015

- First compliance date:
  - May 30, 2017.
- FDA published draft FSVP guidance and the small entity compliance guide for this rulemaking in January 2018.

Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications – published November 27, 2015

- In January 2018, FDA announced ANSI-ASQ National Accreditation Board as the first recognized accreditation body under this program.
- In March 2018, FDA announced American National Standards Institute as the second recognized accreditation body under this program.

Sanitary Transportation of Human and Animal Food – published April 6, 2016

- Compliance dates:
  - For businesses that are not small: April 6, 2017.
  - For small businesses: April 6, 2018.
- FDA published waivers for businesses whose transportation operations are subject to separate state and/or federal controls on April 6, 2017.
- FDA published the small entity compliance guide for this rule on November 22, 2017.

Mitigation Strategies to Protect Food Against Intentional Adulteration – published May 27, 2016

- Compliance date:
  - The first compliance date for this rule is July 26, 2019.
- FDA published the small entity compliance guide for this rule in August 2017.
- FDA plans on issuing additional guidance to help industry comply with this rule well in advance of the compliance date, with the first chapters of the three-part draft guidance publishing soon.

Since finalizing the rules, FDA has been in constant communication with stakeholders and has heard concerns about various provisions. As a result, FDA has stated our intent to exercise enforcement discretion with regard to specific provisions in the foundational rules, some while FDA considers ways to address their concerns. FDA has stated our intent to exercise enforcement discretion for written assurances; facilities that would qualify as secondary activities farms except for ownership (i.e., some produce packinghouses, grain elevators, cotton ginners); certain facilities making silage food for animals, certain human food by-products for use in animal food; and importation of food contact substances, grain when brought by certain importers, and certain live animals.

22. Please provide the Committee with the actions the FDA plans to take to measure specific food safety outcomes.

Response: FDA is currently developing and implementing performance measures for monitoring FSMA implementation. These performance measures are at various stages of development, review, prioritization, approval, and implementation. Since the FSMA rules have staggered compliance dates, not all performance measures will be implemented at the same time. The first major FSMA compliance dates were for large businesses under the Preventive Controls for Human Food (PCHF) rule and certain provisions of the Preventive Controls for Animal Food (PCAF) rule. Performance measures for those rules will be the first to be implemented, including a set of measures to be published via FDA's Agency-wide performance management system, FDA-TRACK, during 2018.

Regarding performance measures for food safety outcomes, FDA will evaluate the number of reported outbreaks and estimated illnesses in the U.S. population as measures of the effectiveness of the rules.

The development of additional public health outcome measures related to FSMA activities will be subject to the availability of sufficient data. For example, while there are surveillance systems for human disease, there is no similar surveillance system to track either pet or production animal diseases. As a result, for animal food, FDA tracks recalls attributed to food produced at facilities subject to the PCAF rule instead of tracking outbreaks or illnesses in animals. Likewise, for certain commodities or types of firms, relevant public health data either may not exist or may not be sufficient to track meaningful changes over time.

Additional food safety outcome measures are being developed to monitor FSMA implementation. For example, as more data becomes available from the ongoing PCHF inspections, there are opportunities to develop outcome measures to monitor the implementation of that rule.

23. Specifically, how will FDA monitor compliance and what outcome based metrics does the Agency plan to track and measure?

Response: FDA will continue to monitor compliance with FSMA using facility inspections and sampling, and FDA will work with its regulatory partners to carry out inspection and compliance in the risk-based, prevention-oriented manner envisioned by FSMA. Regarding performance measures for compliance, FDA will report percentages of final inspection results.

Under FSMA, FDA established a foreign supplier verification program (FSVP) to ensure that importers perform risk-based foreign supplier verification activities to verify that imported food is produced using processes and procedures that provide the same level of public health protection as the preventive controls rules and the produce safety rules, as appropriate, and is not adulterated or misbranded with respect to allergen labeling, when applicable. FDA will similarly track percentages of final inspection results for importers subject to FSVP.

Regarding performance measures for food safety outcomes, FDA will evaluate the number of reported outbreaks and estimated illnesses in the U.S. population as measures of the effectiveness of the rules. The development of additional public health outcome measures related to FSMA activities will be subject to the availability of sufficient data.

24. When does FDA expect to show a correlation between its work and reduced deaths, illnesses, and hospitalizations?

Response: FDA is working now to gather information that will be used to demonstrate the correlation between its work and reduced deaths, illnesses, and hospitalizations. However, there are several challenges with predicting when reductions in foodborne illness may be observed. The seven foundational FSMA rules have staggered compliance dates, extending as far as January 2022 for some farms subject to the Produce Safety rule. As a result, the benefits from the rules are expected to be phased in as well. With implementation of the Produce Safety rule

alone, FDA estimates that about 515,000 illnesses per year are expected to be prevented by the provisions of this rule, but these full benefits will not be reached until seven years after publication of the rule, according to the Regulatory Impact Analysis. Because there are many factors involved, FDA anticipates that it may take years to detect measurable progress after the implementation of the FSMA regulations. For example, the U.S. Department of Agriculture Food Safety and Inspection Service implemented a Hazard Analysis and Critical Control Point (HACCP) program for meat and poultry with staggered implementation between 1996 and 2000. A 2009 study by Chui et. al. in BMC Public Health found evidence for decreased *Salmonella*-related hospitalizations by looking at 14 years of data—1991 to 2004—spanning the period before and after the rule went into effect.

25. Has the FDA started to measure and track outcomes from FSMA implementation? If so, what does any early data indicate?

Response: FDA is developing and tracking outcomes specific to FSMA, related both to illness reduction and implementation progress. The first major FSMA compliance dates were for large businesses under the Preventive Controls for Human Food (PCHF) rule and certain provisions of the Preventive Controls for Animal Food (PCAF) rule. Performance measures for the Preventive Controls for Human Food (PCHF) rule and certain provisions of the Preventive Controls for Animal Food (PCAF) rule will be the first to be implemented, including a set of measures to be published via FDA's Agency-wide performance management system, FDA-TRACK, during 2018.

Currently, FDA reports several outcome measures that inform FSMA implementation, though most of these measures were initially developed for a separate purpose. The outcome measures are publicly available and are listed in the Congressional Justifications and/or on the FDA's Agency-wide performance management system, FDA-TRACK.

These outcome measures include the following:

- Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Campylobacter species (listed on p. 53 of the FY19 Congressional Justification).
- Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing Escherichia coli O157:H7 (listed on p. 53 of the FY19 Congressional Justification).
- Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Salmonella species (listed on p. 53 of the FY19 Congressional Justification).
- Percentage of the domestic food industry subject to the preventive controls regulation participating in training conducted by FDA or funded by FDA or training using FDA-recognized curricula (listed on FDA-TRACK).
- Number of Class I and Class II recalls, which are indicators of potential serious and adverse health consequences, attributed to food produced at facilities subject to the PCAF rule (listed on FDA-TRACK).

The current data for the outcome measures in Congressional Justification are from 2015 and 2016, and do not reflect the full implementation of FSMA. Of the six foundational rules with compliance dates, none have reached their final compliance dates for the smallest businesses.

The FDA-TRACK measure on industry training for the PCHF rule has shown an increase from four percent in FY 2016-Q2 to 66 percent in FY 2018-Q1.

26. What is the current status of the cooperative agreements with the states to conduct inspections and what are the related costs per year for fiscal years 2017 through 2019? Please include the additional cost of training the state employees for each of these fiscal years.

Response: The Produce Safety Implementation Cooperative Agreement Program (CAP) provides funding for the states to develop an infrastructure within their state to conduct inspections. The CAP does not pay for individual inspections, but provides funding for the states to establish a regulatory program and fund all elements required to do such activity.

Grantees are enrolled in two different competitions in this program. Competition A provides funding for states to educate and train their farmers, build farm inventory, and conduct on-site readiness reviews. Competition B provides funding specifically for the establishment of a regulatory program. There are currently 43 grantees in the CAP program, 40 of which are currently enrolled in and receiving funding for Competition B.

The CAP is currently in Year 2 of funding. The Year 2 budget cycle ends June 30, 2019, and Year 3 starts July 1, 2018. The inspections for large farms start in spring of 2019 (this will vary state-to-state based on weather). Farm inventories are currently under development and verification. There were no inspections conducted in FY 2017. The only inspections that will be done in FY 2018 are "for cause" inspections. The inspections conducted in FY 2019 will cover large farms and "for cause" inspections; the number of inspections performed will be dependent on inventory and inspection prioritization. FY 2019 inspections will begin as early as March and as late as June. It is not possible at this time to provide a specific cost for just inspection work as this activity has not yet started and is not being calculated on a per inspection basis.

Training of state personnel to conduct inspections is an included and allowable expense within the CAP. No additional costs for training beyond those planned in the grantees' budgets are expected.

Intentional Adulteration

We, along with several of my colleagues, have had conversations regarding the FSMA Intentional Adulteration rule. I understand you have made plant visits and have discussed this issue with some in the industry.

27. FDA has indicated that the agency would be issuing guidance on this matter and I was hoping you can give us a timeframe as to when that guidance will be released?

Response: FDA is planning on issuing the draft guidance for industry regarding intentional adulteration in three installments. All three installments will be published well in advance of the 2019 compliance date. FDA expects the first installment to publish this summer, and the second and third installments will follow shortly after. The guidance will cover topics such as conducting a vulnerability assessment; identifying and implementing mitigation strategies; writing procedures for food defense monitoring, corrective actions and verification; performing reanalysis of food defense plans; training; and records.

28. Will you continue to visit plants and discuss the concerns that industry has raised?

Response: FDA has carried out many site visits and has seen how different types of facilities currently handle food defense. These visits have been very helpful to FDA and to industry. FDA welcomes the opportunity to do additional site visits and intends to continue engaging with industry to discuss the concerns they have raised. Since FDA's visit to the Nestle plant in March, additional global companies have initiated conversations regarding their approach to implementation. A meeting is scheduled for May 2018 with one of these companies.

Imported Medical Product Exams

I have raised concerns in the past few years about some of the challenges with inspecting finished drug products or drug ingredients originating from overseas. Three years ago, the Vice President reportedly had to intervene to get FDA inspectors visas to do their work in China. In terms of the FY 2019 budget, there are some initiatives that have the potential to bring manufacturing back to the United States and that would be positive news. In the meantime, human drugs, biologic, and medical device imports are on the rise. What is a bit troubling is the plan for a decreased level of import inspections in the FY 19 budget proposal. On page 90 and 122 of the Congressional Justification, FDA shows a sharp drop in import field exams or tests.

29. Can you help the Subcommittee understand why we would propose funding of new initiatives if we are not even maintaining current levels of medical product import inspections?

Response: The estimates for FY 2018 and FY 2019 are flat with the previous FY 2017 estimates and the planned level of operational activities is not changing. However, the actual FY 2017 accomplishments exceeded the planned levels for several activities including the import work.

The estimated level of activity for each operation is based on the ORA Workplan which sets levels of planned operational activities based on available FTE resources and an estimated average time it will take to conduct each activity. Field workplans calculate available operational capacity based on available program hours of each FTE. As a result, more operations may be conducted if the average time per activity takes less time than planned.

30. Is FDA running into any barriers or obstacles when the agency conducts onsite visits overseas? If so, can Congress help to address these challenges?

Response: There will always be obstacles associated with onsite visits due to the differing cultural barriers, business practices and regulatory environments in countries outside of the United States. FDA's inspection and surveillance activities are prioritized based on risk, and the Agency continues to leverage existing regulatory authorities to overcome barriers to onsite overseas inspections, as well as obtain information learned from multiple sources to best target limited staff. One important source, FDA's Foreign Offices, utilize their overseas presence to gather and share information in real-time to assist with the Agency's decision-making.

Patient's Real World Experience

The Committee has for years worked to enhance the level of attention and recognition given by the FDA to the voices and experiences of patients and caregivers in its complex work of new drug evaluations. This is particularly important when addressing the tight time frames and small patient populations available for research into rare diseases such as Duchenne Muscular Dystrophy, which affect a limited number of children and progress at a devastating pace. The Committee has been a part of efforts to expand the tools available to the agency in this regard - through the FDA Safety and Innovation Act of 2012, the 21st Century Cures Act of 2016, repeated directions through our annual appropriations reports, and more. FDA notes that the agency has announced recent steps to continue building the role for patient input and experience into your deliberations.

31. Please provide the Committee with an update us on those efforts and tell us what additional measures you are exploring that will help to facilitate full consideration in the timeframes patients need.

Response: FDA is using science-based methods to incorporate patients' voices into drug and biologics development and the regulatory decision-making process as stipulated under the 21st Century Cures Act ("Cures") and PDUFA VI. The following are among the ways FDA is implementing patient-focused drug development (PFDD) provisions:

- Publishing (in June 2017) a five-year plan for issuing draft and final PFDD guidances.[1]

- For all new drug applications and biologics license applications submitted and approved at least 180 days after enactment of Cures, requiring FDA reviewers to provide a brief statement regarding patient experience data and related information that were submitted and reviewed as part of the application.

- Holding public workshops to seek stakeholder input to inform FDA development of guidance documents to implement provisions of Cures Section 3002. This includes a public workshop held on December 18, 2017, and publication of a related discussion draft[2] on collecting comprehensive and representative patient experience per Section 3002(c)(1). FDA held another workshop on March 19, 2018,[3] to obtain public input on

[1] www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm563618.pdf
[2] https://www.fda.gov/downloads/Drugs/NewsEvents/UCM586195.pdf
[3] https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm

developing and submitting proposed draft guidance relating to patient experience data for FDA consideration. This will support FDA development of new guidance per Cures Section 3002(c)(5). The Agency plans to issue a draft guidance before the end of FY 2018.

- Establishing a Patient Engagement Staff in the Office of Medical Products and Tobacco to:
    - Serve as a single, central entry point to the Agency for patient communities.
    - Provide triage and navigation services for inquiries from patient stakeholders.
    - Provide a more transparent, accessible, and robust experience for patient communities.
    - Host and maintain data management systems that incorporate and formalize knowledge shared with FDA by patient stakeholders.
    - Provide cross-center coordination around policies FDA adopts regarding how the Agency involves patients in our processes.
    - Maintain/enhance our existing relationships with stakeholders; enable new groups to interact with the Agency.

Regarding Duchenne Muscular Dystrophy (DMD), the newly finalized Guidance for Industry "Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment" was informed by input from the community, including an independent proposed draft guidance submitted by Parent Project Muscular Dystrophy.

Defining the term "Natural"

Dr. Gottlieb, I followed your remarks at the National Food Policy Conference in late March and was pleased to hear that FDA continues to work towards defining the term "natural" and regulating its use on food labeling after receiving thousands of public comments on a number of relevant questions. This is an extremely important and complicated issue within FDA's primary jurisdiction. FDA's expertise is needed to provide certainty and national uniformity for consumers, food producers and the courts about the meaning of the term.

32. With that in mind, can you please provide me with a further update of FDA's ongoing work on this important pre-rulemaking initiative?

Response: On November 12, 2015, FDA issued a notice requesting comments on the use of the term "natural" in the labeling of human food products (80 FR 69905). In light of the strong public interest on the topic and in response to public requests, FDA extended the period for public comment to May 10, 2016 (80 FR 80718, December 28, 2015). FDA has received and reviewed more than 7,600 comments submitted. FDA recognizes that consumers are trusting in products labeled as "natural" without clarity around the term. FDA will have more to say on this issue soon.

Laboratory Developed Tests

Commissioner Gottlieb, as you are likely aware, there's been a long conversation on how best to regulate diagnostics, including laboratory developed tests (LDTs) and in-vitro diagnostic test kits (IVDs). These diagnostics are vital tools as we implement personalized medicine and seek new cures for diseases such as cancer. While this Subcommittee does not have jurisdiction over the policies around this issue, our Members on both sides of the issue care deeply about it.
In FY 2017, the Agriculture Appropriations bill directed your agency to "work with Congress to pass legislation that addresses a new pathway for regulation of [Laboratory Developed Tests] in a transparent manner. "

It is my understanding that the House Authorizing Committees last year made a made a bipartisan request for technical assistance from the FDA on a specific legislative reform proposal for diagnostics. I know Congress and stakeholders would like to get something done this year.

33. Do you know what the status of this technical assistance is and are there any outstanding issues related this issue or further input that you require from Congress?

Response: FDA is committed to continued engagement with Congress and all interested stakeholders on this important public health issue. FDA maintains that legislation will be helpful to clarify the least burdensome path to market for laboratory developed tests (LDTs), while also helping to ensure the accuracy and reliability of the tests that patients and health care providers rely on.

FDA is considering potential approaches to regulatory oversight and look forward to continuing to work with Congress and stakeholders on the best path forward. Other pathways – such as the Pre-Cert program being developed for certain lower-risk digital health technologies – may serve as a good model for part of a legislative framework.

34. Do you have an approximate timeline for responding to this request?

Response: FDA is committed to continued engagement with Congress and all interested stakeholders on this important public health issue. FDA maintains that legislation will be helpful to clarify the least burdensome path to market for LDTs while also helping to ensure the accuracy and reliability of the tests that patients and health care providers rely on.

FDA will keep the Committee updated as the Agency continues to work on this important public health issue.

Sodium

35. There are scientific studies that call into question the long held advice that Americans need to cut back on salt intake. Have you looked at these studies and do you believe they have validity? Is FDA considering this science?

Response: A consensus exists among scientific bodies, qualified experts, and governments around the world that reducing sodium intake is a viable, achievable, and effective strategy to reduce the incidence of cardiovascular disease. The most rigorous science supports FDA's actions to help gradually reduce Americans' sodium intake from 3,400 mg per day by reducing the amount of sodium added to the food supply. FDA's activities on sodium reduction have involved a careful and thorough review of the published literature surrounding sodium and are being carried out through a public process, with the opportunity for public comment. FDA has also conducted extensive outreach with the food industry and public health groups on the voluntary targets to ensure that they are well understood. If any changes to the current DRI for sodium are made, FDA would adjust the targets accordingly.

36. In addition to being concerned about a preconceived outcome of the DRI on sodium, I am also concerned about your agency's lack of attention to potassium when announcing your plans on sodium. As you are well aware, in 2012, a joint US-Canada government committee prioritized the review of sodium AND potassium, not sodium alone. I understand this was done because the two nutrients are dependent on one another. Since the DRI review is far from complete, you can imagine this committee's surprise at your announcement about moving forward with sodium reduction targets.

Response: About 90 percent of Americans exceed the current federally recommended limit of 2,300 mg/day for sodium, and about 2 percent of Americans meet the current recommended adequate intake level of 4,700 mg/day for potassium. Reducing sodium in the diet is the single most effective public health action related to nutrition. The most rigorous science supports FDA's actions to help gradually reduce Americans' sodium intake from 3,400 mg per day by reducing the amount of sodium added to the food supply. Researchers have estimated that reducing sodium intake by one-half teaspoon a day could prevent nearly 100,000 premature deaths a year, and up to 120,000 new cases of coronary heart disease, 66,000 strokes, and 99,000 heart attacks. The FDA is committed to advancing short-term voluntary sodium targets and will align its approach with the Dietary Reference Intake study being conducted by the National Academies.

37. Given that the DRI is on both sodium and potassium, can you give us your detailed plan on potassium, as you did sodium, and how the two plans will work in tandem to advance public health?

Response: In FDA's recent update to the Nutrition Facts label rules, FDA concluded that potassium is a nutrient of public health significance for the general U.S. population and its declaration is necessary to assist consumers in maintaining healthy dietary practices. Therefore, the final rule, at § 101.9(c)(8)(ii), requires the mandatory declaration of potassium. FDA has proposed that the compliance date for the updated Nutrition Facts label rules be January 1, 2020, for most manufacturers, and January 1, 2021, for smaller manufacturers. The inclusion of potassium on the updated Nutrition Facts label helps empower consumers with information to make healthy choices involving potassium intake.

A majority of consumers want to reduce sodium intake, but the levels of sodium in processed and prepared foods make that challenging. The most rigorous science supports FDA's actions to

help gradually reduce Americans' sodium intake from 3,400 mg per day by reducing the amount of sodium added to our food supply. FDA is currently carefully reviewing all public comments in response to our draft guidance relevant to the short-term targets. The National Academies has established a committee to review the scientific evidence and update, as appropriate, the dietary reference intakes (DRIs) for sodium and potassium. If any changes to the current DRI for sodium are made, FDA will adjust the targets accordingly.

Tobacco

Despite the agency's recent actions to solicit and review information on premium cigars and ultimately consider changing how it regulates the product, several current or pending requirements for premium cigar products remain in place, including the August deadline for costly warning labels on packaging and advertising. Even by FDA's own estimates, this will cost industry, including many small businesses, millions of dollars. With some other entities requesting extending the comment period by as much as 90 days, time is the enemy of many of these small businesses.

38. Is the FDA considering a potential combination of a comment period extension with a delay of upcoming requirements to ease the burden on small businesses?

Response: FDA will consider all requests for extension of comment periods for the three Advanced Notices of Proposed Rulemaking (ANPRM) that the Agency issued recently. If FDA decides to grant an extension, the Agency will notify stakeholders by a Federal Register Notice. FDA's final deeming rule included a compliance policy for small-scale tobacco product manufacturers that may need additional time to comply with certain requirements of the FD&C Act. Generally, this compliance policy provided small-scale manufacturers with an additional six-month compliance period for certain requirements. Staff from the Center for Tobacco Products (CTP) Office of Compliance and Enforcement continue to assist such businesses with their rotational warning plans. Since the issuance of the final deeming rule, FDA also has issued guidance regarding a compliance policy for cigars in small packaging. At this time, FDA does not believe that additional compliance policies regarding the cigar warning label requirements are appropriate.

Menu Labeling

The FDA's rule on calorie labeling on menus is going into effect on May 7th. We have heard numerous concerns from regulated businesses over time about the difficulty of understanding those rules and complying with them. It is my understanding that FDA issued new draft guidance last November but that that guidance has never been finalized.

39. What are businesses supposed to make of a situation in which the agency regulating them won't make its guidance final at this stage? Shouldn't this lack of clear, final guidance be a cause for concern for this Subcommittee?

Response: The draft guidance [Menu Labeling: Supplemental Guidance for Industry] directly addresses concerns raised by stakeholders in response to our menu labeling regulation, providing

practical solutions to make it easier for industry to meet their obligations. FDA intends to finalize the guidance by the compliance date. In addition, FDA plans to work cooperatively with covered establishments to come into compliance with the menu labeling requirements. Specifically, FDA plans to continue with education and outreach, especially in the first year, to help covered establishments achieve compliance.

40. What does FDA view as the public health benefit to menu labeling and what are the anticipated measurable outcomes? Please provide the assumptions and basis of the response.

Response: People in the United States currently eat and drink about one-third of their calories away from home and generally underestimate their calories when eating out.[4] While consumers can find calorie and other nutrition information on most packaged foods, this labeling has not generally been available in establishments that serve ready-to-eat, prepared food. Rates of child and adult obesity in the United States are at historic highs, and obesity increases the risk for heart disease, stroke, certain cancers, and diabetes. Research, including a recent RAND Corporation study (Examining Consumer Responses to Calorie Information on Restaurant Menus in Discrete Choice Experiment), suggests that people order menu items with fewer calories when they have access to calorie information and that such information does not affect their satisfaction with the choice they make or their ratings of the restaurant. Under FDA's nationwide menu labeling rule, consumers will be empowered with reliable and actionable information about the foods they eat so that they can make more informed choices about their diets and health for themselves and their families.

These efforts are part of a broader multi-year Nutrition Innovation Strategy that FDA announced in March 2018, which aims to provide all Americans with easier access to nutritious, affordable foods by arming consumers with information and encouraging the food industry to innovate in producing the healthier foods that today's informed consumers want.

21st Century Cures

41. Please provide a detailed description of how FDA is spending the $60,000,000 provided to the Agency in the fiscal year 2018 Omnibus and as well as any additional resources within the Agency? In other words, how will FDA utilize these new funds and does FDA anticipate repurposing base funds to supplement the 21st Century Cures funding?

Response: The 21st Century Cures Act (Cures), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

Cures authorized $500 million over nine years to help FDA cover the cost of implementing specific innovation provisions of the law. The final work plan, which includes the recommendations from the FDA Science Board, was delivered to Congress on June 9, 2017. As per the work plan, FDA will use the $60 million in FY 2018 to support implementation of the

[4] Burton, S., E.H. Creyer, J. Kees, and K. Huggins, "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants." American Journal of Public Health, 96(9):1669-1675, September 2006.

following subtitles.

(Table in thousans of dollars)	FY 2017	FY 2018
Subtitle A—Patient-Focused Drug Development	$0	$2,298
Subtitle B—Advancing New Drug Therapies	$4,975	$14,179
Subtitle C—Modern Trial Design and Evidence Development	$1,900	$4,616
Subtitle D—Patient Access to Therapies and Information	$7,837	$23,855
Subtitle F—Medical Device Innovations	$5,288	$12,263
Subtitle G—Improving Scientific Expertise and Outreach at FDA	$0	$2,789
Grand Total	**$20,000**	**$60,000**

As Cures builds on FDA's ongoing work to support the development and review of drugs, biological products, and devices, FDA Cures activities are complementary with current medical product safety activities and build on current medical product safety resources. FDA's estimated total resources supporting medical product safety at the FY 2018 Enacted level is $3.2 billion, including budget authority and user fees.

42. Please provide an update on FDA's new hiring authority and its impact on current vacancies as well as the impact on the FY 2018 and FY 2019 budgets (i.e., how common or frequent will this authority be utilized and what will that corresponding use translate to in increased costs?).

Response: Cures was enacted in December 2016, and, among other things, gave the Agency important new human (HR) resources. These authorities included a flexible hiring process and the ability to establish a new pay authority for scientific, technical, and professional positions that support the development, review, and regulation of medical products. FDA created a Cures HR governing body shortly after the Act was passed to implement these new HR authorities. The governing body has been hard at work on the implementation of the authority to ensure its use is transparent, fair and sustainable, recognizing that these benefits are dependent on appropriated funds. As part of this work the governing body has been working diligently to design an alternative pay system which did not impact the FY17 budget. The Cures pay system is forecasted to have a minimum effect on the FY18 and FY19 budgets in the medical product centers eligible to use the Cures HR authority, and some of its costs will be offset by user fees. Until the new pay system is fully implemented, the Agency will use the Cures authority in a targeted manner to focus on mission critical positions and retention cases. In fact, as of April 2018, FDA use the Cures HR authority to fill two of the Agency's Deputy Center Director positions.

In FY18, FDA will continue to work on developing the new alternative pay system and the policies needed to appropriately move employees into the new system. During the first phase of implementation, FDA plans on using the Cures HR authority in a targeted and strategic manner on positions that are particularly challenging to fill and to retain critical staff required to sustain FDA's mission.

FDA is also pursuing new methods to enhance the outreach and identification of scientific and regulatory candidates through its newly established Scientific Staffing Team. The Agency has also designed a new and lean hiring process to move recruits through the system rapidly to enable faster recruitment. With the new pay and hiring authorities under Cures, and the anticipated improvements in the hiring process, FDA expects to successfully recruit the highly qualified staff needed to fulfill the Agency's important public health mission.

43. What resources are being devoted to 21st Century Cures Act activities beyond those funds provided to the Agency via the FDA Innovation Account in fiscal years 2017 and 2018?

Response: As Cures builds on FDA's ongoing work to support the development and review of drugs, biological products, and devices, FDA Cures activities are complementary with current medical product safety activities and build on current medical product safety resources. FDA's estimated total resources supporting medical product safety at the FY 2018 Enacted level is $3.2 billion, including budget authority and user fees.

Nutrition Facts Label – Date Harmonization

The regulated industry still faces uncertainty about the harmonization of the deadlines food companies have to meet for complying with the Nutrition Facts label changes and USDA's forthcoming GMO labeling regulation and others. I believe this is a reasonable approach to avoid consumer confusion and lessen the cost on food manufacturers.

44. What is FDA's current position on working with USDA Secretary Perdue to align these deadlines?

Response: In fall 2017, FDA published a proposed rule (82 FR 45753) to extend the compliance dates for the Nutrition Facts Label and Serving Size final rules from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales. Under the proposed rule, manufacturers with less than $10 million in annual food sales would have until January 1, 2021, to comply. One of FDA's highest priorities is to complete this rulemaking, and FDA plans to finalize the rule this spring. This additional compliance time also would provide an opportunity to work towards alignment between compliance dates for the Nutrition Facts label and the compliance date for the U.S. Department of Agriculture's (USDA's) bioengineered food disclosure rule.

FDA and USDA share the belief that all stakeholders benefit from a coordinated approach to labeling. FDA coordinates with USDA on labeling requirements to the greatest extent possible within the constraints of our different statutory requirements, and FDA has provided technical assistance to USDA on their bioengineered food disclosure proposed rule.

Dietary Fiber Guidance

Commissioner Gottlieb, as you know there is a great need for regulatory clarity for the new dietary fiber definition. As you know, the FY18 Omnibus Explanatory Statement directs FDA to issue its conclusions on the statues of pending dietary fiber ingredients expeditiously.

45. When will FDA release the additional guidance on intrinsic and intact fiber sources?

Response: In March, FDA issued final guidance [Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry] which outlines the evidence for which FDA is looking on various non-digestible carbohydrates that may be added to food to count them as fiber on the new label. This guidance provides industry with more clarity on the type and quality of evidence the FDA expects to see on citizen petitions submitted by manufacturers seeking permission to identify an additional non-digestible carbohydrate as dietary fiber on the new label as soon as possible.

46. When will FDA release the decisions on the 20 fiber petitions?

Response: FDA is working to finalize responses to the pending citizen petitions as soon as possible. FDA has been in contact with entities that have pending petitions to address any questions they may have about the final scientific evaluation guidance [Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry].

47. FDA recently reversed its approval for clinical studies that the Agency had previously approved several years ago for some pending fiber source petitions. New studies are going to be needed in some cases, which is very expensive and take at least 18 months to complete.

    How will FDA take this into consideration as you update the Nutrition Facts Label timeline?

Response: In May 2016, FDA published a final rule (81 FR 33742) amending the Nutrition Facts and Supplement Facts labels regulations. The final rule, among other things, defines dietary fiber as including isolated or synthetic non-digestible carbohydrates determined by FDA to have physiological effects that are beneficial to human health. The final rule also identifies seven non-digestible carbohydrates that FDA has determined to have beneficial physiological effects for human health and, therefore, can be declared as dietary fiber on Nutrition and Supplement Facts labels. Interested parties can ask FDA to list additional isolated or synthetic non-digestible carbohydrates that meet the definition of dietary fiber in §101.9(c)(6)(i). FDA has received several citizen petition requests to list additional isolated or synthetic non-digestible carbohydrates. FDA is working to finalize the responses to the pending citizen petitions and provide regulatory clarity on their use as soon as possible.

In fall 2017, FDA published a proposed rule (82 FR 45753) to extend the compliance dates for the Nutrition Facts Label and Serving Size final rules from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales. Manufacturers with less than $10

million in annual food sales would have until January 1, 2021, to comply. FDA proposed the extended compliance dates in response to continued concern that companies and trade associations have shared regarding the time needed for implementation of the final rules. Completing this rulemaking is one of FDA's highest priorities and the FDA plans to finalize the rule this spring.

Added Sugar

On March 1, FDA released draft guidance on added sugar. FDA just extended the comment period an additional 45 days. This again is an area where regulatory clarity is needed before food manufacturers can move forward to make decisions and packaging revisions.

48. When can we expect the finalized guidance?

Response: FDA will work on finalizing the guidance [The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry] as soon as possible following the closing of the comment period on June 15, 2018, and after comments have been reviewed and considered.

Small Format Packaging

49. The food industry has been waiting on guidance on how to proceed on small format packaging as the new format requirements are bigger than small packages can fit. Since this information was not included in the March 1 guidance, when will this guidance be issued?

Response: FDA is working to finalize the draft guidance as soon as possible.

Nutrition Innovation Strategy and Labeling of Plant-Based Proteins

Commissioner Gottlieb, as part of your recently announced Nutrition Innovation Strategy, you included modernizing health claims and standards of identity as key elements to help consumers identify healthy foods. This Subcommittee has been directing FDA to do more in both of these areas over the past few years. When FDA takes action, the agency then needs to follow up with proper enforcement to ensure that labels with health claims and standards of identity are accurate.

For example, FDA is hearing growing concerns from constituents about plant-based protein products hitting the market and the confusion this will create for consumers if such products are allowed to be labeled as "meat." You have the authority to enforce existing labeling laws for these plant-based products, but enforcement of labeling laws has historically been lacking.

50. What is FDA's plan to monitor the market place and ensure existing law and proper labeling of health claims and standards of identity is enforced?

Response: While the agency is concerned that all labeling be accurate and comply with the applicable regulations, FDA takes enforcement action based on public health priorities and resources.

As you note, part of FDA's recently announced Nutrition Innovation Strategy will include undertaking an effort to modernize health claims and standards of identity. Related to these efforts, FDA will evaluate statutory and regulatory provisions that relate to naming and describing products. FDA is proceeding with ongoing work in health claims and standards of identity consistent with FDA priorities and resources while developing this multi-year strategy.

51. Your Nutrition Innovation Strategy states that FDA will issue a Request for Information to help guide the agency in developing an approach for standards of identity. Will this request be directed at specific food items or a more general approach to standards of identity?

Response: FDA believes it is important to take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science with a goal of maintaining the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods. In addition to regulations that establish standards of identity for certain foods, there are statutory and regulatory provisions that relate to the naming and identity of food. As you note, FDA will issue a Request for Information (RFI) to help guide development of an approach to these areas. In addition to the RFI, FDA plans to hold a public meeting this summer to get additional input and help shape the direction of the strategy. FDA will welcome feedback on general approaches as well as on specific standards.

Proprietary Information

52. What is FDA doing to ensure that FDA meets their statutory obligations to protect trade secret, commercial confidential information?

Response: FDA understands the global operating environment and our obligation to protect trade secret information and intellectual property. The Agency relies on a multi-pronged approach and has undertaken a number of key initiatives to ensure sensitive information is appropriately protected by safeguarding against unauthorized disclosure, access, or misuse, including, but not limited to, the following:

- Conducted classified and unclassified cybersecurity, economic espionage, and insider threat awareness training for executives, managers, supervisors, and personnel within FDA Centers and Offices to encourage collaboration and to support the protection of sensitive information and overall security posture.

- Implemented Data Loss Prevention (DLP) measures designed to safeguard personally identifiable and protected health information, commercial, confidential, and trade secret information from inadvertent disclosure, misuse, and/or theft. Implemented DLP Device Control, FDA successfully implemented USB blocking of our FDA laptops and workstations. Implemented DLP Email Protection policy that prohibits personal email or personal online storage accounts to conduct official business.

- Implemented the FDA Systems Management Center (SMC) Center Command and Control Center to provide network, systems, application, and cybersecurity threat management oversight activities and operations to include monitoring of FDA High Value Assets and other sensitive applications and databases on a 24x7 basis.

- Implemented Multi-Factor Authentication which will integrate network and security tools/capabilities for protection of sensitive information.

- Incorporated insider threat and information protection related topics in the FDA New Employee Orientation Course to ensure awareness of security concerns and individual responsibilities.

FDA mandates employee compliance by conducting annual computer security awareness training that includes a module for individual responsibilities for the protection of sensitive information. All new FDA employees are required to complete ethics training which also highlights employees' responsibility to protect proprietary information. The ethics regulations also require employees that file public and confidential financial disclosure reports to receive annual ethics training.

53. Please provide the Committee with an update of any attempts by foreign nationals to steal proprietary, commercial confidential information at FDA.

Response: The FDA Office of Operations conducts pre-employment screening and background investigations to mitigate counterintelligence and insider threat concerns related to FDA applicants, ensuring suitability and eligibility to work in public trust or sensitive positions. However, foreign nationals must have resided in the U.S. for three of the past five years to be eligible for a background check. Under Homeland Security Presidential Directive 12 (HSPD-12) and Office of Management and Budget Memorandum 11-11, individuals who are ineligible for background checks are ineligible for Personal Identity Verification (PIV) cards, or access to federal facilities, networks, or systems.

Due to the volume of sensitive data in our systems and networks, FDA has limited access for personnel, including foreign nationals, who do not meet HSPD-12 requirements, ensured strong collaboration between personnel security, cybersecurity, counterintelligence, and insider threat organizations and have implemented technical controls to prevent, deter, detect, and mitigate data loss. FDA has established and implemented highly restrictive procedures to minimize foreign national accesses and exposure to sensitive information.

Information Technology

54. Please provide the Committee with FDA's actual spending on Information Technology in fiscal years 2016 and 2017, estimated for fiscal years 2018 and 2019.

Response: The FDA spending on Information Technology is as follows:

FY 2016: $579.1M
FY 2017: $603.3M
Estimate FY 2018: $587.7M
Estimate FY 2019: $627.9M

55. What are FDA's top three IT projects in development? Please list the project name, describe the purpose and the estimated cost of development as well as steady state cost when fully developed.

Response:

1. FDA Electronic Submissions Gateway
The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG is a highly scalable, easily available, high performance and secure exchange point for FDA and its partners to transact a variety of documents and submissions over industry-standard protocols. The FDA ESG enables the secure submission of pre-market and post-market regulatory information for review.

Fiscal Year	ESG Budget
FY 2019	$5M
FY 2018	$4.9M
FY 2017	$4.8M

2. Regulatory Review Platform (RRP) User Fee Act Implementation
The Regulatory Review Platform (RRP) facilitates the creation and implementation of a modern, efficient, and integrated drug application review capability for the FDA's Center for Drug Evaluation and Research (CDER). Prior to RRP, the drug application review processes were segregated or siloed, primarily between new drugs, generic drugs and biologics, and separate offices used separate information systems. RRP improves information sharing, facilitates collecting regulatory metrics and Congressional reporting, reduces redundant data and processes, and mitigates the need for costly modifications on legacy systems.

Fiscal Year	RRS UFA
FY 2018	$4.63M
FY 2017	$4.7M

3. FDA Cybersecurity Program
The FDA Cybersecurity Program provides near real-time cybersecurity capabilities and risk management methodologies to protect sensitive data and information systems in support of the FDA's public health mission. The FDA Cybersecurity Program's strategic priorities and investments consist of key objectives that strengthen the FDA's ability to conduct highly effective incident response and insider threat detection, improve operational situational

awareness, and decrease the overall security risks to sensitive FDA information and IT infrastructure.

Fiscal Year	Cybersecurity Budget
FY 2019	$21.3M
FY 2018	$20.5M
FY 2017	$18.1M

Animal Feed Review

56. Please provide the total resources devoted to animal food ingredient review process in fiscal years 2017 through estimated 2019.

Response: FDA's budget authority from fiscal year (FY) 2017 through FY 2019 continues to allocate $2,000,000 funding12 full-time equivalents to work on animal food ingredient review. These positions work across the vital review areas of target animal safety, safety of the human food derived from food-producing animals, manufacturing of the animal food ingredient, functionality of the ingredient, and communication with the ingredient manufacturers during the review process.

57. How many Center for Veterinary Medicine staff review animal food ingredient submissions?

Response: FDA's budget continues to allocate 12 full-time equivalents to work on animal food ingredient review. These positions work across the vital review areas of target animal safety, safety of the human food derived from food-producing animals, manufacturing of the animal food ingredient, functionality of the ingredient, and communication with ingredient sponsors during the review process.

Foreign Inspections

58. Please provide an update on FDA staff overseas. Please specify how many staff, how many FTEs, and the location for FDA staff overseas for the past five years to include FY 2018 to date and plans for FY 2019.

Response:

OIP Overseas Staffing:

Data Past 5 years:

	2014	2015	2016
	01/01/2014 - 12/31/2014	01/01/2015 - 12/31/2015	01/01/2016 - 12/31/2016
How many employees*	**35**	**34 (Includes 1 Pre-Deployment)**	**34 (Includes 1 Pre-Deployment)**
How many FTEs	**56**	**54**	**54**
Locations for FDA employees overseas	Brussels, Belgium; Beijing, China; Guangzhou, China; Shanghai, China; Mumbai, India; New Delhi, India; Mexico City, Mexico; Santiago, Chile; San Jose, Costa Rica; Pretoria, South Africa; & London, United Kingdom	Brussels, Belgium; Beijing, China; Guangzhou, China; Shanghai, China; Mumbai, India; New Delhi, India; Mexico City, Mexico; Santiago, Chile; & San Jose, Costa Rica	Brussels, Belgium; Beijing, China; Mumbai, India; New Delhi, India; Mexico City, Mexico; Santiago, Chile; San Jose, Costa Rica; & London, United Kingdom

	2017	2018
	01/01/2017 – 12/31/2017	01/01/2018 – 05/01/2018
How many employees*	**44 (Includes 22 Pre-Deployment)**	**48 (Includes 23 Pre-Deployment)**
How many FTEs	**54**	**54**
Locations for FDA employees overseas	Brussels, Belgium; Beijing, China; Mumbai, India; New Delhi, India; Mexico City, Mexico; Santiago, Chile; San Jose, Costa Rica; & London, United Kingdom	Brussels, Belgium; Beijing, China; New Delhi, India; Mexico City, Mexico; Santiago, Chile; San Jose, Costa Rica; & London, United Kingdom

How many employees* – This represents the total number of employees currently on board with OIP.
How many FTEs** - This represents the total number of Full Time Equivalent positions authorized for OIP.

Recruitment to Foreign Offices has been hampered by delays associated with clearances and visa approvals, specialized qualifications and experience requirements, and unique geographical and environmental challenges associated with international postings. FDA has made significant progress in filling Foreign Office vacancies by hiring 20 employees in CY2017 and 8 employees in CY2018. Recognizing that some fluctuation in staffing will occur as assigned tours of duty end and new personnel are brought on board, FDA/Office of International Program's plan for CY2018 and CY2019 is to continue efforts to recruit and fill vacant Overseas FTE positions.

59. Does FDA have an updated estimate as to the total number of facilities shipping food products to the United States?

Response: Based on entry data collected by FDA during fiscal year 2017, there were 254,060 food manufacturers from various foreign countries whose FDA-regulated food product(s) were offered for import into the United States. This number represents a 4.1 percent increase from fiscal year 2016.

60. How many compounding pharmacies did FDA inspect in fiscal years 2014 through 2018 to date?

Response: From fiscal year 2014 through April 17, 2018, FDA conducted more than 530 inspections of compounders, including those seeking to operate under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and outsourcing facilities operating under section 503B of the FD&C Act. Many, but not all, of the inspected facilities were state-licensed pharmacies.

61. Please update the record from last year on how many inspections FDA believes it will need to inspect on a continuing basis?

Response: As of April 17, 2018, FDA completed about 533 inspections of compounding facilities. This includes inspections of outsourcing facilities and those facilities that are compounding under section 503A of the Federal Food, Drug, and Cosmetic Act (section 503A facilities) and are not registered with FDA. Of the 533 inspections, 150 were for cause, 158 were follow-up to facilities previously found to be noncompliant, and 225 were surveillance inspections (including surveillance inspections of newly registered outsourcing facilities).

FDA conducts for-cause inspections based upon reports of serious adverse events and complaints about product quality problems. FDA conducts follow-up inspections to determine whether compliance has been achieved. FDA conducts risk-based surveillance inspections to identify problems that could put patients at risk.

FDA continues to find problems at many of the compounding facilities the Agency inspects. Many compounding facilities have voluntarily recalled compounded drugs and ceased sterile compounding as a result of FDA's findings of poor conditions and practices that could lead to drug quality problems.

62. How many staff and how many FTE are devoted to the enforcement of human drug compounding activities in fiscal years 2016 through plans for FY 2019?

Response: For fiscal years (FY) 2016 and 2017, over 150 FTEs have supported the oversight of human drug compounding annually. FDA estimates that in FY 2018, approximately 176 FTEs will continue to support the oversight of human drug compounding, and in FY 2019, 203 FTEs will support the program if the Agency's FY 2019 budget request is approved.

63. How many staff and how many FTE are devoted to the enforcement of animal drug compounding activities in fiscal years 2016 through estimated FY 2019?

Response: In fiscal year (FY) 2016, there were approximately nine (9) FDA Center for Veterinary Medicine (CVM) full-time equivalents (FTE) devoted to the oversight of animal drug compounding activities. In FY 2017 through FY 2019, CVM estimates seven (7) FTE will

continue to support the oversight of animal drug compounding activities. This number includes three (3) FTE for surveillance, two (2) FTE for compliance, and two (2) FTE for policy.

64. Under what conditions can a licensed pharmacist provide compounded pharmaceuticals to a licensed physician or licensed practitioner for administration by a licensed physician or licensed practitioner in advance of receiving a patient specific prescription?

Response: A licensed pharmacist in an outsourcing facility can provide drugs compounded by that outsourcing facility in accordance with the conditions of section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to a licensed physician or other licensed healthcare practitioner without first receiving a prescription for an individually identified patient. See section 503B(d)(4)(C) of the FD&C Act. In contrast, section 503A of the FD&C Act states that compounding under that section must be based on the receipt of a valid prescription for an individually identified patient (see section 503A(a)), and does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient (see *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*).

Drug Compounding – 503A and 503B

I appreciate your recent announcement that the current draft MOU on interstate distributions will be pulled down and a new draft MOU issued this summer that would establish enhanced reporting requirements rather than a hard percentage cap. However, I and many of my colleagues remain concerned about whether the new draft MOU will continue to redefine the key statutory and medical terms of "distribution" and "dispensing" in a way that is inconsistent with how those terms are defined throughout federal and state law and regulations – and inconsistent with clear congressional intent behind the law. If not addressed in the new draft MOU, this will further exacerbate patient access problems, particularly for patients that rely on medications from pharmacies across state borders in states that do not sign the MOU and will therefore be subject to the statutory default cap of 5 percent. The intent of Congress was again clearly expressed in report language accompanying the legislation funding the FDA for FY 2018 that directs the FDA to address this by treating dispensing and distribution as the different activities they actually are.

65. Does FDA intend to follow this directive on congressional intent when issuing the new draft MOU?

Response: FDA takes seriously the concerns that some stakeholders have raised about the implications of the statutory limitation on distribution of compounded drugs out of the state in which they are compounded found in section 503A(b)(3)(B)(ii) of the FD&C Act. This section provides that a drug cannot qualify for the exemptions under Section 503A if it is compounded in a state that has not entered into an MOU with FDA addressing the distribution of inordinate amounts of compounded drugs out of state and providing for the investigation of complaints, and the compounder distributes compounded drugs interstate in excess of 5% of the total prescription orders dispensed or distributed. Stakeholders expressed concern about maintaining patient access to drugs compounded by pharmacies located in states that may decide not to enter into the MOU with FDA, once the MOU is final and offered for signature. FDA anticipates that the

revisions it intends to make to the draft MOU will encourage states to enter into the MOU once it is final.

As FDA works to develop and issue in the coming months a revised draft MOU for public comment, the Agency is considering the concerns and recommendations conveyed in the 3,000 comments submitted on the 2015 draft MOU, including comments regarding the definition of "distribution."

Congress has also been very clear with the FDA, through letters, statements in the record, and in appropriations reports, that the DQSA was not intended to preempt state pharmacy laws and regulations that allow for office use compounding by 503A pharmacies. Although 503A does require a prescription for an identified individual patient, it does not speak to the timing of the prescription. And the statute clearly authorizes compounding in advance of receipt of prescription (anticipatory compounding) in limited quantities. FDA has, through GFI, allowed for an exception to the prescription requirements for hospitals. Given that prescribers are unable to obtain many of the compounded medications they need for office administration to their patients from 503B registered outsourcing facilities, it would seem that a proposed rule could be crafted that allows for limited office use compounding with reporting requirements and other baseline safeguards that would protect patient safety as well as or better than FDA's current policy in this area.

66. Will FDA consider rescinding the current GFI on the prescription requirement and work with stakeholders on a proposed rule that allows for office-use compounding where authorized by state law, with a federal floor of safety and reporting requirements?

Response: FDA does not intend to withdraw the final guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. The Agency also does not intend to issue a proposed rule "that allows for office-use compounding" because section 503A, since it was enacted in 1997, has required that compounding under that section be based on the receipt of a valid prescription for an identified individual patient (section 503A(a)). Compounding can occur either after the receipt of such a prescription (section 503A(a)(1)), or in limited quantities before the receipt of a prescription (section 503A(a)(2)). When Congress enacted the Drug Quality and Security Act (DQSA) in 2013, it did not amend the prescription requirement in section 503A. Rather, the DQSA created the new category of outsourcing facilities and provided that these entities may or may not obtain prescriptions for identified individual patients (section 503B(d)(4)(C)). Outsourcing facilities are subject to greater quality standards than 503A compounders—current good manufacturing practice (CGMP) requirements—and increased federal oversight, including inspections according to a risk-based schedule.

The prescription requirement in section 503A is critical both to ensure that compounding under that section is based on individual patient need, and to distinguish compounding under section 503A from conventional drug manufacturing and from compounding by outsourcing facilities under section 503B. Failure to enforce the prescription requirement would eliminate a key incentive for compounders to elect to register as outsourcing facilities, undermining a critical

protection that Congress put in place in the DQSA to seek to prevent another tragedy like the 2012 fungal meningitis outbreak that killed more than 60 people and sickened more than 750.

FDA has encouraged practitioners to advise the Agency if circumstances arise in which they are unable to obtain a compounded drug that they need for office stock to meet the medical needs of patients. FDA appreciates that practitioners, medical specialty organizations, and other entities have provided the Agency information about such products. FDA takes seriously such reports and is working to take appropriate action to address them. Upon review of these records, FDA has found that, in many cases, FDA-approved drugs sufficient to meet patient need appear to be available or outsourcing facilities have, in fact, produced the drug products that the practitioners seek. It appears that, in many cases, health care providers were unaware of which outsourcing facilities have compounded or would be willing to compound the drug products they need and inquired about the products with only a few outsourcing facilities. To help address this potential information gap, in September 2017, FDA began to post reports that outsourcing facilities submit to the agency every six months of drug products that they compounded during the previous six-month period.

In addition, FDA has announced that it is revising its draft guidance document concerning CGMP requirements for outsourcing facilities. The revised draft guidance will describe a new, flexible, risk-based approach to CGMP requirements for outsourcing facilities. The policies described in the revised draft guidance will consider how CGMP requirements should be applied in light of the size and scope of an outsourcing facility's operations. FDA anticipates that in response to these new, more flexible policies, certain smaller compounders that compound limited volumes of drugs, and presumably present lower risks, may decide to register as outsourcing facilities, which will allow them to compound drugs with or without patient-specific prescriptions under section 503B. FDA's goal is for more compounders to register as outsourcing facilities with the understanding that they can still meet FDA's core requirements for drug quality, based on the size and scope of their compounding operations.

FDA continues to interpret the statute's language on USP and NF "applicable" monographs as excluding dietary supplement monographs. This has led to a policy where a prescriber cannot ask that a dietary supplement be included in a patient's compounded medication, even when in his or her judgment it is medically necessary. This means the patient can go purchase the supplement separately at retail but cannot follow the medical advice of the prescriber, a clear interference with the doctor, pharmacist, and patient interaction.

67. Will FDA reconsider this interpretation of the statute and allow for compounding with dietary supplements containing a USP or NF formulary?

Response: FDA's interpretation of "applicable" United States Pharmacopeia (USP) or National Formulary (NF) monograph does not mean that compounders cannot produce drug products containing dietary supplement ingredients. However, section 503A restricts the use of substances intended to be used as the active ingredients in drug products (bulk drug substances).

Under section 503A, drug products may be compounded from a bulk drug substance under the following conditions: (1) if the bulk drug substance complies with the standards of an applicable

USP or NF monograph and the USP chapter on pharmacy compounding; (2) if no such monograph exists, the bulk drug substance is a component of an FDA-approved drug; or (3) if no such monograph exists and the bulk drug substance is not a component of an FDA approved drug, it appears on a list to be developed by FDA, through notice-and-comment rulemaking after consultation with the PCAC and the USP ("503A Bulks List"). FDA interprets "applicable" USP or NF monograph to refer to a drug substance monograph.

FDA believes that this interpretation is both legally supportable and in the best interest of the public health. For example, understanding "applicable" monograph to include dietary supplement monographs would allow any substance that has a dietary supplement monograph to be compounded and marketed as a "drug," for uses in the diagnosis, cure, mitigation, treatment, or prevention of a disease, even though the standards of the monograph only contemplate the substance's use as a dietary ingredient or supplement. Dietary ingredients and supplements are intended for ingestion only, and the standards contained in the USP dietary supplement monographs are appropriate only for ingestion. Drug products can have different routes of administration (e.g., intravenous, intra-muscular, topical). The standards in a dietary supplement monograph may not be appropriate for all routes of drug administration. In addition, the USP limits for elemental impurities are different for drugs and dietary supplements. For example, there are limits specified in USP General Chapters for many more elemental contaminants for drugs than there are for dietary ingredients and supplements. Accordingly, administration of a drug product compounded from a dietary ingredient that does not meet USP/NF monograph standards for drug substances, and that has not been evaluated by FDA, in consultation with the PCAC and the USP, for safety, effectiveness, physical and chemical characterization, and historical use, the criteria FDA proposed for evaluating substances, could put patients at risk.

We are concerned that FDA continues to inspect 503A state licensed pharmacies under cGMP standards rather than under applicable state quality standards. Often, agency inspectors cite a violation of FDA's interpretation of the statute as contained in a GFI to remove the pharmacies exemptions under 503A, for example the prohibition on insanitary conditions or for doing office-use compounding pursuant to state law.

68. Will FDA consider rescinding these guidance documents and issuing a proposed rule that requires FDA inspectors to work closely with State Boards of Pharmacy to inspect pharmacies under state adopted standards (e.g. USP 795 and 797)?

Response: FDA does not intend to rescind these guidance documents describing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that apply to pharmacies seeking to produce drugs under section 503A. FDA's guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, describes the Agency's policies concerning the requirement in section 503A that compounding under that section be based on the receipt of valid prescriptions for individually identified patients. The draft guidance, *Insanitary Conditions at Compounding Facilities*, describes examples of insanitary conditions whereby a drug may become contaminated with filth or rendered injurious to health.

FDA works closely with the state boards of pharmacy on inspections of state-licensed pharmacies. For example, the Agency routinely invites the states to participate on such

inspections and shares inspectional information with them. When appropriate, FDA collaborates with states on regulatory action resulting from the inspections.

During these inspections, FDA evaluates compliance with the production standards to which pharmacies are subject. For example, under federal law, all entities, including pharmacies, that prepare, pack, or hold drugs are subject to the prohibition on insanitary conditions in section 501(a)(2)(A) of the FD&C Act. As discussed further below, depending on whether the pharmacy meets the conditions of section 503A, the compounded drug may be subject to current good manufacturing practice (CGMP) requirements.

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or federal facility, or by a licensed physician, to be exempt from certain sections of the FD&C Act, including section 501(a)(2)(B) (concerning CGMP requirements). For a compounded drug to be exempt from CGMP requirements, it must have been compounded in accordance with the conditions of section 503A, including the requirement that compounding be based on the receipt of valid prescriptions for individually identified patients (section 503A(a)). FDA does not inspect pharmacies for compliance with CGMP requirements if it appears that the conditions of section 503A, including the prescription requirement, have been met.

In the past, during an inspection, FDA reviewed a pharmacy's operations for deviations from appropriate sterile practices and conditions that could lead to patient harm, without regard to whether those deviations constituted violations of CGMP requirements or insanitary conditions. FDA would then assess the pharmacy's status of compliance with conditions of section 503A to determine whether to include CGMP violations in any action resulting from the inspection.

In response to stakeholder feedback, FDA announced a change in this procedure effective August 1, 2016. Since then, if, during an inspection of a compounding pharmacy, FDA's investigator makes a preliminary assessment that the pharmacy appears to produce drugs in accordance with the conditions of section 503A, FDA does not inspect for compliance with CGMP. FDA may instead assess whether the pharmacy prepares, packs, or holds drugs under insanitary conditions whereby they may become contaminated with filth or rendered injurious to health (section 501(a)(2)(A) of the FD&C Act). As noted above, the insanitary conditions provision of federal law applies to all producers of drugs, including pharmacies, irrespective of section 503A compliance. Other provisions of Federal law that similarly apply include, for example, sections 501(c) (concerning a drug that is adulterated because its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess) and 502(a) (concerning a drug that is misbranded because its labeling is false or misleading).

Irrespective of whether the pharmacy complies with the conditions in section 503A, FDA inspects for the appropriate provisions of federal, not state, law. FDA does not enforce state laws, which vary widely. For example, some states require compliance with USP Chapter 797, while others do not.

We are concerned that FDA's draft guidance on "essentially a copy" is overbroad and would greatly reduce patient access to compounded medications. This is a policy that should go through the more rigorous rulemaking process rather than through a GFI.

69. Will the agency consider rescinding the current draft GFI on "essentially a copy" and issue a proposed rule that will better incorporate stakeholder input into the implications of the policy on patient access?

Response: On January 18, 2018, FDA issued final guidance documents, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" and "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act." FDA developed these documents with robust stakeholder input. For example, consistent with FDA regulations on good guidance practices, FDA first issued these guidances in draft form for public comment and evaluated all the comments that were submitted during the public comment period before finalizing the guidances. These guidance documents describe FDA's current thinking regarding the "essentially a copy" provisions of sections 503A and 503B.

In the future, the Agency intends to continue to promulgate rules regarding sections 503A and 503B. In the meantime, FDA expects that guidance documents will provide some clarity on FDA's policies regarding these provisions. Compounding in accordance with the provisions of sections 503A and 503B will benefit the public health by, for example, reducing patient exposure to compounded drugs when an FDA-approved drug is appropriate to meet their medical needs.

The section of the GFI on the prescription requirement dealing with "anticipatory compounding" is overly restrictive and does not reflect the Beyond Use Dates of non-sterile medications in its supply limitations.

70. Will the FDA consider rescinding the GFI and issuing a proposed rule reflecting stakeholder input on anticipatory compounding?

Response: Consistent with FDA regulations on good guidance practices, FDA solicited and received comments on the draft guidance document, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act." For example, FDA received and considered stakeholder comments stating that the anticipatory compounding policy proposed in the draft guidance was too stringent. Some commenters expressed concern about the implications for non-sterile drug products assigned beyond-use dates that exceed the period of time for which an anticipatorily compounded drug can be held. FDA also received and considered comments from other stakeholders indicating that the policy described in the guidance with respect to anticipatory compounding was too lenient and could allow a compounder to operate on the scale of a conventional drug manufacturer. Underlying the Agency's policy on anticipatory compounding in its final guidance are statutory requirements, public input received, and public health considerations. For example, the limitations on anticipatory compounding help to protect patients from product quality issues. Because drug products compounded in accordance with section 503A are exempt from current good manufacturing practice requirements, there is an

inherently greater chance of a production mistake or contamination of a sterile or non-sterile drug. Restricting anticipatory compounding, among other things, helps to limit the number of patients likely to be affected if there are drug product mix-ups, potency issues, or contamination.

As another example, FDA clarified in the final guidance that its policy on the "limited quantities" that can be compounded under section 503A in anticipation of receiving a patient specific prescription relates to the amount of inventory held by the compounder, and does not alter the product's BUD.

While FDA states that the Pharmacy Compounding Advisory Committee (PCAC) does have seven pharmacists, it does not appear to have a voting member who is a compounding pharmacist. Additionally, it is concerning that a member of the PCAC is part of an organization that actively lobbies Congress and the agency against compounding interests.

71. Will FDA consider removing representatives of the PCAC with such conflicts and appoint a voting member who is a practicing compounding pharmacist?

Response: The PCAC consists of a core of up to twelve voting members, including the Chairperson, who are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. Currently, seven committee members are pharmacists and five members are physicians. Twelve committee members have experience related to drug compounding, including experience in the preparation, prescribing, and use of compounded medications, as well as compounding-related research activities.

On January 13, 2014, FDA issued a notice in the Federal Register seeking nominations of individuals to serve on the PCAC. FDA selected qualified individuals from the more than 100 names that were submitted to the Agency in response to that request. Candidates with actual or potential conflicts of interest in matters that would come before the committee were eliminated from consideration. For example, for those candidates not representing a particular group, FDA reviewed whether the candidate owned a compounding pharmacy, consulted for the compounding industry, or supplied bulk drug substances for compounding since those activities would likely raise a financial interest that could be affected by the matters expected to come before the committee. In addition, FDA identified qualified candidates from its own pool of special government employees.

On March 27, 2018, FDA issued a notice in the Federal Register soliciting nominations for additional qualified individuals to serve on the PCAC to replace members whose terms will soon expire. In reviewing the nominations, the Agency will, as it has to date, strive to select members with robust and relevant experience and expertise related to drug compounding.

The process by which the PCAC considers substances for the difficult to compound list has not provided stakeholders with adequate time to research and prepare for response to the nomination with only three-weeks' notice.

72. Does the FDA intend to consider every substance nominated and if so, under what time frame?

Response: FDA is reviewing the list, but cannot provide a timeframe under which every nomination will be considered. Under sections 503A and 503B of the FD&C Act, FDA must develop the list of drugs or categories of drugs that present demonstrable difficulties for compounding by regulation, after consulting with the PCAC.

FDA has made significant progress toward establishing the list. The Agency initially solicited nominations for the list in December 2013. Seventy-one drugs or categories of drugs were nominated. In June 2017, in response to stakeholder feedback, FDA opened a new docket, which remains open today, to provide the public with additional opportunity to submit nominations and comments about nominations. FDA developed the criteria that it intends to use to evaluate drugs or categories of drugs for the difficult to compound list and discussed those criteria with the PCAC. FDA has presented to the PCAC proposals to include six categories of drugs on the list. In each case, the PCAC has agreed with FDA's proposal. FDA is working on a proposed rule, for public comment, to address those categories of drugs. While the Agency is working diligently to complete this process, FDA cannot provide an exact timeframe.

FDA appreciates the feedback that it would be helpful for stakeholders to have more time to prepare presentations before the PCAC. FDA seeks to accommodate stakeholder recommendations for process improvements whenever possible.

73. Will the agency consider more advanced notice on upcoming PCAC meetings to allow for more meaningful participation?

Response: FDA appreciates the feedback that it would be helpful for stakeholders to have more time to prepare for matters brought before the PCAC. FDA continues to work to accommodate stakeholder recommendations for process improvements whenever possible.

We were pleased with FDA's decision to pull down the GFI on animal compounding that inappropriately applied DQSA standards to animal compounding.

74. Will FDA issue a proposed rule on animal compounding guidelines and if so, under what statutory authority?

Response: FDA does not intend to issue a proposed rule on compounding animal drugs from bulk drug substances. However, FDA does intend to issue a new draft Guidance for Industry, "Compounding Animal Drugs from Bulk Drug Substances," for public comment later this year. This draft guidance will describe the policies and conditions under which the Agency generally would not intend to take action for certain violations of the federal Food, Drug, and Cosmetic Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk drug substances. The policies and conditions in the guidance aim to protect human and animal health by limiting the use of animal drugs compounded from bulk drug substances primarily to situations in which a veterinarian is acting within a valid veterinarian-client-patient relationship and there is no medically appropriate drug that is FDA-approved.

We are concerned that the language of the recently released draft GFI on 503B outsourcing facilities use of bulk substances seems to require compounding from FDA approved products over bulk substances without appropriate consideration of the clinical needs of patients and inconsistent with the intent of the statute.

75. Will FDA rescind the draft GFI and issue a proposed rule on bulk substances that better balance patient safety with patient access to compounded medications?

Response: FDA's March 2018 draft guidance *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* proposed for public comment, FDA's policy for evaluating bulk drug substances nominated for use in compounding by outsourcing facilities. Section 503B of the FD&C Act directs FDA to develop a list of bulk drug substances for which there is a clinical need (the 503B Bulks List). If finalized as written, this guidance will address FDA's policies for developing the 503B Bulks List, including the Agency's interpretation of the phrase *bulk drug substances for which there is a clinical need*, as it is used in section 503B. The guidance would also address the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

If finalized as written, this draft guidance would not "require compounding from FDA approved products over bulk substances without appropriate consideration of the clinical needs of patients." Rather, two factors that FDA would consider include:

- Whether there is a basis to conclude, for each FDA-approved product that includes the nominated bulk drug substance, that (i) an attribute of the FDA-approved drug product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation, and (ii) the drug product proposed to be compounded is intended to address that attribute; and

- Whether there is a basis to conclude that the drug product proposed to be compounded must be produced from a bulk drug substance.

Should stakeholders have concerns about these factors or other provisions of the draft guidance, FDA encourages them to submit comments to the open docket describing their views. FDA is committed to implementing section 503B of the FD&C Act, including the provision concerning bulk drug substances, in a way that preserves access to compounded drugs for patients who have a medical need for them, while protecting patients from poor-quality or otherwise unsafe compounded drugs that could cause them serious harm.

Financial Charges from the Department of Health and Human Services

76. Please provide table showing a list of all financial charges and assessments to FDA from HHS and the respective OPDivs between fiscal years 2011 and 2018 to date.

Response: FDA would be happy to provide that information for the record. Please see the table below.

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2011 - 2019

Activity	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Actuals	FY 2018 Estimate	FY 2019 Estimate
Assessments	**$ 2,573,109**	**$ 1,731,048**	**$ 1,663,553**	**$ 1,671,603**	**$ 851,748**	**$ 872,042**	**$ 189,676**	**$ 195,000**	**$ 214,517**
Fee for Service	**$ 51,695,674**	**$ 50,873,758**	**$ 33,921,692**	**$ 32,257,550**	**$ 35,214,072**	**$ 45,924,743**	**$ 50,347,571**	**$ 62,660,699**	**$ 65,237,000**
Program Support Center/OS	$ 13,338,939	$ 11,900,677	$ 15,457,143	$ 12,715,848	$ 13,401,223	$ 10,732,477	$ 11,922,372	$ 15,406,922	$ 16,754,000
Federal Occupational Health	$ 2,194,358	$ 1,715,000	$ 2,109,878	$ 2,153,133	$ 2,752,152	$ 2,930,519	$ 2,541,189	$ 3,324,855	$ 3,405,000
Information System Management Service	$ 15,395,377	$ 14,255,081	$ 13,822,413	$ 15,028,969	$ 16,566,789	$ 24,205,476	$ 28,333,746	$ 36,288,950	$ 37,438,000
Human Resource Services	$ 20,767,000	$ 23,003,000	$ 2,532,258	$ 2,359,602	$ 2,495,908	$ 8,056,271	$ 7,548,264	$ 7,639,972	$ 7,640,000
Jointly Funded Services	**$ 7,566,465**	**$ 7,453,627**	**$ 5,962,832**	**$ 4,764,717**	**$ 4,486,371**	**$ 3,445,524**	**$ 3,586,825**	**$ 3,794,775**	**$ 3,673,336**
Enterprise Information Management	$ 4,631,581	$ 3,413,466	$ 2,893,013	$ 1,644,990	$ 1,239,804	$ -	$ -	$ -	$ -
International Health - Bilateral Agreement	$ 1,093,464	$ 1,093,646	$ 1,147,338	$ 1,148,338	$ 1,231,159	$ 1,231,159	$ 1,231,159	$ 1,231,159	$ 1,231,159
Other Jointly Funded Projects	$ 1,841,420	$ 2,946,515	$ 1,922,481	$ 1,971,389	$ 2,015,408	$ 2,214,365	$ 2,355,666	$ 2,563,616	$ 2,442,177
Total	**$ 61,835,248**	**$ 60,058,433**	**$ 41,548,077**	**$ 38,693,870**	**$ 40,552,191**	**$ 50,242,309**	**$ 54,124,072**	**$ 66,650,474**	**$ 69,124,853**

77. What formula does HHS use to charge FDA? Does HHS charge based upon FDA positions, FTE or some other measure? Or does it vary amongst charges?

Response: The formula for the charges varies, mainly between FTE and actual usage.

78. What has FDA assumed for charges and assessments from HHS and other OPDivs in the fiscal year 2019 budget?

Response: FDA would be happy to provide that information for the record. Please see the table below.

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2011 - 2019

Activity	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Actuals	FY 2018 Estimate	FY 2019 Estimate
Assessments	**$ 2,573,109**	**$ 1,731,048**	**$ 1,663,553**	**$ 1,671,603**	**$ 851,748**	**$ 872,042**	**$ 189,676**	**$ 195,000**	**$ 214,517**
Fee for Service	**$ 51,695,674**	**$ 50,873,758**	**$ 33,921,692**	**$ 32,257,550**	**$ 35,214,072**	**$ 45,924,743**	**$ 50,347,571**	**$ 62,660,699**	**$ 65,237,000**
Program Support Center/OS	$ 13,338,939	$ 11,900,677	$ 15,457,143	$ 12,715,848	$ 13,401,223	$ 10,732,477	$ 11,922,372	$ 15,406,922	$ 16,754,000
Federal Occupational Health	$ 2,194,358	$ 1,715,000	$ 2,109,878	$ 2,153,133	$ 2,752,152	$ 2,930,519	$ 2,541,189	$ 3,324,855	$ 3,405,000
Information System Management Service	$ 15,395,377	$ 14,255,081	$ 13,822,413	$ 15,028,969	$ 16,566,789	$ 24,205,476	$ 28,333,746	$ 36,288,950	$ 37,438,000
Human Resource Services	$ 20,767,000	$ 23,003,000	$ 2,532,258	$ 2,359,602	$ 2,495,908	$ 8,056,271	$ 7,548,264	$ 7,639,972	$ 7,640,000
Jointly Funded Services	**$ 7,566,465**	**$ 7,453,627**	**$ 5,962,832**	**$ 4,764,717**	**$ 4,486,371**	**$ 3,445,524**	**$ 3,586,825**	**$ 3,794,775**	**$ 3,673,336**
Enterprise Information Management	$ 4,631,581	$ 3,413,466	$ 2,893,013	$ 1,644,990	$ 1,239,804	$ -	$ -	$ -	$ -
International Health - Bilateral Agreement	$ 1,093,464	$ 1,093,646	$ 1,147,338	$ 1,148,338	$ 1,231,159	$ 1,231,159	$ 1,231,159	$ 1,231,159	$ 1,231,159
Other Jointly Funded Projects	$ 1,841,420	$ 2,946,515	$ 1,922,481	$ 1,971,389	$ 2,015,408	$ 2,214,365	$ 2,355,666	$ 2,563,616	$ 2,442,177
Total	**$ 61,835,248**	**$ 60,058,433**	**$ 41,548,077**	**$ 38,693,870**	**$ 40,552,191**	**$ 50,242,309**	**$ 54,124,072**	**$ 66,650,474**	**$ 69,124,853**

79. What functions or activities does the fiscal year 2018 assessment support? Is FDA anticipating a corresponding increase in services as well?

Response: The functions and activities these assessments support includes the Financial Management Portfolio, Occupational Health Portfolio, Real Estate and Logistics Portfolio, Human Resources Services, Information Technology (IT) Infrastructure and Operations, Enterprise Application Development, Information Security, IT Strategy, and Policy & Governance.

FDA is not anticipating a corresponding increase in services for these types of services. But as additional employees come on board, the services billed by usage or FTE may increase.

GAO/OIG Reports

80. Please provide a listing of all GAO reports conducted on FDA programs and activities in fiscal years 2016, 2017 and 2018 to date.

Response: FDA managed 62 studies that closed from 2016-2018, and is currently managing 18 open studies.

Closed GAO Reports – 2016-2018	
Report Number	**Final Report Title and number**
GAO-16-132	Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks
GAO-16-128	Federal Research Opportunities: DOE, DOD, and HHS Need Better Guidance for Participant Activities
GAO-16-241	Genetically Engineered Crops: USDA Needs to Enhance Oversight and Better Understand Impacts of Unintended Mixing with Other Crops
GAO-16-432	Medical Product Oversight: FDA Needs More Strategic Planning to Guide Its Scientific Initiatives
GAO-16-595	Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge
GAO-16-192	Drug Safety: FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement
GAO-16-305	High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety
GAO-16-425	Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed
GAO-16-399	Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible
GAO-16-513	Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk

Closed GAO Reports – 2016-2018	
Report Number	**Final Report Title and number**
GAO-16-500	Food and Drug Administration: Comprehensive Strategic Planning Needed to Enhance Coordination between Medical Product Centers
GAO-16-110	Information Quality Act: Actions Needed to Improve Transparency and Reporting of Correction Requests
GAO-16-319	Rare Diseases: Too Early to Gauge Effectiveness of FDA's Pediatric Voucher Program
GAO-16-312	VEHICLE SAFETY: Enhanced Project Management of New Information Technology Could Help Improve NHTSA's Oversight of Safety Defects (GAO-16-312)
GAO-17-64	Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges
GAO-16-492	Small Business Research Programs: Agencies Have Improved Compliance with Spending and Reporting Requirements, but Challenges Remain
GAO-16-706	Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases
GAO-16-642	High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk" (Job code 460640/GAO-16-642)
GAO-17-35	Emergency Funding for Ebola Response: Some USAID Reimbursements Did Not Comply with Legislative Requirements and Need to Be Reversed (GAO-17-35)
GAO-16-510	Managing for Results: Agencies Need to Fully Identify and Report Major Management Challenges and Actions to Resolve them in their Agency Performance Plans
GAO-17-115	Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired (GAO-17-115)
GAO-17-119	Environmental Protection: Information on Federal Agencies' Expenditures and Coordination Related to Harmful Algae
GAO-16-325	Cloud Computing: Agencies Need to Incorporate Key Practices to Ensure Effective Performance
GAO-16-833	Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access
GAO-16-548	Federal Workforce: Opportunities Exist to Improve Data on Selected Groups of Special Government Employees

Closed GAO Reports – 2016-2018	
Report Number	**Final Report Title and number**
GAO-16-470T	Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak (GAO-16-470T)
GAO-16-667	Freedom of Information Act: Litigation Costs For Justice and Agencies Could Not Be Fully Determined
GAO-17-14	Open Innovation: Practices to Engage Citizens and Effectively Implement Federal Initiatives
GAO-17-123	Federal Building Management: Building Disposal Authorities Provide Varying Degrees of Flexibility and Opportunities for Use
GAO-17-98R	Food Safety: FDA's Efforts to Evaluate and Respond to Business Concerns Regarding the Produce Rule
GAO-18-61	Sunscreen: FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed (GAO-18-61)
GAO-18-292	Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts
GAO-18-22	Federal Regulations: Key Considerations for Agency Design and Enforcement Decisions
GAO-17-150	Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness, GAO-17-150
GAO 17-87	FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges (GAO-17-87)
GAO-17-129	Foster Care: HHS Has Taken Steps to Support States' Oversight of Psychotropic Medications, but Additional Assistance Could Further Collaboration
GAO-17-74	Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight
GAO-17-347	Technology Assessment: Medical devices: Capabilities and challenges of technologies to enable rapid diagnoses of infectious diseases
GAO-17-416	Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness"
GAO-17-189	Antibiotics: FDA Has Encouraged Development, but Needs to Clarify the Role of Draft Guidance and Develop Qualified Infectious Disease Product Guidance
GAO-17-143	Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices-
GAO-17-443	Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residue" (GAO-17-443)
GAO-17-546	GAO-17-546: Low-Dose Radiation: Interagency Collaboration on Planning Research Could Improve Information on Health Effects

Closed GAO Reports – 2016-2018	
Report Number	**Final Report Title and number**
GAO-17-231	MEDICAL DEVICES: Cancer Risk Led FDA to Warn Against Certain Uses of Power Morcellators and Recommend New Labeling
GAO-17-360	Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts
GAO-17-564	Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used
GA0-17-452	Generic Drug User Fees: Application Review Times Declined, but FDA Should Develop a Plan for Administering Its Unobligated User Fees
GAO-18-40	Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals
GAO-17-212	National Institutes of Health: Kidney Disease Research Funding and Priority Setting
GAO-17-445	Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks
GAO-18-155	Biodefense: Federal Efforts to Develop Biological Threat Awareness" (Job code 100751/GAO-18-155).
GAO-18-12	WORKPLACE SAFETY AND HEALTH: Better Outreach, Collaboration, and Information Needed to Help Protect Workers at Meat and Poultry Plants
GAO-18-44	Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment (GAO-18-44)
GAO-18-32	Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome" (GAO-18-32)
GAO-17-507	Open Innovation: Executive Branch Developed Resources to Support Implementation, but Guidance Could Better Reflect Leading Practices
GAO-18-85	Food Safety: FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule
GAO-18-271	Customs and Border Protection: Automated Trade Data System Yields Benefits, but Interagency Management Approach Is Needed
GAO-18-205	Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts (GAO-18-205)
GAO-18-219	Inter-American Organizations: U.S. Agencies Support Oversight Mechanisms but Could Enhance Their Monitoring of U.S. Assistance Agreements (GAO-18-219)

Closed GAO Reports – 2016-2018	
Report Number	**Final Report Title and number**
GAO-18-272	FOOD SAFETY: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products
GAO-18-80	Generic Drugs: FDA Should Announce Plans to Issue and Revise Guidance on Nonbiological Complex Drugs (GAO-18-80).
GAO-18-199	Food Safety: Federal Efforts to Manage the Risk of Arsenic in Rice

Ongoing GAO Studies, May 2018	
Job Code Number	**Name of Study**
101198	Federal Cybersecurity Workforce Assessment
101985	Animal Welfare in Federal Research Facilities
101360	Federal Paperwork Burden
101932	Memory Supplement Testing
102139	Inventory Controls and Purchases of Firearms, Ammunition, and Tactical Equipment at Federal Agencies
102688	Opioid Public Health Emergency Declaration
102684	Risk Evaluation and Mitigation Strategies (REMS)
102526	Transparency of Federal Grant Funding
102032	Information Technology (IT) Noncompetitive and Bridge Contracts
102451	Access to Federally Funded Research Data
102371	Orphan Drugs and Biologics
102425	FDA Food Products Import Alerts
102595	Date Labeling on Packaged Food
102502	Food Loss and Waste
102509	Federal Preparedness for Responding to Antimicrobial-Resistant Pathogens
102423	Internet Privacy and Security
102547	FDA Tobacco User Fees
100774	Use of budget authority and permanent appropriations -- also referred to as "backdoor authority"

81. Please provide a full status of FDA's recent progress in resolving OIG or GAO recommendations in the past five years as well as a list of open items.

Response: From 2013 to 2017, FDA has resolved 119 GAO recommendations in 43 GAO reports. GAO has closed 87 of these as "implemented" and 32 as "not implemented." FDA is currently working on resolving 50 open recommendations in 27 GAO reports.

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health	GAO-12-46	To enhance FDA's efforts to combat the economic adulteration of food and medical products, the Commissioner of FDA should adopt a working definition of economic adulteration	Closed - Implemented	2013
Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts	GAO-09-523	To help ensure the success of FDA's modernization efforts, the Commissioner of FDA should require the CIO to take expeditious actions to accelerate development of the segment and enterprise architecture, including "as is," "to be," and transition plans, and in the meantime develop plans to manage the increased risk to modernization projects of proceeding without an architecture to guide and constrain their development.	Closed - Implemented	2013
Oversight of Clinical Investigators: Action Needed to Improve Timeliness and Enhance Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators	GAO-09-807	Pursue debarment authority for medical devices that is consistent with the current debarment authority for drugs and biologics and prohibit any debarred individual from involvement with drugs, biologics, and medical devices.	Closed - Not Implemented	2013
Bottled Water: FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA	GAO-09-610	Issue a standard of quality regulation for DEHP, or publish in the Federal Register the agency's reasons for not doing so one year after the	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Protections for Tap Water		conclusion of its task force study on this matter.		
FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters	GAO-11-607	To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, the Secretary of Health and Human Services (HHS) should direct the Commissioner of FDA to work with the ISSC to conduct further study of the six issues of concern we identified regarding the FDA-commissioned Research Triangle Institute International (RTI) report's economic analysis to ensure a more accurate assessment of the feasibility of developing adequate capacity and before FDA and the ISSC move forward with revising the National Shellfish Sanitation Program's shellfish safety guidelines to provide postharvest processing for oysters harvested from Gulf Coast waters during warmer months and intended for raw consumption.	Closed - Implemented	2013
Privacy and Security: Food and Drug Administration Faces Challenges in Establishing Protections for Its Postmarket Risk Analysis System	GAO-09-355	Ensuring consistent application of protections to all Sentinel partners; Limiting use of personal health information to a clear and specific purpose; Involving the public in the development of the system and informing the public of the	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		program's planned uses of personal health information and privacy protections; Using de-identified data; Establishing comprehensive security controls; Overseeing and enforcing key privacy requirements.		
Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts	GAO-09-523	To help ensure the success of FDA's modernization efforts, the Commissioner of FDA should require the CIO to take expeditious actions to complete the criteria for setting priorities for the segment architecture and prioritize the segments.	Closed - Implemented	2013
Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health	GAO-12-46	To enhance FDA's efforts to combat the economic adulteration of food and medical products, the Commissioner of FDA should enhance communication and coordination of agency efforts on economic adulteration.	Closed - Implemented	2013
Bottled Water: FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water	GAO-09-610	Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers how to obtain comprehensive information. Should FDA determine it lacks the necessary authority to implement its findings, it	Closed - Not Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		should seek legislation to obtain such authority.		
Human Capital: Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives	GAO-10-226	To better align the use of 3R incentives with the agency's human capital goals, the Commissioner of FDA should update FDA's strategic workforce plan to document the agency's recruitment and retention goals and strategies and as part of that update, identify indicators to better track the progress of 3R incentives over time in addressing the agency's recruitment and retention goals.	Closed - Implemented	2013
Human Capital: Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives	GAO-10-226	As FDA implements the results of its 2009 review of 3R incentives, the Commissioner of FDA should continue to strengthen FDA's internal controls for requesting, approving, and processing 3R incentives by updating the guidance for awarding 3R incentives to include the payment method used for retention incentives and all the conditions for terminating a retention incentive when no service agreement is required.	Closed - Implemented	2013
Human Capital: Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives	GAO-10-226	As FDA implements the results of its 2009 review of 3R incentives, the Commissioner of FDA should continue to strengthen FDA's internal controls for requesting, approving, and processing 3R incentives by	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		ensuring 3R incentive files are properly completed and reviewed to address policy and regulatory requirements before the employees receive the incentive payments.		
Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts	GAO-09-523	Develop a skills inventory, needs assessment, and gap analysis, and develop initiatives to address skills gaps as part of a strategic approach to IT human capital planning.	Closed - Implemented	2013
Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process	GAO-06-402	To improve the postmarket drug safety decision-making process, the Commissioner of FDA should improve the Center for Drug Evaluation and Research's dispute resolution process by revising the pilot program to increase its independence.	Closed - Implemented	2013
Pediatric Medical Devices Provisions Support Development, but Better Data Needed for Required Reporting	GAO-12-225	The Commissioner of FDA should collect reliable information to report data related to pediatric medical devices. Specifically, FDA should take steps to consistently collect information using its existing pediatric electronic flag or otherwise develop internal controls to readily and reliably collect and report information on devices for pediatric use.	Closed - Implemented	2013
Antibiotic Resistance Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals	GAO-11-801	To enhance surveillance of antibiotic-resistant bacteria in food animals, we recommend that the Secretaries of Agriculture and Health and Human Services direct	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		agencies to, consistent with their existing authorities modify NARMS sampling to make the data more representative of antibiotic resistance in food animals and retail meat throughout the United States.		
Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention	GAO-09-258	To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration publicize the criteria FDA uses to revise the Seafood List, provide the opportunity for stakeholder comments prior to formalizing any changes to the list not required by law or regulation, and routinely update the public version of the list whenever FDA makes any changes.	Closed - Implemented	2013
Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process	GAO-06-402	To improve the postmarket drug safety decision-making process, the Commissioner of FDA should clarify ODS's role in FDA's scientific advisory committee meetings involving postmarket drug safety issues.	Closed - Implemented	2013
Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring	GAO-09-60	To reduce the risk and impact of unauthorized releases, we recommend that the Secretary of Agriculture and the FDA Commissioner develop a formal agreement to share information concerning GE crops with novel genetic traits that, if unintentionally released	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		into the food or feed supply, present or are likely to present public health concerns and, as a result, also could have negative financial consequences for the food and agriculture industry. With information from USDA about permits or notifications for field trials of such GE crops, FDA could identify which GE crops might benefit from an early food safety evaluation and encourage developers of those crops to participate in evaluations. With assistance from FDA, USDA could make meaningful and transparent use of the health evaluation data available through FDA's early food safety evaluations in its risk assessments of GE crops.		
Women's Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement	GAO-01-754	The FDA should adopt management tools that will ensure drug sponsors' compliance with current regulations regarding the presentation of data by sex and that its reviewers' consistently and systematically discuss sex differences in their written reviews of NDAs. Specifically, FDA should promptly implement management tools, such as the proposed demographic worksheet and the standardized template for Medical Officer Reviews, that will allow the agency to determine if NDAs and IND annual reports are in compliance with regulations	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		that mandate the presentation of available safety and efficacy outcome data for women in NDAs and the tabulation of study participants by sex in the annual reports.		
Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food	GAO-09-873	To better leverage state resources for protecting the safety of imported food, GAO recommends that the FDA Commissioner reach out to states to find opportunities for additional collaboration through contracts, cooperative agreements, and informal partnerships.	Closed - Implemented	2013
Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding	GAO-09-250	To improve consumer understanding about dietary supplements and better leverage existing resources, we recommend that the Secretary of the Department of Health and Human Services direct the Commissioner of FDA to coordinate with stakeholder groups involved in consumer outreach to (1) identify additional mechanisms—such as the recent WebMD partnership—for educating consumers about the safety, efficacy, and labeling of dietary supplements, (2) implement these mechanisms, and (3) assess their effectiveness.	Closed - Implemented	2013
Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts	GAO-09-523	Develop a documented EA program management plan that includes a detailed work breakdown of the tasks, activities, and time frames	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		associated with developing the architecture, as well as the funding and the staff resources needed;		
Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews	GAO-09-205	To improve the monitoring and evaluation of rules development and the transparency of the review process, and to be consistent with internal controls for information in managing agency operations, for significant rules, the Commissioner of FDA and the Chairman of SEC should routinely track major milestones in regulatory development and report internally and externally when major milestones are reached against established targets.	Closed - Implemented	2013
Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts	GAO-09-523	Set milestones and a completion date for developing a comprehensive IT strategic plan, including results oriented goals, strategies, milestones, performance measures, and an analysis of interdependencies among projects and activities, and use this plan to guide and coordinate its modernization projects and activities.	Closed - Implemented	2013
Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews	GAO-09-205	To improve the monitoring and evaluation of rules development and the transparency of the review process, and to be consistent with internal controls for information in managing agency operations, the Administrator of EPA, the	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		Commissioner of FDA, and the Chairman of SEC should each evaluate actual performance versus the targeted milestones and when they are different determine why.		
Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention	GAO-09-258	To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration update the Fish and Fisheries Products Hazards and Controls Guidance to reflect the seafood labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004.	Closed - Implemented	2013
Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention	GAO-09-258	To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and Commissioner of the Food and Drug Administration develop goals, strategies, and mechanisms to share information and resources related to seafood fraud	Closed - Not Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		detection and prevention across agency boundaries.		
Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention	GAO-09-258	To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and Commissioner of the Food and Drug Administration create a federal agency-wide library of seafood species standards.	Closed - Implemented	2013
Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding	GAO-09-250	To improve the information available to FDA for identifying safety concerns and better enable FDA to meet its responsibility to protect the public health, we recommend that the Secretary of the Department of Health and Human Services direct the Commissioner of FDA to request authority to require dietary supplement companies to: • Identify themselves as a dietary supplement company as part of the existing registration requirements and update this information annually, • Provide a list of all dietary supplement products they sell and a copy of the labels and	Closed - Implemented	2013

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		update this information annually, and • Report all adverse events related to dietary supplements.		
Medical Devices FDA Should Enhance Its Oversight of Recalls	GAO-11-468	To enhance FDA's oversight of medical device recalls, and in particular, those medical device recalls that pose the highest risk, the Commissioner of FDA should document the agency's basis for terminating individual recalls.	Closed - Implemented	2014
Medical Devices FDA Should Enhance Its Oversight of Recalls	GAO-11-468	To enhance FDA's oversight of medical device recalls, and in particular, those medical device recalls that pose the highest risk, the Commissioner of FDA should develop explicit criteria for assessing whether recalling firms have performed an effective correction or removal action.	Closed - Implemented	2014
Medical Devices FDA Should Enhance Its Oversight of Recalls	GAO-11-468	To enhance FDA's oversight of medical device recalls, and in particular, those medical device recalls that pose the highest risk, the Commissioner of FDA should clarify procedures for conducting medical device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.	Closed - Implemented	2014
Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims	GAO-11-102	To ensure that the health-related claims on food labels are not false or misleading to consumers, the Secretary of Health and Human Services should direct the Commissioner of FDA to	Closed - Not Implemented	2014

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		amend the "Compliance Program Guidance Manual" instructions to FDA inspectors for reviewing food labels during inspections of food facilities, to include steps for identifying potentially false or misleading structure/function claims for further review.		
Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims	GAO-11-102	To ensure that the health-related claims on food labels are not false or misleading to consumers, the Secretary of Health and Human Services should direct the Commissioner of FDA to identify and request from Congress the authorities needed to access evidence from food companies regarding potentially false or misleading structure/function or other claims on food that would allow the agency to establish whether there is scientific support for the claims.	Closed - Not Implemented	2014
Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring	GAO-09-60	To help ensure that unintended consequences arising from the marketing of GE crops are detected and minimized, we recommend that the Secretary of Agriculture, the EPA Administrator, and the FDA Commissioner develop a coordinated strategy for monitoring marketed GE crops and use the results to inform their oversight of these crops. Such a strategy should adopt a risk-based approach to	Closed - Not Implemented	2014

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		identifying the types of marketed GE crops that warrant monitoring, such as those with the greatest potential for affecting the environment or non-GE segments of agriculture, or those that might threaten the food safety through the unintentional introduction of pharmaceutical or industrial compounds into the food supply. The strategy should also identify criteria for determining when monitoring is no longer needed. In developing a strategy, the agencies should draw upon the analysis and conclusions of the National Research Council and the National Science and Technology Council.		
Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program	GAO-08-970	To address weaknesses in FDA's oversight of foreign establishments manufacturing drugs for the U.S. market, the Commissioner of FDA should establish mechanisms for verifying information provided by the establishment at the time of registration.	Closed - Implemented	2014
Drug Shortages FDA's Ability to Respond Should Be Strengthened	GAO-12-116	To strengthen FDA's ability to protect the public health through its response to drug shortages, the Commissioner of FDA should assess the resources allocated to the Drug Shortage Program to determine whether reallocation is needed to improve the agency's response to drug shortages.	Closed - Implemented	2014

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions	GAO-10-309R	To more effectively manage its food irradiation petitions, GAO recommends that the Commissioner of the Food and Drug Administration direct the Office of Food Additive Safety to communicate its key decisions to its petitioners and, for the new petitions, the status of its decision making, consistent with regulatory timeframes to be consistent with FDA regulations.	Closed - Implemented	2014
Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions	GAO-10-309R	To more effectively manage its food irradiation petitions, GAO recommends that the Commissioner of the Food and Drug Administration direct the Office of Food Additive Safety to document its key decisions in its administrative files to be consistent with FDA regulations.	Closed - Implemented	2014
Food and Drug Administration: Opportunities Exist to Better Address Management Challenges	GAO-10-279	To encourage greater use of performance information, the Commissioner of FDA should work to build FDA's capacity to collect and analyze performance information by expanding training for managers on topics related to performance information.	Closed - Implemented	2014
Food and Drug Administration: Opportunities Exist to Better Address Management Challenges	GAO-10-279	To more clearly demonstrate the alignment of activities to strategic goals, the Commissioner of FDA should direct each of the agency's main centers and offices to clearly align their program activities to FDA's strategic goals in documents, such as	Closed - Implemented	2014

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		the budget request or center- and office-level documents.		
Food and Drug Administration: Opportunities Exist to Better Address Management Challenges	GAO-10-279	To more strategically manage its human capital, the Commissioner of FDA should develop a strategic human capital plan and issue an updated workforce plan.	Closed - Implemented	2014
Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program	GAO-08-970	To address weaknesses in FDA's oversight of foreign establishments manufacturing drugs for the U.S. market, the Commissioner of FDA should enforce the requirement that establishments manufacturing drugs for the U.S. market update their registration annually.	Closed - Implemented	2014
Medical Devices - FDA Should Enhance Its Oversight of Recalls	GAO-11-468	To enhance FDA's oversight of medical device recalls, and in particular, those medical device recalls that pose the highest risk, the Commissioner of FDA should create a program to routinely and systematically assess medical device recall information, and use this information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. This assessment should be designed, at a minimum, to identify trends in the numbers and types of recalls, devices most frequently being recalled, and underlying causes of recalls.	Closed - Implemented	2014
Drug Shortages: Better Management of the	GAO-15-202	To strengthen DEA's and FDA's ability to respond to	Closed - Implemented	2015

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Quota Process for Controlled Substances Needed: Coordination between DEA and FDA should be improved		shortages of drugs containing controlled substances, the Administrator of DEA and the Commissioner of FDA should promptly update the MOU between the two agencies.		
Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations	GAO-10-221	To ensure OCI's compliance with investigative policies the Secretary of Health and Human Services (HHS) should instruct the Commissioner of FDA to have regular assessments of OCI's field offices conducted in accordance with its existing policy.	Closed - Implemented	2015
Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations	GAO-10-221	To ensure OIA's compliance with investigative policies, the Secretary of HHS should instruct the Commissioner of FDA to establish a review procedure for the assessment of OIA's compliance with its investigative policies.	Closed - Implemented	2015
Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources	GAO-11-286	To better ensure the safety of seafood imports, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop a strategic approach with specific time frames for enhancing collaborative efforts with NMFS and better leveraging NMFS inspection resources.	Closed - Not Implemented	2015
Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better	GAO-11-286	To better ensure the safety of seafood imports, the Secretary of Health and Human Services should direct the Commissioner of FDA to	Closed - Not Implemented	2015

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Leverage Limited Resources		develop a more comprehensive import sampling program for seafood by more effectively using its laboratory resources and taking into account the imported seafood sampling programs of other entities and countries.		
Information Technology FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks	GAO-12-346	help ensure the success of FDA's modernization efforts, the Commissioner of FDA should direct the CIO to take immediate steps to identify all of FDA's IT systems and develop an inventory that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the agency's IT investment management process.	Closed - Implemented	2015
Information Technology FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks	GAO-12-346	To help ensure the success of FDA's modernization efforts, the Commissioner of FDA should direct the CIO to assess information-sharing needs and capabilities of the Center for Food Safety and Applied Nutrition (CFSAN) to identify potential areas of improvements needed to achieve more efficient information sharing among databases and develop a plan for implementing these improvements.	Closed - Implemented	2015
Food Safety: FDA Should Strengthen Its Oversight of Food	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO	Closed - Implemented	2015

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Ingredients Determined to Be Generally Recognized as Safe (GRAS)		recommends that the Commissioner of FDA develop a strategy to help ensure the safety of engineered nanomaterials that companies market as GRAS substances without the agency's knowledge, including taking steps such as issuing guidance recommended by the agency's nanotechnology taskforce, developing an agency definition of engineered nanomaterials, and requiring companies to inform FDA if their GRAS determinations involve engineered nanomaterials.		
Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding	GAO-09-250	To help ensure that companies follow the appropriate laws and regulations and renew a recommendation we made in July 2000, we recommend that the Secretary of the Department of Health and Human Services direct the Commissioner of FDA to provide guidance to industry to clarify when products should be marketed as either dietary supplements or foods with added dietary ingredients.	Closed - Implemented	2015
Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA	GAO-11-457	The Commissioner of FDA should move expeditiously to track applications upon their submission and throughout its review process and maintain aggregate data, including the total number of applications that are subject to PREA and	Closed - Implemented	2015

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		whether those applications include pediatric studies.		
Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations	GAO-10-221	To assess whether OCI's criminal investigative program is achieving its desired results, the Secretary of HHS should instruct the Commissioner of FDA to establish performance measures and assess program results against them.	Closed - Not Implemented	2015
Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention	GAO-09-258	To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration propose amendments to FDA's seafood HACCP regulations to include requirements that covered facilities include control points that can be used to identify and mitigate economic fraud risks.	Closed - Not Implemented	2015
Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims	GAO-11-102	To ensure that the health-related claims on food labels are not false or misleading to consumers, the Secretary of Health and Human Services should direct the Commissioner of FDA to provide guidance to industry on the type and strength of scientific evidence needed to prevent false or misleading information in a structure/function claim.	Closed - Not Implemented	2015
Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better	GAO-11-286	To better ensure the safety of seafood imports, the Secretary of Health and Human Services should direct the	Closed - Not Implemented	2015

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Leverage Limited Resources		Commissioner of FDA to study the feasibility of adopting other practices used by other entities, such as requiring foreign countries that want to export seafood to the United States to develop a national residues monitoring plan to control the use of aquaculture drugs, to more efficiently ensure the safety of imported seafood and report its findings to the Secretary.		
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To address FDA's communication challenges in advising the public about food recalls and outbreaks, the Secretary of Health and Human Services should direct the Commissioner of FDA to implement recommendations following from our prior work and others' input to consult with USDA on lessons learned in advising consumers about recalls to determine whether any of United States Department of Agriculture's (USDA) practices may be feasible at FDA, as consistent with applicable law.	Closed - Not Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop a policy for system maintenance.	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Drug Shortages FDA's Ability to Respond Should Be Strengthened	GAO-12-116	To strengthen FDA's ability to protect the public health through its response to drug shortages, the Commissioner of FDA should ensure that FDA's strategic plan articulates goals and priorities for maintaining the availability of all medically necessary drugs--including generic drugs.	Closed - Implemented	2016
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To address FDA's communication challenges in advising the public about food recalls and outbreaks, the Secretary of Health and Human Services should direct the Commissioner of FDA to implement recommendations from FDA's risk communication committee to develop a policy for communications during emerging events.	Closed - Not Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to review and approve security plans for the six systems reviewed at least annually.	Closed - Implemented	2016
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To strengthen FDA's process for ordering recalls, the Secretary of Health and Human Services should direct the Commissioner of FDA to	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		identify and implement ways to improve information sharing among its databases that contain recall data.		
Food and Drug Administration: Opportunities Exist to Better Address Management Challenges	GAO-10-279	To more clearly demonstrate alignment of resources to strategic goals, once FDA creates a more results-oriented set of performance measures, the Commissioner of FDA should direct FDA's centers and offices to track their workload by strategic goals.	Closed - Not Implemented	2016
Food and Drug Administration: Opportunities Exist to Better Address Management Challenges	GAO-10-279	To help decision makers more effectively gauge agency progress, the Commissioner of FDA should work to make FDA's performance measures more results-oriented.	Closed - Not Implemented	2016
Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced	GAO-02-566	To enhance FDA's safety evaluations of GM foods, the Deputy Commissioner of Food and Drugs should direct the agency's Center for Food Safety and Applied Nutrition to obtain, on a random basis, raw test data from companies, during or after consultations, as a means of verifying the completeness and accuracy of the summary test data submitted by companies.	Closed - Not Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop and document a security plan for one system	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		supporting FDA's scientific research.		
Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability	GAO-14-194	To enhance its oversight of drug shortages, particularly as the agency fine-tunes the manner in which it gathers data on shortages and transitions from its database to a more robust system, the Commissioner of FDA should develop policies and procedures for the use of the existing drug shortages database (and, ultimately, the new drug shortages information system) to ensure staff enter information into the database in a consistent manner and to ensure the accuracy of the information in the database.	Closed - Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to complete a risk assessment and authorization to operate for one FDA system.	Closed - Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to ensure that completed risk assessments for six systems reviewed address the	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		likelihood and impact of threats to FDA.		
Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products	GAO-13-244	To enhance FDA's ability to use AERs and to oversee dietary supplement products, the Secretary of the Department of Health and Human Services should direct the Commissioner of FDA to implement the agency's efforts to facilitate industry reporting of mandatory AERs electronically.	Closed - Implemented	2016
Food Safety: Improvements Needed in FDA Oversight of Fresh Produce	GAO-08-1047	To enhance FDA's oversight of fresh produce safety, Commissioner of FDA should see that the agency updates its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices.	Closed - Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to update FDA's incident response policy in accordance with agency requirements.	Closed - Implemented	2016
Drug Shortages FDA's Ability to Respond Should Be Strengthened	GAO-12-116	To strengthen FDA's ability to protect the public health through its response to drug shortages, the Commissioner of FDA should develop results-oriented performance metrics to assess and quantify	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		the implementation of the agency's goals and FDA's response to drug shortages.		
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should clarify or provide new guidance on which antibiotic sponsors are responsible for annually evaluating and maintaining up-to-date breakpoints on drug labels.	Closed - Not Implemented	2016
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should notify sponsors when one of their drugs becomes or ceases to be a reference-listed drug.	Closed - Not Implemented	2016
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should establish a process to track sponsors' submissions of breakpoint information included in their annual reports to ensure that such information is submitted to FDA and reviewed by the agency in a timely manner.	Closed - Not Implemented	2016
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should ensure that all sponsors responsible for the annual review of breakpoints on their antibiotics' labels—including discontinued brand-name antibiotics and reference-listed antibiotics designated since 2008—have been reminded of their responsibility to evaluate	Closed - Not Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		and maintain up-to-date breakpoints.		
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should take steps to obtain breakpoint information from sponsors that have not yet submitted breakpoint information in response to the 2008 letters sent by the agency.	Closed - Implemented	2016
Antibiotics FDA Needs to Do More to Ensure That Drug Labels Contain Up-to-Date Information	GAO-12-218	To help ensure that antibiotics are accurately labeled, the Commissioner of FDA should expeditiously review sponsors' submissions regarding the breakpoints on their antibiotics' labels.	Closed - Implemented	2016
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To address FDA's communication challenges in advising the public about food recalls and outbreaks, the Secretary of Health and Human Services should direct the Commissioner of FDA to implement recommendations from the Institute of Medicine and National Research Council to develop, in conjunction with other federal agencies, a coordinated plan for crisis communications.	Closed - Not Implemented	2016
Food and Drug Administration Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health	GAO-12-46	To enhance FDA's efforts to combat the economic adulteration of food and medical products, the Commissioner of FDA should provide written guidance to agency centers and offices on	Closed - Not Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		the means of addressing economic adulteration.		
Antibiotic Resistance Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals	GAO-11-801	To better focus future federal research efforts on alternatives to current antibiotic use practices, the Secretaries of Agriculture and Health and Human Services should direct agencies to (1) assess previous research efforts on alternatives and identify gaps where additional research is needed, in collaboration with the animal production industry, and (2) specify steps in the draft 2010 interagency plan that agencies will take to fill those gaps.	Closed - Not Implemented	2016
FDA Should Expand Its Consideration of Information Security for Certain Types of Devices	GAO-12-816	Recommendation: To better ensure the safety and effectiveness of active implantable medical devices, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop and implement a more comprehensive plan to assist the agency in enhancing its review and surveillance of medical devices as technology evolves, and that will incorporate the multiple aspects of information security. This plan should include, at a minimum, four actions, such as determining how FDA can (1) increase its focus on manufacturers' identification of potential unintentional and intentional threats, vulnerabilities, the	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		resulting information security risks, and strategies to mitigate these risks during its PMA review process; (2) utilize available resources, including those from other entities, such as other federal agencies; (3) leverage its postmarket efforts to identify and investigate information security problems; and (4) establish specific milestones for completing this review and implementing these changes.		
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to test controls at least annually for the two systems that support FDA's scientific research and IT infrastructure.	Closed - Implemented	2016
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To strengthen FDA's process for ordering recalls, the Secretary of Health and Human Services should direct the Commissioner of FDA to document definitions for categories of ordered recalls in the agency's central recall database.	Closed - Implemented	2016
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To strengthen FDA's process for ordering recalls, the Secretary of Health and Human Services should direct the Commissioner of FDA to	Closed - Implemented	2016

GAO Closed Recommendations, 2013-2017				
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		document FDA's process for ordering food recalls in publicly available procedures.		
Food Safety: Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters	GAO-11-607	To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, the Secretary of Health and Human Services (HHS) should direct the Commissioner of FDA to work with the ISSC to agree on a nationwide goal for reducing the number of V. vulnificus illnesses caused by the consumption of Gulf Coast raw oysters and develop strategies to achieve that goal, recognizing that consumer education and time and temperature controls have not resulted in achievement of the 60 percent V. vulnificus illness rate reduction goal and that the capacity to use postharvest processing on Gulf Coast oysters harvested from April through October that are intended for raw consumption does not currently exist.	Closed - Not Implemented	2016
Food Safety: Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters	GAO-11-607	To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, the Secretary of Health and Human Services (HHS) should direct the Commissioner of FDA to work with the ISSC to regularly evaluate the effectiveness of V. vulnificus illness reduction strategies, such as consumer education and time and	Closed - Not Implemented	2016

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		temperature controls, to determine whether they are successful and should be continued or are ineffective and should be stopped.		
FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources	GAO-12-933	To better leverage the oversight resources of foreign countries and ensure the safety of food imports, the Secretary of Health and Human Services should direct the Commissioner of FDA to revise FDA's comparability approach to one that allows for the flexibility of assessing foreign food safety systems for particular food products, such as seafood, when a full comparability assessment of foreign countries' food safety systems may not be feasible.	Closed - Not Implemented	2016
Food Safety: Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters	GAO-11-607	To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, the Secretary of Health and Human Services (HHS) should direct the Commissioner of FDA to work with the ISSC to correct the limitations in the current approach to measuring progress toward the 60 percent V. vulnificus illness rate reduction goal or design and implement a new approach without these limitations.	Closed - Not Implemented	2016
Information Security: FDA Needs to Rectify Control Weaknesses That	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
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Place Industry and Public Health Data at Risk		Human Services should direct the Commissioner of FDA to ensure that personnel with significant security responsibilities receive role-based training.		
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to implement remedial actions in accordance with FDA's prescribed time frames or update milestones if actions are delayed.	Closed - Implemented	2017
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to update security plans to ensure the plans fully and accurately document the controls selected and intended for protecting each of the six systems.	Closed - Implemented	2017
Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program	GAO-08-970	To address weaknesses in FDA's oversight of foreign establishments manufacturing drugs for the U.S. market, the Commissioner of FDA should conduct more inspections to ensure that foreign establishments manufacturing drugs currently marketed in the United States are inspected at a frequency comparable to	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
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		domestic establishments with similar characteristics.		
Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program	GAO-08-970	To address weaknesses in FDA's oversight of foreign establishments manufacturing drugs for the U.S. market, the Commissioner of FDA should conduct timely inspections of foreign establishments that have received warning letters to determine continued compliance.	Closed - Implemented	2017
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to review and update as needed per FDA's frequency, the policies for the following 11 security control families: Access Control, Audit and Accountability, Contingency Planning, Identification and Authentication, Incident Response, Media Protection, Physical and Environmental Protection, Security Planning, Personnel Security, System and Services Acquisition, and System and Information Integrity.	Closed - Implemented	2017
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
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		enhance procedures for the following 7 security control families: Access Control, Awareness and Training, Security Assessment and Authorization, Configuration Management, Program Management, Personnel Security, and System and Services Acquisition.		
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to implement a process to effectively monitor and track training for personnel with significant security roles and responsibilities.	Closed - Implemented	2017
Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO recommends that the Commissioner of FDA develop a strategy to conduct reconsiderations of the safety of GRAS substances in a more systematic manner, including taking steps such as allocating sufficient resources to respond to citizen petitions in a timely manner, developing criteria for the circumstances under which the agency will reconsider the safety of a GRAS substance, and considering how to collect information from companies on their reconsiderations.	Closed - Not Implemented	2017

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight	GAO-13-702	The Secretary of Health and Human Services should direct the Commissioner of the FDA to take steps to consistently collect reliable and timely information in FDA's existing databases on inspections and enforcement actions associated with compounded drugs.	Closed - Implemented	2017
Drug Shortages FDA's Ability to Respond Should Be Strengthened	GAO-12-116	To strengthen FDA's ability to protect the public health through its response to drug shortages, the Commissioner of FDA should develop an information system that will enable the Drug Shortage Program to manage its daily workload in a systematic manner, track data about drug shortages--including their causes and FDA's response--and share information across FDA offices regarding drugs that are in short supply.	Closed - Implemented	2017
Antibiotic Resistance Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals	GAO-11-801	To track the effectiveness of policies to curb antibiotic resistance, including FDA's voluntary strategy designed to reduce antibiotic use in food animals and to address action items in the surveillance focus area of the 2001 interagency plan, the Secretaries of Agriculture and Health and Human Services should direct agencies to, consistent with their existing authorities, (1) identify potential approaches for collecting detailed data on antibiotic use in food animals, including the species in which	Closed - Not Implemented	2017

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		antibiotics are used and the purpose for their use, as well as the costs, time frames, and potential trade-offs associated with each approach; (2) collaborate with industry to select the best approach; (3) seek any resources necessary to implement the approach; and (4) use the data to assess the effectiveness of policies to curb antibiotic resistance.		
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to update incident response procedures to include (1) instructions for coordinating incident response with contingency planning and (2) lessons learned from incident response tests.	Closed - Implemented	2017
Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed	GAO-10-960	To help ensure that FDA's overseas offices are able to fully meet their mission of helping to ensure the safety of imported products, the Commissioner of FDA should develop a strategic workforce plan for the overseas offices to help ensure that the agency is able to recruit and retain staff with the experience and skills necessary for the overseas offices and to reintegrate returning overseas staff into FDA's domestic operations.	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO recommends that the Commissioner of FDA develop a strategy to finalize the rule that governs the voluntary notification program, including taking into account the experience of the program to date, incorporating input from a new public comment period, and reporting to Congress and the public the agency's timeline for making it final.	Closed - Implemented	2017
Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products	GAO-13-244	To enhance FDA's ability to use AERs and to oversee dietary supplement products, the Secretary of the Department of Health and Human Services should direct the Commissioner of FDA to continue efforts to explore all possible options to obtain poison center data if the agency determines that the data could inform FDA's ability to identify potential safety concerns from adverse event reports for dietary supplements.	Closed - Implemented	2017
Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO recommends that the Commissioner of FDA develop a strategy to require any company that conducts a GRAS determination to provide FDA with basic	Closed - Not Implemented	2017

GAO Closed Recommendations, 2013-2017				
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		information about this determination, such as the substance's identity and intended uses, and to incorporate such information into relevant agency databases and its public Web site.		
Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products	GAO-13-244	To enhance FDA's ability to use AERs and to oversee dietary supplement products, the Secretary of the Department of Health and Human Services should direct the Commissioner of FDA to establish a time frame for issuing final guidance for the draft (1) New Dietary Ingredient (NDI) guidance and (2) guidance clarifying whether a liquid product may be labeled and marketed as a dietary supplement or as a conventional food with added ingredients.	Closed - Not Implemented	2017
Information Security: FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk	GAO-16-513	Recommendation: To effectively implement key elements of the FDA's information security program, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop procedures for the following 8 security control families: Audit and Accountability, Identification and Authentication, Maintenance, Media Protection, Physical and Environmental Protection, Security Planning, Systems Communication and	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
Final Report Title	**Report Number**	**Recommendation**	**GAO Status**	**Yr Rec Closed by GAO**
		Protection, and System Information and Integrity.		
Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight	GAO-13-702	The Secretary of Health and Human Services should direct the Commissioner of the FDA to clearly differentiate in FDA's database, those manufacturers of FDA approved drugs that FDA inspects for compliance with good manufacturing practices from those entities compounding drugs that are not FDA-approved and that FDA does not routinely inspect.	Closed - Implemented	2017
Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used	GAO-17-564	To help FDA meet its goal of facilitating expanded access to investigational drugs by patients with serious or life-threatening diseases or conditions, when appropriate, the Commissioner of FDA should clearly communicate how the agency will use adverse event data from expanded access use when reviewing drugs and biologics for approval for marketing and sale in the United States.	Closed - Implemented	2017
Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible	GAO-16-399	To further enhance FDA's PREDICT tool and its ability to ensure the safety of imported food, the Secretary of Health and Human Services should direct the Commissioner of FDA to establish a timeline for implementing, as resources become available, the remaining recommendations	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
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		from FDA's 2013 evaluation of PREDICT.		
Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed	GAO-16-425	To help ensure meaningful and timely consultation with Indian tribes on future rulemaking, the Secretary of Health and Human Services should direct the Commissioner of the FDA to make certain that FDA's tribal consultation policy explicitly provides for early consultation with tribes on all rules with tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes, including before promulgation of proposed regulations.	Closed - Implemented	2017
Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed	GAO-16-425	To help ensure meaningful and timely consultation with Indian tribes on future rulemaking, the Secretary of Health and Human Services should direct the Commissioner of the FDA to develop a timetable, with milestones and interim steps, for finalizing FDA's tribal consultation policy.	Closed - Implemented	2017
High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	GAO-16-305	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of	Closed - Implemented	2017

GAO Closed Recommendations, 2013-2017				
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		Health and Human Services should direct the Commissioner of FDA to establish a regular schedule for reviewing and updating agency policies for managing hazardous biological agents in high-containment laboratories.		
Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products	GAO-13-244	To enhance FDA's ability to use AERs and to oversee dietary supplement products, the Secretary of the Department of Health and Human Services should direct the Commissioner of FDA to determine what additional information FDA can provide to the public about dietary supplement AERs consistent with existing law and make the information publicly available and readily accessible on its website.	Closed - Implemented	2017

Open GAO Recommendations, May 2018		
Final Report Title	**Report Number**	**Recommendation**
Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process	GAO-09-190	GAO recommends that FDA expeditiously take steps to issue regulations for class III device types currently allowed to enter the market via the 510(k) process by requiring PMAs or reclassifying them to a lower class.
Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO recommends that the Commissioner of FDA develop a strategy to minimize the potential for conflicts of interest in companies' GRAS determinations, including taking steps such as issuing guidance for companies on conflict of

Open GAO Recommendations, May 2018		
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		interest and requiring information in GRAS notices regarding expert panelists' independence.
Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)	GAO-10-246	To better ensure FDA's oversight of the safety of GRAS substances, GAO recommends that the Commissioner of FDA develop a strategy to monitor the appropriateness of companies' GRAS determinations through random audits or some other means, including issuing guidance on how to document GRAS determinations.
Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed	GAO-10-960	To help ensure that FDA's overseas offices are able to fully meet their mission of helping to ensure the safety of imported products, the Commissioner of FDA should ensure, as it completes its strategic planning process for the overseas offices, that it develops a set of performance goals and measures that can be used to demonstrate overseas office contributions to long-term outcomes related to the regulation of imported products and that overseas office activities are coordinated with the centers and Office of Regulatory Affairs (ORA).
Information Technology FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks	GAO-12-346	To help ensure the success of FDA's modernization efforts, the Commissioner of FDA should direct the CIO to, in completing the assessment of Mission Accomplishments and Regulatory Compliance Services (MARCS), develop an integrated master schedule (IMS) that (1) identifies which legacy systems will be replaced and when; (2) identifies all current and future tasks to be performed by contractors and FDA; and (3) defines and incorporates information reflecting resources and critical dependencies.
Information Technology FDA Needs to Fully Implement Key Management	GAO-12-346	To help ensure the success of FDA's modernization efforts, the Commissioner of FDA should direct the CIO to monitor

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Practices to Lessen Modernization Risks		progress of MARCS against the integrated master schedule IMS.
FDA's Food Advisory and Recall Process Needs Strengthening	GAO-12-589	Recommendation: To strengthen FDA's process for ordering recalls, the Secretary of Health and Human Services should direct the Commissioner of FDA to document FDA's process for ordering food recalls in regulations or industry guidance to include information on how the agency will weigh evidence on whether a recall is necessary.
Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products	GAO-13-244	To enhance FDA's ability to use AERs and to oversee dietary supplement products, the Secretary of the Department of Health and Human Services should direct the Commissioner of FDA to incorporate a mechanism to collect information on when AERs are used to support and inform consumer protection actions (i.e., surveillance, advisory, and regulatory actions).
Generic Drug User Fees: Application Review Times Declined, but FDA Should Develop a Plan for Administering Its Unobligated User Fees	GAO-17-452	To ensure efficient use of generic drug user fees, facilitate oversight and transparency, and plan for risks, the Commissioner of FDA should develop a plan for administering user fee carryover that includes analyses of program costs and risks and reflects actual operational needs and contingencies.
Antibiotics: FDA Has Encouraged Development, but Needs to Clarify the Role of Draft Guidance and Develop Qualified Infectious Disease Product Guidance	GAO-17-189	In order for drug sponsors to benefit from FDA's revised guidance on antibiotic development and take full advantage of the QIDP designation, FDA should clarify how drug sponsors should utilize draft guidance documents that were released in accordance with GAIN.
Antibiotics: FDA Has Encouraged Development, but Needs to Clarify the Role of Draft Guidance and Develop Qualified Infectious Disease Product Guidance	GAO-17-189	In order for drug sponsors to benefit from FDA's revised guidance on antibiotic development and take full advantage of the QIDP designation, FDA should develop and make available written guidance on the QIDP designation that includes information about the process a drug

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		sponsor must undertake to request the fast track designation and how the agency is applying the market exclusivity incentive.
Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices	GAO-17-143	To help ensure that FDA's foreign offices are able to fully meet their mission of helping to ensure the safety of imported products, as the agency continues to test performance measures and evaluate its Office of International Programs (OIP) strategic workforce plan, the Commissioner of FDA should assess the effectiveness of the foreign offices' contributions by systematically tracking information to measure whether the offices' activities specifically contribute to drug safety-related outcomes, such as inspections, import alerts, and warning letters.
Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices	GAO-17-143	To help ensure that FDA's foreign offices are able to fully meet their mission of helping to ensure the safety of imported products, as the agency continues to test performance measures and evaluate its OIP strategic workforce plan, the Commissioner of FDA should establish goals to achieve the appropriate staffing level for its foreign offices, which would include separating foreign office vacancies from the OIP-wide vacancy rate, and setting goals by position type.
Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness	GAO-17-416	To enhance consumer understanding of agency oversight roles and to strengthen agency oversight of Internet marketing, the Secretary of the Department of Health and Human Services and the Chair of the FTC should develop and provide additional guidance to consumers delineating the agencies' differing roles in their shared oversight of memory supplement and other dietary supplement marketing on the Internet.
Antibiotic Resistance: More Information Needed to	GAO-17-192	The Secretary of Health and Human Services should direct the Commissioner

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Oversee Use of Medically Important Drugs in Food Animals		of FDA to develop a process, which may include time frames, to establish appropriate durations of use on labels of all medically important antibiotics used in food animals.
Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals	GAO-17-192	The Secretary of Health and Human Services should direct the Commissioner of FDA to establish steps to increase veterinary oversight of medically important antibiotics administered in routes other than feed and water, such as injections and tablets.
Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals	GAO-17-192	The Secretary of Health and Human Services should direct the Commissioner of FDA to develop performance measures and targets for actions to manage the use of antibiotics such as revising the veterinary feed directive and developing guidance documents on judicious use.
Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA should be improved	GAO-15-202	To strengthen DEA's and FDA's ability to respond to shortages of drugs containing controlled substances, the Administrator of DEA and the Commissioner of FDA should, either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and time frames for sharing such information, in response to a potential or existing drug shortage.
Food Safety: Additional actions needed to help FDA's foreign offices ensure safety to imported food	GAO-15-183	To help ensure the safety of food imported into the United States, the Commissioner of Food and Drugs should complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different from the inspection targets mandated in FSMA, FDA should report the results to Congress and recommend appropriate legislative changes.
Pesticide Safety: Improvements Needed in	GAO-14-289	In addition, the EPA Administrator and the FDA Commissioner should develop a

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EPA's Good Laboratory Practices Inspection Program		formal written agreement, such as a memorandum of understanding, that outlines how the two agencies plan to regularly collaborate and share information on GLP inspections and avoid duplication of inspections so that EPA can more efficiently use its limited resources.
Information Technology: FDA has taken steps to address challenges but needs a comprehensive strategic plan	GAO-16-182	To help ensure that FDA's IT strategic planning activities are successful in supporting the agency's mission, goals and objectives, we recommend that the Commissioner of FDA require the CIO to establish schedules and milestones for completing a version of an IT strategic plan that incorporates elements to align the plan's strategies with agency-wide priorities; includes results-oriented goals and performance measures that support the agency's mission, along with targets for measuring the extent to which outcomes of IT initiatives support FDA's ability to achieve agency-wide goals and objectives; identifies key IT initiatives that support the agency's goals; and describes interdependencies among the initiatives.
Information Technology: FDA has taken steps to address challenges but needs a comprehensive strategic plan	GAO-16-182	To help ensure that FDA's IT strategic planning activities are successful in supporting the agency's mission, goals and objectives, we recommend that the Commissioner of FDA require the CIO to implement the plan to ensure that expected outcomes of the agency's key IT initiatives are achieved.
Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible	GAO-16-399	To further enhance FDA's PREDICT tool and its ability to ensure the safety of imported food, the Secretary of Health and Human Services should direct the Commissioner of FDA to document the process for identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data.

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Food and Drug Administration: Comprehensive Strategic Planning Needed to Enhance Coordination between Medical Product Centers	GAO-16-500	To ensure that FDA can effectively coordinate and integrate its medical product centers' programs and emerging issues, the Secretary of Health and Human Services should direct the Commissioner of FDA to engage in a strategic planning process to identify challenges that cut across the medical product centers and document how it will achieve measurable goals and objectives in these areas.
Medical Product Oversight: FDA Needs More Strategic Planning to Guide Its Scientific Initiatives	GAO-16-432	In order to improve FDA's strategic planning for regulatory science efforts, the Secretary of Health and Human Services should direct the Commissioner of FDA to develop and document measurable goals, such as targets and time frames, for its regulatory science efforts so it can consistently assess and report on the agency's progress in regulatory science efforts.
Medical Product Oversight: FDA Needs More Strategic Planning to Guide Its Scientific Initiatives	GAO-16-432	In order to improve FDA's strategic planning for regulatory science efforts, the Secretary of Health and Human Services should direct the Commissioner of FDA to systematically track funding of regulatory science projects across each of its priority areas.
High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	GAO-16-305	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should direct the Director of NIH and the Commissioner of FDA to require routine reporting of the results of agency laboratory inspections--and in the case of FDA, require routine reporting of select agent inspection results--to senior agency officials.

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High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	GAO-16-305	Recommendation: To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should require routine reporting of incidents at CDC, FDA, and NIH laboratories to senior department officials.
High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	GAO-16-305	Recommendation: To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Director of CDC and the Commissioner of FDA to incorporate these requirements into their respective policies.
High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	GAO-16-305	Recommendation: To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should develop department policies for managing hazardous biological agents in high-

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		containment laboratories that contain specific requirements for training and inspections for all high-containment component agency laboratories and not just for their select-agent-registered laboratories; or direct the Director of CDC to provide these requirements in agency policies.
Drug Safety: FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement	GAO-16-192	Recommendation: To improve the data on tracked safety issues and postmarket studies that are needed for required reporting and for systematic oversight of postmarket drug safety, the Secretary of HHS should direct the Commissioner of FDA to develop comprehensive plans, with goals and time frames, to help ensure that identified problems with the completeness, timeliness, and accuracy of information in its database on tracked safety issues and postmarket studies are corrected.
Drug Safety: FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement	GAO-16-192	Recommendation: To improve the data on tracked safety issues and postmarket studies that are needed for required reporting and for systematic oversight of postmarket drug safety, the Secretary of HHS should direct the Commissioner of FDA to work with stakeholders within FDA to identify additional improvements that could be made to FDA's current database or future information technology investments to capture information in a form that can be easily and systematically used by staff for oversight purposes.
Drug Compounding for Animals: FDA Could Improve Oversight with Better Information and Guidance [Reissued on January 8, 2016]	GAO-15-671	Recommendation: To help ensure that FDA has relevant and timely information to support management decisions, including the critical information necessary to ensure the safety and effectiveness of drugs compounded for animals, the Secretary of Health and Human Services should direct the Commissioner of the FDA to modify the

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		voluntary reporting form FDA uses to obtain information on adverse events to ask whether drugs involved in adverse events were compounded.
Drug Compounding for Animals: FDA Could Improve Oversight with Better Information and Guidance [Reissued on January 8, 2016]	GAO-15-671	Recommendation: To help ensure that FDA has relevant and timely information to support management decisions, including the critical information necessary to ensure the safety and effectiveness of drugs compounded for animals, the Secretary of Health and Human Services should direct the Commissioner of the FDA to develop policy or guidance for agency staff that specifies circumstances under which FDA will or will not enforce compounding regulations for animals and clearly define key terms.
Drug Compounding for Animals: FDA Could Improve Oversight with Better Information and Guidance [Reissued on January 8, 2016]	GAO-15-671	Recommendation: To help ensure that FDA has relevant and timely information to support management decisions, including the critical information necessary to ensure the safety and effectiveness of drugs compounded for animals, the Secretary of Health and Human Services should direct the Commissioner of the FDA to consistently document the bases for FDA's decisions about how or whether it followed up on warning letters, adverse event reports, and complaints about drug compounding for animals.
Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations	GAO-15-38	Recommendation: To better inform users of the annual monitoring report about the frequency and scope of pesticide tolerance violations, the Secretary of Health and Human Services should direct the Commissioner of FDA to disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its pesticide monitoring

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		program and the potential effect of not testing for those pesticides.
Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations	GAO-15-38	Recommendation: To gather and report reliable, nationally representative data on pesticide residue violations, the Secretary of Health and Human Services should direct the Commissioner of FDA to design and implement a statistically valid sampling methodology that would enable the agency, within existing resources, to gather nationally representative pesticide residue incidence and level data for both domestically produced and imported foods, or justify statistically the use of a nonprobability method that can measure the estimation error. In designing either approach, FDA should consider the extent to which the benefits exceed the costs.
Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations	GAO-15-38	Recommendation: To gather and report reliable, nationally representative data on pesticide residue violations, the Secretary of Health and Human Services should direct the Commissioner of FDA to report the nationally representative incidence and level data in its annual pesticide monitoring reports, including disclosing the limits of its chosen sampling methodology.
Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations	GAO-15-38	Recommendation: To evaluate and refine its targeted pesticide compliance and enforcement monitoring program, the Secretary of Health and Human Services should direct the Commissioner of FDA to use the incidence and level data to assess the effectiveness of FDA's targeted pesticide compliance and enforcement monitoring program, including its use of the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting targeting tool for imported foods, by comparing the rate of violations detected through the program to the overall rate of

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		pesticide residue violations within the domestic and imported food supplies.
Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability	GAO-14-194	To enhance its oversight of drug shortages, particularly as the agency fine-tunes the manner in which it gathers data on shortages and transitions from its database to a more robust system, the Commissioner of FDA should conduct periodic analyses using the existing drug shortages database (and, eventually, the new drug shortages information system) to routinely and systematically assess drug shortage information, and use this information proactively to identify risk factors for potential drug shortages early, thereby potentially helping FDA to recognize trends, clarify causes, and resolve problems before drugs go into short supply.
Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations	GAO-15-38	Recommendation: To evaluate and refine its targeted pesticide compliance and enforcement monitoring program, the Secretary of Health and Human Services should direct the Commissioner of FDA to identify any types of domestic and imported foods that are at high risk for pesticide residue tolerance violations to improve the ability of its targeted pesticide compliance and enforcement monitoring program to consistently identify food likely to have violations.
FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges	GAO-17-87	Recommendation: In order to ensure that the agency is adequately protecting the White Oak campus as a designated high-risk facility and strategically planning for the White Oak campus's future, as FDA moves forward with its proposed planning efforts, the Commissioner of FDA, in consultation with the Administrator of GSA, should implement vehicular access control measures on the White Oak campus to meet the requirements of the high-risk facility level designation

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		assigned in the 2014 risk assessment report, or fully document the rationale for any deviations from these requirements.
FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges	GAO-17-87	Recommendation: In order to ensure that the agency is adequately protecting the White Oak campus as a designated high-risk facility and strategically planning for the White Oak campus's future, as FDA moves forward with its proposed planning efforts, the Commissioner of FDA, in consultation with the Administrator of GSA, should further incorporate leading strategic facilities planning practices into FDA's proposed planning efforts by ensuring that FDA establish strategic linkage between its strategic priorities and its facilities plans.
FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges	GAO-17-87	Recommendation: In order to ensure that the agency is adequately protecting the White Oak campus as a designated high-risk facility and strategically planning for the White Oak campus's future, as FDA moves forward with its proposed planning efforts, the Commissioner of FDA, in consultation with the Administrator of GSA, should document the key information related to daily operational activities and ongoing benefits and challenges that are needed to inform FDA's proposed planning efforts in the areas of needs assessment, gap identification, and alternatives analysis, and incorporate into proposed planning efforts a detailed strategy for collecting and analyzing this information.
Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks	GAO-17-445	The Secretary of Health and Human Services should direct the Commissioner of the Food and Drug Administration to consolidate information from individual diagnostic test labels and make this information available in a form that enables users to more readily compare information across tests

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Final Report Title	**Report Number**	**Recommendation**
New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process	GAO-13-723	To improve CTP's ability to operate efficiently, achieve effective results, and plan appropriately, the Secretary of Health and Human Services should direct the Commissioner of FDA to establish performance measures that include time frames for making final decisions on SE submissions and Exemption from SE submissions.
New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process	GAO-13-723	To improve CTP's ability to operate efficiently, achieve effective results, and plan appropriately, the Secretary of Health and Human Services should direct the Commissioner of FDA to monitor FDA's performance relative to those time frames, such as evaluating whether staff are performing reviews of these submissions efficiently and effectively.
Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks	GAO-17-445	The Secretary of Health and Human Services should direct the Commissioner of the Food and Drug Administration to require manufacturers to list the identity of comparator assays on their diagnostic test labels
Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues	GAO-17-443	The Commissioner of FDA should pursue formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding maximum residue levels (MRLs) that FDA established for these drugs. (Recommendation 1)
Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues	GAO-17-443	The Commissioner of FDA should coordinate and communicate with FSIS in developing drug residue testing methods and corresponding maximum residue levels for imported seafood that may also be applicable to imported catfish. (Recommendation 4)

From 2013 to 2017, FDA has resolved 34 OIG recommendations in 16 OIG reports. OIG has closed 29 of these as "implemented" and 5 simply as "closed." FDA is currently working on resolving 29 open recommendations in 13 OIG reports.

OIG Closed Recommendations 2013=2018				
Report Name	**Report No.**	**Recommendation**	**OIG Status**	**Year Closed**
Adverse Event Reporting for Medical Devices	01-08-00110	Seek legislative authority to eliminate the requirement for user facilities to submit annual reports.	Closed-Implemented	3/1/2017
Adverse Event Reporting for Medical Devices	01-08-00110	Develop a protocol for reviewing adverse event reports that specifically addresses the following needs: Follow up with manufacturers that routinely submit reports late or with incomplete information.	Closed-Implemented	3/1/2017
Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements	01-11-00210	FDA should improve the notification system to make it more organized, complete, and accurate	closed	2/1/2017
Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements	01-11-00210	FDA should expand market surveillance of dietary supplements to enforce the use of disclaimers for structure/function claims and detect disease claims	closed	2/1/2017
FDA has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs	01-13-00600	FDA should use its authority to request records in lieu of or in advance of an inspection.	closed	3/1/2017
FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	04-11-00510	Identify incomplete sponsor assessments and work with sponsors to obtain missing information.	closed	3/1/2017
FDA's Oversight of Clinical Trials	01-06-00160	Establish a mechanism to provide feedback to Bioresearch Monitoring investigators on their inspection reports and findings.	Closed-Implemented	5/4/2014
Management of Information Technology Contracts at FDA's CDER	01-07-00450	Use documented QA plans.	Closed-Implemented	9/1/2013
Management of Information Technology Contracts at FDA's CDER	01-07-00450	Use performance incentive plans when appropriate.	Closed-Implemented	6/1/2014

OIG Closed Recommendations 2013=2018				
Report Name	**Report No.**	**Recommendation**	**OIG Status**	**Year Closed**
Management of Information Technology Contracts at FDA's CDER	01-07-00450	Convert ongoing time-and-materials contract actions to fixed-price contract actions when appropriate.	Closed-Implemented	9/1/2013
Management of Information Technology Contracts at FDA's CDER	01-07-00450	We recommend that FDA minimize its contract risk by defining information technology (IT) requirements more clearly.	Closed-Implemented	9/1/2013
Scientific Disagreements Regarding Medical Device Regulatory Decisions	01-10-00470	FDA should more clearly assign accountability for the contents of the administrative files of all submissions	Closed-Implemented	2/1/2013
Scientific Disagreements Regarding Medical Device Regulatory Decisions	01-10-00470	FDA should train all reviewers and managers on the new policies and procedures for resolving scientific disagreements.	Closed-Implemented	2/1/2013
Scientific Disagreements Regarding Medical Device Regulatory Decisions	01-10-00470	FDA should define more clearly its requirements for documenting and resolving scientific disagreements	Closed-Implemented	2/1/2013
FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs	01-13-00600	FDA should ensure compliance with the requirement for manufacturers of generic drugs to register with FDA.	Closed-Implemented	12/1/2015
FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs	01-13-00600	FDA should conduct outstanding preapproval inspections of manufacturers of generic drugs, where appropriate.	Closed-Implemented	8/1/2016
Traceability in the Food Supply Chain	02-06-00210	Seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements	Closed-Implemented	6/1/2014
Traceability in the Food Supply Chain	02-06-00210	Conduct education and outreach activities to inform the food industry about records requirements	Closed-Implemented	6/1/2014
Traceability in the Food Supply Chain	02-06-00210	Work with the Food industry to develop additional guidance to strengthen traceability	Closed-Implemented	6/1/2014
FDA's Food Facility Registry	02-08-00060	Work with the food industry to increase facilities' awareness of the registry requirements	Closed-Implemented	6/1/2014
FDA's Inspections of Domestic Food Facilities	02-08-00080	Provide additional guidance about when it is appropriate to lower OAI classifications.	Closed-Implemented	3/1/2015

OIG Closed Recommendations 2013-2018				
Report Name	**Report No.**	**Recommendation**	**OIG Status**	**Year Closed**
Vulnerabilities In FDA's Oversight of State Food Facilities	02-09-00430	Ensure that all contract inspections are completed, properly documented, and appropriately paid for.	Closed-Implemented	6/1/2014
Vulnerabilities In FDA's Oversight of State Food Facilities	02-09-00430	Ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations	Closed-Implemented	6/1/2014
Vulnerabilities In FDA's Oversight of State Food Facilities	02-09-00430	Ensure that the minimum audit rate is met in all States.	Closed-Implemented	6/1/2014
Vulnerabilities In FDA's Oversight of State Food Facilities	02-09-00430	Ensure that contract inspections are properly classified in accordance with FDA guidance.	Closed-Implemented	6/1/2014
Vulnerabilities In FDA's Oversight of State Food Facilities	02-09-00430	Address any systemic problems identified by audits	Closed-Implemented	6/1/2014
FDA's Approval Status of Drugs Paid for by Medicaid	03-08-00500	Improve the completeness and accuracy of the NDC Directory.	Closed-Implemented	7/1/2014
FDA's Clearance of Medical Devices Through the 510(k) Process	04-10-00480	FDA should improve its maintenance of administrative files for devices and continue to implement new policies on how to compile an administrative file	Closed-Implemented	12/1/2015
FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	04-11-00510	Evaluate the ETASUs of one REMS each year as required by Federal law.	Closed-Implemented	7/1/2014
FDA's Oversight of Clinical Investigators' Financial Information	05-07-00730	FDA should check that sponsors have submitted all required attachments to financial forms	Closed-Implemented	6/1/2014
FDA's Oversight of Clinical Investigators' Financial Information	05-07-00730	FDA should provide additional guidance and training to reviewers	Closed-Implemented	6/1/2014
FDA's Oversight of Clinical Investigators' Financial Information	05-07-00730	FDA should update guidance to sponsors regarding the due diligence exemption.	Closed-Implemented	6/1/2014
FDA's Oversight of Clinical Investigators' Financial Information	05-07-00730	FDA should require that all centers consistently use a template that includes a prompt to document a review of financial information	Closed-Implemented	6/1/2014

OIG Closed Recommendations 2013=2018				
Report Name	Report No.	Recommendation	OIG Status	Year Closed
FDA's Food Facility Registry	02-08-00060	FDA should consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not comply with the registry requirements.	Closed	2/1/2016

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Report No	Report Name	Recommendation
A-01-07-01503	Review of FDA's Authorities and Procedures Over the Recall of Pet Food Products	Consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls;
A-01-07-01503	Review of FDA's Authorities and Procedures Over the Recall of Pet Food Products	Seek additional legislative changes to establish mandatory requirements for firms to follow in conducting recalls, including: a written recall strategy, prompt initiation of effectiveness checks, and periodic status reports
A-01-07-01503	Review of FDA's Authorities and Procedures Over the Recall of Pet Food Products	Comply with its procedures for monitoring recall
A-01-07-01503	Review of FDA's Authorities and Procedures Over the Recall of Pet Food Products	Revise its procedures to require FDA staff to: document the approved recall strategy, including the specified effectiveness check levels and target dates for initiating and completing effectiveness checks, promptly determine the accuracy of the firm's
A-01-09-01500	FDA FOOD Recalls - Effectiveness of Recall Initiation & Firm Inspection	donsider the results of this review in implementing the FDA Food Safety Modernization Act
A-01-09-01500	FDA FOOD Recalls - Effectiveness of Recall Initiation & Firm Inspection	comply with its procedures for monitoring recalls
05-14-00640	Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information	FDA should provide technical assistance regarding the exchange of drug product tracing information for sales to 340-B-covered entities that use 340-B contract pharmacies
05-14-00640	Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information	FDA should provide technical assistance on requirements regarding direct purchase statements
05-14-00640	Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information	FDA provide technical assistance regarding exempt products

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Report No	**Report Name**	**Recommendation**
02-14-00420	Challenges Remain in FDA's Inspections of Domestic Food Facilities	FDA should conduct timely follow-up inspections to ensure that significant inspection violations are corrected.
02-14-00420	Challenges Remain in FDA's Inspections of Domestic Food Facilities	FDA should improve how it handles attempted inspections to ensure better use of resources
02-14-00420	Challenges Remain in FDA's Inspections of Domestic Food Facilities	FDA should improve the timeliness of FDA's actions, including warning letters, so that facilities do not continue to operate under harmful conditions.
02-14-00420	Challenges Remain in FDA's Inspections of Domestic Food Facilities	FDA should take appropriate action against all facilities with significant inspection violations
01-08-00510	Challenges to FDA's Ability to Monitor and Inspect Clinical Trials	FDA should require standardized electronic clinical trial data and create an internal database
01-11-00210	Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements	FDA should seek explicit statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading
01-11-00211	Dietary Supplements: Companies May be Difficult to Locate in an Emergency	FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements
01-14-00390	FDA is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist	FDA should provide a standardized form for ASRs, ensure that they are complete, and require sponsors to submit them electronically
01-14-00390	FDA is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist	FDA should build capacity in DAARTS to support PMR oversight
02-06-00210	Traceability in the Food Supply Chain	Address issues related to mixing raw food products from a large number of farms.
02-08-00080	FDA Inspections of Domestic Food Facilities	Take appropriate actions against facilities with OAI classifications
02-08-00080	FDA Inspections of Domestic Food Facilities	Ensure that violations are corrected for all facilities that receive OAI classifications, particularly those that have histories of violations.
02-08-00080	FDA Inspections of Domestic Food Facilities	Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.
04-10-00480	FDA's Clearance of Medical Devices Through the 510(k) Process	FDA should, in accordance with the law, finish classifying the remaining 19 types of Class III preamendment devices that include devices still used as predicates in the 510(k) process

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Report No	**Report Name**	**Recommendation**
04-11-00510	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	Clarify expectations for sponsors' assessments in FDA assessment plans.
04-11-00510	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	Seek legislative authority to enforce FDA assessment plans.
04-11-00510	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	Ensure that assessment reviews are timely.
04-11-00510	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	Develop and implement a plan to identify, develop, validate, and assess REMS components.
04-11-00510	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety	Identify REMS that are not meeting their goals and take appropriate actions to protect the public health.
05-07-00730	FDA's Oversight of Clinical Investigators' Financial Information	FDA should require that sponsors submit financial information for clinical investigators as part of the pretrial application process

Genomic Editing

82. Please describe FDA's role in reviewing applications related to genetic modification of human embryos. Please specify if FDA has consulted with the stakeholders on genetic modification of embryos in fiscal year 2017 or FY 2018 to date.

Response: Since December 2015, Congress has included provisions in annual federal appropriations laws that prohibit FDA from receiving or reviewing investigational new drug (IND) applications for human subject research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Human subject research utilizing genetic modification of embryos would require an IND application that has been received (or accepted for review) by FDA and is in effect. However, in accordance with the prohibition in the federal appropriations law, FDA will not accept for review an IND application for human subject research utilizing genetic modification of embryos – and, therefore, such research cannot be conducted in the United States in compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations.

In August 2017, FDA posted on its website an advisory on the use of mitochondrial replacement techniques (MRT) to introduce donor mitochondria into reproductive cells for transfer into a

human recipient, which advised readers of the prohibition in federal appropriations law on accepting IND applications for such research.[5] As noted in the Advisory, FDA maintains the authority to investigate and take enforcement action in the event that FDA becomes aware of noncompliance with the laws and regulations administered by FDA.

In September 2014, FDA commissioned the Institute of Medicine (IOM) to produce a consensus report on the ethical and social policy issues related to genetic modification of eggs and embryos to prevent transmission of mitochondrial disease. The IOM released the consensus report in February 2016.

In December 2015, the FDA, along with several other organizations, commissioned the National Academy of Sciences and National Academy of Medicine (NAS/NAM) to produce a consensus report on the scientific underpinnings, clinical implications, and ethical, legal, and social aspects of the use of current and developing human gene editing technologies in biomedical research and medicine. The NAS/NAM released the consensus report in February 2017.

83. Please describe FDA's role in reviewing applications related to the genetic modification of animals or other species. Are applications currently pending for genetically modified animals or other species?

Response: FDA regulates intentional genomic alterations of animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In general, unless otherwise excluded, the Agency considers intentional genomic alterations to meet the definition of a drug under the FD&C Act because they are intended to affect the structure or function of the animal. With regard to FDA's review process, the Agency applies a flexible, risk-based approach. As described in revised draft Guidance for Industry #187, "Regulation of Intentionally Altered Genomic DNA in Animals," FDA outlines, based on risk, when the Agency intends to use enforcement discretion or when FDA intends to enforce the requirement for an approved application related to intentional genomic alterations of animals. For example, following a review focused on areas of risk-related concern, FDA has exercised enforcement discretion over approval requirements (i.e. FDA has not required approval) for glowing aquarium fish.

Applicants must demonstrate target animal safety and safety of the animal's lineage; safety of food derived from any food-producing animal; and effectiveness related to the intended use of the genomic alteration in the animal. The Agency also must assess whether an approval would significantly impact the environment of the United States under the National Environmental Policy Act. As part of the review process, FDA consults, as appropriate, with other federal agencies with relevant expertise. With regard to intentional genomic alterations in animals that result from genome editing, in January 2017, FDA issued draft revised Guidance for Industry #187 that clarifies FDA's regulatory approach. The public comment period on this draft revised guidance closed on June 19, 2017. FDA is reviewing the comments it received as well as current science as it determines next steps.

[5] https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm570185.htm.

84. What is the FDA's process for receiving an application related to genomic editing for humans and animals?

Response: Since December 2015, Congress has included provisions in annual federal appropriations laws that prohibit FDA from receiving or reviewing investigational new drug (IND) applications for human subject research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Human subject research utilizing genetic modification of embryos would require an IND application that has been received (or accepted for review) by FDA and is in effect. However, in accordance with the prohibition in the federal appropriations law, FDA will not accept for review an IND application for human subject research utilizing genetic modification of embryos – and, therefore, such research cannot be conducted in the United States in compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations.

However, FDA may receive an IND application related to genome editing of human somatic cells, which, by definition, cannot pass a genetic alteration from one generation to another. Under the IND regulations (21 CFR Part 312), FDA can put a proposed study on hold (i.e., prevent the study from proceeding) within 30 days of receiving the application (312.42); however, if FDA receives an IND application and does not put the proposed study on hold within 30 days, the study may proceed.

For animals, the FDA Center for Veterinary Medicine (CVM) currently regulates genetically engineered animals under the new animal drug provisions of the FD&C Act. In January 2017, FDA issued draft Guidance for Industry 187, "Regulation of Intentionally Altered Genomic DNA in Animals," that would extend the scope of regulation to other types of genomic alterations, including those produced by genome editing technology. Under the draft guidance, the Agency considers intentional genomic alterations to meet the definition of a drug under the FD&C Act, unless otherwise excluded, because they are intended to affect the structure or function of the animal. CVM intends to work closely with applicants seeking approval of applications for intentional genomic alterations in animals. As described in the draft guidance, the Agency encourages sponsors of applications to reach out to the Agency early in the development of the animal to discuss applicable regulatory requirements. The Agency intends to meet regularly with these sponsors during the review process to address requirements and concerns – and facilitate resolution of deficiencies.

The public comment period on draft Guidance for Industry 187 closed on June 19, 2017. FDA is reviewing the comments it received as well as current science as it determines next steps.

Guidance for Industry #187 can be found at:

www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf.

Medical Countermeasures initiative (MCMi)

85. Provide a current update on the minimum spending of $24,504,000 that the Congress required by FDA in fiscal years 2017 and 2018. Also provide updates on the $25 million appropriated to FDA for the Ebola effort in fiscal year 2015, including how much of this appropriation has been obligated to help combatting the Ebola outbreak or other related efforts as well as the $10 million provided for Zika in fiscal year 2017.

Response: In FY 2017 and FY 2018, Congress provided FDA $24,504,000 to support the Medical Countermeasures Initiative (MCMi) to which FDA applied an additional $48K, for a total of $24,552,000. The following table lists the breakdown of the FY 2017 and FY 2018 MCMi base funding by Center/Office.

MCMi Base Funding *(dollars in millions)*				
Center/Office	**FY 2017**		**FY 2018**	
	BA	**BA FTE**	**BA**	**BA FTE**
CBER	2.395	10.00	2.395	10.00
CDER	6.020	21.50	6.020	21.50
CDRH	4.001	16.00	4.001	16.00
HQ – OC*	10.312	33.00	10.312	33.00
GSA Rent & Rent Related	1.824	0.00	1.824	0.00
Total	**24.552**	**80.50**	**24.552**	**80.50**

*HQ – OC base resources include $8.686M to support FTE as well as $1.626M to support the MCMi Regulatory Science Program.

In FY 2015, Congress provided FDA $25,000,000 supplemental funding under H.R. 83, the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law No.: 113-235) for Ebola response activities. FDA obligated $20 million of this funding to: (1) support Ebola response activities, including conducting product review, engaging with U.S. Government agencies and international regulatory health agencies and organizations to facilitate product development and evaluation, and monitoring for fraudulent Ebola products; and (2) to support research under the FDA's MCMi Regulatory Science Program to help expedite the development and availability of medical products for Ebola.

The FDA reprogrammed $5.0 million of the $25 million it received for Ebola response activities under PL 113-235 to support: (1) research under the FDA's MCMi Regulatory Science Program to help expedite the development and availability of medical products for Zika virus; and (2) Zika virus response activities, including conducting product review, engaging with U.S. Government agencies and international regulatory health agencies and organizations to facilitate product development and evaluation, and monitoring for fraudulent Zika virus products. As of April 17,2018, the FDA has obligated $4.758 million of the reallocated funding for Zika response, and anticipates obligating the balance of $0.217 million in FY 2018.

H.R.244, the Consolidated Appropriations Act 2017, (Public Law No: 115-31), provided $10 million in no-year funding for FDA "to prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and for related administrative activities." The following table lists the FDA spend plan for the $10 million received under PL 115-31 by program.

FDA $10 Million No-Year Funding Received under Public Law No: 115-31 FY 2017 - FY 2019 Estimated Obligations *(dollars in millions)*				
	FY 2017 (Q3 + Q4) Actual	**FY 2018 Estimated**	**FY 2019 Estimated**	**Total**
Support the development and availability of medical countermeasures[a]	$0.610	$1.265	$1.250	$3.125
Medical Countermeasures Regulatory Science	$1.207	$2.834	$2.834	$6.875
Total	$1.817	$4.099	$4.084	$10.000

a. 5 FTE for 3rd and 4th quarter of FY 2017 and FY 2018 through 2019 for CDRH

86. What are MCMi's top three priorities in fiscal year 2018? Fiscal year 2019?

Response: FDA's top three priorities under the MCMi in Fiscal Year 2018—2019 are to: (1) sustain long-term response efforts to Zika virus and Ebola virus as necessary, and respond to any other emerging infectious disease outbreaks; (2) continue to support the development and availability of medical countermeasures (MCMs) to respond to chemical, biological, radiological, and nuclear (CBRN) threats, emerging infectious diseases, and antimicrobial resistance as well as the development and availability of MCMs to support the unique needs of the warfighter; and (3) continue to support high-priority regulatory science necessary to fill critical scientific gaps and advance technologies to facilitate the efficient development and availablility of MCMs to respond to public health or military emergencies.

Reagan-Udall Foundation & Critical Path Institute

87. Please provide the Committee with an update on what FDA is doing in partnership with the Reagan-Udall Foundation and the Critical Path Institute for fiscal years 2017 through 2019.

Response: The Reagan-Udall Foundation (RUF) and Critical Path Institute (CPI or C-Path) are non-profit public-private partnerships (PPPs) that bring FDA together with stakeholders to work on critical innovation and regulatory science issues. Additional information is available at the RUF and C-Path websites (http://reaganudall.org/ and https://c-path.org/programs/cptr/, respectively), as well as at FDA's Center for Drug Evaluation and Research (CDER) webpage on

PPP and scientific consortia activities, at
https://www.fda.gov/drugs/scienceresearch/ucm575772.htm .

FDA worked with RUF to launch, in fiscal year 2017, the Innovation in Medical Evidence Development and Surveillance (IMEDS) system, a national resource for broader public health and medical evidence generation. Through IMEDS, FDA's Sentinel System (Sentinel's) distributed data, as well as scientific methods and tools, are available for entities outside of FDA. This includes regulated industry and academic institutions that want to conduct important research to advance patient safety in an environment that is secure and protects patient privacy. FDA continues to provide liaison support to ensure that Sentinel and IMEDS operate in a complementary manner.

In 2017, FDA provided technical assistance in the development of the Expanded Access Navigator, an online directory of companies' policies and contact information related to expanded access to investigational therapies, serving to make their expanded access programs more accessible and transparent to patients and health care providers. After the launch in July 2017, FDA staff continue to work closely with the RUF to publicize the service and promote company engagement.

Also in 2017, FDA and RUF developed a Memorandum of Understanding (MOU 225-17-030) to establish a RUF Fellowship at FDA. The goals of the Fellowship are to (1) train scientists in regulatory science and policy for post-fellowship employment at FDA, industry, academia, or other government agencies; and (2) contribute to research projects that address FDA's regulatory challenges. FDA and RUF are forming a Steering Committee to further define the program goals and curriculum, approve projects, and review and select candidates for the Fellowship Program. On May 4, 2018, an Annual Public Meeting was convened by RUF and FDA to discuss the foundation's activities and how it supports the FDA.

Critical Path Institute (CPI or C-Path):
During 2017-2019, FDA will continue to partner with CPI to support a number of ongoing collaborative activities to help streamline drug development efforts. These include but are not limited to the following:

The Data Collaboration Center in CPI is creating an aggregation of data (**integrated data platforms)** from multiple sources in a standard format to create new insights in unmet healthcare needs areas. Examples of databases for various therapeutic areas include tuberculosis (TB), multiple sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease (PD), Type 1 Diabetes and Duchenne Muscular Dystrophy. The integrated databases include curated, de-identified, and standardized data that are made publicly available to researchers. Sharing standardized data advances understanding of the diseases and related drug development.

The Development and qualification of biomarkers is continuing under the 21st Century Cures Act provisions and several consortia under the CPI (examples include Predictive Safety Testing Consortium, Coalition Against Major Diseases, Critical Path to TB Drug Regimens) are collaborating with FDA to address some goals. Examples of biomarkers under review include baseline hippocampal volume as an enrichment biomarker in Alzheimer's disease clinical trials,

lipoarabinomannan (LAM) as a pharmacodynamics/monitoring biomarker to implement adaptive trial designs for TB drugs where LAM in sputum likely reflects bacterial load in the lung, clinical nephrotoxicity biomarkers for limited and full contexts of use, and the development of glutamate dehydrogenase as a clinical biomarker for drug induced hepatic injury. Development and qualification of **Clinical Outcome Assessments** (COAs) to inform regulatory decisions is ongoing under the Cures Act, and the patient reported outcomes (PRO) Consortium under the CPI is leading the effort with FDA advice. Some successful qualifications in 2017 of PRO instruments include a Major Depressive Disorder Scale and a Non-Small Cell Lung Cancer Symptom Assessment Questionnaire. Examples of other PRO instruments in the qualification program include measures of fatigue in rheumatic arthritis, pediatric asthma severity, functional dyspepsia symptoms, and cognition and physical functioning in MS.

Through the **Qualification Advice Pilot Program** under Cures, CPI was named in 2017 as an advisor to the requestors of Drug Development Tools (DDT) (biomarkers and COAs) qualification. The purpose of the program is to utilize an existing biomedical research organization to provide expertise and advice to DDT developers for the purpose of regulatory qualification. FDA will refer DDT qualification requestors to CPI for advice and strategy. To date, FDA has referred about 10 DDT developers to CPI for advice, and the process is ongoing.

To assess the impact and benefit of such an effort, FDA plans to continue this pilot program beyond the initial 1 year period.

The **Biomarker Data Repository (BmDR)** was launched by CPI in 2016 as a pilot project to collect and analyze kidney safety biomarkers data used by industry and academic investigators in their drug development programs. Due to the potential value of such a data repository, FDA is encouraging the drug developers to share this data with CPI and is interested in CPI continuing this effort.

Through the **Quantitative Medicine Team** under the CPI and their collaboration with FDA, in-Silico Modeling and Simulation is ongoing to streamline clinical trials. The clinical trial simulator that was previously endorsed as Fit-for-Purpose for AD will be updated to include new data, statistical modifications, and a user-friendly graphical interface. The database is being expanded by CPI to develop a disease progression model for mild cognitive impairment; a Letter-of-Intent (LOI) has been submitted from CPI to the FDA and there are ongoing discussions with the FDA reviewers for the Fit-for-Purpose Initiative acceptance pathway. CPI is also developing a model-based clinical trial enrichment platform for PD, and a LOI has been submitted and discussed with FDA reviewers. For Duchenne Muscular Dystrophy, efforts are ongoing to model the patient's clinically meaningful outcomes over time based on various patient factors to map clinically meaningful disease milestones during disease progression and drug development.

Data Standards are being developed to allow datasets from different sources to be compared or combined for data collection, sharing, and analyses, because it is important that the data across studies are generated in a standard format. CPI's consortium CFAST is collaborating with the FDA and other data standards organizations to develop and publicly share, as user guides, the standard format for several drug development concepts. The Duchenne Therapeutic Area User

Guide was completed in 2017. Other examples of data standards efforts in the process of testing and acceptance include asthma, breast cancer, colorectal cancer, post-traumatic stress disorder, clostridium difficile associated disease, human immunodeficiency virus treatment and schizophrenia.

Some other key efforts initiated in 2017 by various consortia under CPI that will continue with FDA collaboration include the quantitative understanding of disease progression and biomarker dynamics across the AD continuum in partnership with The Collaboration for Alzheimer's Prevention (CAP) and the establishment of new consortia (T1D, TTC, Huntington's Disease).

Sunscreen Ingredients

88. When can the Committee expect decisions on sunscreen ingredients?

Response: FDA has approved sunscreen products under new drug applications. However, most of the sunscreen products purchased by U.S. consumers are marketed under the OTC monograph system.

At issue are eight sunscreen ingredients that industry wishes to be able to market without NDA approval. FDA has outlined the data needed to evaluate the eight ingredients and stands ready to review the data. So far, industry has not submitted the data for FDA review.

As required under FD&C Act provisions added by the SIA, in November 2016, FDA issued a final guidance for industry describing the safety and efficacy data recommended to support future requests under the SIA process for a determination that a sunscreen active ingredient is generally recognized as safe and effective (GRASE) for use in OTC sunscreens.

Although review timelines are specified under these SIA-added provisions, the timelines are not triggered until a sponsor submits the data requested for FDA to make a positive GRASE determination. Therefore, the timing will depend on when sponsors submit the requested data. As of April 2018, no additional data for the pending requests has been submitted.

Sentinel Initiative

89. Please provide a history on FDA's expenditures for the Sentinel Initiative from fiscal year 2015 through fiscal year 2018 to date?

Response:

Sentinel Contract Award Amounts by Year of Award				
Year Awarded	**CDER**	**CBER**	**ASPE IAA***	**Total Contract Awards**
2015	$10,572,000	$ 9,306,777	$6,000,000	$25,878,777
2016	$19,067,000	$ 5,181,262	$1,750,000	$25,867,000
2017	$14,774,316	$4,970,107	$0	$19,744,423
2018**	$19,250,000	$ 6,000,000	$0	$25,250,000

** FY 2015 and FY 2016 figures include funds awarded to FDA by the HHS Assistant Secretary for Planning and Evaluation (ASPE) to help build the national capacity and infrastructure needed to conduct patient-centered outcomes research (PCOR), and to enable PCOR findings to be integrated into clinical practice.*

***FY 2018 reflect estimates for planned expenditures.*

90. What are the planned expenditures for fiscal years 2019?

Response:

Fiscal Year	CDER	CBER	Total
2019*	$25,500,000	$30,500,000*	$56,000,000

In Sept 2019, the FDA will be awarding a new five-year base contract for a Sentinel Coordinating Center. If a new contractor is selected, FDA would need to support two Coordinating Centers to enable knowledge, processes and operations to transition from the existing to the new contractor, and to ensure continuity of operations to meet ongoing safety surveillance needs. If the same contractor is selected, the cost structure is likely to remain stable. To plan for this contingency, the Sentinel funding estimates are both higher and more uncertain in FY2019 compared to prior years.

* The budget estimate for the CBER Sentinel Program in FY 2019 is currently $7.5 million and if the President's budget is approved, CBER may receive up to $23 million additional funding for FY 2019.

91. Who has FDA partnered with as part of the Sentinel Initiative?

Response:

Sentinel System Coordinating Center and Collaborating Institutions
The Sentinel System Coordinating Center, led by the Harvard Pilgrim Health Care Institute, partners with a broad range of Data and Academic Partners. This network of collaborating institutions provides access to both healthcare data and scientific, technical, and organizational expertise.

A complete listing of collaborating institutions is provided below:

Aetna Informatics
America's Health Insurance Plans: Clinical Affairs Department
Blue Cross Blue Shield of Massachusetts
Brigham and Women's Hospital: Division of Pharmacoepidemiology & Pharmacoeconomics in the Department of Medicine
Department of Population Health Sciences, Duke University School of Medicine
Harvard T.H. Chan School of Public Health
HealthCore, Inc. Government & Academic Research

Health Care Systems Research Network ◦Harvard Pilgrim Health Care Institute
- HealthPartners Institute
- Henry Ford Health System: Public Health Sciences Department
- Marshfield Clinic Research Institute
- Meyers Primary Care Institute, a joint endeavor of Fallon Community Health Plan

Hospital Corporation of America
Humana, Inc., Comprehensive Health Insights
IQVIA
Kaiser Permanente Center for Effectiveness and Safety Research ◦Kaiser Permanente Colorado Institute for Health Research
- Kaiser Permanente Center for Health Research Hawaii
- Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.
- Kaiser Permanente Northern California, Division of Research
- Kaiser Permanente Northwest Center for Health Research
- Kaiser Permanente Washington Health Research Institute

Optum
Rutgers University: Center for Health Services Research on Pharmacotherapy, Chronic Disease Management and Outcomes at the Institute for Health, Health Care Policy and Aging Research
University of Alabama at Birmingham: Center for Outcomes and Effectiveness Research and Education
University of Florida College of Pharmacy: Department of Pharmaceutical Outcomes & Policy
University of Illinois at Chicago: Department of Pharmacy Systems, Outcomes and Policy
University of Iowa: Department of Epidemiology in the College of Public Health
University of North Carolina Gillings School of Global Public Health: Center for Pharmacoepidemiology
University of Pennsylvania School of Medicine: Center for Clinical Epidemiology and Biostatistics and Department of Biostatistics and Epidemiology
Vanderbilt University School of Medicine, Department of Health Policy
Weill Cornell Medicine, Healthcare Policy & Research

Biologics Effectiveness and Safety (BEST) Initiative Coordinating Center and Collaborating Institutions

The BEST Initiative is a component of the Sentinel Program within the Center for Biologics Evaluation and Review and is led by IQVIA Institute which serves as a coordinating center and Data Partner. IQVIA partners with a network of academic partners and organizations to provide access to both healthcare data and scientific, technical, and organizational expertise.

A complete listing of collaborating institutions within the BEST Initiative is provided below:

IQVIA
Regenstrief Institute
Stanford University
Columbia University
University of California Los Angeles (UCLA)
Georgia Institute of Technology
Odysseus Data Services Inc.

Observational Health Data Sciences and Informatics (OHDSI) Collaboration

92. Please provide a full list of projects for the sentinel initiative in fiscal year 2016 through fiscal year 2018 to date.

Response: The table below provides a listing of formal Sentinel projects that were completed or ongoing in FY2016-2018. The list does not include activities that are part of routine operations of Sentinel, including outreach, communication, staff training, and program management.

Project Title
Safety Analyses
Venous Thromboembolism Following Combined Oral Contraceptives Compared with Cyclic Oral Contraceptives
Combined oral contraceptives containing ethinyl estradiol and levonorgestrel and venous thromboembolism
Exposure to Intravenous (IV) Iron Procedures and Anaphylaxis and Epinephrine Events
Ranexa (Ranolazine) and Seizures
Sinus Stents with Mometasone and Diminished Visual Acuity
Concomitant Use of Opioid Analgesics and Cytochrome P450 (CYP) Inhibitors and Inducers
Metabolic Effects of Second Generation Antipsychotics in Youth, Subprojects 1, 2, and 3
A Protocol for Assessment of Dabigatran and Selected Safety Outcomes
Gadolinium-Based Contrast Agents (GBCAs) Use in Pregnancy
Niacin and Fenofibrate Use and Outcomes with Propensity Score Matching
Parenteral Iron and Anaphylactoid Reactions
Anti-Diabetes Drugs and Acute Myocardial Infarction, Hospitalized Heart Failure
Influenza Vaccines and Birth Outcomes
Influenza Vaccines and Pregnancy Outcomes (PRISM)
Influenza Vaccines and Febrile Seizures in the 2013-2014 and 2014-2015 Influenza Seasons
Rapid Surveillance Capability: 2017-18 Seasonal Influenza Vaccines Surveillance
Sequential Analysis of Gardasil 9 Safety
Thromboembolic Events After Immunoglobulin Administration
Transfusion-Related Acute Lung Injury after Red Blood Cell, Plasma and Platelet Administration 2013-2015
Kawasaki Disease and PCV13 Vaccine
Evaluation of HPV9 (Gardasil9) Vaccine Safety Surveillance Using the TreeScan Data Mining Method Surveillance Protocol
Exploratory Analyses
Identifying Suicide Codes in the Sentinel Distributed Database (SDD) new
Clostridium difficile Infection Following Use of Vancomycin, Fidaxomicin, or Metronidzaole
Availability of International Normalized Ratio (INR) Laboratory Test Values and Test Procedures among Warfarin Users
Warfarin Use Followed by International Normalized Ratio (INR) Lab Codes

Top Ten Causes of Death
Prevalent and Incident Use of Fingolimod
Risk of Acute Myocardial Infarction and Stroke among Carbidopa/Levodopa, Entacapone, and Carbidopa/Levodopa/Entacapone Users
Prevalence and Incident Use of Promethazine
Use of Clonzepam
Diagnosis of Agranulocytosis Following New Use of Anti-epileptic Drugs, Clozapine, and Olanzapine
Counts and Prevalence of Alendronate, Risedronate, Ibandronate, and Zolendronate
Counts and Prevalence of Linezolid and Vancomycin
Use of Atrial Fibrillation Drugs
Incident Use of Hepatitis C Virus (HCV) Drugs
Concomitancy and Indications for Idelalisib Use
Prevalent and Incident Use of Generic Name Kinase Inhibitors
Incident Use of Rivaroxaban
Selected Medications and Death, with Linkage of Mini-Sentinel Distributed Database with NDI+
Drug Utilization Over Time for Three Drug Classes
Counts, Prevalence, and Incidence of Intravenous (IV) Iron Products
Rhabdomyolysis and/or Creatine Kinase Laboratory Results Following New Use of Statins or Angiotensin-Converting Enzyme Inhibitors
Use of Tyrosine Kinase Inhibitors (TKIs)
Length of Follow-up Time for New Users of Immunosuppressive Drugs
Boceprevir, Ledipasivir/Sofosbuvir, Simeprevir Sodium, Sofosbuvir, and Telaprevir Use
Prevalent and Incident Use of SGLT2 Inhibitors
Antiepileptic Drug (AED) Injection Procedure Codes
Counts of Commonly used Angiostensin-Converting Enzyme (ACE) Inhibitors and Beta Blockers
Drug and Medical Enrollment Counts
Use of Tumor Necrosis Factor (TNF) Blocker Drugs
Characterization of Pediatric Medical Conditions: Respiratory Syncytial Virus (RSV) Associated Illness
Molecularly Targeted Anti-Cancer Therapies
Stroke Diagnosis Codes
Length of Enrollment in Pediatric Population
Prevalent and Incident Use of Isotretinoin
Occurrence of Selected Generic Drugs 13
Use of Dronedarone HCL
Clostridium Difficile Prevalence and Vancomycin, Fidaxomicin, and Tocilizumab Use
Incident and Prevalent Dispensings of Mirabegron
Use of Ospemifene, Boceprevir, and Telaprevir
Prevalent and Incident Use of Testosterone Products
Top 100 Procedures and Diagnoses 30 Days Surrounding Incident Warfarin Use
Anti-Tumor Necrosis Factor (TNF) Utilization Among Pregnant Women
Prevalent and Incident Use of Romiplostim

Suicide Diagnoses
Incident and Prevalent Use of Generic Drugs for Overactive Bladder
Antipsychotic Use and Dementia Diagnoses
Genetic Testing Procedures
Atrial Fibrillation Prevalence
Mycophenolate Dispensings and Procedures
Mycophenolate Dispensings and Procedures (by Quarter)
Antipsychotics and Stroke (PSM)
Antipsychotics/SSRIs and Stroke (PSM)
Antipsychotics and Stroke
Sodium/Glucose Cotransporter (SGLT2) Inhibitors- Type 1 and Type 2 Diabetes Cohort Identification
Niacin and Niacin Combination Products, Fenofibrates, and Omega-3 Products
Alosetron Use
Mirabegron Use
Pegylated Products Use
Pegylated Products Follow-Up Request
Indications of Use Among Oral Antifungal Drug Users
Actemra (Tocilizumab) Utilization Among Pregnant Women
Anti-epileptic Drugs and Angioedema
Multiple Births and Preterm Deliveries
Drug Use Following Genetic Testing Among Patients with Cancer
Influenza Antiviral Drug Use 2010-2015
ADHD Medications and Heart Failure
PROMPT: Mirabegron Surveillance
Dronedarone and Electrocardiograms
Dabigatran and Warfarin Use Among Members with Atrial Fibrillation and Other Pre-Existing Conditions
MRI and GBCA Procedures
Hysterectomy Procedures Among Females
Most Frequent Generic Dispensings Among Members Aged 65+
Incident Testosterone Indication Diagnoses and Testosterone Use
Hypogonadism and Testosterone Use
Incident Testosterone Use
Immunoglobulin Products and Hemolysis
New Use of Statins and Rhabdomyolysis
Epidural Steroid Use
Serum Creatinine Procedures and Labs
Isotretinoin and Long-term Antibiotic Use and Multiple Sclerosis
Omalizumab or Montelukast Use Among Individuals with Asthma and Acute Myocardial Infarction, Stroke, Intracranial Hemorrhage, or Pulmonary Embolism
Laparoscopic Hysterectomy With and Without Robotic Assistance and Adverse Outcomes

New Use of Dabigatran or Warfarin and Gastrointestinal Hemorrhage or Intracerebral Hemorrhage Events
New Use of Anti-Epileptic Drugs and Agranulocytosis
Concomitant Use of Niacin and Statins and Concomitant Use of Fenofibrates and Statins
IVIg Product Use and Hemolysis Events
Incident Use of Testosterone Products Among All Members and Members with Pre-Existing Testosterone Use
Anticoagulant Use Among Members with Atrial Fibrillation and Various Pre-Existing Exlusions
Anticoagulant Use Among Members with Pre-Existing Atrial Fibrillation and Various Pre-Existing Exclusions
Anti-depressant Use and Bleeding Events
Dabigatran Uptake and Persistence
Incident Antipsychotic Use
Indications of Intravenous Immunoglobulin Use
Anticoagulants and Bleeding Events
Anticoagulant Use Among Patients with Atrial Fibrillation
Postlicensure Medical Product Safety Data-Mining: Power Calculations for Bernoulli Data
Counts and Prevalence of 50 Venous Thromboembolism (VTE) Diagnosis Codes
Tdap Vaccination During Pregnancy
Pertussis Cases in Infants
Blood Transfusions
Length of Enrollment Among Adolescents after HPV Vaccination
Use of Stents
Trends in Fibroid Surgery and Use of Power Morcellation
Catalyst Analyses
Implementation of a Randomized Controlled Trial to Improve Treatment with Oral Anticoagulants in Patients with Atrial Fibrillation (IMPACT-AFib)
Collection of Patient-Provided Information through a Mobile Device Application for Use in Comparative Effectiveness and Drug Safety Research
Additional Biologics-Related Projects in Sentinel
Assessing Feasibility of Identifying Infants with Pertussis Under Three Months of Age
Assessing Feasibility of Identifying Specific Codes for Lead Poisoning and Lead Testing
Assessing Feasibility of Identifying Specific Codes for Presence of Factor VIII Inhibitors
Assessing Geographic Clusters Babesiosis
Assessing Guillain-Barre Syndrome (GBS) After Influenza Vaccination
Assessing Rate of Lead Toxicity by Geographic Regions
Assessing the Feasibility of Identifying Acellular Dermal Matrix Allograft in Inpatient, Outpatient, and Emergency Room Care Settings of Sentinel Distributed Database
Assessing the Feasibility of Identifying Allograft Heart Valve Transplant in Inpatient Care Settings of Sentinel Distributed Database
Assessing the Feasibility of Identifying Amniotic Membrane Transplant in Inpatient, Outpatient, And Emergency Room Care Settings of Sentinel Distributed Database
Assessing the Feasibility of Identifying Corneal Transplants in Inpatient and Outpatient Care Settings of Sentinel Distributed Database

Assessing the Feasibility of Identifying Fc-Fusion Proteins and PEGylated In Inpatient and Emergency Room Care Settings of Sentinel Distributed Database
Assessing the Feasibility of Identifying Imlygic (Talimogen Laherparepvec- Genetically Modified Oncolytic Viral Therapy) In Inpatient Care Settings of Sentinel Distributed Database
Assessing the Feasibility of Identifying MACI (Autologous Cultured Chondrocytes on Porcine Collagen Membrane) In Inpatient Care Settings of Sentinel Distributed Database
Assessment of Health Outcomes After Treatment with Platelet Concentrates Prepared Using the INTERCEPT Blood System (IBS)
Background Rate of Adverse Events Associated with Whole Blood, Red Blood Cells, And Platelets for The Period 2013 – 2017 Using the Sentinel HCA Database
Data Mining Infrastructure
Determining Historical Background Rates for Influenza Vaccination and Known Vaccine-Associated Outcomes
Determining Prevalence of Rapid Influenza Test Use and Oseltemivir in Children
Determining Prevalence of Billing Codes for Influenza Vaccination and Influenza Hospitalization Outcomes in Children
Determining Prevalence of Immunoglobulin (Ig) Exposure and Renal Failure
Determining Prevalence of Inactivated Influenza Vaccine Use and Outcomes
Determining Prevalence of Influenza Vaccination and Laboratory Test Use
Determining Prevalence of Inhibitors in Hemophilia a Population Post-Transfusion of Factor VIII Products
Determining Prevalence of Leukoreduced Platelets and Red Blood Cells Utilization
Determining the Distribution of Covariates Among Those Receiving Live Attenuated and Inactivated Influenza Vaccination
Determining the Utilization of Hepatitis B-Containing Vaccines (Engerix-B, Recombivax-B, Twinrix) In Adults From 2006-2016
Determining Uptake of Human Papillomavirus Vaccine (HPV9) To Perform Power Calculation for The HPV9 Treescan Activity
Assessing HPV9 Utilization and Pregnancy Outcomes
Flumist-Inactivated Influenza Vaccine and Hospitalized Influenza During Geographically Defined Influenza High Season: Person Time Analysis, 2013-14 Season
Flumist- Inactivated Influenza Vaccine and Hospitalized Influenza During Geographically Defined Influenza High Season: Person Time Analysis, 2015-16 Season
Flumist- Inactivated Influenza Vaccine and Hospitalized Influenza During Geographically Defined Influenza High Season: Logistic Analysis, 2015-16 Season
Identification of Hemophilia A Patients in Claims Databases
Pilot of Self-Controlled Tree-Temporal Scan Analysis for Gardasil Vaccine
Pilot Query to Evaluate Thromboembolic Events Post Intravenous Immunoglobulin Transfusion
Post-Transfusion Related Outcome of Leukoreduced And Non-Leukoreduced Platelets and Red Blood Cells
Safety of Influenza Vaccine Among Those Receiving Checkpoint Inhibitors
Scan Statistics for Assessing Vaccine Safety in Pregnancy
Self-Controlled Risk Interval Tool (SCRI) Pilot
Transfusion Rates of Blood and Blood Components by Geographic Regions
Transfusion Rates of Blood Components by Georaphic Regions in Immunocompromised, Neonates, And Elderly Population
Identification of Blood Components and Products and Adverse Events Using Natural Language Processing Within the BEST Initiative
Inclusion Of ~20 Million Electronic Health Records (EHR) For Surveillance of Biologics within the BEST Initiative

Developing the Infrastructure to Conduct Vaccine Safety Surveillance within the BEST Initiative: Febrile Seizures and MMR And MMRV Vaccination as a Use Case within the BEST Initiative
Development of Library of Codes to Identify Exposure to Blood Components and Products in Administrative and EHR Data Sources within the BEST Initiative
Addition of Information Standard for Medical Products (ISBT)-128 Into the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) within the BEST Initiative
Transfusion Related Acute Lung Injury (TRALI) After Red Blood Cells, Plasma, and Platelet Administration within the BEST Initiative
Transfusion Associated Circulatory Overload (TACO) After Red Blood Cells, Plasma, and Platelet Administration within the BEST Initiative
CBER Patient Experience Data (PED) Collection Via Mobile Devices
ICD-10 Trend Analysis: Cancer Drug and Flu Vaccines
Data Characterization of Sentinel Distributed Database
Assessment of Tdap Vaccination During Pregnancy
Feasibility Analysis of CBER Patient Experience Data (PED) Collection Via Mobile Devices
Frequency Distribution of Billing/Administration Codes for Blood Components During the Period Of 2010-2017 Within the BEST Initiative
Frequency Distribution Of ISBT-128 Codes for Blood Components During the Period Of 2010-2017 Within the BEST Initiative
Frequency Distribution of Whole Blood, Red Blood Cells, Platelets, And Plasma by Demographics Using Billing and Administrative Codes Within the BEST Initiative
Frequency Distribution of Whole Blood, Red Blood Cells, Platelets, Plasma, Cryoprecipitate by Demographics Using ISBT-128 Codes Within the BEST Initiative
Validating the Self-Controlled Risk Interval (SCRI) Design Using a Known Safety Signal [Febrile Seizures and MMR And MMRV Vaccination]

93. What is the current number of records available to the sentinel system?

Response: Through Sentinel, FDA can rapidly and securely access electronic healthcare data from over 292.5 million patients from multiple data partners while securing the privacy of patients.

Antibiotic Resistance

94. What are the FDA's current efforts related to antibiotic resistance? Please specify any coordination with USDA or any other public or private sector group.

Response: FDA is committed to reducing the rate of development of antibiotic resistance by fostering the judicious use of antimicrobial drugs in animals. The Agency has issued a number of important guidance documents and regulations to support its judicious use strategy and has actively engaged in outreach efforts to support effective implementation.

FDA and USDA continue to work in close collaboration to foster antimicrobial stewardship in veterinary settings and enhance data collection on antimicrobial use and resistance. For example, USDA worked in consultation with FDA to implement training modules on antimicrobial resistance and veterinary feed directives as part of USDA's veterinary accreditation program.

An important interagency collaboration is the National Antimicrobial Resistance Monitoring System (NARMS). This collaboration between FDA, USDA, and the Centers for Disease Control and Prevention (CDC), is critical for tracking antimicrobial resistance in foodborne bacteria in the U.S. FDA's Science Board recently recommended activities to enhance NARMS, including expanding the scope of NARMS to test seafood products at retail, test for other pathogenic foodborne bacteria, examine other animal sources for resistant bacteria, and enhance data collection capabilities to strengthen the scientific basis for regulatory decision making and public health interventions to address this important public health challenge.

Following collaboration with USDA and CDC to devise approaches for collecting additional on-farm antimicrobial drug use and resistance data, FDA has provided input to USDA's Center for Epidemiology and Animal Health on surveys to collect information on antimicrobial use in animal agriculture. Additionally, FDA continues to fund two cooperative agreements to support collection of data on antimicrobial use in U.S. animal agriculture, specifically in the poultry and swine industries and on-farm use data for dairy and feedlot cattle. FDA expects these pilots to provide part of the baseline information about on-farm antimicrobial use practices and assist in developing long-term functional and efficient antimicrobial use monitoring and reporting systems for food animal production settings.

95. Please provide a funding history of NARMS between fiscal years 2012 and 2018 to date and show how the funds were distributed outside of FDA and within FDA by Program (e.g., CFSAN, CDER, CVM, etc.). What does FDA plan to spend on NARMS in fiscal year 2019?

Response: While the base budget authority for the National Antimicrobial Resistance Monitoring System (NARMS) has remained the same since fiscal year (FY) 2015, changes have occurred in how the funds are distributed among FDA, CDC, and USDA. The CDC was appropriated an additional $160 million in FY 2016 to address issues related to antimicrobial resistance, and, for the first time, funded NARMS activities with its own appropriation. The funding is summarized, for the record, in the table below and includes the estimate for funding in FY 2018.

	FY 2010	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
USDA[1]	$1.4M	$1.6 M	$1.3M	$1.3 M	$0.4 M	$0.8M	$0.6M	$0.6M	$0.6M
CDC[2]	$1.8M	$2.2 M	$2.0M	$2.0 M	$2.0 M	$4.1M	$0	$0	$0
FDA/ CVM[3]	$3.5M	$4.0 M	$4.5M	$4.5 M	$5.4 M	$5.9M	$10.2M	$10.2M	$10.2M
TOTAL[4]	**$6.7M**	**$7.8 M**	**$7.8M**	**$7.8 M**	**$7.8 M**	**$10.8 M**	**$10.8M**	**$10.8M**	**$10.8M**

[1] *Funding to the USDA decreased in FY 2014 because on-farm pilot work completed the field phase. Funds were used to start building whole genome sequencing (WGS) capacity at FDA's Center for Veterinary Medicine (CVM). In FY 2015, USDA on-farm work was funded for one*

additional year and USDA began using WGS to characterize bacteria. These are reflected in the USDA allocation.

[2] *FDA purchased laboratory supplies for CDC in FY 2009 – FY 2015 and funded state laboratories by FDA/CVM sending funds to CDC, which then sent funds to state laboratories. In 2016, CDC received NARMS funding through its AMR initiative so it is no longer funded by the FDA, and FDA/CVM began funding state laboratories directly for retail meat testing.*

[3] *The FDA figure includes laboratory supplies the FDA purchases for the USDA and CDC. Starting in FY 2015, FDA NARMS increased the number of state laboratories. In FY 2018, there are 19 state laboratories sampling 21 states. Totals also include funding for cooperative agreement grants to explore options for collecting new antimicrobial use data. Starting in FY 2016, retail meat testing includes WGS of target pathogenic bacteria (*Salmonella *and* Campylobacter*) and sentinel bacteria (*E. coli *and* Enterococcus*).*

[4] *Totals represent the FDA NARMS allocation before funds are distributed to the USDA and CDC.*

For FY 2019, FDA expects to spend the same amount as for FY 2018 to expand WGS to include at least 50 percent of all *E. coli* isolates and selected isolates of *Enterococcus* species recovered from retail meats. In addition, with the requested increase, FDA plans to explore testing of more meat types and seafood to leverage existing partnerships to obtain veterinary pathogens isolated from companion and food production animals for *in vitro* antimicrobial susceptibility testing. FDA also will continue to investigate the use of new techniques for surveillance activities and analysis of WGS data that may allow prediction of antimicrobial resistance from WGS data. If funds are available, more state laboratories will be added.

96. Of the NARMS total, how much was spent on meat testing for fiscal years 2015 through 2018 to date?

Response: The following table provides how much of the $10.8 million National Antimicrobial Resistance Monitoring System (NARMS) total was spent on retail meat testing in fiscal years (FY) 2015 through 2018 to date. FDA's Center for Veterinary Medicine (CVM) is on track to spend the total $10 million by the end of FY 2018.

	FY 2015	FY 2016	FY 2017	FY 2018
NARMS Retail Meat Testing	$7.3M	$10M	$10M	$2.4M[1]

[1] *Funding spent as of March 31, 2018. These funds do not include retail meat testing supplies for the entire fiscal year nor grants to state laboratory partners that are awarded in the fourth quarter.*

97. Please update FDA's response to last year with any new research FDA utilizes to determine the major sources of antibiotic resistance.

Response: Data from NARMS – a collaboration with USDA and CDC – are key to evaluating progress toward slowing the rate of development of antibiotic resistance.

NARMS recently published its *2015 NARMS Integrated Report*, which highlights antimicrobial resistance patterns in bacteria isolated from humans (by CDC), raw retail meats (by FDA), and

animals at slaughter (by USDA). The report also provides information derived from whole genome sequence data about resistance genes for all *Salmonella* and some *Campylobacter* isolates. The report includes NARMS Now, a set of interactive data tools that allow users to explore the dynamics of antibiotic resistance and the genes involved.

The report shows that overall resistance remains low for most human infections and includes measurable improvements in resistance levels in some important areas, including *Salmonella* infection. The report also highlights areas FDA and NARMS will continue to monitor and study, such as multidrug resistance, erythromycin resistance in chicken carcasses, and the residence of resistance traits on mobile genetic elements, which means they are at higher risk for transmission to other bacterial strains.

NARMS will continue to take advantage of whole genome DNA sequencing technology. This technology makes it possible to determine the complete complement of genes in a bacterium within a single laboratory workflow, supplanting other traditional methods and saving time and money. NARMS research shows that antibiotic resistance can be predicted reliably from the genomic sequence. Therefore, FDA is developing data visualization tools to make these large data sets easier to understand. These enhancements will help set priorities and help public health authorities respond to food safety challenges in a more timely manner.

98. What is FDA doing to address antimicrobial resistance as it relates to prescribing practices of human drugs?

Response: The labeling for all systemic drug products intended for human use indicated to treat a bacterial infection (except a mycobacterial infection) requires information about unnecessary use and the link between such use and the emergence of drug-resistant bacterial strains (21 CFR 201.24). FDA believes that physician labeling can contribute to ongoing educational efforts by reminding physicians that their individual prescribing decisions have a collective impact on resistance. Clinical trial results provided in labeling inform physicians about the risks and benefits when prescribing.

FDA has taken significant steps towards fully implementing section 511A of the FD&C Act, as added by section 3044 of Cures (Pub. L. 114-255). It clarifies the Agency's authority to efficiently identify and update susceptibility test interpretive criteria ("breakpoints") for antimicrobial drugs, including those established by standards development organizations, which may be utilized by sponsors of antimicrobial susceptibility testing devices. Susceptibility testing is performed in laboratories to determine which antibacterial drugs are likely to be active against the bacteria causing a patient's infection. In the context of antibacterial drug resistance, it is important that healthcare providers have up-to-date information when prescribing.

On December 13, 2017, FDA announced the timely launch of webpages required under section 511A(b). These webpages contains a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. See the FDA Susceptibility Test Interpretive Criteria webpage at: https://www.fda.gov/STIC. At the same time, FDA published a guidance providing recommendations on fulfilling the new labeling requirements for susceptibility test interpretive criteria for prescription systemic antibacterial and

antifungal drugs. FDA is currently requesting comments on the susceptibility test interpretive criteria recognized by the Agency through an open docket established in the Federal Register. The Agency continues to work with sponsors and the healthcare community in the implementation of this important new provision.

99. What has been FDA's success with their voluntary efforts to reduce veterinary drugs in farm animals produced for human consumption?

Response: On January 3, 2017, FDA announced that it had completed implementation of Guidance for Industry (GFI) #213, a process begun in 2013 to transition antimicrobial drugs with importance in human medicine – medically important antimicrobials – used in the feed or drinking water of food-producing animals to veterinary oversight and eliminate the use of these products in animals for production – such as growth promotion – purposes.

As of January 3, 2017, all affected animal drug sponsors voluntarily worked with FDA to make the requested changes to their product labels. All affected animal drug applications have either aligned with the Agency's recommendations or been voluntarily withdrawn by the drug sponsor. As a result of these changes, these products cannot be used for production – such as growth promotion – purposes and may only be used under the authorization of a licensed veterinarian.

Of the 292 new animal drug applications affected by GFI #213, 84 new animal drug applications were completely withdrawn. Of the remaining 208 applications, 93 applications for oral dosage form products intended for use in water were converted from over-the-counter to prescription status, and 115 applications for products intended for use in feed were converted from over-the-counter to veterinary feed directive (VFD) status. Production – such as growth promotion – indications were withdrawn from all 31 applications that included such indications for use. Based on inspection activities carried out by FDA's Office of Regulatory Affairs (ORA) and state feed regulatory programs, implementation of the VFD final rule has generally been successful. FDA believes affected stakeholders have been learning and adopting the practices necessary for ensuring compliance with the VFD regulation and supporting antimicrobial stewardship.

Reprogramming Provision in the Annual Appropriations Law

100. Has FDA notified Congress on all reprogramming requirements as required by law in fiscal years 2016 and 2017 to date? Please explain any circumstances of why not if applicable.

Response: Consistent with law, FDA notified Congress on all reprogramming requirements in FY 2016 and FY 2017.

101. Has FDA notified all of its senior officials, career or otherwise, of the requirements placed on the Agency of reprogramming appropriated funds? If so, please explain how and when this information is communicated across all program areas.

Response: FDA ensures its senior officials are aware of the requirement to notify Congress regarding the reprogramming of funds. This is done at various points throughout the year. For example, senior leaders are provided summaries of the House, Senate and Conference markups, including reference to the reprogramming section. Budget staff across the agency have received training on the notification requirements. Additionally, in internal discussions, budget staff brief their senior leaders on any notification requirements related to potential reorganizations and reprogrammings. Also, the operating plan is shared with budget staff across the agency to ensure they can keep track of spending expectations, and it serves as a reference in determining whether an action constitutes a reprogramming so they can alert senior leaders, as necessary.

Legal Fees

102. Please provide a total cost of legal fees incurred by FDA for calendar years 2014 through 2017. Provide a detailed list of the source of the costs and respective amounts, including the cost of settlements associated with employee grievances, complaints, etc. Please explain any increases or decreases in such legal fees as well as the total number of settlements for each year.

Response:

FDA Legal Fees for Calendar Years 2014 - 2017			
Calendar Year	**Attorney Payments**	**Claimant Payments**	**Total Settlements**
2014	$240,045	$103,155	$343,200
2015	$621,166	$736,508	$1,357,674
2016	$955,859	$1,577,864	$2,533,723
2017	$508,143	$1,208,702	$1,716,845

Title 42 Pay

103. Please provide a table that shows total FTE and dollars related to the use of Special Title 42 Pay Authority" for fiscal years 2015, 2016 and 2017 actuals, and projected for fiscal years 2018 and FY 2019.

Response: The Excel table contains FY 2016, FY 2017, FY2018, and FY 2019. Please note, FY 2015 information is unavailable as the Integrated Budget and Acquisition Planning System (IBAPS) used was not implemented until FY 2016. Below, are details about the content in the attached Excel table.

NOTES	TABLE

Year	Description	RF_00_00	RG_00_00	RS_00_00	Total	Comments
FY19	Dollars	34,571,208.64	99,745,135.17	10,154,892.17	144,471,235.98	Projections based on FY18->PP8 Actuals
	FTE	160.63	883.47	48.00	1,092.10	Projections based on FY18->PP8 Actuals
FY18	Dollars	34,365,426.86	98,998,256.56	9,865,659.13	143,229,342.55	Actuals YTD PP8 + Projections
	FTE	158.56	890.27	47.54	1,096.37	Actuals YTD PP8 + Projections
FY17	Dollars	33,407,298.60	105,815,241.80	9,813,934.45	149,036,474.85	Actuals
	FTE	153.22	952.99	48.12	1,154.33	Actuals
FY16	Dollars	30,298,306.10	90,824,427.20	9,949,471.96	131,072,205.26	Actuals
	FTE	144.85	877.76	47.26	1,069.87	Actuals

Please Note:	Dollars are excluding Employer Paid Benefit Cost (Below OC Codes)
	12102-FICA EMPLR CONTB CIV 12104-FEGLI EMPLR CONTB CIV 12107-FEHBA EMPLR CONTB CIV 12128-FERS EMPLYR CONTB CIV 12101-CSRA EMPLR CONTB CIV 12116-COLA ABROAD CO

Immunotherapies

104. What guidance documents have FDA issued as it relates to the submission of drug applications for personalized drugs such as immunotherapies?

Response: Many personalized immunotherapies, including genetically-modified cellular therapies such as chimeric antigen receptor T-cells and other cellular therapies, intended for serious or life-threatening diseases are eligible for a variety of programs intended to expedite their development and review, including fast track designation, breakthrough therapy designation, priority review, accelerated approval, and Regenerative Medicine Advanced Therapy (RMAT) designation created by the 21st Century Cures Act. Information about these expedited programs, as well as considerations for the clinical development of regenerative medicine therapies, are addressed in a draft guidance on Expedited Programs for Regenerative Medicine Therapies for Serious Conditions, issued in November 2017, as part of our comprehensive regenerative medicine policy framework.[6] In the draft guidance, FDA reiterates our commitment to working with sponsors of regenerative medicine therapies and encourage flexibility in clinical trial design, particularly for products for patients who have serious conditions with unmet medical needs. In addition, later in 2018, FDA plans to issue several draft guidances related to gene therapies, which will address manufacturing issues as well as clinical considerations for the development of gene therapies. FDA believes that the issuance of these guidance documents will provide information to sponsors to help advance the development of immunotherapies. In addition, a recent guidance (Targeted Therapies in Low-Frequency

[6] Our guidance on Expedited Programs for Serious Conditions – Drugs and Biologics, issued in May 2014, may also be helpful to sponsors for developing these and other drugs and biologics.

Molecular Subsets of a Disease) provides CDER's thinking on the development of therapies that target uncommon specific molecular defects such as those that occur in cancers or genetic disorders. This approach is applicable to immunotherapies and other types of drugs.

Seafood Consumption

I am concerned that in January 2017, prior to your confirmation, FDA finalized advice to pregnant women on seafood consumption that contradicts FDA's own nutrition science in the FDA net effects report and contradicts the American Academy of Pediatrics recommendation to introduce seafood to children at 6 months.

105. When will FDA reissue its seafood advice to pregnant women to ensure that it is based on sound nutrition science?

Response: In 2017, FDA and the Environmental Protection Agency (EPA) issued final advice regarding fish consumption.[7] The 2017 final advice reflects the agencies' best effort to communicate to the public about how to gain the nutritional benefits of eating fish while minimizing the risk of exposure to methylmercury. The seafood advice was the culmination of a process that involved input from numerous experts in academia, risk communications, industry, states, various organizations, and concerned individuals.

The advice was issued to help individuals in the target population limit their exposure to methylmercury while still obtaining the health benefits of fish consumption. The wording and organization of the advice is intended to enhance the likelihood that it will be followed by the targeted audience. Specifically, with respect to infants, the advice states that parents may feed fish to children at 6 months of age, but advises parents feeding fish to their children for the first time to monitor for signs of an allergic reaction.

On October 13, 2017, FDA issued a denial letter in response to a citizen petition requesting FDA withdraw and reissue the 2017 seafood advice. FDA's response letter, which includes information about FDA's consideration of the FDA Net Effects Assessment, is available in Docket No. FDA-2017-P-3296 at https://www.regulations.gov/document?D=FDA-2017-P-3196-0071.

FDA considers fish a valuable source of nutrition for pregnant women and children. The Agency has noted the positive nutritional value of fish in the Questions & Answers from the FDA/EPA final fish advice on the FDA's website.[8] FDA notes that fish are important sources of selenium, zinc, iodine, iron, and other minerals needed by the body. Fish are also natural sources of many B vitamins, and oily fish provide vitamins A and D. Most fish are low in fat and most of the fat that is present in fish is healthy polyunsaturated fat. FDA notes that "studies with pregnant women have found that the nutritional benefits of fish, like other protein-rich foods, are important for their children's growth and development during pregnancy and childhood." FDA also believes that pregnant women and children should diversify their sources of protein-rich

[7] https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm393070.htm
[8] https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm534873.htm

foods and the 2017 final advice will make it easier than ever for the target audience to follow our advice with confidence.

FDA is developing educational materials for various populations to enhance the ability of consumers to follow the Agency's seafood advice and to encourage the consumption of fish.

Elderly Participation in Clinical Trials

106. The number of Americans aged 65 and older today is projected to double by 2060. This increase in aging populations will only place a greater stress on our healthcare system and demand for new treatments will increase simultaneously. To reflect on this growth, countries are adopting new strategies in clinical trials. For example, the European Medicines Agency recently adopted a Geriatric Medicines Strategy designed to take the need of older people into account in the development, approval, and use of medications. Many current clinical trials in the U.S. have upper age limits and do not reflect the target population for which the treatments would be used. What is the FDA's view of the EMA's approach and has FDA considered any changes to its regulations or guidance to require trials to include aging populations?

Response: FDA has been addressing the need to include a broad patient population in clinical development programs, including geriatric patients. For example, given the importance of including geriatric data in the development and review of drugs, FDA issued a guidance, titled *E7 Studies in Support of Special Populations: Geriatrics – Questions and Answers* (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM189544.pdf), to clarify certain key issues related to the design and conduct of clinical trials of medicines that are likely to have significant use in the elderly population. Specifically, FDA recommends that drug developers enroll patients who are representative of the geriatric population in clinical development programs to adequately characterize efficacy and safety in the geriatric population and allow for comparisons with the nongeriatric population.

Additionally, FDA recently conducted a retrospective pilot study that reviewed eligibility criteria from a sample of pivotal trials supporting drug and biological product approvals with approximately 41,000 subjects, which showed that 84% of trials did not exclude patients over 75 years, and indicated that restrictive eligibility criteria on age were not common in trial protocols. Nonetheless, exclusion criteria may just be one factor that determines whether older individuals enroll in clinical trials and there may be a need for additional strategies to gain experience with drugs in older patients, as discussed below.

There may be challenges in enrolling patients who are representative of the older population in clinical development programs. FDA has engaged with industry and other stakeholders to discuss potential solutions to these problems, and plans to continue this important effort. For example, in November 2017, FDA and the American Society of Clinical Oncology (ASCO) co-sponsored a public workshop on improving the evidence base for treating the geriatric oncology population, including issues related to representation of older adults in oncology-related clinical trials (www.fda.gov/Drugs/NewsEvents/ucm575006.htm). More recently (April 2018), FDA sponsored a public workshop on addressing limitations in clinical trial enrollment titled

"Evaluating Inclusion and Exclusion Criteria in Clinical Trials". One of the sessions from this workshop focused on strategies to enhance enrollment of older patients in clinical trials. FDA is also actively evaluating the potential use of real world data and evidence to provide additional data on how an approved drug product works in real world populations. For instance, real world evidence may be able to provide experience with a drug post-approval in broader populations, including in older patients.

In summary, FDA is continuing to explore strategies and approaches to increase participation of older patients in clinical trials, and to find additional ways of obtaining information on experience with drugs post-approval in older patients.

Tobacco Compliance and Enforcement

107. In displaying FY 2017 Civil Monetary Penalties under the Center for Tobacco Products in the FDA's FY 2019 budget justifications, disparities seems to exist between states and the number of Civil Monetary Penalties relative to the population and size of the states. For example, South Carolina received 294 civil monetary penalties while California only received 32. California's population is approximately 40 million while South Carolina is only 5 million. Please briefly describe this specific distinction and other similar examples spread across the states.

Response: There are many factors that affect inspection numbers and results throughout the country. One of the most substantial factors is that FDA has separate contracts to perform inspections in each state. The Tobacco Control Act (TCA) requires FDA to contract with the states, where feasible, to carry out inspections of retailers. As such, the FDA establishes individual contracts, which provides a consistent approach to the inspection process in each state, but allows flexibility to address individual state needs and the resources they can dedicate. While FDA seeks to allocate sufficient resources to enforce the law in every state, other factors can result in some variation in the number and frequency of inspections. Beyond the differences in inspection numbers, states also have different violation rates, which are highly affected by individualized local elements, such as training and enforcement conducted at the state and local levels, more stringent laws, such as age 21 purchasing requirements, and community structure and support. Lastly, natural disasters can also have an impact on the number of inspections that can be performed in a given time period.

Specifically, the states identified, California and South Carolina, have much different retail environments, geographic layouts, and communities. California is a very large state which requires a great deal of resources to cover the retail community. California proposed the amount of FDA tobacco enforcement that they were able to accommodate and the final contract reflects this proposed level of work. This state also has a very high cost of living, which can lead to a more expensive inspection program. Additionally, California has a history of strong public health initiatives at the state and local level, which potentially lead to a lower violation rate overall. South Carolina, on the other hand, has a much smaller geographic footprint and a very active inspection team. This allows inspectors to reach the many establishments which sell tobacco with fewer resources in a shorter period of time, which results in higher inspection numbers and a larger amount of identified violations.

108. What factors are determined in allocating resources by state for Tobacco Retailer Inspections?

Response: In accordance with Section 702(a)(1)(B)(i) of the FD&C Act, FDA contracts, where feasible, with the U.S. States to carry out inspections of retailers within that State. Each year, FDA issues a Request for Proposals (RFP) for the Tobacco Retail Compliance Check Inspection contracts to which the states and territories submit proposals that detail their respective program structure, inspection plan, and cost. These proposals generally account for the cost of living, resources availible to dedicate to the program, and other circumstances unique to each state program. FDA reviews the proposal packages to determine whether the business and technical plans fulfill the requirements established in the RFP. FDA must balance the abilities and resources outlined in each proposal with the funds the Agency has to allocate to the retail inspection contracts. While FDA attempts to contract with every State and U.S. Territory, when the Agency has been unable to contract with a state government despite our best efforts, FDA has pursued other means to facilitate the performance of compliance check inspections of tobacco retailers to ensure inspection coverage throughout the U.S. FDA currently has tobacco retail inspection contracts with U.S. States, Territories, Tribal Nations, and third-party entities.

109. Please provide a table for FY 2016 and FY 2017 showing the number of inspectors (FTE) by state, the amount of funding for each state, the number of retail inspections performed by state, the number of warning letters by state, the number of civil money penalties by state, and the number of No-Tobacco-Sale-Orders by state in rank from greatest to least based upon the number of inspectors in each state.

Response: Provided are tables outlining much of the retail inspection contract data requested. The retail inspections conducted under FDA contracts have consistent processes and procedures.

FDA commissions inspectors working under these contracts to conduct tobacco compliance check inspections using the processes and procedures outlined through nationwide inspector training. Currently, there are more than 800 active inspectors. The number of inspectors and whether they are full-time or part-time, varies from state to state based on the way each state has proposed to structure the inspections under the contract. That makes providing the FTE data you requested more difficult to provide in such a format.

Many States are under a cost-reimbursement structured contract in which inspector time is reported and reimbursed based on the actual time spent working on the contract. There are factors that can impact the FTE's utilized under a contract for a given year or time of year. Some of these include the natural disasters FDA has recently and historically experienced, increased inspections when the minors have greater availibity (i.e., summer and school holidays) or when seasonal businesses are open (such as beach or ski resorts), and decreased inspections when travel is extremely limited in some states during certain times of the year. Although state programs may estimate yearly time/salary for each inspector, these factors can contribute to that time varying throughout the year.

FDA Tobacco Retailer Inspection Program Annual Funding by State

State/Territory	Fiscal Year 2016	Fiscal Year 2017
Alabama	$1,645,400.32	$1,263,693.00
Alaska	$410,243.04	$260,499.17
Arizona	$611,225.00	$561,113.39
Arkansas	$836,101.00	$861,310.36
California	$4,344,123.00	$5,052,268.00
Colorado	$1,172,020.76	$1,494,056.36
Connecticut	$1,197,334.00	$1,144,192.00
Delaware	$451,370.59	$474,964.02
Florida	$1,975,336.55	$899,948.16
Georgia	$643,818.86	$643,818.86
Hawaii	$386,608.33	$501,754.00
Idaho	$1,066,494.00	$1,137,164.00
Illinois	$1,272,489.26	$1,455,309.00
Indiana	$878,349.13	$904,659.66
Iowa	$494,296.81	$546,698.27
Kansas	$456,448.61	$336,844.83
Kentucky	$723,211.51	$631,406.95
Louisiana	$685,349.00	$485,358.48
Maine	$565,564.47	$612,016.00
Maryland	$1,043,337.00	$1,044,523.00
Massachusetts	$982,082.31	$1,002,860.00
Michigan	$1,426,668.00	$1,380,364.00
Minnesota	$956,782.00	$906,818.00
Mississippi	$840,506.00	$833,806.24
Missouri	$642,630.00	$637,182.00
Montana	$179,697.00	$184,185.00
Nebraska	$469,093.62	$250,191.78
Nevada	$0.00	$0.00
New Hampshire	$245,346.20	$211,157.12
New Jersey	$1,725,098.00	$1,762,978.48
New Mexico	$347,257.48	$516,399.21
New York	$1,490,346.40	$735,937.48
North Carolina	$1,205,930.00	$1,218,417.00
North Dakota	$307,607.31	$220,636.62
Ohio	$2,089,184.96	$2,836,153.26
Oklahoma	$402,515.07	$328,275.18
Oregon	$0.00	$332,506.44
Pennsylvania	$1,006,442.00	$976,020.00

Rhode Island	$498,569.00	$528,368.00
South Carolina	$2,232,415.08	$2,302,783.10
South Dakota	$296,576.58	$206,168.04
Tennessee	$370,111.00	$389,231.12
Texas	$1,531,878.00	$1,665,667.00
Utah	$275,897.70	$198,663.80
Vermont	$326,987.00	$332,484.82
Virginia	$1,152,089.92	$1,152,089.92
Washington	$1,379,075.07	$1,324,224.37
West Virginia	$831,261.00	$863,139.38
Wisconsin	$923,155.79	$1,387,685.00
Wyoming	$257,314.50	$206,390.15
American Somoa	$191,509.00	$147,387.00
CNMI	$0.00	$0.00
Guam	$249,572.05	$249,860.91
Puerto Rico	$878,311.32	$895,881.43
USVI	$176,589.56	$179,068.00
Washington, DC	$221,357.86	$225,791.24
Rincon	$11,645.00	$9,896.48
Shoshone-Bannock	$12,902.00	$13,182.20
Mescalero Apache	$23,898.60	$24,234.60

FDA Tobacco Retailer Inspection Program
Total Inspections and Enforcement Actions by State

Fiscal Year	State/Territory	Warning Letter	CMP	NTSO	Total Inspections
FY16	Alabama	180	8		3754
FY16	Alaska	74	19		726
FY16	American Samoa	19			306
FY16	Arizona	189	52		1653
FY16	Arkansas	137	30	1	3330
FY16	California	183	19		5332
FY16	Colorado	249	75		4018
FY16	Connecticut	305	41	3	4633
FY16	District of Columbia	167	13		642
FY16	Florida	2334	691		16123
FY16	Georgia	107	8		1885
FY16	Guam	19	8		396
FY16	Hawaii	12	1		317
FY16	Idaho	131	21		1876
FY16	Illinois	164	83	1	2288

FY16	Indiana	358	138	1	4606
FY16	Iowa	63	12		2088
FY16	Kansas	108	7		2292
FY16	Kentucky	127	7		3230
FY16	Louisiana	636	67		6465
FY16	Maine	47	1		2524
FY16	Maryland	139	71	3	3150
FY16	Massachusetts	413	97	1	7648
FY16	Michigan	713	234	10	5487
FY16	Minnesota	253	57		5614
FY16	Mississippi	116	22		4109
FY16	Missouri	445	145	2	4039
FY16	Montana	18			1158
FY16	Nebraska	130	61		1731
FY16	Nevada	18			526
FY16	New Hampshire	97	63		748
FY16	New Jersey	522	163	3	4556
FY16	New Mexico	123	1		1813
FY16	New York	437	192		6303
FY16	North Carolina	247	19		2016
FY16	North Dakota	59	41		507
FY16	Oklahoma	228	47	2	1402
FY16	Oregon		33		38
FY16	Pennsylvania	394	235	2	5873
FY16	Puerto Rico	1356			2576
FY16	Rhode Island	66	16		1391
FY16	South Carolina	632	194		9168
FY16	South Dakota	91	52		835
FY16	Tennessee	93	15		2378
FY16	Texas	332	81	1	5300
FY16	Utah	52	4		1253
FY16	Vermont	74	11		979
FY16	Virgin Islands	9	4		183
FY16	Virginia	258	28		2406
FY16	Washington	549	270		8166
FY16	West Virginia	208	65		2866
FY16	Wisconsin	161	72		1499
FY16	Wyoming	77	20		877
FY17	Alabama	245	23		4433
FY17	Alaska	19	20		511
FY17	American Samoa	6	5		265

FY17	Arizona	252	109		1675
FY17	Arkansas	188	53		3607
FY17	California	135	32		4423
FY17	Colorado	363	141	1	4220
FY17	Connecticut	317	118	5	3866
FY17	Delaware	113	8		817
FY17	District of Columbia	96	56		604
FY17	Florida	1486	980	3	14972
FY17	Georgia	118	13		2710
FY17	Guam	28	5	1	330
FY17	Hawaii	14	2		240
FY17	Idaho	112	25	1	2216
FY17	Illinois	489	166	1	3786
FY17	Indiana	470	239	5	4855
FY17	Iowa	131	24		2450
FY17	Kansas	167	28		2268
FY17	Kentucky	178	58		3243
FY17	Louisiana	369	133		4759
FY17	Maine	75	10		2510
FY17	Maryland	143	103	3	2253
FY17	Massachusetts	383	148	1	6303
FY17	Michigan	582	542	18	5117
FY17	Minnesota	266	117	1	6012
FY17	Mississippi	193	65		4081
FY17	Missouri	508	369	3	4528
FY17	Montana	49	2		1182
FY17	Nebraska	174	93	1	2356
FY17	Nevada	18	6		160
FY17	New Hampshire	69	52		539
FY17	New Jersey	526	222	4	4879
FY17	New Mexico	110	2		393
FY17	New York	746	232		8060
FY17	North Carolina	339	98		3186
FY17	North Dakota	40	36		335
FY17	Northern Mariana Islands				1
FY17	Ohio	878	17		3210
FY17	Oklahoma	193	152	2	1020
FY17	Pennsylvania	547	223	3	5266
FY17	Puerto Rico	942	356		3741
FY17	Rhode Island	57	46	1	1115
FY17	South Carolina	624	291	3	8604

FY17	South Dakota	104	110		951
FY17	Tennessee	168	39		1992
FY17	Texas	293	131	1	5496
FY17	Utah	30	6		1079
FY17	Vermont	54	16		941
FY17	Virgin Islands	2	1		130
FY17	Virginia	202	65		2768
FY17	Washington	529	303	2	8659
FY17	West Virginia	191	109	1	2665
FY17	Wisconsin	331	141		2234
FY17	Wyoming	69	57		743

110. What tobacco enforcement actions has FDA taken with regards to the electronic vapor market and what actions does it plan to take in regards to the "secondary" market for these products, specifically with regards to online retailers?

Response: FDA conducts surveillance of websites, social media, and magazines and other publications that promote and sell regulated tobacco products in the U.S. market. In FY 2016, FDA began surveillance of websites that sell deemed tobacco products, including electronic nicotine delivery system (ENDS) products and took compliance actions when violations were found. Since August 8, 2016, the effective date of the "deeming" rule, FDA has issued over 200 warning letters as a result of these surveillance activities.

On April 24, 2018, FDA announced several enforcement actions as part of a new Youth Tobacco Prevention Plan to stop youth use of,and access to,JUUL and other e-cigarettes. As part of this prevention plan, FDA has been conducting a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes—specifically JUUL products—to minors at both brick-and-mortar and online retailers. The blitz, which started April 6 and will continue to the end of the month, has already revealed numerous violations of the law. FDA has also begun taking steps to foreclose online sales of JUUL to minors.

FDA has also recently contacted eBay to raise concerns over several listings for JUUL products on its website, as eBay has a policy on restricting tobacco products on its website. FDA is thankful for eBay's swift action to remove the listings and voluntarily implement measures to prevent listings from being posted to the web retailer's site.

The illegal sale of these JUUL products to minors is concerning. Since the beginning of March, FDA compliance checks have uncovered 40 violations for illegal sales of JUUL products to youth, and FDA has issued 40 warning letters for those violations. While some of these warning letters are the result of our blitz, others are a result of FDA's sustained enforcement efforts to reduce tobacco product sales to minors. FDA anticipates taking many more similar actions as part of the ongoing blitz and our focus on enforcement related to youth access.
However, this is not the first time FDA has taken action against retailers for selling e-cigarettes and other tobacco products to minors. FDA has conducted 908,280 inspections of retail establishments that sell tobacco products, issued 70,350 warning letters to retailers for violating

the law, and initiated about 17,000 civil money penalty cases. FDA has also issued more than 110 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from even selling tobacco products for specified periods of time.

QUESTIONS SUBMITTED BY RANKING MEMBER SANFORD D. BISHOP, JR.

No Increase for Opioid Work

As I mentioned in my opening statement, I understand FDA is considering new ways to facilitate appropriate prescribing practices.

111. Can you please elaborate on this? Have you begun this process? What specific actions may FDA taking?

Response: FDA believes that all health care providers involved in the management of pain should be educated about the safe use of opioids. In line with this, FDA took several important steps in recent months as part of our efforts to address the opioid epidemic.

In January 2018, FDA released a revised Blueprint[9] for opioid prescriber education. The Blueprint, "Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain," contains core educational messages for health care providers involved in the treatment and monitoring of patients with pain. It also includes information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic).

Through the REMS for Opioid Analgesics,[10] training will be made available to other health care professionals involved in the management of patients with pain such as nurses and pharmacists, not only prescribers. Training will be aimed at making sure providers who write prescriptions for any opioids are doing so for properly indicated patients and under appropriate clinical circumstances.

Also in January 2018, FDA hosted a Part 15 hearing[11] gathering a broad group of stakeholders, both private and public, to seek feedback on how the Agency can strengthen our oversight of opioids. The Agency discussed, among other topics, the potential use of our REMS authority to facilitate the creation of an electronic prescribing tool that would require prescribers to document medical necessity when prescribing opioids above certain threshold amounts.

In addition, the Duke-Margolis Center hosted a public workshop in which FDA officials participated[12] in February 2018, exploring strategies for promoting the safe use and appropriate prescribing of prescription opioids. This public workshop brought together top experts and speakers to examine the landscape of strategies and tools being used to support safe opioid

[9] www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf
[10] www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm
[11] www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm
[12] https://healthpolicy.duke.edu/events/public-workshop-strategies-promoting-safe-use-and-appropriate-prescribing-prescription

prescribing, how data and health IT can advance these efforts, and how stakeholders are addressing barriers to implementation and potential unintended consequences.
FDA is continuing to consider the information, comments, and recommendations discussed in these forums and is committed to engaging stakeholders as part of our broader effort to to address the opioid epidemic.

Opioid Data Warehouse

You have made recent statements saying that vital opioid information is siloed across the healthcare system, and this information is needed to generate evidence-based recommendations related to the ongoing crisis.

112. What additional resources does the FDA require to be able to better collect the large amounts of opioid data available? Would a data house be a viable option?

Response: Ascertaining the extent of prescription drug abuse presents unique challenges because the data sources and methods typically used to study drug safety may not provide relevant information. Currently available data resources generally capture one aspect of interest (abuse, clinical, or mortality data) without the ability to link to other relevant datasets, and outcomes that come to medical attention generally, this information cannot be attributed to a specific product. While it is unlikely that a single data source would be sufficient to address all opioid-related issues, the most useful data systems (or linked data sources) for such studies would feature characteristics, including:

- Identification of product-specific information, including brands, formulations, and routes of abuse.
- The ability to rapidly respond to changes in the opioid market, and to expand to evaluate potential product formulations with abuse-deterrent properties that are not opioids.
- The ability to generate national and regional estimates for abuse of specific products that can be reliably trended over time and in different sub-populations (e.g., geographic regions, demographic groups, severity of substance use disorders).

Prescription Drug Monitoring Programs (PDMPs) continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. A PDMP is an electronic database that tracks controlled substance prescriptions in a state. As a public health tool, PDMPs can be used by state health departments to understand the behavior of the epidemic and inform and evaluate interventions.

Currently, 49 states (as well as DC and Guam) already operate statewide PDMPs. In this sense, a "data house" can be created by linking information from all operating state PDMPs, but each state has its own PDMP regulations and policies.

Another approach the FDA Opioid Policy Steering Committee is considering a nationally interoperable PDMP network – an approach that the Agency believes could be more effective in helping health care providers identify patients who could be misusing or abusing prescription opioids and provide real-time alerts about potentially harmful drug-drug combinations.

Medical Device Proposal

The budget proposes a new voluntary program under which medical device manufacturers could have third parties certify that they are meeting quality requirements. In exchange, "regulatory incentives" would be offered to those manufacturers.

113. Can you explain what those regulatory incentives would be? Aside from providing the requested $12 million for this initiative, what role does Congress have in terms of reviewing this proposal before it is implemented?

Response: The voluntary program assesses a medical device manufacturer's quality maturity and that manufacturers are exceeding compliance requirements by focusing on continuous improvement and operational excellence. To facilitate continuous improvement by medical device manufacturers, the agency seeks resources to interact earlier and more often with device manufacturers to ensure those manufacturers implement practices and technologies intended to improve the maturity of their quality systems. Among the regulatory incentives are earlier and more frequent interactions with FDA. Additional FDA interactions allow for the agency to have greater confidence in the manufacturer and provide feedback earlier in the development stages so that quality is considered during the design of manufacturing processes. FDA could also consider shifting some oversight typically conducted in the premarket phase into the postmarket phase; this is another regulatory incentive.

Additional incentives could include FDA foregoing traditional inspections for satisfactory quality appraisals conducted by third-parties in addition to monitoring metrics about product performance. FDA could also seek to streamline submission requirements so there is more focus on the clinical relevance and risk of certain manufacturing changes. Lastly, FDA could accelerate reviews of submissions seeking authorization to implement changes that enhance or improve device quality. FDA believes it has sufficient authority to implement this program, but will work with Congress if challenges arise that require a legislative solution.

Generic Drug Development

114. All members of Congress are deeply interested in facilitating development and approval of generic drugs. In your testimony, you say you want to "establish a new review platform to modernize generic drug review."

Food Safety Funding

This subcommittee has devoted a great deal of money to the implementation of the Food Safety Modernization Act over the last seven or so years and FDA did yeoman's work to get the basic rules to carry out FSMA finished.

But now the rubber is hitting the road from the farmer's perspective. Large farms must now be in compliance with the produce safety requirements of FSMA, with medium and smaller farms due one and two years later. As I mentioned in my opening statement, I expected to see significant increase in funding.

115. How sure are you that FDA is on track for a smooth roll-out of the on-farm inspections of small and medium farms in just a few years? How sure are you that the National Association of State Departments of Agriculture and the industry alliances that FDA has funded in the past will have adequate budgets this year with a flat FDA food safety budget?

Response: FDA has engaged a number of partners to ensure a smooth roll-out of activities related to implementation of the Produce Safety rule. This roll-out and inspectional oversight will also involve the states since many have entered into cooperative agreements with FDA to conduct all of the produce inspections within their state. With FDA funding and FDA input, National Association of State Departments of Agriculture (NASDA) developed a produce regulatory framework that provides states with a roadmap for establishing a produce regulatory program, including inspections and training. FDA has been working with NASDA to develop materials states can use to establish their state regulatory programs, including materials to establish inspection programs.

FDA recognizes that a successful roll-out of inspections also relies on farms having knowledge of the requirements.

FDA, in collaboration with USDA, evaluates industry training needs related to FSMA and leverages resources to ensure that needs are being met to the extent that budgets allow. In addition to the industry alliances, funding has been provided to other partners in state, federal, and tribal governments, industry, and academia to develop and deliver training, particularly training for small businesses, local growers, and tribal growers. In the current budget cycle, FDA has secured nearly $500,000 for the Produce Safety Alliance and will provide additional funding if resources allow. FDA and USDA are working with the Produce Safety Alliance so that it can eventually become self-sustaining over the longer term.

Drug Shortages

116. Some smaller companies who are interested in selling shortage drugs at pre-shortage process have approached us and suggested that FDA issue guidance for the accelerated treatment of ANDAs for shortage drugs. Would FDA be in favor of such guidance?

Response: FDA is committed to our mission to protect the public health and takes great efforts, within its legal authority, to address and prevent drug shortages.

- As reflected in FDA's Manual of Policies and Procedures (MAPP) 5240.3, Prioritization of the Review of Original ANDAs, Amendments, and Supplements, the Agency generally prioritizes the review of ANDA submissions that could help mitigate or resolve a drug shortage and prevent future shortages.
- In addition, under the Generic Drug User Fee Amendments, as amended by the FDA Reauthorization Act of 2017, ANDAs for products that are on the drug shortage list are now eligible for a shorter review goal date if the applicant submits complete, accurate facility information (i.e., pre-submission facility correspondence) at least 60 days prior to submitting the ANDA.

- FDA recently issued a draft Guidance for Industry, ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications, to aid ANDA applicants in submitting this pre-submission facility correspondence.

FDA continually re-evaluates policies and processes to make sure they are effective and efficient. The Agency makes improvements as needed, and will consider whether providing further guidance or taking other appropriate actions could aid ongoing efforts to mitigate or prevent drug shortages.

QUESTIONS SUBMITTED BY CONGRESSMAN DAVID YOUNG

Costs of Prescription Drugs

Too often I hear from Iowans across my district struggling to pay for needed prescription medicine, and stories about folks having to choose between food and their medications. We all must do more to address the overall public health issue of increased prescription drug costs and Americans' access to more affordable prescription drugs is a top issue.

117. Can you elaborate on FDA's generic review process? How can we increase competition and remove regulatory obstacles that make it difficult to earn approval of generic versions of certain complex drugs? I believe we need increased transparency in the pricing of prescription drugs and I'd be interested to learn your perspective on this issue and how to effectively accomplish this.

Response: FDA's review process ensures that generic medications perform the same way in the human body and have the same intended use as the name brand medication. All generic drugs approved by FDA have the same high quality, strength, purity, and stability as brand-name drugs. In addition, FDA inspects facilities to make certain the generic manufacturing, packaging, and testing sites pass the same quality standards as those of brand-name drugs.

While FDA does not regulate drug pricing, it does play a critical role in increasing access to safe, high-quality and affordable generic drugs. Under the Drug Competition Action Plan (DCAP), FDA has been working to strengthen the generic drug review process and thereby increase competition. FDA has already made significant progress in each of the three major components of the Plan: (1) streamlining the generic drug review process to increase efficiency and effectiveness with the ultimate goal of more approvals, (2) enhancing development and streamlining review of complex generic drug products, and (3) reducing "gaming" that frustrates and delays generic drug approvals and extends brand monopolies beyond what Congress intended.

With respect to complex generic drug products, FDA held several public meetings and workshops to engage and educate stakeholders regarding these products over the last year, and issued a number of agency guidances on complex generics including recommendations on generic synthetic peptides and abuse-deterrent formulations for generic opioids. Under the Generic Drug User Fee Amendments, as amended by the FDA Reauthorization Act of 2017, the Agency also established a pre-Abbreviated New Drug Application (pre-ANDA) program that is designed to support the development of complex generic drug products. FDA intends to continue to take actions to advance this and the other goals of the DCAP, and help ensure consumers can get the medicines they need at affordable prices.

Medical Marijuana

Commissioner, I've heard from constituents who have found benefit from using medical marijuana products. The FDA has not approved marijuana as a safe and effective drug for any indication. However, I understand that the agency has approved two drugs containing a synthetic

version of a substance that is present in the marijuana plant and one other drug containing a synthetic substance that acts similarly to compounds from marijuana but is not present in marijuana.

118. If the DEA reclassified marijuana from Schedule I to Schedule II or III, would you support scientific research into and expanded access for the medical uses of marijuana?

Response: FDA has long supported research into potential therapeutic uses of marijuana, and that support will continue, regardless of whether marijuana remains in Schedule I or is downscheduled. The Agency continues to believe that the FDA drug approval process represents the best way to ensure that safe and effective new medicines derived from marijuana are available as soon as possible for the largest numbers of patients, and it is important and appropriate for FDA to apply consistent scientific standards to the development and assessment of marijuana for any therapeutic uses. Thus, FDA supports research on marijuana and its components that complies with FDA regulations for research under an Investigational New Drug (IND) application, and also with the Controlled Substance Act (CSA) and the Single Convention on Narcotic Drugs. The Agency is also aware of the desire of researchers, patients, and their loved ones to have safe and effective therapies developed as quickly as possible.

FDA strongly supports the use of expanded access, in which a company or investigator with an active drug development program provides access to their investigational drug under an IND treatment protocol for patients with serious or immediately life-threatening diseases or conditions and no comparable or satisfactory alternative treatment, while preserving important protections for those patients. The CSA and the Federal Food, Drug, and Cosmetic Act contain provisions to allow for both clinical research with, and treatment uses of, investigational drugs, including Schedule I substances, provided certain steps are taken to protect the rights, safety, and welfare of human subjects and to safeguard against diversion of investigational drugs to illicit uses. In a recent example, FDA authorized the use of a cannabidiol product, Epidiolex, under expanded access INDs for the treatment of Dravet syndrome, a rare and catastrophic treatment-resistant form of childhood epilepsy. According to the company's website, several hundred patients received cannabadiol as a part of this program.

119. What kind of research is the FDA reviewing when it comes to the efficacy of marijuana?

Response: As prefaced above, the FDA has not approved a marketing application for marijuana for any indication to date, although FDA has approved products containing dronabinol, which is the same drug substance, although synthetically derived, as trans-delta-9-tetrahydrocannabinol (THC), a chemical component of marijuana. As part of the FDA's mission to protect and promote the public health, the Agency ensures the safety, efficacy, and quality of medical products, including prescription drugs. Accordingly, although FDA does not conduct drug research itself, the Agency nevertheless plays an important role in the regulation of research on marijuana and its constituents for potential medical uses in the United States and in supporting the scientific assessment of marijuana and its constituents in drug development. These activities are critical if safe and effective drugs are to be developed from marijuana.

Please note that if you are inquiring specifically about what types of indications are being studied or are under development for marijuana or marijuana-related products, the Agency is legally prohibited from divulging the existence or content of any unapproved applications. FDA is aware that there has been considerable interest in marijuana's use for the treatment of a number of conditions, including glaucoma, AIDS wasting, neuropathic pain, treatment of spasticity associated with multiple sclerosis, Parkinson's and chemotherapy-induced nausea. The FDA encourages research on these conditions.

It is also important to note that the Agency does not have authority to compel certain drugs be developed, nor does FDA dictate marijuana research priorities: investigators and drug sponsors decide independently from FDA which compounds they wish to study, and for which therapeutic indications. It is the responsibility of these drug sponsors, within the boundaries of FDA's legal and regulatory frameworks, to conduct the necessary studies to support drug approval. The mission of FDA's Center for Drug Evaluation and Research (CDER) is to review drug applications, approve those that meet the legal and regulatory standards for safety and effectiveness, and continue to ensure that drugs marketed in the U.S. are safe and effective.

Opioid Crisis

Prescription opioids are powerful pain-reducing medications that have benefits as well as potentially serious risks. As I travel across the Third District, families share heartbreaking stories with me and communities are being torn apart by addiction. Last year, the opioid crisis was responsible for the deaths of 146 Iowans and according to the CDC, nearly 30,000 people died nationwide. Congress passed the 21st Century Cures Act which included $1 billion to fight addiction in our communities. We must do more to address opioid abuse and addiction.

120. How are the FDA and the Opioids Policy Steering Committee working to decrease exposure to opioids and prevent new addiction?

Response: FDA's strategies to decrease exposure to opioids and prevent new addiction include the following key areas: 1) facilitating appropriate prescribing of opioid analgesics; 2) the role of packaging storage, and disposal; and 3) health care provider education.

The Opioid Policy Steering Committee held a public meeting January 30, 2018, to solicit input on how FDA's authorities could facilitate appropriate prescribing. The docket for the public meeting closed in late March 2018, and FDA is reviewing over 500 comments received. Further, FDA is considering ways to reduce the occurrence of new addiction that FDA believes may be derived from the initial medical use of prescription opioids through encouraging the development of evidence-based clinical practice guidelines. FDA's goal is that these guidelines will encourage the use of an appropriate dose and duration of an opioid for some common procedures and promote the use of rational prescribing.

In addition, FDA held a public workshop Dec 11-12, 2017, to solicit input on packaging strategies, which also had a public docket that closed March 2018 with 44 comments submitted. These comments are currently under review. New types of packaging – rather than a typical bottle with a 30-day supply – could remind prescribers to restrict the number of opioids

dispensed to patients, in turn reducing the total number of opioids dispensed per prescription. Packaged in this fashion, more doctors may opt for these shorter durations of use. It could also reduce inappropriate access to opioids by kids and families and help address the problem of excess supply in the U.S.

With respect to education, FDA issued letters in September 2017 notifying sponsors of Immediate Release (IR) opioids that these products will be subject to Risk Evaluation and Mitigation Strategy (REMS) requirements. Under the new REMS requirements, opioid analgesic companies must make education available to health care providers who prescribe IR opioid analgesics. FDA also took steps to ensure training is made available to non-physician health care providers who participate in the treatment and monitoring of patients who receive opioid analgesics, including nurses and pharmacists. On January 30, 2018, FDA posted revised opioid analgesic prescriber training blueprint, which will be final when the Opioid Analgesic REMS is approved later this year.

121. How is the FDA engaging with stakeholders to ensure the safe use and appropriate prescription of opioids?

Response: Engaging with stakeholders is critical to FDA's efforts to address the opioid epidemic. Furthermore, FDA believes that all health care providers involved in the management of pain should be educated about the safe use of opioids. In line with this, FDA took several important steps in recent months as part of our broader effort to make sure providers are properly informed about suitable prescribing and the risks and benefits associated with all opioid analgesics.

In January 2018, FDA hosted a Part 15 hearing[13] gathering a broad group of stakeholders, both private and public, to seek feedback on how the Agency can strengthen our oversight of opioids. FDA discussed, among other topics, the potential use of our REMS authority to facilitate the creation of an electronic prescribing tool that would require prescribers to document medical necessity when prescribing opioids above certain threshold amounts.

Also in January 2018, FDA released a revised Blueprint[14] for opioid prescriber education. The Blueprint, "Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain," contains core educational messages for health care providers involved in the treatment and monitoring of patients with pain. It also includes information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic).

Through the REMS for Opioid Analgesics,[15] training will be made available to other health care professionals involved in the management of patients with pain such as nurses and pharmacists, not only prescribers. Training will be aimed at making sure providers who write prescriptions

[13] https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm
[14] https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf
[15] https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm

for any opioids are doing so for properly indicated patients and under appropriate clinical circumstances.

In addition, FDA and the Duke-Margolis Center co-hosted a public workshop[16] in February 2018, exploring strategies for promoting the safe use and appropriate prescribing of prescription opioids. This public workshop brought together top experts and speakers to examine the landscape of strategies and tools being used to support safe opioid prescribing, how data and health IT can advance these efforts, and how stakeholders are addressing barriers to implementation and potential unintended consequences.

FDA is continuing to consider the information, comments and recommendations discussed in these forums. The Agency is committed to continue engaging stakeholders including patients, healthcare providers, manufacturers, and other partners in our efforts.

Partially Hydrogenated Oils (PHO)

I want to raise an issue that this committee has looked at before related to partially hydrogenated oils, or PHOs. FDA made its determination that PHOs need to be removed from the marketplace and manufacturers have acted accordingly. However, I understand some of the foods made with PHOs can have a shelf life of up to three years and possibly longer. The compliance date for industry is in June, but given shelf lives, PHO-containing products will be in commerce, on retail shelves, and presumably in consumers' pantries for a period of time past this date. Without a clear statement from FDA regarding the status of these PHO-containing products, the same companies that have worked to successfully remove PHOs could be forced to recall those products from the market that are then deemed adulterated as a matter of law.

122. To avoid these unnecessary complications, is the agency willing to issue a statement making it clear FDA does not consider it necessary for companies to recall those PHO-containing products in commerce on the date of the compliance date?

Response: After an extensive public process, in June 2015, FDA issued a formal determination that added partially hydrogenated oils (PHOs) (i.e., those not naturally present in certain foods) are not generally recognized as safe (GRAS) under federal law. A substance that is not GRAS may not be added to food unless the use of the substance is specifically authorized by regulation. In FDA's determination, a compliance period was set at three years. As explained at the time, that time frame was intended to give food companies ample time to reformulate products without PHOs or to petition the FDA to permit specific uses of PHOs. Many companies have worked hard to remove PHOs from processed foods in order to meet the three-year compliance date. FDA has heard concerns from industry about products containing added PHOs that were produced before the compliance date and the need for an orderly transition of these products out of the marketplace. FDA does not plan on requiring recalls for these products and will provide additional written clarification in the near future.

[16] https://healthpolicy.duke.edu/events/public-workshop-strategies-promoting-safe-use-and-appropriate-prescribing-prescription

In response to the 2015 determination, the Grocery Manufacturers Association submitted a food additive petition that requested approval for certain specific, limited uses of PHOs. FDA is completing a review of that petition and acknowledges concerns from the industry that they will need sufficient time to reformulate their products for the petitioned uses if the petition is denied. FDA is taking those concerns into consideration as the Agency completes its review .

Regulatory Reform

Last year, FDA published a Request For Information on regulations and related paperwork requirements that could be modified, repealed, or replaced to achieve meaningful burden reduction for products under the Center For Science and Applied Nutrition. This was part of the Administration's regulatory reform agenda. The Agency received almost 70 responses with detailed recommendations to modify, repeal or replace onerous rules while honoring public health mission and fulfilling statutory obligations.

123. When can we expect FDA to act on those regulatory reform recommendations and what, exactly, is your strategy to ease the regulatory burden at the Agency?

Response: In September 2017, FDA announced that the Agency was initiating a comprehensive review of FDA regulations to strengthen and modernize FDA's regulatory framework. FDA is analyzing its regulations to determine how current regulations could be reshaped to achieve FDA's public health objectives through more efficient approaches and to ensure they reflect the new benefits that science and technology offer to strengthen our mandate to protect Americans. FDA's goal is to have regulations that reflect modern risks and opportunities, and use the full scope of our authorities to achieve our consumer protection mission.

To support this work, in September 2017, FDA published a set of seven Requests for Information (RFIs) in the *Federal Register*, including the one that you refer to for products under our Center for Food Safety and Applied Nutrition, soliciting public comments to help us identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with law, to achieve meaningful burden reduction while allowing the Agency to achieve its public health mission. The comment period for the RFIs closed on February 5, 2018 (after a 60-day extension). Agency staff are currently reviewing and analyzing all comments received to all regulatory reform dockets. Information submitted to the public dockets will be incorporated into ongoing regulation reviews and will help inform FDA's regulatory reform implementation.

124. You recently announced a Nutrition Innovation Strategy that would be administered by the Center for Science & Applied Nutrition. Given your experience at FDA, what sort of regulatory changes would be necessary to implement such a strategy?

Response: The Nutrition Innovation Strategy is in the beginning stages of development. FDA's goal is to update policies and standards in line with current science and provide consumers with information on food labels that can help them make healthful choices. In addition, many companies have requested certain changes in policies for labeling and standards of identity to meet consumer demands. Throughout this process, FDA will be mindful of opportunities that

may exist to allow industry flexibility for innovation while maintaining the basic nature and nutritional integrity of food products. FDA will be holding a public meeting this summer to gather stakeholder input and further inform the strategy.

Rare Disease Therapies

Drug development for rare disease therapies can be especially complex because of small population sizes that make traditional clinical trials infeasible. FDA has helped develop novel approaches to review treatments for a number of rare diseases including cystic fibrosis, a rare genetic disease that causes progressive lung damage and life-threatening lung infections. Only 30,000 people in the United States have cystic fibrosis, and the population is further subdivided by more 1,700 different mutations that can cause the disease. FDA has released several guidance documents on this issue.

125. Can you speak to the Agency's current thinking about how we can ensure treatments are safe and effective as clinical trial designs are updated to accommodate this new paradigm?

Response: Regardless of the size of the patient population, the FDA requires that a sponsor demonstrate that its drug is safe, i.e., its benefits outweigh its risk, and that there is substantial evidence of its effectiveness for its intended use. Due to a lack of therapeutic options, rare disease drug development programs typically have a higher proportion of patients assigned to the investigational drug, though the absolute numbers of exposed patients are small compared to common diseases. Since many rare diseases are serious and patients with these diseases often have unmet medical needs, the Agency exercises flexibility in the design and size of the trials necessary to demonstrate the safety and effectiveness of drugs for these diseases. Rare disease drug development programs also frequently use one or more of the expedited programs, including Fast Track Designation, Breakthrough Therapy Designation, Priority Review, Accelerated Approval, and Regenerative Medicine Advanced Therapy Designation, which provide mechanisms for enhanced communication between drug developers and FDA, and for application of flexibility regarding the design and conduct of clinical trials capable of demonstrating efficacy while preserving safety standards and supporting appropriate benefit-risk determinations. In addition, the Agency continues to explore the use of complex innovative trial designs for drugs and biologics for rare diseases, launching a pilot program in March 2018 to implement key provisions of the 21st Century Cures Act and PDUFA VI. After approval, continued post marketing surveillance is necessary for all drugs, including those for rare diseases, to monitor for the emergence of new safety issues, since the clinical trial process generally does not provide information on the use of the drug in real world settings. The Agency has issued a draft guidance entitled Rare Diseases: Common Issues in Drug Development Guidance for Industry that details the Agencies advice and guidance to the industry on how to develop drugs for small populations to provide evidence of safety and efficacy. The draft guidance on Developing Targeted Therapies in Low -Frequency Molecular Subsets of a Disease Guidance for Industry provides additional recommendations to developers in this area.

Kalydeco Expansion

In addition to reviewing new treatments to ensure they are safe and effective, the FDA also plays a critical role in developing innovative ways to review therapies when a traditional clinical trial may not be possible. Just recently the agency approved a label expansion of Kalydeco, a drug that targets the underlying defect that causes cystic fibrosis, using a novel approach based on a combination of in-vitro laboratory results, data from the Cystic Fibrosis Foundation's patient registry, and the drug's established safety record. Cystic fibrosis is a rare genetic disease that causes progressive lung damage and life-threatening lung infections, and Kalydeco's label was expanded to include people with CF ages two and older who have one of 23 rare mutations that were not included in the original trials. Novel approaches such as this are an exciting advancement in drug development for unique cases where the patient population is not large enough to carry out a full clinical trial.

126. What do you see as the path forward for drug development and review when traditional clinical trials are not feasible, and what can the federal government can do to support the development of innovative solutions in this area?

Response: In order to obtain marketing approval, new drug and biologic product manufacturers must demonstrate, among other things, the effectiveness of their products through the conduct of adequate and well-controlled studies. Generally, FDA requires the submission of two adequate and well-controlled clinical studies to meet the statutory requirement to provide substantial evidence of effectiveness, though FDA has been flexible within the limits imposed by Congress in determining what constitutes evidence of effectiveness. For example, FDA can approve a drug for a serious disease based on evidence of effectiveness from a single adequate and well-controlled clinical trial and confirmatory evidence. For rare diseases, including cancers, that are serious and for which there is an unmet medical need, there are many examples in which a single clinical trial with confirmatory data has been sufficient evidence of effectiveness for approval. Further, FDA has long shown flexibility in the kind and size of clinical trials that can be used to support approval for rare, serious diseases, including single arms studies using historical controls, with many fewer patients than would be studied in a traditional Phase 3 program. For many years, through the Accelerated Approval pathway, FDA has relied on surrogate endpoints for approval of therapies for certain serious diseases and/or life-threatening diseases and conditions; confirmatory evidence of clinical benefit is obtained after the drug is on the market.

Notably, FDA recently expanded the approved use of Kalydeco (ivacaftor) for treating cystic fibrosis, an uncommon serious disease occurring from a wide range of different genetic mutations, with many mutations very rarely occurring. Studying each of these mutations in sufficient size clinical trials would be infeasible. To address this, each individual mutation was studied in a cell-based in vitro assay to determine response to drug, with drug responsive mutations added to the label. This approach tripled the number of rare cystic fibrosis gene mutations that the drug was approved to treat, expanding the indication from the treatment of 10 mutations to 33. The innovative approach provides a pathway for adding additional, rare mutations of a disease, based on laboratory data. FDA also published a draft Guidance in December 2017 on Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.

Recently, FDA has taken steps to encourage the use of different clinical trial designs, new tools, and different types of data to help advance drug development. On March 20, 2018, FDA conducted a public workshop to discuss the use of complex innovative designs in clinical trials for drugs and biologics. This workshop will inform a complex innovative design pilot project. FDA has widely discussed, presented on, and encouraged sponsors to use designs such as "platform" trials and "umbrella" trials that can more efficiently examine a range of drugs for less common diseases, or study a range of disease subtype responses to a particular drug. In addition, in the area of regenerative medicine, FDA has recently discussed an innovative approach to clinical development whereby it may be appropriate for multiple clinical sites to participate in a multi-center trial with the intent of sharing the combined clinical trial data to support biologic license applications from each of the individual centers/institutions (in contrast to the traditional development model under which data from multiple sites would support a single biologics license application from one sponsor).[17] Such innovative approaches that enhance efficiency can more effectively, and more rapidly, study less common, but serious diseases.

Biotech Animals

As you know, FDA has oversight over biotech animals and recently claiming jurisdiction over gene edited animals as well. FDA regulates these under its "New Animal Drug" authority – which means these animals must go through years of testing as drugs, and producers and retailers may even be required to register as drug producers to raise or sell these animals. These onerous requirements have prevented valuable products, like PRRS-resistant pigs, from reaching farmers. I know USDA and FDA recently signed an MOU to discuss biotech regulation.

127. Can you tell me what collaboration with USDA your agency has for animal biotech regulation?

Response: FDA collaborates with the U.S. Department of Agriculture (USDA) in several fora. FDA participates with USDA and the Environmental Protection Agency (EPA) in the Interagency Biotechnology Working Group, which facilities the agencies' information sharing and policy coordination, including on regulation of products of biotechnology under each agency's respective jurisdiction. FDA, USDA, and EPA have worked, under the coordination of the White House Office of Science and Technology Policy, on the *Coordinated Framework for Biotechnology* since its initial issuance in 1986 and on each update, including the most recent one issued in 2017. FDA and USDA signed a formal agreement on January 30, 2018, in which both agencies commit to modernizing the *Coordinated Framework for the Regulation of Biotechnology* and the U.S. agricultural biotechnology regulatory system to develop efficient, science-based regulatory practices for products of biotechnology by working in partnership with other federal agencies on the corresponding *National Strategy for Modernizing the Regulatory Systems for Biotechnology Products*.

With regard to FDA's review process, the Agency applies a flexible, risk-based approach. As described in Guidance for Industry #187, "Regulation of Intentionally Altered Genomic DNA in

[17] NEJM 2018; 378: 954-959

Animals," FDA outlines, based on risk, when the Agency intends to use enforcement discretion or when FDA intends to enforce the requirement for an approved application related to intentional genomic alterations of animals. For example, following a review focused on areas of risk-related concern, FDA has exercised enforcement discretion over approval requirements (i.e. FDA has not required approval) for glowing aquarium fish. In addition, FDA approved on a very short time frame a biopharm goat and a biopharm chicken that produce human therapeutics. FDA also has approved a genetically engineered salmon with enhanced growth. FDA has kept USDA informed of these actions.
As far as registration is concerned, FDA notes that only manufacturers, repackers, or re-labelers are required to register.

Antibiotic Use and Resistance

FDA has been very focused on the connection between on-farm antibiotic use and antibiotic resistance. The agency has taken significant steps to encourage restrictions on such use, but doing so has also left the industry without some valuable tools to meet its obligation to protect animal health. The investment and regulatory challenges for new drugs to reach the market are significant.

128. What steps will FDA take to encourage research and development of non-antimicrobial drugs to address animal health issues currently treated with antibiotics?

Response: In conjunction with FDA's strategy to eliminate the production – such as growth promotion – uses of medically important antimicrobial drugs under Guidance for Industry #213, FDA encouraged drug sponsors to seek approval for new therapeutic uses of these products, particularly where such new uses would help address unmet animal health needs. A key objective of FDA's strategy is to take steps, in collaboration with affected industry, to help address the public health concern associated with antimicrobial resistance while preserving the availability of antimicrobials for treating, controlling, and preventing disease in animals.

Since 2003, FDA's funding has been supplemented through the Animal Drug User Fee Act (ADUFA) and, since 2008, has also been supplemented through the Animal Generic Drug User Fee Act (AGDUFA). Additional resources provided through these user fee programs has enabled the Agency to acquire additional scientific experts and develop and implement policies and procedures for streamlined evaluation of new animal drugs.

ADUFA and AGDUFA are highly successful programs that have accelerated the review of innovative new animal drugs – and more affordable generic alternatives – advancing both animal and human health. The programs have enabled FDA to dramatically reduce the time needed to review pioneer and generic animal drug products for premarket approval, improve timely communications with sponsors, and achieve other efficiencies in the drug review process, while ensuring that the drugs are safe and effective.

Innovative new animal drug products and approaches, including alternatives to antimicrobials, are being developed that offer the promise of a longer and healthier life for animals. In March 2016, FDA's Center for Veterinary Medicine approved the first alternative to antimicrobial

drugs. Imrestor is an immune-stimulating drug approved for use in dairy cows and replacement heifers to reduce the incidence of clinical mastitis (udder infection). Its mechanism of action strengthens the overall bovine immune response, rather than acting directly on the infectious bacteria. Incidentally, Imrestor was also the first animal drug for use in food-producing animals simultaneously reviewed and approved in both the United States and Canada.

FDA employs multiple best practice methods of analysis and approaches to arrive at safety and efficacy conclusions, including the following: use of pharmacokinetic/pharmacodynamic information; *in vitro* testing of product characteristics; meta-analysis of broad sources of information such as published literature; new statistical analyses and presentations of data; and risk analysis methodologies, among others.

129. Will faster approval times for these drugs be a priority?

Response: FDA continues to enhance the efficiency of the new animal drug review process and to work with industry sponsors to expedite overall drug approval time.

Congress, through the ADUFA and AGDUFA, has supplemented budget authority funding that has enabled the Agency to acquire additional scientific experts and develop and implement policies and procedures for the streamlined evaluation of new animal drugs. As a result of additional resources provided through the animal drug user fee programs, FDA maintains a stable scientific and technical workforce and provides the animal drug industry with more timely and predictable premarket product review. These programs have been highly successful and have enabled FDA's Center for Veterinary Medicine (CVM) to eliminate the backlog in applications, dramatically reduce the time needed to review animal drug applications and other submissions, improve timely communications with drug sponsors, and achieve other efficiencies in the drug approval process. FDA has met or exceeded virtually all performance goals established under both programs, without sacrificing scientific standards for safety and efficacy. Additionally, CVM utilizes a phased review process that allows sponsor submissions to come in earlier in the drug development process and when they have the data available.

Proprietary Information

I've heard from food industry representatives that they're concerned with food industry trade secret and confidential commercial information in possession of the FDA, as a result of FSMA, Menu Labeling, and Nutrition Facts Labeling final rules. FDA has a statutory obligation to protect industry trade secrets.

129a. Report language accompanying the Omnibus directed FDA to provide a detailed description of your procedures to protect this information and I believe this is important. I encourage you to provide the report we have directed on time and designate a senior FDA official to ensure FDA is meeting its statutory duty. Will you commit to doing so?

Response: FDA understands the global operating environment and our obligation to protect trade secret information and intellectual property. The Agency relies on a multi-pronged approach and has undertaken a number of key initiatives to ensure sensitive information is

appropriately protected by safeguarding against unauthorized disclosure, access, or misuse, including, but not limited to, the following:

- Conduct classified and unclassified cybersecurity, economic espionage, and insider threat awareness training for executives, managers, supervisors, and personnel within FDA Centers and Offices to encourage collaboration and to support the protection of sensitive information and overall security posture.

- Implemented Data Loss Prevention (DLP) measures designed to safeguard personally identifiable and protected health information, as well as commercial, confidential, and trade secret information, from inadvertent disclosure, misuse, and/or theft. As part of DLP Device Control, the Agency successfully implemented USB blocking of FDA laptops and workstations. Implemented DLP Email Protection policy that prohibits use of personal email or personal online storage accounts to conduct official business.

- Implemented the FDA Systems Management Center (SMC) Center Command and Control Center to provide network, systems, application, and cybersecurity threat management oversight activities and operations, including monitoring of FDA High Value Assets and other sensitive applications and databases on a 24/7 basis.

- Implemented Multi-Factor Authentication which will integrate network and security tools/capabilities for protection of sensitive information.

- Incorporated insider threat and information protection related topics in the FDA New Employee Orientation Course to ensure awareness of security concerns and individual responsibilities.

FDA mandates employee compliance by conducting annual computer security awareness training that includes a module for individual responsibilities for the protection of sensitive information. All new FDA employees are required to complete ethics training that also highlights employees' responsibilities to protect proprietary information. The ethics regulations also require employees who file public and confidential financial disclosure reports to receive annual ethics training.

QUESTIONS SUBMITTED BY CONGRESSMAN STEVEN PALAZZO

Food Safety Modernization Act

As I understand it, FDA is in the first phase of implementing the Food Safety Modernization Act. Produce farmers in my district are a little uneasy about this new federal law and how it will be administered on the ground. As you know, it's very complicated and has added another layer of federal government regulation to our small businesses. I understand that funding is available to the states to implement this rule for a 5-year period and that we are now in year three of that period. My home state department of agriculture has gotten a state law enacted in the current legislative session that will permit them to enter into cooperative agreements with FDA.

130. Can you update me on the overall status of implementation of the rule and ways that FDA is making it simpler for our farmers to comply with this new complex rule?

Response: Although the first major compliance date for the Produce Safety Rule arrived in January 2018 for larger farms, FDA has announced that routine inspections under the rule will not begin until spring 2019 (other than for sprout growers). Delaying routine inspections for an additional year will give farmers more time to prepare. FDA has also proposed to extend compliance dates for the agricultural water standards for covered produce other than sprouts in the Produce Safety Rule as the Agency considers how it might simplify the water standards while still protecting public health.

FDA has taken several steps to help farmers prepare for Produce Safety Rule implementation, including establishing the Produce Safety Alliance (PSA), a collaboration among FDA, Cornell University, and USDA, to develop a standardized curriculum. As of March 2018, more than 20,000 growers have participated in PSA training in the U.S. and internationally. FDA also has funded a cooperative agreement to the National Farmers Union Foundation to develop and provide food safety training, education, and outreach for local food producers and processors, as well as a cooperative agreement with the University of Arkansas at Fayetteville for a similar program for tribal nations.

FDA and the National Association of State Departments of Agriculture, funded by an FDA cooperative agreement, have developed a voluntary on-farm readiness review program for farmers wanting a free evaluation of their readiness to comply with the Produce Safety Rule, prior to a regulatory inspection.

In addition, FDA published a Small Entity Compliance Guide to help small and very small farms understand whether and how the rule's requirements apply, and whether they are eligible for a qualified exemption and modified requirements. The Agency also continues to operate the Technical Assistance Network for stakeholder questions about interpreting the Produce Safety Rule and other FDA Food Safety Modernization Act rules.

131. Do you feel confident that the states will see additional funding after the 5-year period or perhaps permanent funding for the states?

Response: FDA remains committed to partnering with the states on Produce Safety Rule implementation, including work relating to the current 5-year Cooperative Agreement Program. Concurrently FDA is assessing longer-term resource needs and objectives as FDA explores options for ensuring sustainability of our Produce Safety partnership with states. FDA recognizes the central role of states in Produce Safety Rule implementation and that, for some states, their produce safety programs could end if federal funding ends.

132. I have also been asked if there was funding available to farmers to comply with this rule. Is that a possibility?

Response: FDA recognizes that compliance is key to the success of the Produce Safety Rule, and the Agency is devoted to ensuring that farmers have the tools they need for successful implementation. FDA has dedicated significant resources to ensuring that technical assistance is available at little or no cost to farmers to support their compliance.

FDA has a network of subject matter experts located across the country to provide free technical assistance to farmers. FDA has also funded a local foods grantee (National Farmers Union) and a tribal grantee to provide education and outreach to farms, and they offer training at little or no cost to farmers. Some states are using State Cooperative Agreement Program funds to offer low-cost training to farmers.

FDA remains committed to ensuring that tools are available to assist farmers in complying with the Produce Safety Rule. In addition, USDA manages several programs that may be able to provide funds to assist farmers in understanding how to comply with the rule. For example, the USDA National Institute for Food and Agriculture provides grant opportunities for a variety of initiatives including the Food Safety Outreach Program, and the USDA Agricultural Marketing Service provides for State Departments of Agriculture to manage the Specialty Crop Block Grant Program.

Lab-Grown Meat Issue

A major portion of my congressional district is very rural, with a very heavy concentration of cattle farmers. As you know, several companies in the U.S. are in the process of growing meat in a lab, with intentions of later commercialization. Many of these companies have called their product "clean meat," insinuating that meat derived from traditional beef cattle is somehow unclean.

133. As the central federal agency in charge of food labeling, can you update the committee on efforts by the FDA to restrict this type of misleading labeling, which would be a detriment to the traditional livestock production of meat?

Response: FDA is sensitive to the concerns you have raised. Foods should be properly labeled in accordance with the Federal Food, Drug, and Cosmetic Act—and its implementing regulations—and consumers should have the information they need to make informed choices. As this new technology is rapidly being developed and entering the consumer market, FDA recognizes the need to provide clarity on labeling with a focus on name and statement of identity.

The Agency is in dialogue with its USDA regulatory counterparts on this issue and will work with industry and consumers to ensure that food labeling is truthful and not misleading.

"Added Sugar" Honey Labeling Issue

I have had several inquiries from beekeepers from my district about the FDA's interpretation of naturally occurring sugar in honey and how it has been characterized as "added sugar" under the new Nutrition Label proposed by FDA. My local beekeepers and I believe this labeling rule will cause consumers to perceive that "added sugar" has been indeed "added" to their product and as a result causing economic hardship on their industry.

134. Can you update me on the status of the overall new nutrition labeling rule and any adjustments or exemptions the agency is planning to make in regard to honey specifically?

Response: In fall 2017, FDA published a proposed rule (82 FR 45753) to extend the compliance dates for the Nutrition Facts Label and Serving Size final rules from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales. Manufacturers with less than $10 million in annual food sales would have until January 1, 2021, to comply. Completing this rulemaking is one of FDA's highest priorities, and the Agency plans to finalize it this spring.

FDA published a draft guidance titled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry" on March 2, 2018. The guidance states FDA's intent to allow manufacturers of specific products to use a symbol immediately after the added sugars Daily Value, directing consumers to language that provides truthful and not misleading contextual information about "added sugars" and what it means for each of these specific products.

The draft guidance is out for public comment, and FDA recently extended the comment period by 45 days to close on June 15, 2018. Although the comment period is still open, the Agency has received comments asking consideration of alternative approaches to what FDA proposed in the draft guidance to address added sugars labeling for these products. The Agency will look at all proposed options once the comment period closes and consider the feedback FDA receives in determining how best to go forward with finalizing the guidance.

FDA also plans to educate consumers on the meaning of the new "added sugars" declaration in the context of other information on the label (e.g., total sugars) and on how they can use the "added sugars" declaration and percent Daily Value to help make informed choices about the food they purchase and consume.

in silico Modeling

As I am sure you are aware, *in silico* modeling is a computer based model of the entire human body that can be used to predict outcomes of drugs or devices. As I understand it, the creators of this model have been able to show success and failure over a long period of time as it relates to the impact of a specific treatment on humans, and can be done quickly at a very low cost. I recently read a blog post by the Commissioner about this technology and why it is so useful.

135. My question is simple, what is the FDA doing to advance this form of clinical trial?

Response: FDA routinely advises sponsors on the use of computer models and simulations to help predict clinical outcomes, inform clinical trial designs, support evidence of effectiveness, optimize dosing, identify the most relevant patients to study, help predict product safety, and evaluate potential adverse event mechanisms. In some cases, in silico trials have been used to replace some clinical studies, such as studies intended to evaluate the risk of drug interactions. Specifically, CDER staff:

- Advises drug developers on the appropriateness of in silico clinical trial approaches during Investigational New Drug (IND) application reviews;
- evaluates data derived from in silico models and simulations during New Drug Application (NDA) and Biologics License Application (BLA) reviews; and
- translates findings from in silico modeling and simulation into prescription drug labeling and patient information where appropriate.

CDER also runs the Drug Development Tools Fit-for-Purpose Initiative (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm505485.htm). This mechanism allows for the regulatory evaluation of models (including in silico clinical trial platforms) to determine whether they are fit for proposed use in drug development.

CDER is also actively engaged in research and policy development in the area of Model Informed Drug Development (MIDD), of which in silico clinical trials is a subset. FDA is collaborating with scientists developing natural history models, based on placebo arms, in Parkinson's disease, Huntington's disease, Alzheimer's disease, and muscular dystrophy, among others.

CBER is also actively engaged in research in this area, and recently published on the use of in silico approaches for predicting immune responses to therapeutic proteins, which is the fastest growing class of drugs. Immune responses reduce the efficacy of these medications and can cause severe adverse effects, which can lead to companies abandoning development during or after clinical trials. CBER worked with one such company, the development of whose drug was stopped during clinical trials due to immunogenicity issues. Together, they provided a validation of the in-silico and non-clinical approaches and used a CBER-developed algorithm to correctly predict (identify) all patients in the clinical trial who had developed anti-drug antibodies. The work is now in the public domain for all companies and clinicians to use. These approaches and others currently being developed by CBER to de-immunize immunogenic molecules could potentially save hundreds of millions of dollars. Moreover, by identifying at-risk patients, it is possible to provide valuable (sometimes life-saving) medicines to those who would benefit while protecting those who could develop life-threatening complications.

Public workshops are regularly organized by FDA in collaboration with external organizations to highlight challenges in various disease areas and identify opportunities to apply in silico trials to facilitate drug development. FDA also announced a pilot program that affords sponsors or applicants who are selected for participation the opportunity to meet with Agency staff to discuss

MIDD approaches in drug and biological product development. Clinical trial simulations are listed as a priority area for this program.

FDA intends to continue advancing these methodologies and techniques to best take advantage of the benefits for continued product innovation and more rapid introduction of life saving technology to US patients. FDA has demonstrated the Virtual Patient Model as one framework for in silico clinical trials, and by creating a virtual population to enable computer-based simulations for medical devices. FDA employs a broad range of modeling disciplines, including mechanistic-based, chemistry-based, physics-based, exposure-based, biological, and statistical models. These techniques can also enhance the mechanistic understanding of disease progression and the complex interplay between genetics and predictive biomarkers with response to therapy. FDA will develop guidances and standards related to use of modeling and simulation in device and drug development and evaluation.

Regulatory evaluation of modeling and simulation is advancing alongside the power and sophistication of the tools. Therefore, FDA formed an Agency-wide working group on modeling and simulation with objectives that include aligning regulatory decision-making with modeling and simulation, and where appropriate, employing in silico clinical trials. Completing these objectives will advance the in silico clinical trial framework for the medical product Centers, and help clarify appropriate methods and guidelines for in silico clinical trials.

Glass Vials Partial Recall

As I'm sure you are aware there has recently been a partial recall on certain drugs over concern for "glass lamellae" or thin flexible glass fragments being shed by the vials in which the medication is stored. These fragments are difficult to detect and can cause a multitude of health complications.

136. How large of a threat human health is the shedding of these fragments into medication, and are there ongoing efforts to find new materials to store medication that will make this process safer?

Response: FDA is aware that quality issues with container closure systems, including glass vials, may occur during manufacturing. The potential for problems such as breakage, cracking, and formation of glass lamellae (glass fragments) to occur has been known for some time, and the Agency has taken steps to provide information to manufacturers to help them reduce the incidence of quality issues with their container closure systems. FDA has a long-standing guidance for industry on *Container Closure Systems for Packaging Human Drugs and Biologics,*[18] which addresses qualification of and quality controls for packaging components, including factors such as sterility assurance.

In addition to the container closure system guidance, FDA has also cautioned manufacturers when there have been new trends in quality issues that posed public health risks. In 2011, FDA issued an advisory to drug manufacturers regarding the potential formation of glass lamellae in

[18] www.fda.gov/downloads/drugs/guidances/ucm070551.pdf

injectable drugs filled in small-volume glass vials. The advisory noted that the Agency was drawing attention to the issue due to several drug recalls in 2010 and 2011. The advisory also noted that there were no known adverse events reported or directly attributed to the problem; however, glass lamellae in injectable drug products pose potential risks, particularly when drugs are administered intravenously or subcutaneously.

The advisory noted that a number of conditions have been associated with a higher incidence of formation of glass lamellae in drug products including, among other factors, glass vials manufactured by the tubing process at higher heat, drug solutions formulated at high pH, the duration of time the drug product is in contact with the glass container, and terminal sterilization processes. The advisory also provided recommendations to help prevent the formation of glass lamellae, along with literature references for the recommendations. These recommendations were also issued in a Question and Answer guidance for industry.[19] Drug manufacturers can continue to follow these recommendations to reduce the likelihood of formation of glass lamellae.

Glass manufacturers have been working on developing new glass designs for use in pharmaceutical containers with a goal of addressing quality issues such as the formation of glass lamellae. Companies have approached FDA's Emerging Technology Program (ETP)[20] with requests to discuss their glass designs. The ETP promotes the adoption of innovative approaches to pharmaceutical product design and manufacturing through early engagement, and the ETP provides feedback on proposed technologies to facilitate anticipated regulatory submissions. Early engagement gives FDA reviewers a better understanding of a new technology when it comes in for review or is referenced in a submission. ETP's role is to discuss, identify, and resolve potential concerns regarding the development and implementation of a novel technology. Each technology still must be evaluated in the context of the regulatory submission that it is associated with.

At the request of the ETP, the Office of Pharmaceutical Quality's laboratory has developed methodology and conducted studies to evaluate the performance characteristics of glass containers for injectable drug products. These laboratory studies will help inform future quality assessments and provide insight for feedback that can be provided to companies as they work on developing their products.

While conducting laboratory studies, the ETP also consulted with colleagues within the Agency to evaluate surveillance data to determine whether there were any new or emerging safety signals related to quality issues associated with glass containers used in pharmaceutical products on the market. FDA analyzed surveillance data from FY 2008 through FY 2017. A new safety signal

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19 www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm#11

20 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM478821.pdf

or change in frequency of reports of a known safety concern could reflect the emergence of an issue that would warrant a new or updated advisory by the Agency to inform manufacturers. However, FDA's analysis of available data did not identify any new or increasing safety signals since the advisory was issued in 2011. At a recent glass quality conference with presentations by FDA and industry experts, participants noted progress has been made in improving glass quality for pharmaceutical packaging.[21] Given this trend and the lack of any new safety signals related to quality issues, FDA will not update the 2011 advisory at this time.

FDA will continue to monitor drug quality, evaluate and assess incidents involving quality issues, and respond with appropriate actions when information suggests a need to correct an issue with drug safety or availability. FDA will continue to evaluate its policies and related guidelines on drug containers to ensure manufacturers use containers appropriate for their specific operations, formulations, and labeled storage conditions. FDA remains committed to enabling the use of innovative products and approaches that support drug quality, and will continue to meet with companies through the ETP to support their development of novel manufacturing technologies.

[21] https://www.pda.org/global-event-calendar/event-detail/2018-pda-glass-quality-conference, see also https://pink.pharmaintelligence.informa.com/PS122458/GlassRelated-Drug-Recalls-Decline-After-Industry-Improves-Practices

QUESTIONS SUBMITTED BY CONGRESSMAN MARK POCAN

Drug Shortages

Drug shortages continue to be a problem for FDA. Some smaller companies who are interested in selling shortage drugs at pre-shortage process have approached us and suggested that FDA needs to issue guidance for the accelerated treatment of ANDAs for shortage drugs.

137. Would you as Commissioner support updating the guidance?

Response: FDA is committed to our mission to protect the public health and takes great efforts, within its legal authority, to address and prevent drug shortages.

- As reflected in FDA's Manual of Policies and Procedures (MAPP) 5240.3, Prioritization of the Review of Original ANDAs, Amendments, and Supplements, the Agency generally prioritizes the review of ANDA submissions that could help mitigate or resolve a drug shortage and prevent future shortages.
- In addition, under the Generic Drug User Fee Amendments, as amended by the FDA Reauthorization Act of 2017, ANDAs for products that are on the drug shortage list are now eligible for a shorter review goal date if the applicant submits complete, accurate facility information (i.e., pre-submission facility correspondence) at least 60 days prior to submitting the ANDA.
- FDA recently issued a draft Guidance for Industry, ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications, to aid ANDA applicants in submitting this pre-submission facility correspondence.

FDA continually re-evaluates policies and processes to make sure they are effective and efficient. FDA makes improvements as needed, and the Agency will consider whether providing further guidance or taking other appropriate actions could aid our ongoing efforts to mitigate or prevent drug shortages.

QUESTIONS SUBMITTED BY CONGRESSMAN ANDY HARRIS

Sodium

It seems that many of the people setting policy on sodium, including members appointed to the DRI Committee, are already committed to lowering sodium intake on a population-wide basis (*not just for individuals vulnerable to sodium*). For example, two members of the DRI Committee recently wrote an article in Journal of the American Medical Association advocating for reduced sodium intake – and the DRI is supposed to be an unbiased committee. Yet the science on sodium intake is not nearly as settled. The 2013 Institute of Medicine sodium committee presented a much different perspective and, very importantly, cast doubt about using blood pressure as a surrogate marker for health. The Cochran meta-analysis and other studies also indicate negative health outcomes for intake below 3,000 mg.

138. We need to carefully consider the scientific studies that show harm to otherwise healthy people at low sodium intake levels. Have you considered moving beyond use of blood pressure as a surrogate marker? Have you reviewed the Cochran meta-analysis?

Response: A consensus exists among scientific bodies, qualified experts, and governments around the world that reducing sodium intake is a viable, achievable, and effective strategy to reduce the incidence of cardiovascular disease. The most rigorous science supports FDA's actions to help gradually reduce Americans' sodium intake from 3,400 mg per day by reducing the amount of sodium added to our food supply. The National Academies has established a committee to review the scientific evidence and update, as appropriate, the dietary reference intakes (DRIs) for sodium and potassium. If any changes to the current DRI for sodium are made, FDA would adjust our targets accordingly.

FDA Guidance

There is a long list of FDA Guidance that is necessary for food providers to meet FDA regulatory deadlines. To name just a few:

139. The new labeling requirement has now been proposed for January 1, 2020. However, even at this extended deadline, Guidance is needed by July 1rst (less than three months from now) to make that work for product reformulation. What is the status of this guidance?

Response: FDA is working to finalize the guidance [Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry] as soon as possible.

140. Small packaging – Food providers still need Guidance on how to proceed on small format packaging as the new format requirements are actually larger than small packages can fit. Since this critical information was not included in the March 1 guidance, when can food manufacturers expect to see it?

Response: FDA is working to finalize the draft guidance as soon as possible.

141. The new dietary fiber definition. The March 1 final guidance did not provide regulatory clarity. When will FDA release the additional Guidance on Intrinsic and Intact fiber sources? When will FDA release decisions on the 20 fiber petitions?

Response: FDA is working to finalize the responses to the pending citizen petitions and provide regulatory clarity on the labeling of isolated and synthetic non-digestible carbohydrates as soon as possible. FDA has been in contact with those with pending petitions to address any questions they may have about the final scientific evaluation guidance [Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry].

142. Added Sugars: Final Guidance is still needed. What is the status?

Response: FDA published a draft guidance titled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry" on March 2, 2018. The draft guidance is out for public comment, and FDA recently extended the comment period by 45 days. FDA will work on finalizing the guidance as soon as possible once the comment period closes and comments have been reviewed and considered.

143. Listeria - As FDA considers new guidance on listeria and ready to eat foods, how will guidance account for economic diminishing returns and additional risk assessment data?

Response: FDA is developing *Listeria* guidance that is solidly grounded in current science and that offers flexibility to firms in implementing controls as appropriate to their products, processes, and facilities. The Agency recognizes that not all ready-to-eat (RTE) foods present the same risk to consumers, and the *Listeria* guidance is designed to reflect the best available science and contain recommendations that will adequately protect the public health and avoid recalls that are costly to industry and consumers. FDA continually monitors relevant scientific developments relating to *Listeria*, such as new science related to *Listeria* in the environment, risk assessments, and data on consumption patterns and consumer behavior (such as how consumers respond to package instructions) that are available.

FDA currently is considering comments received on the 2017 draft guidance, "Control of *Listeria monocytogenes* in Ready-to-Eat Foods," which incorporated industry best practices together with recommendations for preventive controls and current good manufacturing practices for firms that manufacture, process, pack, or hold RTE foods. The comments received from industry have provided suggested changes that are intended to result in a final guidance that will be even more flexible and practical. FDA is also taking stakeholder viewpoints into consideration as the Agency develops a draft guidance on classifying foods as RTE and not RTE.

As always, FDA guidance is non-binding and firms can take a different approach, so long as they satisfy the requirements of the applicable regulation. Moreover, FDA updates guidance as appropriate when new scientific knowledge or information is pertinent so that industry can consider all relevant information in their operations.

144. Given the short timelines for compliance – particularly when product reformulation is necessary - will FDA provide enforcement discretion for food providers acting in good faith?

Response: FDA is sensitive to the concerns that companies and trade associations have shared regarding the time needed for implementation of new requirements. In response, FDA has extended several compliance dates and considered providing additional flexibilities in meeting those requirements. These extensions allow for further consideration of opportunities to reduce regulatory burden and enhance flexibility beyond those reflected in the final rules.

For example, FDA extended the compliance date for the menu labeling requirements from May 5, 2017, to May 7, 2018 (82 FR 20825), and published a proposed rule (82 FR 45753) to extend the compliance dates for the Nutrition Facts Label and Serving Size final rules from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales. Manufacturers with less than $10 million in annual food sales would have until January 1, 2021, to comply. FDA is also working on finalizing several guidance documents related to the updated Nutrition Facts label requirements to provide further clarity to the food industry. Finalizing these guidances is one of our highest priorities.

As another example, FDA published a draft supplemental guidance on menu labeling [Menu Labeling: Supplemental Guidance for Industry] in November 2017 that reflects FDA's commitment to establishing a practical and sustainable framework for implementing the new menu labeling requirements and demonstrate FDA's plans to work cooperatively with covered establishments to come into compliance with the new requirements. FDA also plans to continue with industry education and outreach, especially in the first year, to help covered establishments achieve compliance.

Tobacco

Advertising tobacco to youth – thank you for your continued efforts to ensure tobacco products do not end up in the hands of children. I understand that in the case of rolling paper manufacturers that the CTP has issued do not sell orders to some manufacturers.

145. Will the CTP ensure compliance with these do not sell orders? If so, how and is there a compliance timeline?

Response: To legally sell a new FDA-regulated tobacco product, including rolling papers, a manufacturer must receive authorization from FDA permitting the sale of a new tobacco product through one of the following pathways: Substantial Equivalence (SE) Report, Exemption from Substantial Equivalence, or Premarket Tobacco Application. If an applicant's SE Report does not contain sufficient information to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product (or demonstrates that the new tobacco product is not substially equivalent to a predicate), FDA issues a "Not Substantially Equivalent" (NSE) order. When an NSE order is issued, a tobacco product is immediately misbranded under section 903(a)(6) and adulterated under section 902(6)(A) of the Food, Drug, and Cosmetic Act (FD&C Act). This means that, effective immediately upon issuance of an NSE order, it is a prohibited act to sell or distribute the product in interstate commerce, to import such products into the United

States, or to receive from interstate commerce and sell or offer to sell or otherwise deliver products. In addition, a tobacco product that is the subject of an NSE order is subject to seizure at any time.

Products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a SE report was submitted no later than March 22, 2011 are permitted to remain on the market pending FDA's review of such report. Because the FD&C Act permits this specific group of products to remain on the market pending FDA's review of the report, there will very likely be products at retail locations within the United States when FDA issues an order finding one of these particular tobacco products NSE.

To address those specific products, including rolling papers that are now the subject of NSE orders, during tobacco retailer compliance check inspections, FDA-commissioned inspectors check whether the retailer has products that are subject to an NSE order in its store. If the inspector observes products subject to an NSE order in the retail establishment, FDA notifies the retailer that those products are subject to an NSE order, and as such are adulterated and misbranded, and may be subject to enforcement action, including seizure. FDA, however, has stated that it does not intend to take enforcement action for at least 30 calendar days from the date an NSE order issues for those products that are in the retailer's current inventory at a specific retail location on the date FDA issues the NSE order. FDA encourages the retailers to contact their supplier or manufacturer to discuss possible options for these products that they have in current inventory. In addition, FDA performs comprehensive and directed inspections of manufacturers to identify misbranded and adulterated tobacco products that may be imported, sold, or distributed to customers in the United States and to take enforcement action, where appropriate.

146. Product approval process. FDA recently announced a change to the Provisional Substantial Equivalence (SE) process. Will FDA take a similar approach for newly deemed products under the regular SE process and prioritize products "less likely to raise different questions of public health?"

Response: FDA does not intend to take a similar approach to the recently announced change to the provisional SE process for the review of the new deemed products, though FDA will continue to pursue the principles of efficiency and effectiveness that informed that approach. Since the first decisions on SE Reports were issued in 2013, the Agency has reviewed and resolved thousands of SE Reports for new cigarette, smokeless, and roll-your-own products. Based on this review experience and the fact that FDA is not required to act on provisional SE Reports in order for the products to continue to be legally marketed, FDA decided to Remove From Review some provisional SE Reports. The same considerations do not hold true for deemed products. First, FDA has not had the years of experience with review of deemed tobacco product applications. Second, under the statute, new tobacco products must receive premarket authorization unless they were introduced into commercial distribution after February 15, 2007, but before March 22, 2011, and were the subject of an SE Report submitted no later than March 22, 2011; given that the deeming rule became effective on August 8, 2016, we do not expect that any new, deemed products could be legally marketed without premarket authorization .

147. And what does "less likely to raise different questions of public health" mean? Does it take usage patterns into account? Will FDA issue a rulemaking or guidance document clarifying this reference for substantial equivalence purposes?

Response: FDA intends to issue a proposed rule for public comment on substantial equivalence to address many factors around format, content, and review. With respect to the change to the provisional SE process, FDA assessed a host of factors to determine which new tobacco products subject to provisional SE Reports had the greatest potential to raise different questions of public health, including, for example, whether the new product had a significant increase in any harmful or potentially harmful constituent. This is in contrast to those determined to have a lower potential to raise different questions of public health. For example, many of these provisional SE Reports are for cigarettes where the only change is a switch to fire standard compliant cigarette paper when compared to the predicate product.

Shellfish

Thank you for your work to establish equivalency with the EU on molluscan shellfish. The recent announcement of an agreement between the FDA and EU to accept their respective safety systems for live and raw molluscan shellfish is an encouraging development.
However, I remain concerned that processed molluscan shellfish is not included in these equivalency proceedings.

148. Because processed shellfish, clams included, do not pose the same health risk as raw and live shellfish, why are they not being included in the ongoing talks to establish equivalency between the EU and US?

Response: The proposed EU-US molluscan shellfish equivalence determination does, in fact, include processed shellfish, including clams. Even though processed shellfish products are lower risk, the EU requires processed shellfish exported to EU to come from the same waters from which raw product is approved for export. The rationale for this is that all shellfish (raw or processed) that come from unapproved waters are considered adulterated; the FDA employs a similar regulatory policy. If the proposed equivalence determination is finalized, raw and processed shellfish harvested from approved growing areas in the states of Massachusetts and Washington can initially be exported to the EU until such time as additional U.S. states are approved for export of shellfish.

QUESTIONS SUBMITTED BY CONGRESSWOMAN ROSA DELAURO

FSMA Implementation

I want to reinforce a point the National Association of State Departments of Agriculture (NASDA) has made about the importance of providing funding to continue your implementation of the Food Safety Modernization Act (FSMA) at the state level. As you know, while FDA is charged with writing the rules, significant implementation and enforcement activities under FSMA are the primary responsibilities of state agencies. It is crucial that sufficient resources be made available to ensure farmers have the tools and education necessary to comply with these new federal requirements. NASDA has estimated that state programs will need an investment of as much as $100 million annually in new funding to ensure the systematic and timely implementation of the elements of FSMA for which states have primary responsibility. Your Agency's budget request fails to provide any new funding for continued FSMA implementation.

149. What are going to be the shortfalls that are directly caused by this lack of resources? How are you going to ensure proper training and outreach programs for small and medium sized farms ahead of the next two compliance dates?

Response: In FY18, FDA funded 43 state agencies to develop produce safety programs to help implement the FSMA Produce Safety Rule, including education, outreach, and technical assistance. Under the cooperative agreement, each state grantee is developing and implementing outreach and education programs that address the specific and unique needs of their farmers and growing community to ensure that they are educated and prepared for Produce Safety Rule implementation.

In addition to the education and outreach provided by state agencies, FDA, together with USDA, has funded the Produce Safety Alliance and the Sprout Safety Alliance to develop and disseminate standardized curricula to train domestic and foreign food businesses—including small and very small farms —on the Produce Safety Rule. In addition, FDA funded a tribal foods grantee at the University of Arkansas and a local foods grantee (National Farmers Union) to provide education and outreach to farms in their specific communities to facilitate compliance with the Produce Safety Rule. FDA and USDA have also funded four regional centers to better understand unique regional training needs of the growers/processers, and then work to address those needs.

FDA has also established a Produce Safety Network of FDA produce safety experts, located throughout the country, to work closely with key produce stakeholders, such as state produce safety programs and the regulated industry, to provide regulatory support, technical assistance and outreach in support of rule implementation.

FDA anticipates that the combined efforts of the state cooperative grantees, the Produce Safety Network, our state and educational partners will help address the training and outreach needs for small and medium sized farms prior to and after the compliance dates pass for the Produce Safety Rule.

Food Safety Recalls

In the December OIG report found that FDA did not always ensure the safety of our nation's food supply. The report found that it took food companies an average of 57 days to recall contaminated items, with some companies waiting more than four months to initiate recalls. We all agree that this is unacceptable. We must ensure that food recalls are quickly initiated and effectively monitored. Of particular concern to me is the time that elapses from when FDA first learns of a contamination problem to when a recall is initiated. FDA has only mandated a recall twice since Congress provided the Agency with the authority to do so.

150. How many times has FDA initiated a mandatory recall process before a company decided to voluntarily recall its product?

Response: FDA has initiated use of its mandatory recall authority three times since the Agency was granted mandatory recall authority by the FDA Food Safety Modernization Act of 2011. Two times, the firms voluntarily initiated recall after receiving a letter from FDA initiating the mandatory recall process. In the third instance, Triangle Pharmanaturals, LLC failed to respond to FDA's letter initiating the mandatory recall process related to the ongoing outbreak investigation of *Salmonella*-contaminated kratom products. On April 2, 2018, FDA took the next step and proceeded to issuance of a final order requiring mandatory recall.

151. With respect to the ongoing *E. coli* outbreak linked to Romaine Lettuce – why can FDA identify the geographic location of where this contaminated lettuce was grown, but not the names of implicated growers, suppliers, or distributors?

Response: FDA and CDC are working closely to conduct a traceback investigation from the *E. coli* O157:H7 illnesses linked to this outbreak. This is an ongoing outbreak investigation and romaine lettuce has been identified as the common food source, but the available packaging provides limited information on the source of the products. With limited packaging information, FDA scientists and investigators are working with federal and state partners and companies as quickly as possible to collect, review, and analyze hundreds of records to trace back the source of the contaminated romaine lettuce. To date, FDA traceback has revealed that romaine lettuce potentially contaminated with *E. coli* O157:H7 came from the Yuma, Arizona, growing region, but was supplied to restaurants and retailers through multiple processors, grower/shipper companies, and farms.

This region generally supplies romaine lettuce to the U.S. from November to March each year. One characteristic of the growing region is the use of shared equipment, which can be a route of contamination or cross-contamination. This type of characteristic adds complexity to investigations of short shelf-life products, such as lettuce.

Out of an abundance of caution, FDA warned the public early based on preliminary data FDA has from the supply chain. FDA is committed to completing our investigation swiftly and ensuring the Agency provides clear messages and advice to consumers to protect public health.

152. When is FDA going to release the names of the implicated growers, suppliers and distributors involved in this outbreak?

Response: As the investigation and supporting records allow FDA to confidently identify specific processors, grower/shipper companies, and farms, FDA will make that information publicly available as allowed by applicable laws and regulations.

Arsenic in Rice

Yesterday, the GAO released a report on FDA's actions to manage the risk of arsenic in rice. The GAO report shows a lack of urgency in addressing this threat, and, among other things, recommends the Agency update its 2016 risk assessment. Previously, FDA found that inorganic arsenic has been detected in infant rice cereal and brown rice syrup that is being used in an increasing number of products including toddler formula and snack bars. FDA's inaction on this issue leads me to believe it does not take this threat seriously.

153. Why has FDA not committed to updating the 2016 risk assessment of arsenic in rice, and furthermore, how does FDA plan to address exposure to arsenic early in life that may be putting our children at an unacceptably high risk?

Response: FDA partially concurred with GAO's recommendation to develop a timeline for updating the risk assessment on arsenic in rice, noting that an update to the 2016 Arsenic in Rice and Rice Products Risk Assessment Report[22] would be dependent on any new and evolving science that would impact our conclusions in the assessment. FDA continually monitors the scientific literature and collaborates with partners, such as the Environmental Protection Agency (EPA). FDA will certainly initiate an update to the assessment should new science become available which could change the conclusions of the existing risk assessment.

FDA continues to analyze products intended both for infants and young children. In February 2018, FDA issued an assignment for collection of white and brown rice infant cereals for determination of total and inorganic arsenic. The FDA will speciate samples above 100 ppb total arsenic to determine the inorganic arsenic level and appropriate follow up actions. FDA will also speciate samples below the proposed 100 ppb action level to get additional data on inorganic arsenic concentrations in infant rice cereals. The agency also monitors toxic elements, including arsenic, in selected domestic and imported foods under the Toxic Elements Program, including those that children are likely to eat or drink, such as juices, rice-based toddler foods, puffed rice cereals, and rice-based beverages.

Our work to reduce consumer exposure to arsenic from rice is part of a broader initiative underway to reduce the risks posed by arsenic and other toxic metals in food. As part of the initiative, FDA recently created a Toxic Elements Working Group that has been charged with identifying, targeting and prioritizing our efforts to achieve the public health goal of reducing exposure to toxic elements to the greatest extent possible. The initial focus of the Toxic Elements Working Group is on metals like lead, arsenic, cadmium, and mercury in foods,

[22] https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM486543.pdf

cosmetics, and dietary supplements that can be especially harmful to children because of concerns about the effects on neurological development.

QUESTIONS SUBMITTED BY CONGRESSMAN KEVIN YODER

Sales Estimates

Under Section 105 of the Animal Drug User Fee Amendments of 2008, Congress requires animal drug sponsors to report the amount of antimicrobial drug products sold for use in food-producing animals. Sales data is problematic because it does not reflect actual drug use, but it is often misinterpreted as correlating to public health risk. ADUFA reporting should promote public understanding in a meaningful and accurate way.

154. Rather than benchmarking arbitrary reduction goals based on enhanced sales data, has FDA considered any alternative methods to better identify and reduce inappropriate antimicrobial drug uses?

Response: The FDA has acknowledged that there are certain inherent limitations on how sales information may be appropriately interpreted and used. FDA has also stated that assumptions about actual product use should not be made based solely on sales information. But it is also important to note that even methods for attempting to characterize drug use may also have their own limitations in representing actual use practices at a national level. The FDA has not benchmarked any reduction goals with respect to the sales of antimicrobial drugs sold for use in food-producing animals.

In addition to receiving sales information, FDA is collecting data characterizing drug use in cattle, swine, chickens, and turkeys through two cooperative agreements. FDA is also collaborating with the U.S. Department of Agriculture's plans to collect drug use information through National Animal Health Monitoring System (NAHMS) surveys and through on-farm data collected on antimicrobial use and resistance. Such data are intended to supplement existing information, including data on the quantity of antimicrobials sold or distributed for use in food-producing animals and data on antimicrobial use and resistance, collected under the NAHMS and National Antimicrobial Resistance Monitoring System programs. FDA believes that data from multiple sources are needed to provide a comprehensive and science-based approach to assessing antimicrobial drug use and resistance in animal agriculture and that judicious use practices should be followed that support the continued availability of safe and effective antimicrobials for use in treating animals and humans. Each source provides unique, species-specific data, none of which can fully provide that picture on its own.

Species-specification Estimates

FDA recently expanded ADUFA reporting to require animal drug sponsors to provide species-specific drug sales estimates for the major food-producing species (cattle, swine, chickens, and turkeys). This new estimated species-specific data was submitted by sponsors in April 2017, along with other required sales and distribution data, and incorporated into an enhanced summary report on antimicrobials sold or distributed for use in food-producing animals that published in December 2017.

155. Given that species-specification estimates do not constitute sound scientific data, do you believe including this additional information has improved FDA's understanding about antimicrobial use in major food-producing animals?

Response: The FDA has acknowledged that there are certain inherent limitations on how sales information may be appropriately interpreted and used. FDA has also stated that assumptions about actual product use should not be made based solely on sales information.

The collection of species-specific sales and distribution estimates, in addition to other information about antimicrobial use in food-producing animals and drug resistance, is necessary to enable a better understanding of our actions to reduce the rate of development of antimicrobial resistance. In addition to receiving sales information, FDA is collecting data characterizing drug use in cattle, swine, chickens, and turkeys through two cooperative agreements. FDA is also collaborating with the U.S. Department of Agriculture's plans to collect drug use information through National Animal Health Monitoring System (NAHMS) surveys and through on-farm data collected on antimicrobial use and resistance. Such data are intended to supplement existing information, including data on the quantity of antimicrobials sold or distributed for use in food-producing animals and data on antimicrobial use and resistance, collected under the NAHMS and National Antimicrobial Resistance Monitoring System programs. FDA believes that data from multiple sources are needed to provide a comprehensive and science-based approach to assessing antimicrobial drug use and resistance in animal agriculture and that judicious use practices should be followed that support the continued availability of safe and effective antimicrobials for use in treating animals and humans. Each source provides unique, species-specific data, none of which can fully provide that picture on its own.

156. Are you concerned that it has contributed to consumer confusion and negative perception regarding agricultural animal production without providing a public health benefit?

Response: The FDA does not consider the enhanced summary report to have contributed to consumer confusion or the negative perception of agricultural animal production. While we are aware of some news reports by several consumer interest groups immediately after publication of the December 2017 summary report, we are unaware of any subsequent news that indicated confusion with the published estimated species-specific sales.

An article published by the National Pork Producers Council at the same time used the December 2017 summary report to support positive perceptions of the swine industry. More specifically, the article noted that the summary report had validated the "hard work" U.S. pig farmers had put in to reduce the overall need for antibiotics while still protecting the health and welfare of the pigs under their care. The article noted that despite the shortcomings of the species-specific estimates, the FDA report nonetheless clearly showed that the overall use of antibiotics in livestock was at its lowest since 2009. The article concluded that those figures suggested that today's pig farmers are using far fewer total antibiotics per pound of pork produced. A recent news report from the American Veterinary Medical Association similarly cited the enhanced summary report as evidence of the reduced use of antimicrobials in the swine industry.

157. Is FDA considering any additional actions or efforts to ensure judicious use of medically important antimicrobials?

Response: FDA is developing additional actions to ensure judicious use of medically important antimicrobials. Last January, FDA published its key initiatives for the next five years, which include the following: (1) Align antimicrobial drug products with the principles of antimicrobial stewardship in veterinary settings; (2) Support efforts to foster stewardship of antimicrobials in veterinary settings; (3) Assess the impact of strategies intended to curb the emergence of antimicrobial resistance associated with the use of antimicrobial drugs in veterinary settings. FDA is working to incorporate these key initiatives into a more detailed multi-year plan to further build on progress to date and ensure judicious use of antimicrobial drugs in veterinary settings.

FDA continues to work with federal, academic, and industry partners to obtain more information about how, when, and why animal producers and veterinarians use medically important antimicrobial drugs.

Data Confidentiality

In 2017, FDA funded for the second year cooperative agreements for projects to characterize the use of animal drugs in food-producing animals. The FY 19 budget justification states that "Both projects have made significant progress in their first year and may be funded for up to five years, if progress continues and funding is available. Once the data is collected, analyzed, and aggregated, FDA will have an opportunity to further refine platforms designed for long-term antimicrobial use data collection, benchmarking and analysis of trends in antimicrobial use over time."

158. How have these projects enhanced FDA's understanding of antimicrobial use in animal agriculture?

Response: The cooperative agreement projects are collecting on-farm antimicrobial use data for segments of the U.S. broiler chicken, turkey, swine, and cattle industries. This is the FDA's first coordinated attempt at collecting this type of data, which is designed to ultimately be representative of national antimicrobial use estimates in these industries.

The investigators for both cooperative agreements have noted important challenges, including the large range of farm recordkeeping and record storage procedures and differences in granularity of available records. For this reason, the first two years of the cooperative agreements have been focused on establishing viable methods to handle the disparity of different recordkeeping methods across the industries.

The key to the success of these projects is the ability of the investigators to establish credibility with participants and develop trust that data confidentiality will be protected. Developing trust is vital to gain participation and longer-term support for data collection from producers, animal industry groups, and veterinarians. FDA expects the first report from both cooperative agreement awardees with a summary and evaluation of aggregated data by fall 2018.

159. Is any on-farm data collected? If so, what is FDA's role in terms of data confidentiality? Does FDA have adequate resources to protect the confidentiality of voluntary participants?

Response: Yes, investigators have collected some on-farm data, and FDA expects reports with a summary and evaluation of aggregated data submitted to the FDA by fall 2018. The FDA's Funding Opportunity Announcement for the cooperative agreements specified as one of its goals that the awardees would "collect data in a manner that protects disclosure of farm and production unit identifying information or other confidential business information." FDA evaluated the applications on these merits and reviewed the applicants' plans for ensuring anonymity and confidentiality of participants. Awardees sign confidentiality agreements with participants who supply data. Depending on the commodity, the producers or companies retain ownership of the data. Data are initially collected at the on-farm level and contain identifiable information for input into the investigators' privately owned computers, which are not accessible via Internet connections.

The awardees have an agreement with the U.S. Department of Agriculture's Center for Epidemiology and Animal Health (CEAH), in which CEAH analysts will evaluate the de-identified aggregate data sets and provide advice on methods for handling outliers and other potential issues with data accuracy and validity. The awardees will submit to FDA the aggregate data with a summary analysis. FDA will not receive identifying data or confidential business information for producers, farms, or production companies that provided the data to the awardees as part of the cooperative agreement projects.

The awardees have also agreed to terms and conditions set forth by FDA, including the requirement that FDA's Center for Veterinary Medicine will approve of the substance of any publications, oral presentations, or data release to parties other than FDA. FDA resources to protect the confidentiality of voluntary participants are thus inherent in the continued funding of the cooperative agreements.

Ionophores

The 2015 ADUFA Summary Report stated that "… FDA has identified certain antimicrobial active ingredients as "medically important" based on their utility for treating disease in humans. Certain other antimicrobial drugs are not considered medically important. Ionophores, for example, lack utility in human medicine and their use in animals does not pose cross resistance concerns; thus, they do not have the same public health risks as medically important antimicrobials."

160. Given that the mode of action for ionophores is extremely different from that of antibiotics and that the use of ionophores on-farm does not pose any risk to humans, why does the FDA still include ionophores in a report focused on antimicrobial resistance?

Response: FD&C Act section 512(1)(3), as added by Section 105 of the Animal Drug User Fee Amendments of 2008 ("ADUFA Section 105") requires that drug sponsors annually submit to FDA sales and distribution information for approved antimicrobial drugs intended for use in

food-producing animals. In addition, FDA is required to annually publish a report that summarizes the sales and distribution information collected from drug sponsors.

Ionophores are considered antimicrobial drugs. This drug class lacks utility in human medicine, and ionophores do not have the same public health risks as medically important antimicrobials. As antimicrobials, however, ionophores are included in the summary report. The report explains the relevance of including ionophores and other antimicrobial drug classes when they are not considered to be medically important.

Dairy Nutrition & Food Standards

In January 2018, the Government Accountability Office (GAO) reported in its "FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities" report that of FDA's $1 billion plus budget for food safety and nutrition, only about 2% of funds go toward nutrition and food standards activities. We all support food safety and agree that it should be prioritized, but small amount of dollars going toward nutrition certainly explains why lots of food companies wait a long time for federal food standards to be updated. Just take the yogurt standard of identity which has been in proposed rule status since 2009.

161. Of the approximately 4,200 full time employees at FDA who spend their time on food safety and nutrition, how many of these employees are actually dedicated to nutrition and food standard activities?"

Response: Food standards activities are included as part of FDA's broader nutrition portfolio. In FY 2016, FDA dedicated 127 employees to nutrition activities, including work on food standards. A smaller subset of these employees is dedicated to working on food standards. FDA appreciates the Committee's concern about the amount of time required to update federal food standards. FDA prioritizes updates to food standards based on relative public health outcomes and within its limited nutrition resources. FDA is committed to modernizing food standards in light of marketing trends and the latest nutrition science, as noted in FDA's Nutrition Innovation Strategy.

Opioid Data

When considering the benefits of surveillance and data collection to combat the opioid crisis, two different types of data sets are usually discussed; "traditional" (morbidity and mortality data, CDC longitudinal studies, CMS insurance claims data, nation-wide electronic systems such as National Survey on Drug Use and Health, etc.) and "non-traditional" (first responder reporting, information from public school systems, USPS shipments identified with illegal opioids, etc.).

Collecting, storing, and analyzing data is important to understanding the breadth of the crisis, identifying vulnerable populations, and forming evidence-based public health decisions. Non-traditional data of vulnerable populations could supplement longitudinal studies of the larger population to assess benefit and risk of emerging therapies.

There is a lot of data that FDA needs to develop to better inform policies. For example, you've mentioned FDA has a role to play with monitoring drug shipments through the mail.

162. Is USPS information available to the FDA already? If not, would the FDA benefit from being able to collect and analyze opioid data from these more non-traditional sources?

Response: USPS receives advanced electronic data (AED) from postal services in some countries, and U.S. Customs and Border Protection receives this information for initial screening of packages. While AED can be very useful for targeting parcels for examination, this information by itself ordinarily does not identify opioids in a reliable way. FDA agrees that the Agency would benefit from obtaining and analyzing additional opioid data and is working with its partners to advance this objective.

Added Sugar

FDA's current enforcement discretion requires that "added sugar" be put on the label for pure honey. The National Honey Board has found that more than 80% of consumers understand "added sugars" to mean an additional sweetener has been added to processed foods.
One of FDA's core missions is protecting consumers from fraud, and honey has long attracted unscrupulous actors that adulterate or falsely market honey. The definition in the Nutrition Facts Label rule calling pure, natural honey - "added sugar" makes it hard for consumers to distinguish the real from the phony. The National Honey Board found that more than one in four consumers report the proposed "added sugar" label would make them less likely to buy honey. They also found that consumers are about one-third less likely to believe that honey with the "added sugars" label is pure or natural.

163. Has FDA done a consumer survey to assess the impact of the added sugar definition on honey?

Response: In response to concerns from the honey industry, FDA published draft guidance on added sugars labeling that states the Agency's intent to allow manufacturers of specific products such as honey to use a symbol immediately after the added sugars Daily Value, directing consumers to language that provides truthful and not misleading contextual information about "added sugars" and what it means for each of these specific products. The draft guidance is open for comment.

FDA believes that education is an important step in helping consumers understand how to use the new label and make healthy dietary choices. The added sugars declaration on the updated Nutrition Facts label is new information that consumers have not seen. FDA plans to engage in educational and outreach activities for consumers and health professionals, in collaboration with other federal partners, about the use of information on the Nutrition Facts and Supplement Facts labels. Part of that education will include information about added sugars. A key message related to added sugars will be that consumers should consider all the information on the label when constructing a healthful dietary pattern and not focus on one specific nutrient, such as added sugars. The message related to consumption of added sugars is not to eliminate added sugars or foods high in added sugars from the diet; instead, the message is to limit overall

consumption of added sugars in the diet to less than 10 percent of total calorie intake, as recommended by the recent Dietary Guidelines for Americans.

164. Would you consider extending FDA's enforcement discretion to not require that added sugar be put on the label for pure honey?

Response: FDA published a draft guidance titled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry" on March 2, 2018. The guidance states our intent to allow manufacturers of specific products to use a symbol immediately after the added sugars Daily Value, directing consumers to language that provides truthful and not misleading contextual information about "added sugars" and what it means for each of these specific products.

The draft guidance is out for public comment and FDA recently extended the comment period by 45 days, to close on June 15, 2018. Although the comment period is still open, FDA has received comments asking the Agency to consider alternative approaches to what was proposed in the draft guidance to address added sugars labeling for these products. FDA will look at all proposed options once the comment period closes and consider the feedback received in determining how best to go forward with finalizing the guidance.

Glass Contamination

Since December 2017, there have been four glass recalls, two for particle contamination and two for cracks that could compromise sterility. In each recall notice, FDA noted the potential for serious adverse effects on patients including blood clots and sepsis that are life-threatening.

165. What options are under consideration at FDA to address the glass issues affecting the quality and safety of injectable drugs?

Response: FDA is aware that quality issues with container closure systems, including glass vials, may occur during manufacturing. The potential for problems such as breakage, cracking, and formation of glass lamellae (glass fragments) to occur has been known for some time, and the Agency has taken steps to provide information to manufacturers to help them reduce the incidence of quality issues with their container closure systems. FDA has a long-standing guidance for industry on *Container Closure Systems for Packaging Human Drugs and Biologics,*[23] which addresses qualification of and quality controls for packaging components, including factors such as sterility assurance.

In addition to the container closure system guidance, FDA has also cautioned manufacturers when there have been new trends in quality issues that posed public health risks. In 2011, FDA issued an advisory to drug manufacturers regarding the potential formation of glass lamellae in injectable drugs filled in small-volume glass vials. The advisory noted that the Agency was drawing attention to the issue due to several drug recalls in 2010 and 2011. The advisory also noted that there were no known adverse events reported or directly attributed to the problem;

[23] www.fda.gov/downloads/drugs/guidances/ucm070551.pdf

however, glass lamellae in injectable drug products pose potential risks, particularly when drugs are administered intravenously or subcutaneously.

The advisory noted that a number of conditions have been associated with a higher incidence of formation of glass lamellae in drug products including, among other factors, glass vials manufactured by the tubing process at higher heat, drug solutions formulated at high pH, the duration of time the drug product is in contact with the glass container, and terminal sterilization processes. The advisory also provided recommendations to help prevent the formation of glass lamellae, along with literature references for the recommendations. These recommendations were also issued in a Question and Answer guidance for industry.[24] Drug manufacturers can continue to follow these recommendations to reduce the likelihood of formation of glass lamellae.

Glass manufacturers have been working on developing new glass designs for use in pharmaceutical containers with a goal of addressing quality issues such as the formation of glass lamellae. Companies have approached FDA's Emerging Technology Program (ETP)[25] with requests to discuss their glass designs. The ETP promotes the adoption of innovative approaches to pharmaceutical product design and manufacturing through early engagement, and the ETP provides feedback on proposed technologies to facilitate anticipated regulatory submissions. Early engagement gives FDA reviewers a better understanding of a new technology when it comes in for review or is referenced in a submission. ETP's role is discuss, identify, and resolve potential concerns regarding the development and implementation of a novel technology. Each technology still must be evaluated in the context of the regulatory submission that it is associated with.

At the request of the ETP, the Office of Pharmaceutical Quality's laboratory has developed methodology and conducted studies to evaluate the performance characteristics of glass containers for injectable drug products. These laboratory studies will help inform future quality assessments and provide insight for feedback that can be provided to companies as they work on developing their products.

While conducting laboratory studies, the ETP also consulted with colleagues within the Agency to evaluate surveillance data to determine whether there were any new or emerging safety signals related to quality issues associated with glass containers used in pharmaceutical products on the market. FDA analyzed surveillance data from FY 2008 through FY 2017. A new safety signal or change in frequency of reports of a known safety concern could reflect the emergence of an issue that would warrant a new or updated advisory by the Agency to inform manufacturers. However, FDA's analysis of available data did not identify any new or increasing safety signals since the advisory was issued in 2011. At a recent glass quality conference with presentations by FDA and industry experts, participants noted progress has been made in improving glass quality

[24] www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm#11
[25] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM478821.pdf

for pharmaceutical packaging.[26] Given this trend and the lack of any new safety signals related to quality issues, FDA will not update the 2011 advisory at this time.

FDA will continue to monitor drug quality, evaluate and assess incidents involving quality issues, and respond with appropriate actions when information suggests a need to correct an issue with drug safety or availability. FDA will continue to evaluate our policies and related guidelines on drug containers to ensure manufacturers use containers appropriate for their specific operations, formulations, and labeled storage conditions. FDA remains committed to enabling the use of innovative products and approaches that support drug quality, and will continue to meet with companies through the ETP to support their development of novel manufacturing technologies.

166. When will FDA complete its studies and inform the industry on how it intends to address the glass issues?

Response: FDA is aware that quality issues with container closure systems, including glass vials, may occur during manufacturing. The potential for problems such as breakage, cracking, and formation of glass lamellae (glass fragments) to occur has been known for some time, and the Agency has taken steps to provide information to manufacturers to help them reduce the incidence of quality issues with their container closure systems. FDA has a long-standing guidance for industry on *Container Closure Systems for Packaging Human Drugs and Biologics,*[27] which addresses qualification of and quality controls for packaging components, including factors such as sterility assurance.

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[26] www.pda.org/global-event-calendar/event-detail/2018-pda-glass-quality-conference, see also pink.pharmaintelligence.informa.com/PS122458/GlassRelated-Drug-Recalls-Decline-After-Industry-Improves-Practices

[27] www.fda.gov/downloads/drugs/guidances/ucm070551.pdf

[28] www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm#11

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FDA will continue to monitor drug quality, evaluate and assess incidents involving quality issues, and respond with appropriate actions when information suggests a need to correct an issue with drug safety or availability. FDA will continue to evaluate our policies and related guidelines on drug containers to ensure manufacturers use containers appropriate for their specific operations, formulations, and labeled storage conditions. FDA remains committed to enabling the use of innovative products and approaches that support drug quality, and will continue to meet with companies through the ETP to support their development of novel manufacturing technologies.

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[29] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM478821.pdf

[30] www.pda.org/global-event-calendar/event-detail/2018-pda-glass-quality-conference, see also pink.pharmaintelligence.informa.com/PS122458/GlassRelated-Drug-Recalls-Decline-After-Industry-Improves-Practices

QUESTIONS SUBMITTED BY CONGRESSMAN THOMAS ROONEY

FDA Tobacco Deeming Rule

The premium, hand-made cigar industry has a rich history in my state of Florida which dates back to the 18th century. Florida is home to hundreds of family owned retail stores and dozens of manufacturers who proudly serve tens of thousands of adult customers. This small industry is suffering tremendously at the hands of FDA's deeming rule. User fees alone will drain millions of dollars from Florida businesses this year and compliance costs are even higher

167. Regarding the regulation of cigars. There are different shapes and sizes of cigars, thousands of SKUs each year. Does FDA agree that it cannot use a "one size fits all" approach to product regulation, but rather must proceed on a category-by-category basis?

Response: In the preamble to the proposed deeming rule, FDA sought comment on two options regarding the categories of cigars that would be covered by this rule—specifically, whether all cigars should be subject to deeming or if only those cigars not considered "premium" should be subject to deeming. FDA sought those comments because it had been suggested that different kinds of cigars may have the potential for varying effects on public health.

FDA carefully reviewed all comments, data, and information submitted to the docket, including many comments from cigar users and the cigar industry, and concluded in the deeming final rule that regulating all cigars, rather than a subset, more completely protects the public health. Ultimately, FDA concluded that all cigars pose serious negative health risks and "premium" cigars are used by youth and young adults.

However, there continues to be interest in the regulatory status of "premium" cigars. As part of FDA's comprehensive plan for nicotine and tobacco regulation, on March 23, 2018, the Agency announced an Advanced Notice of Proposed Rulemaking (ANPRM) to provide interested parties an opportunity to submit new or different information or data related to the definition of "premium cigar" and the patterns of use of and resulting public health impacts from "premium" cigars. FDA will explore any new and different questions raised, and carefully consider any additional data submitted that could inform FDA's regulation of "premium" cigars.

168. Do newly deemed products that have the same physical characteristics (i.e., same type of tobacco, no ingredients besides water and adhesive) and are the same size/weight raise different issues of public health that require full scientific review including product testing?

Response: In order to be found substantially equivalent, the Food, Drug, and Cosmetic Act requires applicants to demonstrate that the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. The extent of information and data needed to demonstrate that the new tobacco product does not raise different questions of public health is dependent on the specific differences in characteristics between the new and predicate tobacco products. For example, an applicant would likely need to provide more information where there are significant differences

between the new and predicate tobacco products, as opposed to where there are only a few small differences and less information may be required.

Opioid Crisis

Florida has been hit particularly hard by the opioid crisis. The opioid crisis affects everyone, from those taking pills knowingly, to those unwittingly becoming addicted, to those family members suffering alongside the patients and addicts. Evidence-based data can inform public health decision-making to lessen the burden of opioid abuse and misuse rampant in our communities. There are a number of federal programs spread across all the agencies that collect and analyze data related the opioid epidemic.

169. Aside from a need for more data collection and analysis, are there other tools the FDA can use, such as other health information technologies, to better respond to and combat the nation's opioid crisis? For example, are there early detection models available that can help identify vulnerable sub-populations?

Response: FDA has implemented multiple initiatives responding to the opioids crisis. These include better measures to treat opioid use disorder and prevent deaths from overdose, actions to ensure providers who write prescriptions for opioids are doing so for properly indicated patients and under appropriate clinical circumstances, and efforts to facilitate the development of new therapeutics that will effectively and safely help patients suffering from pain. Going forward, FDA needs to remain vigilant to shifting trends in the addiction landscape and has in place systems to systematically monitor and address these trends.

FDA is committed to employing a multi-component system of pharmacovigilance so that FDA can respond proactively and effectively, in anticipation of changes in drug abuse in the United States, drawing on standard epidemiologic and basic science expertise as well as social sciences. In addition, FDA has recently developed a computational approach to provide rapid assessment of new "designer" drugs that lack pharmacological and toxicological data. In particular, the approach was developed for new fentanyl derivatives that have been cut into heroin. This methodology is comprised of four components that:

1) quantify a compound's structural similarity with all previously scheduled drugs,
2) identify probable biological targets,
3) predict binding affinity at the identified biological targets using a 3D structural representation, and
4) integrate experimental and predicted data to generate an overall conclusion.

Additionally, FDA has initiated a project to develop models that will predict blood-brain barrier permeability and various efflux transporter (i.e., P-gp, BCRP) interactions. This data will aid in determining if the newly emerging street drugs can cross the blood-brain barrier and have a potential for abuse and a risk to public safety.

QUESTIONS SUBMITTED BY CONGRESSMAN DAVID VALADAO

Definition of Natural

Dr. Gottlieb, after receiving thousands of public comments, I was pleased to hear the FDA continues to work towards defining the term "natural" and regulating its use on food labeling. This is an extremely important and complicated issue, and as such, it's important the FDA provide certainty and uniformity for consumers, food producers, and the courts about the definition of the term on a national level.

170. Can you please provide an update of the FDA's ongoing work on this important pre-rulemaking initiative?

Response: On November 12, 2015, FDA issued a notice requesting comments on the use of the term "natural" in the labeling of human food products (80 FR 69905). In light of the strong public interest in the topic and in response to requests from the public, FDA extended the period for public comment to May 10, 2016 (80 FR 80718, December 28, 2015). FDA has received and reviewed more than 7,600 comments submitted. FDA recognizes that consumers are trusting in products labeled as "natural" despite some lack of clarity around the use of that term. FDA will have more to say on this issue soon.

FDA Opioid Data Warehouse

171. You have stated that combatting opioid addiction is your number one priority. How does the FDA collect and share opioid data and other health information?

Response: Ascertaining the extent of prescription drug abuse presents unique challenges because the data sources and methods typically used to study drug safety may not provide relevant information. Currently available data resources generally capture one aspect of interest (abuse, clinical, or mortality data) without the ability to link to other relevant datasets and outcomes that come to medical attention generally cannot be attributed to a specific product. While it is unlikely that a single data source would be sufficient to address all opioid-related issues, the most useful data systems (or linked data sources) for such studies would feature characteristics, including:

• Identification of product-specific information, including brands, formulations, and routes of abuse.

• The ability to rapidly respond to changes in the opioid market, and to expand to evaluate potential product formulations with abuse-deterrent properties that are not opioids.

• The ability to generate national and regional estimates for abuse of specific products that can be reliably trended over time and in different sub-populations (e.g., geographic regions, demographic groups, severity of substance use disorders).

Prescription Drug Monitoring Programs (PDMPs) continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. A PDMP is an electronic database that tracks controlled substance prescriptions in a state. As a public health tool, PDMPs can be used by state health departments to understand the behavior of the epidemic and inform and evaluate interventions.

172. Would the creation of a modern, scalable, and national platform at the FDA, that incorporates analysis of complex and high-volume data, be a meaningful step forward in addressing the opioid crisis?

Response: Currently, 49 states (as well as DC and Guam) already operate statewide Prescription Drug Monitoring Programs (PDMPs), but each state has its own PDMP regulations and policies. In this sense, a "modern, scalable, and national platform" can be created by linking information from all operating state PDMPs.

Another approach the Opioid Policy Steering Committee is considering a nationally interoperable PDMP network – an approach that FDA believes could be more effective in helping health care providers identify patients who could be misusing or abusing prescription opioids and provide real-time alerts about potentially harmful drug-drug combinations.

Overall, FDA fully supports the idea of a national platform, that incorporates analysis of complex and high-volume data, as a meaningful step forward in addressing the opioid crisis.

Antimicrobial Drug Products Sales Estimates

Under Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA), Congress requires animal drug sponsors to report the amount of antimicrobial drug products sold for use in food-producing animals. However, this sales data is problematic because it does not reflect actual drug use, but is often misinterpreted as correlating to public health risk. ADUFA reporting should promote public understanding in a meaningful and accurate way.

173. Rather than benchmarking arbitrary reduction goals based on enhanced sales data, has the FDA considered any alternative methods to better identify and reduce inappropriate antimicrobial drug uses?

Response: The FDA has acknowledged that there are certain inherent limitations on how sales information may be appropriately interpreted and used. FDA has also stated that assumptions about actual product use should not be made based solely on sales information. But it is also important to note that even methods for attempting to characterize drug use may also have their own limitations in representing actual use practices at a national level. The FDA has not benchmarked any reduction goals with respect to the sales of antimicrobial drugs sold for use in food-producing animals.

In addition to receiving sales information, FDA is collecting data characterizing drug use in cattle, swine, chickens, and turkeys through two cooperative agreements. FDA is also collaborating with the U.S. Department of Agriculture's plans to collect drug use information

through National Animal Health Monitoring System (NAHMS) surveys and through on-farm data collected on antimicrobial use and resistance. Such data are intended to supplement existing information, including data on the quantity of antimicrobials sold or distributed for use in food-producing animals and data on antimicrobial use and resistance, collected under the NAHMS and National Antimicrobial Resistance Monitoring System programs. FDA believes that data from multiple sources are needed to provide a comprehensive and science-based approach to understanding antimicrobial drug use and resistance in animal agriculture and that judicious use practices should be followed to support the continued availability of safe and effective antimicrobials for use in treating animals and humans. Each source provides unique, species-specific data, none of which can fully provide that picture on its own.

The FDA recently expanded ADUFA reporting to require animal drug sponsors to provide species-specific drug sales estimates for major food-producing species, which includes cattle, swine, chickens, and turkeys. This new estimated species-specific data was submitted by sponsors in April 2017 and incorporated into an enhanced summary report on antimicrobials sold or distributed for use in food-producing animals that was published in December 2017.

174. Given that species-specification estimates do not constitute sound scientific data; do you believe including this additional information has improved the FDA's understanding on antimicrobial use in food-producing animals?

Response: The collection of species-specific sales and distribution estimates, in addition to other information about antimicrobial use in food-producing animals and drug resistance, is necessary to enable a better understanding of the impact of our actions to reduce the rate of development of antimicrobial resistance. In addition to receiving sales information, FDA is collecting data characterizing drug use in cattle, swine, chickens, and turkeys through two cooperative agreements. FDA is also collaborating with the U.S. Department of Agriculture's plans to collect drug use information through National Animal Health Monitoring System (NAHMS) surveys and through on-farm data collected on antimicrobial use and resistance. Such data are intended to supplement existing information, including data on the quantity of antimicrobials sold or distributed for use in food-producing animals and data on antimicrobial use and resistance, collected under the NAHMS and National Antimicrobial Resistance Monitoring System programs. FDA believes that data from multiple sources are needed to provide a comprehensive and science-based approach to understanding antimicrobial drug use and resistance in animal agriculture and that judicious use practices should be followed to support the continued availability of safe and effective antimicrobials for use in treating animals and humans. Each source provides unique, species-specific data, none of which can fully provide that picture on its own.

175. Are you concerned the inclusion of this data has contributed to consumer confusion and negative perception regarding agricultural animal production while providing no meaningful public health benefit?

Response: The FDA does not consider the enhanced summary report to have contributed to consumer confusion or the negative perception of agricultural animal production. While FDA is aware of some news reports by several consumer interest groups immediately after publication of

the December 2017 summary report, FDA is unaware of any subsequent news indicated confusion with the published estimated species-specific sales.

An article published by the National Pork Producers Council at the same time used the December 2017 summary report to support positive perceptions of the swine industry. More specifically, the article noted that the summary report had validated the "hard work" U.S. pig farmers had put in to reduce the overall need for antibiotics while still protecting the health and welfare of the pigs under their care. The article noted that despite the shortcomings of the species-specific estimates, the FDA report nonetheless clearly showed that the overall use of antibiotics in livestock was at its lowest since 2009. The article concluded that those figures suggested that today's pig farmers are using far fewer total antibiotics per pound of pork produced. A recent news report from the American Veterinary Medical Association similarly cited the enhanced summary report as evidence of the reduced use of antimicrobials in the swine industry.

176. Is the FDA considering any additional actions to ensure judicious use of medically important antimicrobials?

Response: FDA is developing additional actions to ensure judicious use of medically important antimicrobials. Last January, FDA published its key initiatives for the next five years, which include the following: (1) Align antimicrobial drug products with the principles of antimicrobial stewardship in veterinary settings; (2) Support efforts to foster stewardship of antimicrobials in veterinary settings; (3) Assess the impact of strategies intended to curb the emergence of antimicrobial resistance associated with the use of antimicrobial drugs in veterinary settings. FDA is working to incorporate these key initiatives into a more detailed multi-year plan to further build on progress to date and ensure judicious use of antimicrobial drugs in veterinary settings.

FDA continues to work with federal, academic, and industry partners to obtain more information about how, when, and why animal producers and veterinarians use medically important antimicrobial drugs.

Bacterial Contamination of Blood Platelets

The fiscal year 2013 Agriculture Appropriations bill included report language raising concern about bacterial contamination of blood platelets. In particular, patients who suffer from leukemia and lymphoma undergo multiple platelet transfusions during the course of treatment. According to the National Institutes of Health, anywhere between 2,000—to 4,000 patients receive bacterially contaminated platelets each year, resulting is as many as 500 deaths. This is troubling – especially because the current standards for testing platelets fails to catch anywhere between 53 and 89 percent of contaminated doses. (FDA Draft Guidance, March 2016). My understanding is that in 2016 draft guidance, the FDA recommended additional testing to more accurately detect bacterial contamination. However, the agency has indicated that it may now publish guidance recommending a lower standard.

177. Can you explain why a lower standard, with poorer detection rates, would be in the best interest of patients?

Response: FDA agrees that a lower standard would not be in the best interest of patients, and has not indicated that it intends to publish guidance recommending a lower standard. FDA has approved or cleared several devices used to help control bacterial contamination of platelets, including devices used to test for bacterial contamination and a pathogen reduction device. However, no currently available strategy will completely assure that platelets are free from bacteria. FDA has recommended several different strategies that blood collection establishments and transfusion services can use to help assure the safety of platelets by reducing the risk of bacterial contamination.

We have received numerous comments from stakeholders on the strategies proposed in the draft guidance and discussed by the Blood Products Advisory Committee, also known as BPAC, at its November 2017 meeting. In light of these comments, FDA intends to seek advice from the BPAC on July 18, 2018, on all available strategies to control the risk of bacterial contamination of platelets including bacterial testing strategies using culture-based devices, rapid bacterial detection devices, and the implementation of pathogen reduction technology. FDA plans to present all available strategies for reducing the risk of bacterial contamination to BPAC, and request that the Committee consider the totality of the available data, including any newly available data since the last meeting. Following the meeting, FDA intends to issue a revised draft guidance in 2018.

178. What is the scientific basis for adopting a lower standard?

Response: FDA has not indicated that it intends to publish guidance adopting a lower standard. FDA intends to seek advice from BPAC on all available strategies to control the risk of bacterial contamination of platelets before issuing a new draft guidance. FDA intends to ask BPAC to discuss the advantages and disadvantages of each strategy, including the scientific evidence supporting the strategy. Our revised draft guidance will take into account this information and the discussion and recommendations of the BPAC.

179. Will you commit, prior to issuing any further draft or final guidance, to hear from all stakeholders and consider all of the evidence on what testing methodologies are in the best interest of patient safety?

Response: FDA is committed to providing an opportunity for all stakeholders to be heard prior to issuance of a revised draft guidance, and prior to finalizing the guidance. FDA intends to invite the manufacturers of devices used to control bacterial risk and other interested parties to present all available data to the BPAC on July 18, 2018. Other interested members of the public will have the opportunity to speak during the open public hearing portion of the meeting. FDA intends for the BPAC to consider all available strategies to control the risk of bacterial contamination of platelets to protect patient safety. After the July BPAC meeting, FDA plans to publish a revised draft guidance on strategies for controlling bacterial contamination of platelets. Before that draft guidance is finalized, there will be an opportunity for public comment.

Wine Grapes Exemption from Produce Rule

Dr. Gottlieb, I would like to thank you for meeting with the wine industry last week to discuss provisions included in the recently passed Omnibus related to an exemption for wine grapes from the final Produce Safety Rule. I just wanted to follow up with you on this and the path forward at the FDA and the timeline.

180. Have you notified the California Department of Food and Agriculture about the exemption?

Response: Yes, the California Department of Food and Agriculture (Natalie Krout-Greenberg, Director, Division of Inspection Services and Steven Patton, Chief, Inspection and Compliance Branch) was notified via teleconference April 9, 2018, that as per Sec. 773 of the FY 2018 Omnibus, "*None of the funds made available by this or any other Act may be used to enforce the final rule promulgated by the Food and Drug Administration entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," and published on November 27, 2015, with respect to the regulation of the production, distribution, sale, or receipt of grape varietals that are grown, harvested and used solely for wine and receive commercial processing that adequately reduces the presence of microorganisms of public health significance.*"

181. Do you intend to add wine grapes to the list of produce rarely consumed raw to provide further clarity to the industry?

Response: FDA is aware of the concerns expressed by the wine grape industry and has been working to address those concerns. The rarely consumed raw list is one exemption from the Produce Safety Rule, and the commercial processing exemption is another available exemption from the vast majority of requirements in the rule. The only requirements of the Produce Safety Rule that commodities receiving commercial processing to adequately reduce microorganisms of public health significance—such as winegrapes—would be required to follow are certain recordkeeping requirements, i.e., disclosures, written assurances, and related documentation requirements. At this time, per Sec. 773 of the FY 2018 Omnibus, FDA will not use funds to enforce the produce safety rule with respect to the regulation of the production, distribution, sale, or receipt of grape varietals used solely for wine.

In addition, FDA has indicated the intent to exercise enforcement discretion for the written assurances provision of the Produce Safety Rule while considering options, including rulemaking, to address concerns heard from multiple stakeholders about the written assurance provisions of the FSMA rules.

FDA is continuing to review the recordkeeping burden associated with the commercial processing exemption for commodities such as winegrapes and hops, and is working on a solution to address concerns about these burdens. More specifically, FDA is exploring options to allow for exemption from records requirement as part of the commercial processing exemption for certain commodities. FDA would likely need to engage in rulemaking to expand the

exemption. It is the FDA's goal that the provisions of the Produce Safety Rule be workable for industry while protecting public health.

Data Confidentiality

In 2017, FDA funded for the second year cooperative agreements for projects to characterize the use of animal drugs in food-producing animals. The FY 19 budget justification states that "Both projects have made significant progress in their first year and may be funded for up to five years, if progress continues and funding is available. Once the data is collected, analyzed, and aggregated, FDA will have an opportunity to further refine platforms designed for long-term antimicrobial use data collection, benchmarking and analysis of trends in antimicrobial use over time."

182. How have these projects enhanced FDA's understanding of antimicrobial use in animal agriculture?

Response: The cooperative agreement projects are collecting on-farm antimicrobial use data for segments of the U.S. broiler chicken, turkey, swine, and cattle industries. This is the FDA's first coordinated attempt at collecting this type of data, which is designed to ultimately be representative of national antimicrobial use estimates in these industries.

The investigators for both cooperative agreements have noted important challenges, including the large range of farm recordkeeping and record storage procedures and differences in granularity of available records. For this reason, the first two years of the cooperative agreements have been focused on establishing viable methods to handle the disparity of different recordkeeping methods across the industries.

The key to the success of these projects is the ability of the investigators to establish credibility with participants and develop trust that data confidentiality will be protected. Developing trust is vital to gain participation and longer-term support for data collection from producers, animal industry groups, and veterinarians. FDA expects the first report from both cooperative agreement awardees with a summary and evaluation of aggregated data by fall 2018.

183. Is any on-farm data collected? If so, what is FDA's role in terms of data confidentiality?

Response: Yes, investigators have collected some on-farm data, and FDA expects reports with a summary and evaluation of aggregated data submitted to the FDA by fall 2018. The FDA's Funding Opportunity Announcement for the cooperative agreements specified as one of its goals that the awardees would "collect data in a manner that protects disclosure of farm and production unit identifying information or other confidential business information." Awardees sign confidentiality agreements with participants who supply data. Depending on the commodity, the producers or companies retain ownership of the data. Data are initially collected at the on-farm level and contain identifiable information for input into the investigators' privately owned computers, which are not accessible via Internet connections.

The awardees have an agreement with the U.S. Department of Agriculture's Center for Epidemiology and Animal Health (CEAH), in which CEAH analysts will evaluate the de-identified aggregate data sets and provide advice on methods for handling outliers and other potential issues with data accuracy and validity. The awardees will submit to FDA the aggregate data with a summary analysis. FDA will not receive identifying data or confidential business information for producers, farms, or production companies that provided the data to the awardees as part of the cooperative agreement projects.

184. Does FDA have adequate resources to protect the confidentiality of voluntary participants?

Response: FDA's Funding Opportunity Announcement (FOA) for the cooperative agreements specified as one of its goals that the awardees would "collect data in a manner that protects disclosure of farm and production unit identifying information or other confidential business information." FDA evaluated the applications received for the FOA on these merits and reviewed the applicants' plans for ensuring anonymity and confidentiality of participants.

The two cooperative agreement awardees have data collection systems in place that protect the confidentiality of voluntary participants and have signed confidentiality agreements with participants. The awardees will submit to FDA de-identified aggregate antimicrobial use data with a summary analysis. FDA will not receive identifying data or confidential business information for producers, farms, or production companies that provided the data to the awardees as part of the cooperative agreement projects.

The awardees have also agreed to terms and conditions set forth by FDA, including the requirement that FDA's Center for Veterinary Medicine will approve the substance of any publications, oral presentations, or data release to parties other than FDA. FDA resources to protect the confidentiality of voluntary participants are thus inherent in the continued funding of the cooperative agreements.

Ionophores

The 2015 ADUFA Summary Report stated that "… FDA has identified certain antimicrobial active ingredients as "medically important" based on their utility for treating disease in humans. Certain other antimicrobial drugs are not considered medically important. Ionophores, for example, lack utility in human medicine and their use in animals does not pose cross resistance concerns; thus, they do not have the same public health risks as medically important antimicrobials."

185. Given that the mode of action for ionophores is extremely different from that of antibiotics and that the use of ionophores on-farm does not pose any risk to humans, why does the FDA still include ionophores in a report focused on antimicrobial resistance?

Response: Section 512(1)(3) of the FD&C Act, as added by section 105 of the Animal Drug User Fee Amendments of 2008 ("ADUFA Section 105") requires that drug sponsors annually submit to FDA sales and distribution information for approved antimicrobial drugs intended for

use in food-producing animals. In addition, ADUFA Section 105 requires FDA to annually publish a report that summarizes the sales and distribution information collected from drug sponsors.

Ionophores are considered antimicrobial drugs. This drug class lacks utility in human medicine, and ionophores do not have the same public health risks as medically important antimicrobials. As antimicrobials, however, ionophores are included in the summary report. The report explains the relevance of including ionophores and other antimicrobial drug classes when they are not considered to be medically important.

FSMA Training

I appreciate the work of the agency on behalf of our farmers as we near full implementation of the Food Safety Modernization Act's Produce Safety Rule next January.

One thing I have heard from my farm constituents is that there is still a lot of confusion on how to comply with the rule. I do want to make something clear: the confusion is not based on their lack of knowledge of food safety. Farmers in this day and age must follow strict food safety standards for their buyers and for the international market – standards that have been in place for many years. These standards were market driven and not handed down by an agency. Yet the confusion that exists is stemming from the mandatory trainings they have had to participate in over the last year.

It seems that the training is more about how to comply with regulations than it is about food safety. Certain practices they learn about don't harmonize well with the realities on the ground. What's more, the training has come at a significant cost to growers who must give up an entire day and anything from $300 to $600 and in some cases, more, to be trained by someone who isn't a farmer about how to comply with a rule rather than how to make your food more safe. In looking back at the underlying statute, there is a requirement that the regulations "shall not require a business to hire a consultant or other party to…implement…compliance with these procedures, processes, and practices…" (21 USC 350H(c))

I would ask that the agency look at the statute, take a closer look at the training, and determine whether farmers should be paying for this training. Since the training is causing a lot of confusion, I believe it's worth the extra attention to this issue.

QUESTIONS SUBMITTED BY CONGRESSWOMAN CHELLIE PINGREE

Glyphosate Testing

Glyphosate is an herbicide that has been used by farmers to control weeds. Its health impacts are frequently debated, so I was glad to see FDA begin testing food products for glyphosate residues back in 2016. FDA announced it had to suspend glyphosate testing temporarily in late 2016. According to the agency's website, FDA tested four commodities in FY17—soybeans, corn, milk, and eggs—and expanded testing to other foods in FY18.

186. Please provide an update on FDA's glyphosate testing. Which foods are tested currently? Have results revealed any residue violations? And has FDA published results of the glyphosate testing publicly in its Pesticide Residue Monitoring Report?

Response: In FY2016, the FDA issued a special assignment for testing for the herbicide glyphosate in soybeans, corn, milk, and eggs. Preliminary results for samples collected in FY2016 showed no pesticide residue violations for glyphosate in all four commodities tested. The annual pesticide monitoring report for FY2016 is expected to issue in 2018 and will include final FY2016 data. Results from samples collected in FY2017 will be included when the agency releases the FY2017 pesticide report, which is expected to issue in 2019.

In FY 2018, FDA expanded testing of glyphosate and certain acid herbicides to a wide range of raw agricultural commodities, including 16 types of fruits, 29 types of vegetables, and 6 types of grains. FDA is analyzing samples and reviewing results and expects to publish these results in the annual pesticide residue monitoring report.

Food Safety Modernization Act Training

Food Safety Modernization Act (FSMA) compliance dates will be setting in over the next couple of years. FDA's FY19 proposed budget does not include a substantial increase for the agency's food safety work, despite it being in the midst of FSMA implementation. The Produce Safety Alliance, which is a collaboration between FDA, USDA and Cornell, is one way that the agency is making sure training and outreach needs are met.

187. Does FDA have the resources to ensure FSMA training needs are met?

Response: FDA is committed to ensuring that outreach and training on the Produce Safety Rule are available to assist state regulators and farmers. FDA, in collaboration with USDA, evaluates training needs and capacity on an ongoing basis. As of March 2018, more than 20,000 growers have participated in Produce Safety Alliance training in the U.S. and internationally.

FDA continues to explore various opportunities and mechanisms for leveraging resources to help ensure that needs are being met with available resources. In the current budget cycle, FDA has secured nearly $500,000 for the Produce Safety Alliance and will provide additional funding if resources allow.

188. Specifically, when will funding run out for the Produce Safety Alliance?

Response: FDA and USDA remain committed to the Produce Safety Alliance (PSA), and are assessing needs and options for a transition from being federally funded to becoming more self-sustaining. FDA recognizes this will be a gradual process, and PSA funding levels will need to be higher in the near-term. FDA is providing sufficient funding for PSA for FY 18. FDA will continue making PSA funding decisions on an annual basis, leveraging resources to ensure that needs are being met with available resources.

"Added Sugar" Category on Nutrition Facts Label

FDA released guidance in February 2018 indicating that honey and maple syrup, which are single ingredient products, must list their sugars under "added sugar." The guidance also indicated manufacturers can put a symbol next to the "added sugar" category and in a separate box on the label explain that these are naturally occurring sugars. There is concern that it's misleading for a jar of 100% pure honey or maple syrup to label its sugars under the "added sugar" category when nothing has been added to those products.

189. Please explain why the decision was made to require maple syrup and honey to list their sugar content under "added sugar."

Response: In FDA's Nutrition Facts label final rule (81 FR 33742), the definition of added sugar includes sugars that are either added during the processing of foods or are packaged as such (e.g., a jar of honey, a container of maple syrup, or a bag of table sugar). This is consistent with the 2015-2020 Dietary Guidelines for Americans (Dietary Guidelines), which states added sugars include syrups and other caloric sweeteners. The Dietary Guidelines include honey, maple syrup, and table sugar in the "empty calories" or "calories for other uses" category in the USDA Food Pattern. Products such as honey, maple syrup, and table sugar add calories to the diet without contributing essential nutrients whether they are added to other foods or consumed in isolation. Natural sources of sugar present in foods, such as whole fruits, 100 percent juice, and dried fruits, are not considered added sugars because these foods are nutrient rich. Including added sugars and the percent Daily Value on the Nutrition Facts label provides consumers with the information they need to maintain healthy dietary patterns consistent with the Dietary Guidelines.

Food Date Labeling

Studies show that one of the most cost-effective ways to reduce food waste is to standardize food date labels, which currently are not regulated by the federal government, with the exception of infant formula. Because the uniform compliance date for other labeling rules is 2020, it would be ideal to align date label standardization efforts to reduce the burden on industry.

190. Will FDA consider providing, at the very least, guidance to food manufacturers on food date labeling?

Response: FDA is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled. No federal law or regulation requires date labels, such as expiration dates and use by dates, on food products, except for infant formula. Any date labels that are used, however, must be truthful and not misleading.

FDA is aware of ongoing efforts by government agencies, industry groups, non-governmental organizations, academia, and others to promote standardized date label phrases and to educate consumers about the meaning of quality-based dates. FDA has engaged in these discussions and continues to enhance its consumer messages related to the meaning of voluntary date labels. As these efforts continue, FDA will consider what guidance might be appropriate for food manufacturers on food date labeling.

Injectable Opioids

Providers across my state have expressed worry about the ongoing shortages of injectable opioids like morphine and fentanyl. Though I recognize the importance of proper use of these powerful drugs, I have concerns about access for providers of end-of-life care, cancer care, and other situations where pain management is of significant concern. I was glad to see that the DEA raised production quotas for these injectable opioids and recognize their role in addressing this shortage.

191. Could give us an update on FDA's role in tracking these shortages, and how you're working with manufacturers, DEA, and others to address the issue) ?

Response: FDA is doing everything within its authority to help alleviate these shortages and increase supplies in the marketplace, including actively working with stakeholders, manufacturers, and other U.S. federal agencies, including DEA, on this issue.

FDA is in constant communication with the manufacturers regarding this shortage. While at this time, one manufacturer experienced reduced production and expects delays will continue until 2019, FDA has been encouraging that manufacturer to make proposals that will help meet patient needs. FDA also is working with other firms that manufacture FDA-approved injectable analgesics to increase production.

As you know, DEA is responsible for setting aggregate limits on the amount of each controlled substance that may be manufactured and for allocating to each manufacturer a specific percentage of the aggregate limit (a quota). This tight control over controlled-substance products requires FDA and DEA to coordinate in cases of a shortage of a controlled substance. To help streamline and improve communications, FDA and DEA developed a memorandum of understanding (MOU).[31] The MOU sets forth steps and procedures, including identifying contacts, for efficiently tracking and exchanging relevant information.

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31 www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm440091.htm

As part of the process to address a shortage of a controlled substance, manufacturing firms may request an increased quota from DEA to assist with the shortage. FDA encourages these firms that want to increase production to assist with a shortage to let us know when they are requesting additional quota from DEA.

FDA continues to work with manufacturers to tailor its response to the specific situation. FDA frequently communicates available information about a potential shortage or existing shortage to affected stakeholders and monitors the shortage until it has been resolved. FDA maintains a public website to provide more information on drug shortages.[32] FDA also maintains a database on current and resolved drug shortages, which is updated daily.[33]

[32] www.fda.gov/drugs/drugsafety/drugshortages/default.htm
[33] www.accessdata.fda.gov/scripts/drugshortages/default.cfm

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