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EVALUATING THE PAPERWORK REDUCTION ACT PART II: ARE BURDENS BEING REDUCED?

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

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EVALUATING THE PAPERWORK REDUCTION ACT PART II: ARE BURDENS BEING REDUCED?

WEDNESDAY, OCTOBER 11, 2017

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 11:00 a.m., in Room 2360, Rayburn House Office Building, Hon. Steve Chabot [chairman of the Committee] presiding.

Present: Representatives Chabot, Brat, Radewagen, Kelly, Blum, Bacon, Marshall, Norman, Velázquez, Evans, Clarke, and Schneider.

Chairman CHABOT. When we get a few more members of Congress, we will get started.

Good morning. I imagine we will have some more members shortly. The important ones are here. And we appreciate everyone for being here.

This past March, the Committee on Small Business held a hearing on the Paperwork Reduction Act, or PRA, to examine how Federal paperwork requirements continue to be a burden for small businesses. Even though the PRA is supposed to reduce paperwork burdens, small businesses are still faced with an overwhelming amount of paperwork requirements each day. In fact, paperwork requirements are costing America almost $120 billion a year.

But as we heard at our hearing last March, this number is probably much higher because Federal agencies may not be accurately estimating the burden. Yes, agencies need data and information to run their programs, but as with all things in life, it must be in moderation.

The need for this information must be balanced against the burden imposed to comply with these collection efforts, especially the burden imposed on small businesses, our Nation's job creators.

As our hearing in March demonstrated, Federal paperwork requirements come in many different forms, no pun intended. For example, laws such as the Clean Air Act, the National Environmental Policy Act, and the Endangered Species Act require small businesses to prepare lengthy permitting applications; some applications can be thousands of pages long. Small businesses are also subject to many different recordkeeping and reporting requirements for numerous Federal agencies, including the Occupational Safety and Health Administration, the Internal Revenue Service, the Environmental Protection Agency, and others.

Not only do small businesses have to keep piles of paperwork and records for many years, they also have to figure out which agency needs the information and how often. Many times small businesses have to send the same information to different agencies. This is a lot of paperwork.

Small businesses should be focusing their efforts on developing, innovating, and building, on creating jobs and growing our economy. Instead, small businesses too often are devoting precious hours and dollars every month to filling out forms, applications, and reports. Meanwhile, agencies issue more and more paperwork requirements.

Today, this Committee is pivoting to hear the Federal agency perspective. Specifically, we have four agency officials who are responsible for ensuring that their agencies comply with the Paperwork Reduction Act, or PRA. Under the PRA the agency's chief information officer, or CIO, is responsible for ensuring that the agency complies with the Act.

The CIO must determine whether collecting certain information is necessary, how the agency plans to use the information, and estimate what the burden will be on those who provide the information. Only after the CIO reviews the collection requests and certifies that it meets certain requirements can the agency propose the collection request to the public. In other words, the CIO and his or her team have an important role in helping to reduce the paperwork burden on this country's small businesses.

I want to thank all our witnesses for being here today. We look forward to hearing your testimony about how your agency complies with the PRA, and ways your agency reduces the paperwork burden on small businesses.

And I would now like to yield to Ranking Member Ms. Velázquez for her opening statement.

Ms. VELÁZQUEZ. Thank you, Mr. Chairman. In 2015, the public spent an estimated 9.78 billion hours responding to federal information collections. While some of this information was required as disclosures, others were for eligibility in programs or applying for loans.

Whatever the reason, for businesses, preparing these documents require staff, time, and money. This is felt most acutely by small businesses who frequently lack the legal support and resources their larger competitors have to assist with compliance.

The Paperwork Reduction Act, or PRA, was created in 1990 and amended in 1995, with the intent of reducing the growth of paperwork. The results have been mixed, at best. One question I hope today's hearing can answer is whether the current law provides agencies with the appropriate tools to address the escalation of paperwork, or if changes must be made, for the PRA to improve its effectiveness.

Additionally, it will be of great value to hear how agencies strive to keep small businesses' needs in mind when crafting regulations. As they say, the devil is in the details. When it comes to complying with many federal reporting requirements, small adjustments can make a difference in reducing the burden on small firms.

While agencies face a difficult task, small businesses deserve to know exactly why their paperwork burden continues to grow. How-

ever, we must also remember that data collection exists for a reason. Agencies rely on data to make informed decisions achieving important policy outcomes.

These goals include ensuring worker safety, preserving clean air and water, and safeguarding taxpayer dollars against fraud. Yet the PRA should not serve to discourage agencies from conducting proper regulatory flexibility analysis. All too often, with the agencies implementing regulations that ignore or understate economic impacts on small businesses, ensuring that agencies are considering the economic impact of their regulations and paperwork requirements on small firms is critical.

Congress needs to know what steps are needed to help agencies achieve this goal, whether it is embracing technology, working to synchronize and coordinate at all levels of government, or improving communication, it is an important discussion we must have.

I look forward to the insights this panel will provide on those topics. And once again, thank the witnesses for being here today. And I yield back, Mr. Chairman. Thank you.

Chairman CHABOT. Thank you very much. The gentlelady yields. And if members have opening statements I would ask that they be submitted for the record.

And now I would like to take just a moment to explain our rules and lighting system here. We operate under the 5-minute rule. You each get 5 minutes to speak, and there is a light system to help you. The green light will be on for 4 minutes, the yellow light will come on and be on for about a minute to let you know that it is about time to wrap up, and then the red light will come on, and you are supposed to stop.

Most people do, but we will give you a little leeway there, not a whole lot, but a little bit. And we operate, ourselves, under the 5-minute rule, so we will restrict our time to that as well, to be fair.

And I would now like to introduce our very distinguished panel here today. Our first witness is Dr. Steven Fine. Dr. Fine is the Acting Assistant Administrator of the Environmental Protection Agency's Office of Environmental Information and Acting Chief Information Officer. Dr. Fine joined the EPA in 2016, and before that he served at the National Oceanic and Atmospheric Administration in different positions since 2003, including a Deputy Assistant Administrator for Laboratories and Cooperative Institutes, and Director of the Air Resources Laboratory. We welcome you, Dr. Fine, and look forward to your testimony.

Our second witness will be Stephen Guertin. Mr. Guertin is the Deputy Director for Policy at the United States Fish and Wildlife Service. He has been serving as the Deputy Director since 2012. Prior to that Mr. Guertin served as the regional director for the agency's mountain-prairie region from 2007 to '12. He also spent 9 years working at the Department of Interior prior to joining the Fish and Wildlife Service. Mr. Guertin served for 8 years in the United States Marine Corps. And we thank you very much for your service, and welcome you here today.

Our third witness will be Mr. Gundeep Ahluwalia. I have been practicing that since yesterday.

Mr. AHLUWALIA. You did it.

Chairman CHABOT. Thank you very much. And he has been serving as the Chief Information Officer for the U.S. Department of Labor since October 2016, and joined DOL as the Deputy CIO in August of 2016. Prior to the DOL, Mr. Ahluwalia served for 4 years as the Deputy Director of the Office of Business Informatics at the U.S. Food and Drug Administration. We welcome you here today, and look forward to your testimony.

And our final witness is Mr. Todd Simpson; Simpson's a fine name, too. Mr. Simpson has been serving as the Chief Information Officer at the U.S. Food and Drug Administration since 2015. He has also served as the Associate CIO for the Senior Executive Service at the Department of Transportation, and the CIO at the Department of Justice. Mr. Simpson also served for 6 years in the U.S. Air Force. We thank you for your service to our country as well, and we welcome your testimony today.

And Dr. Fine, you are recognized for 5 minutes.

STATEMENTS OF STEVEN FINE, PH.D., ACTING ASSISTANT ADMINISTRATOR, ACTING CHIEF INFORMATION OFFICER, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; STEPHEN D. GUERTIN, DEPUTY DIRECTOR FOR POLICY, UNITED STATES FISH AND WILDLIFE SERVICE; GUNDEEP AHLUWALIA, CHIEF INFORMATION OFFICER,UNITED STATES DEPARTMENT OF LABOR; TODD SIMPSON; CHIEF INFORMATION OFFICER, UNITED STATES FOOD AND DRUG ADMINISTRATION

STATEMENT OF STEVEN FINE

Dr. FINE. Good morning, Chairman Chabot and Ranking Member Velázquez. As you said, I am Steve Fine, the acting CIO for EPA. And thank you for the opportunity to discuss EPA's implementation of the Paperwork Reduction Act.

Congress has charged the EPA with enforcing several statutes to protect human health in the environment. In order to ensure the requirements of these statutes are met, the EPA must collect information from the public. EPA has just over 400 OMB-approved collections with a total overall burden of approximately 174 million hours.

This is approximately 1.5 percent a total Federal Government burden. EPA collections range from over 21 million hours for the National Pollutant Discharge Elimination System Program, and less than 10 hours for the Mobile Air-Conditioner Retrofitting Program.

The Agency is cognizant of the impact these collections have on small businesses and other entities, and works to find ways to reduce that burden while satisfying the responsibilities assigned by statutes. The PRA mandates that Federal agencies follow a necessarily robust process to ensure that they are only collecting information that is needed, and are doing so in the least burdensome way possible.

Under the PRA, the Agency must obtain approval from OMB before using identical questions to collect information from 10 or more persons, even if responding to the request is voluntary for the recipient. To gather information in such circumstances, the EPA

must prepare an information collection request, which describes the information to be collected, gives the reason the information is needed, and estimates the time and cost to the public to answer the request.

Examples of information collections include surveys, permit applications, questionnaires, and compliance reports. At the EPA, subject matter experts in program offices develop ICRs. Each program office follows the process established by EPA's PRA office. ICRs are subject to a 6- to 10-month internal Agency review and approval process. The Agency's PRA office conducts an independent review of each ICR, and each ICR is also shared with the public twice for comment via Federal Register notices.

In addition, the Agency consults with a sample of affected entities. Agency ICR preparers and reviewers consider factors such as whether the collection is required to achieve the stated environmental objective, whether there is a practical utility to the information being collected, whether the proposed collection method is appropriate and efficient, whether less frequent collection of the information would be sufficient, whether the calculation of the estimated burden is accurate, and whether the information is collected elsewhere.

Public comments inform Agency reviews, and after Agency reviews ICRs are sent to OMB for further review. The EPA is sensitive to the burden it places on regulated entities, and uses multiple approaches to reduce unnecessary reporting and recordkeeping burdens on the public.

For example, both the program office and the PRA office independently consider whether each part of a proposed information collection has practical utility, is limited in scope to only that necessary for the intended purpose, and imposes the least burden.

Also, where feasible, the Agency obtains information from other sources instead of the public. For example, instead of requesting some information from coastal States, the EPA obtains that information for the National Oceanic and Atmospheric Administration, which collects information for its own needs.

Additionally, the EPA is increasing using information technologies to reduce burden by streamlining the information collection process. For instance, this year the EPA enhanced a Toxics Release Inventory, which is used by thousands of facilities to describe the toxic chemical inventories, and documents significant events, such as releases.

The enhancements of the system included new features, such as automated data quality checks and simplified password resetting process. These enhancements are expected to reduce the average reporting time by 13 percent for each of the approximately 80,000 forms submitted annually.

Another example is the new software systems that are anticipated to reduce reporting burdens related to public water systems by 23 percent. Further, the Agency is in the process of developing a strategic plan covering fiscal years 2018 to 2022. The draft plan, shared with the public for comment, includes the strategic measure for reduction of reporting burden on the regulated community.

This would be roughly one of two dozen measures that would be tracked at the highest levels of the Agency. EPA remains com-

mitted to working with small businesses and other regulated entities to find ways to collect the information we need to protect human health and the environment in the least burdensome way possible.

Again, thank you for this opportunity to testify. I would be happy to answer any questions you have.

Chairman CHABOT. Thank you very much. Mr. Guertin, you are recognized for 5 minutes.

STATEMENT OF STEPHEN D. GUERTIN

Mr. GUERTIN. Thank you, Mr. Chairman, Ranking Member Velázquez, and Members of the Committee. I am Steve Guertin, deputy director for the United States Fish and Wildlife Service. Thank you for the opportunity to testify this afternoon.

The collection of information from the public is essential to provide good government to the public across all sectors of society, but information collection is a burden for the public. Therefore, the PRA is an important tool that ensures Federal agencies are able to collect the information needed while making sure that they are not arbitrary in how they do it.

The PRA helps make sure we collect only the information we need to effectively carry out our mandates while minimizing burden on the public. The mission of the U.S. Fish and Wildlife Service is working with others to conserve, protect, and enhance fish, wildlife, and plants, and their habitats for the continuing benefit of the American people. Simply put, our job is to maintain America's wildlife heritage.

In carrying out this mission we collect information related to a wide variety of areas, including hunting and fishing itself, oil and gas exploration and development, import and export of fish and wildlife products, and Federal subsistence.

This information is an important component of our analysis, decisions, and plans. A good example to illustrate this is the management of hunting for migratory birds. The Service conserves bird species protected by the Migratory Bird Treaty Act through the administration and establishment of frameworks for annual hunting seasons and bag limits for these migratory bird game species.

In doing so, we rely on the collection of harvest information from migratory bird hunters, which enables us to develop sound, science-based hunting guidelines. These harvest surveys allow the Service to gather information on hunting participation, success rates, and target species. We use this and other types of information to inform our regulatory decisions so that regulations result in sustainable hunting guidelines that also ensure maximum hunting opportunity for the public each year.

This year, for example, we expanded the harvest of black ducks based on information from hunting studies and the harvest survey program. This model for migratory bird hunting has been a great success. Populations of migratory birds that were declining and in danger of elimination a century ago, are now thriving, driven by coordinated Federal and State management informed by data collected from the public.

I would also like to really emphasize the importance of hunting, fishing, and outdoor recreation at large. These activities are part

of the cultural fabric of America. They are also important economic drivers that support jobs and small businesses across the Nation. Our hunting regulations for migratory birds and other species are a boon to local economies in small towns up and down the major migratory flyways and other key wildlife corridors.

To put it in perspective, in 2016, hunters, anglers, and wildlife watchers spent more than 156 billion in their pursuits, nearly 1 percent of the total gross national product. A lot of this is delivered by America's small businesses. For example, guides, outfitters, marinas, tackle shops, the people who support those in the hotel and hospitality industry, and transportation industries.

The administration recognizes this economic contribution, and has placed priority on expanding access to public lands and fish and wildlife resources. Last month Secretary Zinke signed a new Secretarial Order to increase opportunities for outdoor recreation and enhanced-conservation stewardship. On the PRA, we are exploring the most effective and least burdensome way to collect information from our constituent groups that will allow us to deliver our mission.

We recognize, though, that even with the PRA, information collection can be a burden on the public, so we strive to limit the information and paperwork requirements we place on the public, balancing our data and information needs with the associated burden. One way we accomplish this is by making a number of resources available electronically through our web page.

Hunters in certain States can now go online to purchase the required Federal waterfowl hunting permit known as the Duck Stamp. These electronic Duck Stamps are available for immediate use, saving hunters time that can be better spent in a duck blind. The Service will continue to balance our information evaluation needs with the burdens we place on the public through implementation of the PRA, and other efforts.

We look forward to working with the Committee to find ways to continue to collect essential information to support our mission while minimizing associated burden on the public. And we are happy to answer any questions that you or the members may have. Thank you.

Chairman CHABOT. Thank you very much. Mr. Ahluwalia, you are recognized for 5 minutes.

STATEMENT OF GUNDEEP AHLUWALIA

Mr. AHLUWALIA. Good morning, Chairman Chabot, Ranking Member Velázquez, and Members of the Committee. I am Gundeep Ahluwalia, Chief Information Officer of the Department of Labor. Thank you for inviting me here today to discuss DOL's efforts to reduce paperwork burden through compliance with the Paperwork Reduction Act.

As the Department's CIO, I provide strategic leadership for the Department's IT programs, staffing and services. The Department is committed to reducing the paperwork burdens on Americans, the Paperwork Reduction Act being an important tool for DOL and all Federal agencies.

In carrying out the DOL's broad and varied mission the Department administers more than 180 Federal laws. DOL programs

cover workplace protections, economic security and benefits, workforce development, and labor-related statistical programs, and all of these entail information collection as outlined in my written statement.

Some requirements help the Department to hold those who do not comply with worker protection standards accountable. Others provide for employees and employers to share information to facilitate compliance reducing the need for our intervention. Other information collections allow the Department to provide important economic statistics that enable decision-makers at all levels of the government and in the private sector to make informed decisions.

In administering these 180 laws the Department actively seeks to minimize the paperwork burden it imposes on the American public, while maintaining its mission and fulfilling its statutory and programmatic responsibilities. DOL currently maintains an inventory of 467 active information collections, with a combined burden of 168 million hours. The Office of Chief Information Officer submits about 300 information collection requests (ICRs) a year for OMB's consideration.

I am pleased to report that DOL's paperwork time burden has remained virtually flat over the last 12 years, the last time our CIO testified in front of a congressional committee on this topic. As a mission-critical responsibility DOL has established well-defined policies and procedures for implementing and managing PRA and the lifecycle of each information collection.

Effectively managing the lifecycle allows the Department to control the amount of burden it imposes. We employ five key strategies to reduce the burden on the American public and businesses: review all rulemaking actions, assessing the use of technology, the routine review of information collection activities, burden reduction initiatives, and public consultation.

The Department also has a very strong program of compliance assistance. We maintained a National Contact Center that may be reached at 1-866-4-USA-DOL or through our website. The Department's Employment Law Guide describes the major statutes and regulations that affect businesses and employees, and the Department's Employment Law Systems for Workers and Small Businesses, our E-Laws Program, includes interactive eTools to assist with navigating and interpreting the law.

Online systems for information submission provide ease for all Americans, including small business owners. Our Benefits.gov Program, an interagency e-Gov initiative that includes 17 cabinet-level agencies, offers a gateway to about 1,200 assistance programs across the Federal and State governments.

Through the Benefits.gov platform, DisasterAssistance.gov recently received more than 30 million sessions, during which 3 million hurricane survivors completed online applications for much-needed assistance. DOL has been supporting FEMA through record levels of online traffic to assist with recovery efforts in the recent hurricanes that have impacted the U.S.

As a former small business owner myself, I appreciate this opportunity to discuss DOL's effort to provide relief and fair treatment to all business owners, particularly small ones and individuals. The

Department is committed to reducing unnecessary burdens on all U.S. employers and the American public.

Thank you. I will be happy to respond to any questions.

Chairman CHABOT. Thank you very much. Mr. Simpson, you are recognized for 5 minutes.

STATEMENT OF TODD SIMPSON

Mr. SIMPSON. Thank you, Mr. Chairman, Ranking Member Velázquez, and Members of the Committee. My name is Todd Simpson. I am the chief information officer for the U.S. Food and Drug Administration, part of the Department of Health and Human Services. Thank you for inviting me here today to testify about the Paperwork Reduction Act,

FDA has extensive experience dealing with small businesses.

For instance, approximately 95 percent of U.S. medical device manufacturing establishments have fewer than 500 employees. We balance the need to collect the information necessary to carry out our mission with the desire to minimize the burden on the businesses that feed the Nation and develop lifesaving medical products.

To assist businesses in filing paperwork that is timely and accurate, we employ seminars, workshops, educational conferences, information materials, and contact via email and a toll-free telephone number. We also offer access to regional small business advisors and administrative and scientific support.

FDA is making major investments in technical infrastructure to improve the customer experience. We have revamped our website to make it more user-friendly. It now presents the public with information broken down by product. It contains a section aimed at small businesses and includes an improved search engine.

I would be happy to walk you through some of the ways FDA seeks approval to collect information for use by the agency. For collections of information in any form or format, including those contained in regulations, guidance documents, forms, surveys and studies, focus groups, customer satisfaction surveys, and message testing, FDA must first receive OMB approval.

FDA also seeks OMB approval for extensions of currently approved collections of information. For instance, when FDA conducts notice-and-comment rulemaking to issue a new regulation, the comment period for the information collection provisions is normally 30 days. Comments are sent to OMB and FDA transmits the information collection request, or ICR, to HHS, which reviews and certifies the proposed collection. HHS then sends the ICR to OMB, which files comments on the proposed rule and approves any collection of information at the final rule stage.

For ongoing collections of information such as those in regulations, FDA must go through PRA notice and comment procedures and request an extension of OMB approval every 3 years. For example, the regulation that covers the information collection associated with the pre-market approval requirements for new drugs has been approved every 3 years since the initial approval in 1977.

FDA also uses forms as an efficient way to collect standardized information. For example, FDA has forms that healthcare professionals, patients, and consumers use to submit adverse event re-

ports. The data from these reports help FDA assess and evaluate the risk associated with the product. These forms allow FDA to consider what action may be necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

FDA has several generic clearances in place for conducting focus groups, customer satisfaction surveys, rapid response surveys, and user and message testing. Generic clearances can be used when an agency seeks to conduct a series of collections of information using very similar methods, and generally cover collections of information that are voluntary, low burden, and uncontroversial,

The plan for the series of information collection goes through the normal public notice and comment procedures required by the PRA, but the agency is not required to seek further public comment on the specific information collection it conducts under the generic clearance.

Instead, the agency may submit the information collection instrument directly to OMB for review and approval. Under the generic clearance for FDA focus groups, FDA recently reviewed approval of a focus group entitled "Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications."

This project is designed to provide FDA centers, the Drug Evaluation and Research, with a better understanding of current knowledge, practice, beliefs, behaviors, and perceptions about opioid use, misuse, and abuse among health care professionals, patients, and other members of the lay public. Gaining this knowledge will assist in more appropriate, directed, and focused communication efforts, aimed at raising awareness and educating the public.

Thank you again for inviting FDA to testify. I would be happy to answer any questions you may have.

Chairman CHABOT. Thank you very much. And now the chair will recognize himself. I will begin our 5-minute questioning. And Dr. Fine, I will begin with you.

Small businesses' stakeholders are concerned that multiple agencies are asking for the same information when filling out forms and other paperwork requirements. Is the EPA doing anything to coordinate within the Agency and also across with other government agencies to ensure that the government is not collecting duplicative information?

Dr. FINE. We work, as part of our standard process, to check and see if other agencies are collecting the information that our staff, our programs are seeking. We look at some standard references such as provided by the National Archives and Records Administration, catalogues any information public. Also, the people who prepare our information collection requests are experts in their field and are expected to have some knowledge of other information that is collected across the government. When we find opportunities to reuse information that becomes part of our standard practice.

Chairman CHABOT. Okay. Thank you very much. Mr. Guertin, I'll move to you next. In your testimony you mentioned that the Fish and Wildlife Service has many paperwork requirements for

the hunting and angling community in particular. Does the Service consult with small businesses in those industries to ensure it is reducing paperwork burden? And if so, how? And how often would you do that sort of thing?

Mr. GUERTIN. Thank you for your question, Mr. Chairman. Yes, we work very closely with the large manufacturers and the wholesalers and retailers at all levels of the distribution chain to try to get the information we need, whether it is on what they are producing or how they are selling that to the public. And then our interest is to take that as associated with fishing and hunting success.

There are a number of forms. We work with these groups to make sure we are reducing burden. And Secretary Zinke this past summer has had several high-level industry summits with manufacturers, with the recreation vehicle associations, with hunters and anglers as well, to work with their trade groups on ways to streamline engagement with the Federal agencies and support small business while minimizing the collection of information from the Federal agencies.

Chairman CHABOT. Thank you very much. Mr. Ahluwalia, I will go to you next. Your written testimony states that the time burden for the Department of Labor's information collection request has remained virtually unchanged from what it was 12 years ago. How has the Department of Labor managed to double the number of information collection requests, but still estimate the total number of hourly burden to be essentially the same?

Mr. AHLUWALIA. Thank you for the question. So, the number doubling is basically responding to program needs over a period of time. These 467 information collections that we maintained are like bank accounts, and we do about 300 transactions a year on them.

Some of these can be to adjust it to mission needs or a change in a law, or sometimes reducing the burden, sometimes increasing it. So, even though the number itself has gone up, the burden has remained flat over a period of time. And I would argue, over 12 years, if you account for all the growth and the population growth, et cetera, that is actually effectively a drop. But that is the explanation for why the number has doubled while the burden has remained what should be flat.

Chairman CHABOT. All right. Thank you. And I will conclude my questioning with you, Mr. Simpson. What is the FDA doing to make sure small businesses can more easily determine what labeling is required for their businesses? Does FDA have resources for small businesses to easily navigate the labeling system?

Mr. SIMPSON. We employ seminars, workshops, educational conferences, information materials, and of course the toll-free number, and help by email to provide access to small business advisors and any kind of administrative support staff that may need help with that. But as far as the actual labeling guidelines go, that is slightly outside of my purview as CIO.

Chairman CHABOT. Thank you very much. I am going to yield back my time and recognize the ranking member for 5 minutes.

Ms. VELAZQUEZ. Thank you. My first question is for the entire panel. And Dr. Fine, if you could start. Some have suggested that to make the PRA more effective the volume of requests being sent

to OMB should be reduced. This could be done by limiting OMB review to significant paperwork collections and shifting more responsibility to the agencies. Do you believe that delegating more authority to agencies unless significant information requests will help a wider focus on bigger paperwork issues?

Dr. FINE, I do.

Ms. VELÁZQUEZ. Without compromising the public policy goals, right?

Dr. FINE. I do. That allowing the simpler and smaller ones to go through without that extra step would, I think, save OMB effort, would also save our Agency effort that we could invest in greater scrutiny on the larger and more significant requests.

Ms. VELÁZQUEZ. And how would you envision this delegation to happen?

Dr. FINE. I would expect there would be some criteria by which Congress and/or OMB decide that below this threshold in terms of perhaps number of people or a number of anticipated burden hours that perhaps delegation could be provided to the agencies.

Ms. VELÁZQUEZ. Thank you. Mr. Guertin?

Mr. GUERTIN. We don't have certainly the volume and workload some of these other large agencies do. We do about 2.7 million annual responses and about 1.7 million burden on the public, totaling about 11 million in fees charged to them. That said, though, we have been working very closely with OIRA at OMB on trying fast-track or do programmatic clearances to batch some of these added requests into logical building blocks.

And this notion or strategy of them delegating some of that back to us would be, I think, a very effective tool to set a threshold or volume up where the agencies had prerogative to operate within that window, and then elevate the larger, more challenging packages over to OMB.

Ms. VELÁZQUEZ. Thank you. Mr. Ahluwalia?

Mr. AHLUWALIA. Thank you. So, we work very effectively with OMB at this time to manage our paperwork burden. It is a challenge to have one size fits all, so whether you are collecting things from 10 people and it is a hundred hours or it is a million hours, you are collecting from 100,000 people. It has to go through the same process.

So that does present its own challenges, and I think a little bit of more autonomy, while it helps, I am reluctant to prescribe a formula, though. I think the problem needs a little more analysis to——

Ms. VELÁZQUEZ. But you don't see the value on delegating to the agencies, you know, less significant information requests, so that then OMB will focus on the big paperwork issues?

Mr. AHLUWALIA. I do clearly see that value. Yeah.

Ms. VELÁZQUEZ. Yes, sir, Mr. Simpson?

Mr. SIMPSON. I, too, see the value in that, and I guess I would defer to the generic clearance process as one of the tool sets that OMB has provided that we can utilize to see that through. But also, I just want to go on record, the PRA staff at FDA work very closely with OMB and work through issues as they arise on all matters.

Ms. VELÁZQUEZ. Thank you. Mr. Guertin, OIRA receives thousands of information requests to review each year. One way we could reduce the volume is to extend beyond 3 years the length of time that OMB approvals are valid, particularly for routine types of collections. Do you believe that the OMB approval timetable should be extended?

Mr. GUERTIN. For some of the more routine packages we deal with, hunter success and the number of animals taken, I think that would be very appropriate. If something started, covering over the area, OMB had a significant policy interest; or a national issue that was important they may want to retain that 3-year check-in to make sure there were no bigger issues arising.

Ms. VELAZQUEZ. Sure. Dr. Fine?

Dr. FINE. I agree with what Mr. Guertin described, that there would be some value in that with appropriate limits to make sure the public interest was served.

Ms. VELAZQUEZ. Sure. Thank you. Thank you, Mr. Chairman. I yield back.

Chairman CHABOT. The gentlelady yields back. The gentleman from Mississippi, Mr. Kelly, who is the chairman of the Subcommittee on Investigations, Oversight, and Regulations, is recognized for 5 minutes.

Mr. KELLY. Thank you, Mr. Chairman and Ranking Member. And thank you, witnesses, for being here. I think sometimes we forget in government that our purpose is to serve the people, not them to serve our agency, whatever that may be, whether it be Congress or the EPA or the Fish and Wildlife. And I had a small business, a private law practice, and so I started, and so I thought I was going to practice law. That is what I went to law school to do, was to be a lawyer and to do trials and to help people.

But I spent an inordinate amount of my time doing bookkeeping, deciding what supplies we need, when to upgrade equipment, where to get insurance from, and what type of insurance I needed. And so I wound up spending probably 60 to 70 percent of my time doing things other than practicing law, doing payroll for my employees, paying taxes.

I didn't have to deal with the small business side of that or filling out additional surveys, and I think sometimes we think it is not that big a deal. But let me tell you, I am in the Guard also, the National Guard, and I was writing down just the surveys that I have done. I get survey requests all the time that I am required to do, okay, I don't get paid for them. I had to do my Periodic Health Assessment online and answer questions which took 30 or 45 minutes. I have to do a training class for the Blended Retirement System, I have to do sexual harassment training, and all that online, which I don't get paid for.

I had to do my credit card to teach me how to use a government credit card that I have been using for 32 years. I had to do training on that that lasted an hour and a half or two. And I also had to do a travel—I had to fill out a government travel thing, which I have been doing successfully for the last 15 years, because some bureaucrat decided that I needed this hour training.

And I am scared to death that we are doing the same thing with our small businesses. The purpose is not to get information for any

of your agencies, the purpose is to make these small businesses productive. And I hope that at some point we will understand that we have to do that.

So, what alternative means are you using to get there? And here is one other thing, if you had to pay by the hour for the amount of time that these small business owners had to do, and you had to pay them out of your budget and you didn't get any appropriations for that, out of your budget, would you request the same information? If you will start. What alternative messages or methods are you using to collect information? And I will start with you, Dr. Fine.

Dr. FINE. Thank you for the question. And I do understand the concern both from the small business perspective and as a Federal employee. I have taken mandatory training. One of the things we are doing is to try to use—make greater use of information technology.

There are ways that we can make it easier for people to fill out required information and take less of their time to do that, for instance by catching errors right away so there isn't a back-and-forth. We also, when we do have a need to collect information, we actually call individuals as part of our process to see what would the burden be. You know, are there ways where we can collect this information more effectively?

So, it is not just somebody in Washington making those decisions. We actually reach out across the country to affected parties, as well as having public Federal Register notices, so it would get broad input as well. So, we are actively seeking input from the regulated groups and from others on ideas.

Also, we do check and see if other agencies are already collecting the information; no need for us to collect duplicative information. Hopefully, that helps answer your question.

Mr. KELLY. And one of you other gentlemen, and either one of you three, if you had to pay for the information to create a data bank like most civilian things do, if they want data on something, they have to pay to create that data. What are you doing to make sure that there is a test in the public that says, if I had to pay for it, would I pay for it or not, to decide what we want to know versus what we need to know? Because those are very distinct things, and either one of you three gentlemen can respond.

Mr. GUERTIN. Congressman, I would go back to my example of our wildlife management objectives with waterfowl. We rely to the best we can on scientific surveys. We apply a lot of surveys in the breeding grounds. We do a lot of GIS map habitat, and we don't go out to the public unless we need to. The key missing piece of information for us is actual harvest, hunter success.

And so we have put a lot of this feedback from the public on our web page. Hunters can just let us know how many ducks they are taking. We also have voluntary programs like annual Wingbees, where folks can just send an envelope in with some of the tail feathers from birds. We can, on a voluntary basis, collect that. We are trying to balance the benefit we can give the public with a stronger season each year, bigger bag limits, more hunter opportunity and success, and minimize the actual reporting that comes in from our constituent groups.

Mr. KELLY. And Mr. Chairman, I yield back. Thank you.

Chairman CHABOT. Thank you. The gentleman's time has expired. The gentleman from Nebraska, Mr. Bacon, is recognized for 5 minutes.

Mr. BACON. Thank you. And as a 30-year Air Force exec, I can appreciate all those training requirements he went through. I had to do a bunch of that myself. And thank you all for being here.

I just want to start off by saying, I am from the Omaha area. Our small businesses are the local farmers, folks who are putting up wind generation. I will just let you know, I get feedback in all four of your agencies of that friction of them trying to perform and make a profit, and some of the pushback of the red tape and bureaucracy, so there is always those impacts on those small businesses, as you all know.

Let me just start off with a question for Mr. Fine, if I may. At our March meeting we had a witness testify that agencies required duplicative recordkeeping requirements for different programs, but from within the same agency. Examples of EPA's regulations regarding spill prevention regulations and stormwater pollution, prevention regulations where these two programs require a lot of the same information from the same business.

What is the EPA doing to identify instances where just asking for the same information from a business, but for different reasons?

Dr. FINE. Thank you very much for that question. The people in the Agency, who developed these information collection requests, are experts in their field and are familiar with information that has been collected within the Agency, and should be familiar with the information collected outside the Agency. As an example, the example that came up in the March hearing was, if I remember correctly, both stormwater and spill requests.

Mr. BACON. Mm-hmm.

Dr. FINE. And they are serving different purposes, a lot of the information is different. The stormwater is routine releases, it rains and you get stormwater runoff. The spill is an exceptional event, so there are a lot of different information collected, but there is some small overlap information.

So that in developing our programs we have allowed businesses to say, we have a comprehensive plan to address one of the information collection requests, and have the other information collection request refer to that, instead of submitting the duplicate of information. So the staff have awareness of that and take that into account when designing this information collection request.

Mr. BACON. Okay. Thank you. Maybe related to this, we have examples where agencies ask for some duplicate information from within an agency. How can we do better when multiple agencies are asking for the same information? So we had, also in March, we have heard about lead paint, and different agencies wanting the same information. Is there a way that instead of putting the burden on the small business, is there a way to put the burden on the Federal Government to streamline that? Whoever would like to respond.

Mr. AHLUWALIA. So the Occupational Safety and Health Administration at the Department of Labor works very hard across agencies as well to make sure that we, in the initial stage itself,

reduce any redundancy from that perspective. Once we go further down, there is a recurring cycle of revisiting these and we try and minimize any redundancy.

Under the Small Business Regulatory Enforcement Fairness Act, SBREFA, OSHA engages with small businesses quite a bit. We develop special aids and things that would allow them to understand, *What is the overlap? Why is it different? What am I getting out of this?* I think that that appreciation sort of helps a little bit as well. We work very hard to reduce that overlap.

Recently there was WIOA, which is the Workforce Innovation and Opportunity Act that was passed. And there, Congress actually built into the act the collaboration between us, Department of Education, HHS, to go out and work with the States together. And that is why in that particular case Department of Labor is the lead agency in managing the information collection on behalf of all the aforementioned Departments to implement aspects of that act. So we do a lot of things. More can be done and obviously we will look for the opportunities to do it.

Mr. BACON. I appreciate that. Anybody else? Dr. Fine?

Dr. FINE. I will just add, the example came up in March again with lead paint. The two agencies are looking at different missions: OSHA is obviously working to protect the health of the workers, EPA is looking at the people who are living there.

Mr. BACON. Right.

Dr. FINE. So we are, in that case, focused on the most sensitive population, which is children ages 6 or less, and that leads sometimes to different measures, different training required. Somebody who is actually working to make sure they are protected, they might take different measures if you want to make sure the people who are living in that house are protected day-in and day-out.

Mr. BACON. It may be easier said than done, but it would be nice if we could put it together and have one form, but that is, I know, for multiple agencies it is a hard task to do. But it does all fall on the small business person, often two or three people, having to make a profit and try to work through all this red tape.

So, with that, I am out of time. Thank you. Mr. Chairman, I yield back.

Chairman CHABOT. Thank you very much. Thanks. The gentleman's time has expired. The gentleman from Iowa, Mr. Blum, who is the chairman of Subcommittee on Agriculture, Energy, and Trade, is recognized for 5 minutes.

Mr. BLUM. Thank you, Mr. Chairman. Thank you to the panelists for being here today. I have heard during your testimony you have uttered the following words more than once, that your agency "strives" to limit—strives to limit—the information and paperwork requirements we place on the public, balancing our data and information needs, the government's data and information needs, with the burdens associated with those needs.

Now, I am a small business person. There is not a small business person in my district, in Northeast Iowa, that believes that statement, not one. Here is your opportunity to convince them. Go ahead, and whoever wants to take it. I don't believe you balance those needs, they don't either. Tell me why I am wrong. Because they just continue to grow.

Mr. GUERTIN. Congressman, I hear you loud and clear. And you are talking about an aspirational view and the Federal agencies and a commitment, and clearly we have a lot of work to do to convince our fellow citizens of our seriousness of purpose. But we also would stand by the work that we are doing and are currently doing and plan to do to harness emerging technologies, to reach more effective partnerships within the Federal family, to coordinate upfront, and to put as much of this information needs onto automated systems or frontload it the best we can to keep minimizing the touch we have out there.

In our case, to deliver our mission some of that information is critical to help us set these larger frameworks to support a robust hunting and fishing economy out there. So our pledge to you is we will do the best we can to continue, and we will have to earn some more trust and confidence, clearly, with your constituents and our fellow citizens.

Mr. BLUM. When will small businesses see a reduction in the paperwork? Because that sounded very nice, it sounds good, it sounds beautiful, but they are sitting there in Iowa saying, now this isn't going to happen, it never has in the past.

Mr. GUERTIN. We had a modest reduction of about 25,000 hours of our 11,000 we were involved last year. It is a modest start in the right direction. We also reduced the financial burden by about a half-million dollars by moving many of these systems online. And out of an $11 million program, we think that is starting to show some progress for our small agency.

Mr. BLUM. Can you imagine if we incentivized your agencies with bonuses in your paychecks, if you reduced the regulatory burden on our businesses, I think the results would be amazing in 6 months. Anybody else? Tell my small businesses why they are wrong, that they are going to see reduction in paperwork?

Mr. AHLUWALIA. So, I was a small business owner, and I owned a small business with my wife. And as we were prepping, I was sort of trying to reflect when we did business, you know, how did we perceive the whole thing? And I have been on the other side now, so it is sort of I have the perspective from both sides.

So my wife reminded me that to maintain our relationship with FedEx, we had to fill out five forms a month, with UPS another five. Yet we perceived anything coming out of the local, State, and the Federal Government to be way more burdensome, and those forms aren't really to——

Mr. BLUM. Because you have a choice to work with FedEx or UPS or the United Postal Service, the businesses don't have a choice. The government shows up with a subpoena in hand and a bayonet, and it is by force. There is a big difference.

Mr. AHLUWALIA. Right. And there is that, but I am trying to just share my perspective. I think we probably want to—these are opportunities for us to put our case forward as to why these things are important. How are we protecting the workforce? And strive to reduce the burden over a period of time.

Our Benefits.gov that I was talking about, that knits about 1,200 different programs across States, and all you have to do is go in and plug in a few things, and they will tell you which three, four,

five programs that you would be eligible for. And then you don't fill out or you don't have to go through a hundred things.

Mr. BLUM. Do most of these information requests come from Congress or do they come from your agencies internally? Are we, in Congress, putting the burden on small businesses by forcing you all to collect data? Or is this, most of this, coming internally in your agencies? Be quick, I have only got 30 seconds.

Mr. AHLUWALIA. I think there is a bit of both. I would like to quote the chairman from the last hearing. He said, "We have met the enemy, and it is us." There is a little bit of that, but then there are program needs that are defined by the program areas as well.

Mr. BLUM. I have 15 seconds. I just want to conclude by saying small businesses have zero—zero—resources available, none. Every time we ask them for a bit of information, we just tax them, it is a tax on small businesses. I don't like the word "strive." Let us just do it. Let us just do it.

My time has expired. I yield back Mr. Chairman.

Chairman CHABOT. Thank you very much. The gentleman yields back. And just to clarify on the statement about we met the enemy, and it is us, my staff wrote it, and I think they stole it from Pogo, which was a comic strip back in the papers before most of the people in this room were born. I see a few nodding heads, I won't point out who they are, but it was from Pogo. That was a pretty good strip years and years ago.

The chair will recognize the gentleman from South Carolina, Mr. Norman, for 5 minutes.

Mr. NORMAN. I will just echo what Congressman Blum said. I am a small business owner, we are contractors and developers. I have had to fill out paperwork every time it rains, the inches of rain and the amount of sediment that could have washed over the dams. I have to fill out paperwork on any development we do. Does the one-eyed bat exist? Does the heelsplitter snail exist?

It goes on and on. And like the Congressman was saying, it is time to do something about this.

Now, I know a lot of it may be out of your purview, but one of the great things about President Trump is, he is cutting regulations. Of every one proposed, he is cutting two. For the small business owner that is major. I have had it with paperwork. I have had it with having to fill out every form in the world. The FedEx form that you mentioned is a small thing.

I guess my question is, how have you seen his administration, in your world, cut the regulations? And secondly, and this is for anybody really, secondly, how much is required electronically versus having to be put on our dead trees in a process that are being removed from acres of land?

Dr. FINE. I will start and be brief with the time. EPA has completed 16 deregulatory actions following up on President Trump's Executive Order as a start, so far.

And in terms of paper versus electronic, we still collect a lot of paper, and we would like to collect a lot less paper, and that is something we were working to accomplish. And the strategic plan that EPA has developed for the next 5 years highlights that as one of the goals—one of the methods to reduce paperwork and burden reduction.

Mr. GUERTIN. Congressman, the new administration has taken very aggressive steps so far in the Interior Department, our Fish and Wildlife Service the first day took down a lead regulation on hunting. And the new administration has continued to pursue a lot of streamlining efficiencies.

For example, Secretary Zinke just signed out a new Secretary Order setting page limits and time limits for the agencies to comply with NEPA requirements that would reduce these environmental impact statements and EAs down to a much more size and scope and timeframe envisioned in the original legislation rather than these very large products that the public has been seeing in the last few years.

Mr. AHLUWALIA. We currently have a significant reduction in the information collection burden as a part of the annual budget process that is currently with OMB. We have an internal task force that is looking at each program area, trying to find areas where we can reduce the information collection burden without affecting our mission needs.

From an IT perspective we almost—in fact, every information collection goes through that. Are we using IT properly or not? Are we using mobile devices or not? We implement a three-click rule. Can I find the information in three clicks or not? Sometimes it gets very hard.

But we strive to do all of those things in order to make it easier. That is why I keep referring to our Benefits.gov. I think it is a success story that we should be copying across our results as well.

Mr. SIMPSON. Sir, I can't speak directly to the reduction in regulation under President Trump's administration, but I can say that we are doing everything in our power at the FDA to stabilize and invest in our technical infrastructure. We have a 3-year strategic plan which we are walking diligently, which has a huge customer-facing piece to it. Our goal is to reduce duplication as much as possible and to make as many paper forms electronic as we can.

Mr. NORMAN. That would be a big help. And I will just say, that for every dollar that I have to spend filling out these paperwork, the time, not that you don't take the time to email and doing it electronically, but it is just a lot less of our staff's time worked, is a dollar that I can expand our business, that is a machine I can buy, that is a tractor that I can put to work.

So, in your role, I would really urge you to support this President in what he is doing, because I have seen the benefit of it. And hopefully, as he gets into it and doesn't have as many people fighting him, we can take it to the next level.

I yield back, Mr. Chairman.

Chairman CHABOT. Thank you. The gentleman yields back.

And in closing, the chair and the other Committee members would like to thank the panel for sharing this testimony here this morning on what your agencies are doing to reduce the paperwork burden on America's small businesses. And I would note for the record that there was some skepticism expressed by some of the members that have made much progress recently, or really that we will make much progress in the future. So, prove us wrong.

We would love to see you reduce paperwork on the entire public, but especially America's small businesses because that is what this Committee is all about, you know, trying to help those folks.

So thank you very much for your testimony here today. I would ask unanimous consent that members have 5 legislative days to submit statements and supporting materials for the record. And without objection, so ordered.

And if there is no further business to come before the Committee, we are adjourned. Thank you very much.

[Whereupon, at 12:00 p.m., the Committee was adjourned.]

APPENDIX

Testimony of Dr. Steven Fine

Acting Assistant Administrator

Acting Chief Information Officer

Office of Environmental Information

U.S. Environmental Protection Agency

before the

Small Business Committee

U.S. House of Representatives

October 11, 2017

Good morning, Chairman Chabot, Ranking Member Velazquez and Members of the Committee. I am Steve Fine, acting Chief Information Officer at the Environmental Protection Agency (EPA). Thank you for the opportunity to discuss the EPA's implementation of the Paperwork Reduction Act (PRA).

Congress has charged the EPA with enforcing several statutes to protect human health and the environment. In order to ensure the requirements of these statutes are met, the EPA must collect information from the public. EPA has just over 400 OMB-approved collections with a total overall burden of approximately 174,000,000 hours. This is approximately 1.5% of the total federal government burden. EPA collections range from over 21,000,000 hours for the National Pollutant Discharge Elimination System (NPDES) Program to less than 10 hours for the Mobile Air Conditioner Retrofitting Program. The agency is cognizant of the impact these collections have on small businesses and other entities and works to find ways to reduce that burden while satisfying the responsibilities assigned by statutes.

Implementation of the Paperwork Reduction Act

The PRA mandates that federal agencies follow a necessarily robust process to ensure that they are only collecting information that is needed and are doing so in the least burdensome way possible. Under the PRA, an agency must obtain approval from the Office of Management and Budget (OMB) before using identical questions to collect information from 10 or more persons, even if responding to the request is voluntary for the recipient. To gather in-

formation in such circumstances, the EPA must prepare an Information Collection Request (ICR), which describes the information to be collected, gives the reason the information is needed, and estimates the time and cost for the public to answer the request. Examples of information collections include surveys, permit applications, questionnaires, and compliance reports.

At the EPA, subject matter experts in program offices—who are familiar with the requirements of the program, the information being collected and the affected public—develop ICRs. Each program office follows a process established by EPA's PRA office.

ICRs are subject to a 6- to 10-month internal agency review and approval process. The agency's PRA office conducts an independent review of each ICR, and each ICR is also shared with the public twice for comment via Federal Register Notices. In addition, the agency consults with a sample of affected entities. Agency ICR preparers and reviewers consider factors such as whether the collection is required to achieve the stated environmental objective, whether there is practical utility to the information being collected, whether the proposed collection method is appropriate and efficient, whether less frequent collection of information would be sufficient, whether the calculation of the estimated burden is accurate, and whether the information is collected elsewhere. Public comments inform agency reviews. After agency review, ICRs are sent to OMB for further review.

Approved ICRs are valid for up to three years. If data collection will continue beyond that timeframe, an ICR must be renewed. The review process for a renewal includes the same evaluations as are conducted for a new information collection.

Burden Reduction Efforts

The EPA is sensitive to the burden it places on regulated entities and uses multiple approaches to reduce unnecessary reporting and recordkeeping burdens on the public. For example, both the program office and the ICR office independently consider whether each part of a proposed information collection has practical utility, is limited in scope to only that necessary for the intended purpose, and imposes the least burden.

Also, where feasible, the agency obtains information from other federal sources, instead of the public. For example, instead of requesting some information from coastal states that are seeking final approval of their Coastal Nonpoint Pollution Control Programs, the EPA obtains that information from the National Oceanic and Atmospheric Administration (NOAA), which collects that information for its own needs.

Additionally, the EPA is increasingly using information technologies to reduce burden by streamlining the information collection process. For instance, the Toxics Release Inventory (TRI) involves reporting by more than 20,000 companies per year and has been a flagship for electronic reporting since 2002. This year, the EPA enhanced TRI's primary submission instrument, which is used by thousands of facilities to describe their toxic chemical inven-

tories and document significant events (releases, transfers, disposals, etc.). The enhancements included new features such as automated data quality checks and a simplified password resetting process. These enhancements are expected to reduce average reporting time by 13% for each of the approximately 80,000 forms submitted annually. Another example is new software systems under development that are anticipated to reduce reporting burdens related to public water systems by 23%.

Further, the agency is in the process of developing a Strategic Plan covering Fiscal Years 2018-2022. The draft plan shared with the public for comment includes a strategic measure for the reduction of reporting burden on the regulated community. This would be one of roughly two dozen measures that would be tracked at the highest levels of the agency.

The EPA remains committed to working with small businesses and other regulated entities to find ways to collect the information we need to protect human health and the environment in the least burdensome manner possible. Again, thank you for this opportunity to testify. I would be happy to answer any questions you may have.

Testimony of Stephen Guertin

Deputy Director for Policy, U.S. Fish and Wildlife Service, Department of the Interior

Before the House Committee on Small Business

"Evaluating the Paperwork Reduction Act Part II: Are Burdens Being Reduced?"

October 11, 2017

Introduction

Good morning Chairman Chabot, Ranking Member Velazquez, and Members of the Committee. I am Stephen Guertin, Deputy Director for Policy for the U.S. Fish and Wildlife Service (Service). The Service's mission is "working with others to conserve, protect and enhance fish, wildlife and plants and their habitats for the continuing benefit of the American people." The Service is the oldest Federal conservation agency, tracing its lineage back to 1871, and it is the only agency in the Federal government whose primary responsibility is conservation of fish and wildlife resources for the American public. The goal of the Service and this Administration in the area of information collection is to reduce burdens and improve efficiency; and in general, be a good neighbor and partner to the public and the states.

I appreciate the opportunity to testify before you today on the Paperwork Reduction Act (PRA) of 1995, as amended. The PRA, signed into law in 1980 and reauthorized in 1995 (P.L. 104-13, 44 U.S.C. 3501 *et seq.*), provides the statutory framework for the Federal government's collection, use, and dissemination of information. The primary purpose of the PRA is to minimize the burden of federal paperwork on the public and maximize the usefulness of the information collected in order to improve the government's effectiveness. Information collected by the Service from the public is critical to a number of activities important to the economy. This includes our work with states to manage robust and sustainable migratory bird hunting opportunities for the public in states along migratory bird flyways. This is a significant economic driver for small businesses and local economies across the country.

Implementation of the Paperwork Reduction Act

The PRA applies broadly across federal agencies and its mandates cover a wide range of information—collection requirements and activities. The Service's information collection cover a number of activities, including hunting and fishing license applications and reports; migratory bird and eagle permit management; fish and wildlife import/export compliance; annual surveys of fishing, hunting, and wildlife-associated recreation; marine mammal marking, tagging, and reporting requirements; Federal subsistence regulations; international conservation grant programs; and migratory bird surveys. The Service currently has 44 active collections com-

prised of 2,670,931 total annual responses, 1,684,915 total annual hours, and $11,360,763 total annual costs. In our most recent 2017 Information Collection Budget submission, we reported to the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB-OIRA) a decrease of 24,863 burden hours and a decrease of $497,080 annual costs.

Within the Department of the Interior (Department), the Service is responsible for its own information collection process, which is under the oversight of the Department's Information Collection Clearance Officer, who also provides guidance and support to the Service as needed. This includes the preparation of requests to OMB-OIRA for approval of all information collections. The PRA and Service's Information Collection Clearance Program ensure that the requirements the Service places on the public (e.g., individuals, private sector, and state/local/tribal governments) are justified and controlled. It is a priority of the Service to ensure all information collected from the public adheres to the requirements of the PRA, OMB-OIRA regulations and guidance, and other applicable laws.

The Service's various program areas work closely with our Information Collection Clearance Officer (ICCO) to determine if an information collection requires clearance from OMB-OIRA. If required, the responsible program works with the ICCO to obtain OMB-OIRA's approval and clearance prior to information collection. The ICCO reviews all draft PRA submissions to ensure the burden placed on the public is reasonable and that the Service considered all comments and suggestions from the public. The Department's Information Collection Lead reviews and approves all Service submissions under the PRA before formally submitting the packages to OMB-OIRA. The Service does not make exceptions to legal requirements of the PRA, recognizing that the authority rests solely with OMB-OIRA.

Public participation in the information collection process is important to the Service. As required by the PRA, the Service seeks public comment before requesting or requiring information from the public. For each collection, we publish two separate notices in the *Federal Register*. The first notice opens a 60-day comment period through which the public sends comments to the Service ICCO. The ICCO works with the relevant Service programs to incorporate and address the comments in the final information collection package. Prior to transmitting the information collection to OMB-OIRA, we publish a second notice to give the public a 30-day opportunity to provide comments on the information collection directly to OMB-OIRA, with a copy to the Service ICCO. In addition to the above public comment periods, the Service conducts targeted outreach to individuals to ensure that we are reducing the impact to the public to the greatest extent practicable. Through this targeted outreach, the Service seeks to solicit comments from a sample pool of respondents reflective of potential respondents to the information collection.

It is essential for the Service to understand and solicit feedback on both the time and cost burdens placed on small businesses. If

an information collection affects small businesses, the Service ICCO works to ensure the targeted outreach process includes a representative sampling from small businesses. We document the results of this targeted outreach in the final information collection package and note whether we adjusted the collection based on feedback received through this targeted outreach. Adjustments to the packages may include adjusting burden estimates as appropriate; consolidating similar information collection instruments to streamline compliance; and automating processes to reduce burden time on respondents whenever possible.

Balancing Information Collection Needs with Public Burden

The Service strives to limit the information and paperwork requirements we place on the public, balancing our data and information needs with the burdens associated with those needs. One such example is the collection of harvest information from migratory bird hunters, which enables us to develop sound, science-based hunting guidelines. Harvest surveys allow the Service to gather information on hunter participation, success rates, and target species. We use this, and other types of information, to inform our regulatory decisions so that regulations result in sustainable hunting guidelines that ensure maximum hunting opportunities for the public each year.

An example of how we use information collected from the public is a recent change to hunting guidelines for black ducks. In 2017, the Service expanded the harvest of black ducks based on information from banding studies and the harvest survey program. Our science is well established, and we can demonstrate that populations remain healthy.

The Service places great priority on expanding public access to fish and wildlife resources while maintaining the sustainability of those resources so they can be accessed by the public in future years. We depend on information collected from the outdoor-recreation community in order to do so. The Service recognizes that hunting, fishing and other wildlife-based recreation is not only an important leisure pastime and a way for people to bring food to the table, but it is also a catalyst for economic activity, creating jobs supporting small businesses across the nation. Hunters, anglers, and wildlife watchers spent more than $156 billion on wildlife-related recreation in 2016. This spending contributed to local economies throughout the country, which improved employment, raised economic output, and generated tax revenue.

Efforts to Improve PRA Compliance

The Service is working to further reduce the burden of information collections on both the public and our agency's work. Beyond the standard PRA approval process, the Service also applies the Department's Programmatic Clearance for customer satisfaction surveys and the Department's "Fast Track" Clearance for collection of qualitative feedback. These two processes, when applicable, provide the Service with a streamlined approach to PRA compliance. For collection of customer satisfaction data, the Programmatic

Clearance process significantly reduces the time to internally develop and obtain OMB approval to as few as 45 days, as compared to the six to nine months it typically takes the Department to develop a standard PRA package, issue notices and respond to any public comments, and submit to OMB-OIRA for approval under the standard PRA compliance process. The Fast Track process is designed for a wide range of information collections that focus on the awareness, understanding, attitudes, preferences, or experiences of customers or other stakeholders. Through this process, the Service may proceed with the collection in as soon as five days if OMB-OIRA does not respond with questions, concerns, or issues identified with the submission.

Other Effects to Reduce Public Burdens

The Service and this Administration place great priority on being a good neighbor and improving government efficiency. We are taking actions outside of the scope of the PRA to further reduce burdens on the public and small businesses. The Service is working with the Department to implement Secretary's recent order on streamlining our review processes. One of its primary directives will reduce paperwork by setting standard page limits, consistent with Council on Environmental Quality guidance, for National Environmental Policy Act (NEPA) analyses. The Secretary's order will also ensure timely completion of environmental reviews by designating lead agencies for projects and setting reasonable timelines for analyses. Implementation of these directives will allow for a more transparent process and provide businesses and the public with more certainty.

Through the use of online platforms, the public can quickly and easily conduct business with the Service that was previously more time consuming. The Service has endeavored to make processes easier for the public, as well as to make our operations more efficient, by making forms available electronically through our website. The Service has nearly 200 forms available to the public online, ranging from the "Horseshoe Crab Tagging Release Form" to the "Oil and Gas Operations Special Use Permit Application". In 2013, the Service launched an electronic version of the Federal Duck Stamp that allows users to buy stamps online through participating state licensing systems. A printed receipt, available immediately, is valid for 45 days, during which time a physical duck stamp is mailed. There currently are 23 states that participate in the e-stamp program. The stamp represents the permit required by the Migratory Bird Treaty Act of 1918 to hunt waterfowl and is required to be carried by every waterfowl hunter who is more than 15 years old.

Conclusion

Through implementation of the PRA, the Service ensures that our information collections are not unduly burdensome on the public. We continue to seek improvements in our compliance with the Act to reduce impacts to the public and our agency's work.

Thank you for your interest in examining the Paperwork Reduction Act. I appreciate the opportunity to testify and look forward to working with the Committee on the implementation of the Act.

STATEMENT OF GUNDEEP AHLUWALIA

CHIEF INFORMATION OFFICER

U.S. DEPARTMENT OF LABOR

BEFORE THE

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 11, 2017

Good afternoon, Chairman Chabot, Ranking Member Velazquez, and Members of the House Small Business Committee. I am Gundeep Ahluwalia, Chief Information Officer (CIO) for the Department of Labor (DOL). Thank you for inviting me here today to discuss DOL's efforts to reduce paperwork burden through compliance with the Paperwork Reduction Act (PRA). I appreciate this opportunity to discuss DOL's responsibilities under the PRA and our efforts to provide relief and fair treatment to all business owners, particularly small ones, and individuals.

DOL is committed to reducing the burdens that America's businesses and individuals deal with every day as a result of Federal regulations and paperwork. The Paperwork Reduction Act is an important tool for DOL, and all federal agencies, to use in reducing unnecessary burdens on the American public.

DOL administers three types of information collections covered by the PRA: recordkeeping, reporting, and third-party disclosures. In carrying out DOL's broad and varied mission, the Department administers more than 180 Federal laws. Many of these laws provide for recordkeeping requirements that allow the Department to hold violators of worker protection standards accountable for their non-compliance. Other laws provide for employees and employers to share information to facilitate compliance. DOL reporting requirements allow the Department to provide important economic statistics that enable decision makers at all levels of government and in the private sector to make informed decisions. In administering these laws and related programs, the Department actively seeks to minimize the paperwork burden it imposes on the American public while maintaining its mission and fulfilling its statutory and programmatic responsibilities.

Achieving the aforementioned results is no small task. DOL currently maintains an inventory of 467 active information collections with a combined burden of 168 million hours and nearly $5.7 billion in other costs. Furthermore, the Office of the Chief Information Officer (OCIO) annually reviews and submits for Office of Management and Budget (OMB) consideration more than 300 information collection requests (ICRs). While the number of ICRs has doubled

since the last time a DOL CIO testified before a Congressional committee in 2005, the time burden has remained virtually unchanged from the 166 million hours mentioned 12 years ago. Much of the increased clearance activity can be attributed to new legislation enacted during that time.

The Department remains committed to the goals of the PRA and continues to explore and implement new ways to reduce burden hours imposed on the public. The Department recently developed its response to the FY 2017 data call for the Information Collection Budget (ICB) and is continuing to work to identify paperwork burden reduction initiatives. DOL employs several strategies to reduce burden, including:

- Comprehensively evaluating and periodically updating information collections contained in regulatory text and information collections that implement regulations but do not themselves rise to a regulation;
- Exploring streamlined information collection methodologies;
- Reducing redundancy; and
- Deploying automated information collection techniques when feasible.

With respect to reducing paperwork burden, OMB has called on CIOs in Executive Departments and Agencies not only to consider paperwork burden reduction initiatives that would serve ICB purposes, but to work more closely with regulatory policy officials to identify where paperwork burden reduction initiatives would serve as compliance mechanisms pursuant to President Donald J. Trump's Executive Order (EO) 13771, *Reducing Regulations and Controlling Regulatory Costs* (*i.e.,* would serve as an existing regulatory action the agency plans to eliminate or propose for elimination, consistent with Sections 2 and/or 3 of EO 13771). As you may know, EO 13771 generally requires agencies to issue two deregulatory actions for each regulatory action. The incremental costs associated with the regulatory actions must be fully offset by the savings of deregulatory actions.

The Department takes the PRA very seriously. As a mission-critical responsibility, DOL provides full management support and has established well-defined policies and procedures for implementing and managing the PRA. The following briefly discusses DOL's PRA Management structure.

The PRA requires each agency head to designate a CIO to carry out the responsibilities of the agency under the PRA.[1] The CIO is responsible for establishing and administering a process that is sufficiently independent of program responsibility to evaluate fairly whether a proposed collection of information should be approved.[2] Accordingly, the DOL established such an independent process and issued an internal policy directive for implementing the Department's information collection management program.

[1] *See* 44 U.S.C. 3506(a)(2)(A).
[2] *See* 44 U.S.C. 3506(c)(1).

The Department of Labor Manual Series includes a chapter that establishes DOL's procedures for implementing its PRA program. This internal policy directive assigns to DOL sub-agency heads the responsibility of ensuring sub-agency compliance with the PRA and other applicable laws and policies.

Furthermore, the directive assigns DOL's information collection management to the Departmental Clearance Officer and DOL sub-agency-level management to Agency Clearance Officers who manage the PRA program within each DOL sub-agency and provide both in-depth programmatic and PRA expertise that further ensures DOL's information collections effectively meet the PRA's provisions regarding the need for the information, practical utility of the information collection, minimizing the public burden for the collection, and enhancing the quality and usefulness of the information collected.

As part of assigned duties, the Departmental Clearance Officer manages the day-to-day activities of implementing the PRA for the CIO. The Departmental Clearance Officer reviews information collection requirements contained in regulatory documents and in information collection requests to ensure:

- Legal authority or necessity for the collection of information;
- Compliance with the PRA, the E-Government Act of 2002, Privacy Act, and other applicable laws; and
- The collection imposes minimum burden on the public and offers practical utility.

Additionally, the Departmental Clearance Officer provides overall management of DOL's information collection enterprise, including but not limited to:

- Managing efforts to reduce DOL's public paperwork burden in accordance with applicable laws, Administration directives, such as EO 13771, and Departmental guidance and priorities;
- Coordinating information collection activity with OMB and DOL agencies;
- Conducting public consultations as required by the PRA;
- Providing training and technical assistance on PRA requirements;
- Managing data associated with DOL's information collection inventory;
- Providing leadership for identifying and implementing burden reduction strategies; and
- Coordinating with other agencies on common information collections conducted with other Departments.

Throughout the year, the Departmental Clearance Officer collaborates with Program Agency Clearance Officers to:

- Monitor program performance against the ICB to ensure that reported goals are realized;

- Evaluate program activities to ensure compliance with the PRA;
- Determine the need for an ICR and best mechanism to obtain clearance; and
- Manage the life-cycle of existing collections of information to ensure continued effectiveness, efficiency, and utility, and to ensure that expiring collections are submitted to OMB in a timely manner.

To help program agencies comply, OCIO also developed an internal DOL PRA Manual that provides more detailed guidance to help programs administer their PRA programs. Among other things, the Manual provides samples of various documents and templates an agency may use to make common disclosures such as the PRA's public burden statement.

Through its rigorous internal review process, the Department aggressively controls the amount of burden it imposes on the American public and ensures the practical utility and enhanced usefulness of its information collections with five main strategies:

1. Review of Rulemaking Actions: This strategy ensures regulatory actions are based on mission critical needs and impose minimum practicable burden. The review ensures that the public burden has maximum practical utility and public benefit.

2. Assessing the Use of Technology: This strategy involves implementing the Government Paperwork Elimination Act of 1998, the Clinger-Cohen Act, E-Government Act of 2002, and Federal Information Technology Acquisition Reform Act by strategically deploying automated information collection techniques in order to reduce public paperwork burdens.

3. Routine Review of Information Collection Activities: This strategy involves carefully assessing all new information collection requests and all collections of information seeking OMB approval for any extended or revised information collection requirements to ensure programmatic necessity, legal authority, maximum practical utility and public benefit, and burden reduction strategies.

4. Burden Reduction Initiatives: This strategy involves initiating systemic enterprise-level efforts through Departmental burden reduction initiatives, as already mentioned in the earlier reference to the ICB.

5. Public Consultation: To help ensure the practical utility of information it collects, including the frequency and collection methods, the Department relies heavily on the public consultation process required by the PRA. Key stakeholders and industry experts are consulted as part of the Department's rulemaking process and interested parties as well as the general public are afforded two opportunities to comment on proposed information collection activities, which collectively provide the public 90 days to provide input on the practical utility of DOL's information collections as well as provide insights for reducing the burden imposed. The OCIO encourages DOL program agencies to make information collections available on regula-

tions.gov during the initial 60-day public comment period when comments go to the agency. The OCIO also provides a direct link to each ICR in the 30-day Federal Register Notice when the request is submitted for OMB review. This not only increases transparency; it allows interested parties to provide more meaningful comments for the agency to consider.

Through a rigorous internal review process and aggressive burden reduction strategies, the Department of Labor is committed to reducing the paperwork burden on the American public. In addition, the Department has a very strong program of compliance assistance to help all businesses comply with our requirements. For example, the Department has a National Contact Center that may be reached at 1-866-4-USA-DOL or through a "contact-us" feature on the DOL Website. All DOL agencies provide compliance assistance materials on their agency Websites, along with local office contact information. The Office of the Assistant Secretary for Policy (OASP) maintains the Department's Employment Law Guide which describes the major statutes and regulations administered by the Department that effect businesses and employees. In addition, OASP developed and maintains the Department's Employment Laws Assistance for Workers and Small Businesses (elaws) Program which includes more than 30 interactive e-tools that provide easy-to-understand information about DOL laws and regulations. Elaws is available 24/7 to assist the public, both employees and employers, in understanding their roles and responsibilities to comply with these various laws. Elaws is available at www.dol.gov/elaws.

Information collection and the ease of submission are critical for the American public, including small business owners. Benefits.gov, an interagency e-Gov initiative that includes all cabinet-level agencies, is an example of effective and efficient communication between those of us in Government agencies and the people we serve. Benefits.gov offers over 1,200 assistance programs through its Website and mobile responsive pages that connect small business and other members of the public with online applications that provide loans and other forms of assistance. This online assistance also includes disaster assistance through the Federal Emergency Management Agency (FEMA). DOL has been supporting FEMA through record levels of traffic to assist with recovery efforts for the recent trio of Hurricanes (Harvey, Irma, Maria) that impacted Texas, Florida, and other Territories. The value of this cross-agency initiative is demonstrated by the fact that DiasterAssistance.gov received more than 29.6 million sessions, during which 3 million survivors (including small businesses), completed on-line applications for much needed assistance from August 25 through the end of September of this year.

That concludes my prepared testimony. I would be happy to answer questions you may have.

TESTIMONY

OF

TODD SIMPSON

CHIEF INFORMATION OFFICER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

"EVALUATING THE PAPERWORK REDUCTION ACT

PART II: ARE BURDENS BEING REDUCED?"

OCTOBER 11, 2017

RELEASE ONLY UPON DELIVERY

Chairman Chabot, Ranking Member Velazquez, and members of the committee, thank you for inviting me here today to testify about the Paperwork Reduction Act (PRA). My name is Todd Simpson, and I am the Chief Information Officer for the U.S. Food and Drug Administration (FDA), part of the Department of Health and Human Services (HHS or the Department).

FDA's mission is to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; that human and veterinary drugs are safe and effective; that there is reasonable assurance of the safety and effectiveness of devices intended for human use; that cosmetics are safe and properly labeled; and that public health and safety are protected from electronic product radiation, In addition, FDA promotes the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulation products in a timely manner. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA balances the need to collect the information necessary to carry out our mission with the desire to minimize the burden on the businesses that feed the national and develop life-saving medical products.

Background

According to 44 U.S.C. 3506, each Agency head is to designate a Chief Information Officer responsible for carrying out the responsibilities of the PRA. Under 5 CFR 1320.3, defining "agency" as "any executive department", the agency head for our work is the Secretary of HHS. Accordingly, the hierarchy for PRA oversight from the Department to FDA is as follows:

> The Secretary of HHS
> > HHS Chief Information Officer
> > > FDA Chief Information Officer
> > > > FDA PRA Staff

The FDA PRA staff acts as the liaison among FDA program offices, HHS, the Office of Management and Budget (OMB), and the public on all PRA-related matters, facilitating all communications seeking to fulfill the goals of the PRA.

FDA's current inventory of approved information collections is:

Number of Approved Collections	Total Burden Hours	Total Responses	Total Cost
274	181,533,621	946,776,091	$3,736,696,238

Information Collection Activities

FDA seeks OMB approval for collections of information in any form or format, including those contained in **regulations, guidance documents, forms,** surveys and studies, focus groups, customer satisfaction surveys and message testing. FDA also seeks

OMB approval for extensions of currently-approved collections of information.

FDA has several "generic clearances" in place for conducting focus groups, customer satisfaction surveys, rapid response surveys, and user and message testing. Generic clearances can be used when an agency seeks to conduct a series of collection of information using very similar methods, and generally cover collections of information that are voluntary, low-burden, and uncontroversial. The plan for the series of information collections goes through the normal public notice and comment procedures required by the PRA, but the agency is not required to seek further public comment on the specific information collections it conducts under the generic clearance. Instead, the agency may submit the information collection instrument (e.g., survey or questionnaire) directly to OMB for review and approval, which is typically brief.

Regulations

FDA regulations with collections of information may contain substantive regulatory requirements or can be administrative or procedural in nature. When FDA conducts notice-and-comment rulemaking to issue a new regulation, the comment period for the information collection provisions is normally 30 days (usually, a longer period of public comments is open on the substance of the rule). Comments related to the information collection are sent to OMB. At the time of publication, or shortly thereafter, FDA transmits the information collection request (ICR) to HHS, which reviews and certifies the proposed collection. HHS then sends the ICR on to OMB through the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Combined Information System (ROCIS). OMB usually files comment on the proposed rule and approves any collections of information at the final rule stage.

For ongoing collections of information, such as those in regulations, FDA must go through PRA notice and comment procedures and request an extension of OMB approval every three years. For example, OMB Control Number 0910-0001, "FDA Approval to Market a New Drug," covers the information collection associated with the premarket approval requirements for new drugs and every three years since the initial approval in 1977, FDA has requested an extension of the approval from OMB.

Guidance

FDA guidance documents may contain an information collection that is already covered by an OMB approval. In the case of an information collection covered by OMB approval for a regulation, the guidance document would be uploaded in the ROCIS entry for that rulemaking as an "instrument" and would become part of the ICR for the regulation.

FDA also issues "stand-alone" guidance documents that may contain a new information collection requiring approval by OMB. Although FDA guidance documents are generally non-binding, collections of information authorized or mandated by statute are some-

times implemented through guidance, often because the statute directs FDA to issue guidance on how to comply with the statute. Also, FDA may determine it is preferable to issue guidance with recommendations on how to comply with the statute, rather than binding regulations prescribing the means of compliance.

Forms

FDA also uses forms as an efficient way to collect standardized information. For example, FDA has forms that healthcare professionals, patients, and consumers use to submit adverse event reports. The data from these reports helps FDA assess and evaluate the risk associated with the product. These forms, from FDA Form series 3500, allow FDA to consider what action may be necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

Surveys

FDA may conduct surveys prior to policy decisions or rulemaking in order to understand a target audience, behaviors, needs, and opinions. After a regulation or program is in place, formative research can help to refine and improve activities and communications. An example of a recurring FDA survey is the "Food Safety Survey" (approved under OMB Control Number 0910-0345). The supporting statement indicates that the data generated by this survey is a widely accepted source of information on consumer food handling practices and food safety-related knowledge, and is used to prepare important HHS reports such as Healthy People 2020. Telephone interviews are conducted using a random sample of 4,000 consumers, including at least 400 Hispanic-Americans and at least 400 African-Americans. Data from the survey is used in support of FDA's regulatory policy in diverse areas dealing with food safety and supports consumer education by enabling FDA to track consumer knowledge, attitudes, and practices concerning food safety.

The Center for Drug Evaluation and Research (CDER) and the Center for Tobacco Products (CTP) conduct many studies and consult with OMB about survey questions, statistical methods, and intended use of the information. Most studies and surveys request a one-time approval and do not need to be renewed. Discussions between FDA and OMB are often held to resolve differences of opinion on the methodology of surveys FDA wishes to conduct. At times, FDA must revise the data collection instrument (e.g., a questionnaire) to obtain OMB approval. With surveys and other studies, a contract is often involved and extensions may have to be requested if OMB's review and approval are not timely.

Focus Groups

Focus groups are one of the ways FDA can gather information to inform decisions on how to approach a rulemaking or guidance document. Under the generic clearance for FDA focus groups, FDA recently received approval of a focus group entitled, "Studies to Enhance FDA Communications Addressing Opioids and Other Poten-

tially Addictive Pain Medications." Combating opioid misuse, abuse, and addiction has long been a priority for the Agency. Over the last decade or so, FDA has worked to pursue a targeted, science-based, multi-pronged approach that addresses misuse, abuse, and addiction at critical points in the development of an opioid product and in its use throughout the health care system.

In addition to extensive scientific analysis, FDA has focused on efforts to raise awareness and educate the public and health care professionals about opioids and their inherent safety risks, engaging in public communications and outreach through multiple avenues, such as public meetings, public announcements, discussions with experts, and targeted public outreach. The Agency is committed to ongoing efforts to help enhance the safe and appropriate use of opioids and supports a variety of regulatory, educational, communication, and scientific activities aimed at achieving this goal, both on its own and in collaboration with other agencies and stakeholders. FDA has determined further research is needed in order to better understand how to most efficiently and effectively focus resources to educate and communicate about opioids and their safe and appropriate use to various stakeholder audiences.

As a result, this project is designed to provide FDA's Center for Drug Evaluation and Research (CDER) with a better understanding of current knowledge, practice, beliefs, behaviors, and perceptions about opioid use, misuse, and abuse among several key stakeholder audiences, including health care professionals, patients, and other members of the lay public. Gaining this knowledge will assist in more appropriately directed and focused communication efforts aimed at raising awareness and educating the public.

Reducing the Impact on Small Business

ROCIS reserves one field for the number of small entity respondents for which the information collection will have a significant impact. FDA Centers and program experts provide the details regarding the impact on small business. For instance, the Center for Devices and Radiological Health (CDRH) offered these details regarding the impact on small business in the supporting statement for OMB Control Number 0910-0844, "De Novo Classification Process (Evaluation of Automatic Class III Designation)":

> Approximately 95% of U.S. medical device manufacturing establishments have fewer than 500 employees and would, therefore, be considered small businesses. Submission of a De Novo request is voluntary. Any impact on small businesses should be offset by the guidance and consumer assistance available through CDRH Learn training tools and the information posted on FDA's website. FDA aids small business by providing guidance and information through the Division of International and Consumer Education (DICE) within the Center for Devices and Radiological Health. DICE provides technical and non-financial assistance to small manufacturers, through a comprehensive program that includes seminars, workshops, and educational conferences, information materials, contact via

email and the use of a toll-free telephone number. Other members of the Center staff are also available to respond to questions at any time.

Additionally, the Manufacturers Assistance Branch in the Center for Biologics Evaluation and Research (CBER) provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding CBER policies and procedures.

In the supporting statement for OMB Control Number 0910-0614, "Exceptions or Alternatives to Labeling Requirements for Products Held By the Strategic National Stockpile," CBER described the extra help it provides to small businesses:

> This collection of information applies to both small and well as [*sic*] large establishments. Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communications, Outreach, and Development, Division of Manufacturer's Assistance and Training, the Center for Drug Evaluation and Research, Office of Communication, Division of Drug Information, and the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance provide assistance to small businesses subject to FDA's regulatory requirements.

In the supporting statement for OMB Control Number 0910-0014, "Investigational New Drug Regulations," the Center for Drug Evaluation and Research (CDER) explained:

> FDA's authority and responsibility to ensure the safe use of investigational drugs applies to small as well as to large businesses involved in sponsoring drug studies. FDA believes that its responsibility requires the equal application of the regulations to all businesses. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. A small business coordinator has been assigned to the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep FDA management apprised of how regulatory decisions might impact the small business community. To provide additional assistance to small businesses, FDA has established an office whose exclusive concern is to provide small business with help in dealing with FDA regulatory requirements.

FDA's Tools and Resources

FDA provides tools, templates, and resources for Centers to use when drafting their information collection documents:

- Templates for drafting notices for publication in the Federal Register are made available by the Regulations Editorial Section, Office of Policy.

- FDA developed instructions and a template for completing the supporting statement that OMB reviews prior to taking action on an ICR. This template was developed by the FDA PRA Staff based on instructions from OMB and HHS and on the requirements of ROCIS.
- FDA established SOPs for use with information collection in guidance documents through a cooperative effort between the various Centers, the Office of Chief Counsel, and the Office of Policy.
- FDA provides training to Centers on the PRA process, including as a part of the Quality System for Regulations training offered by the Office of Policy.

Thank you again for inviting FDA to testify. I would be happy to answer any questions you may have.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 2 3 2018

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable Steve Chabot
Chairman
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your October 24, 2017, letter and the opportunity to respond to the questions for the record from the House Committee on Small Business's hearing on October 11, 2017, entitled *Evaluating the Paperwork Reduction Act Part II: are Burdens Being Reduced?"* Please find our responses in the attached document.

Again, thank you for your letter. If you have further questions, please contact me, or your staff may contact Thea J. Williams, in EPA's Office of Congressional and Intergovernmental Relations, at williams.thea@epa.gov or at (202) 564-2064.

Sincerely,

Troy M. Lyons
Associate Administrator

Enclosure

Draft Questions for the Record
EPA Response to Committee on Small Business
Hearing: Evaluating the Paperwork Reduction Act Part II: Are burdens Being Reduced?
October 11, 2017

Chairman Chabot

1. **What flexibilities does EPA provide to help small businesses comply with information collections?**

The Environmental Protection Agency (EPA) offers many flexibilities to minimize reporting and recordkeeping burden on small businesses. As part of the regulatory development process, EPA conducts small entity impact analyses, which are discussed in the preamble to our rules and in the associated ICR Supporting Statement. The Regulatory Flexibility Act requires agencies to determine whether a rulemaking has the potential to impose a significant economic impact on a substantial number of small entities (SISNOSE). For any rule that cannot be certified as "no SISNOSE," EPA prepares a formal analysis of the potential adverse economic impacts on small entities, coordinates and chairs a Small Business Advocacy Review (SBAR) Panel, and prepares a Small Entity Compliance Guide. An SBAR Panel consults with small entities expected to be subject to the proposed regulation and develops recommendations for minimizing the rule's impacts on directly regulated small entities.

In developing the regulations for expanding public involvement in the Resource Conservation and Recovery Act (RCRA) permitting process, for example, EPA conducted a small entity impact screening analysis for the proposed rule and determined that there were no small entities significantly impacted. In cases where small businesses are impacted, EPA offers flexibilities to help them comply with information collections, including requiring fewer reporting elements, allowing reporting exemptions, providing additional time to report, or accepting various reporting formats. Examples of specific EPA programs that provide such flexibilities are discussed below.

- Toxics Release Inventory Program - Under 40 CFR §372.22, facilities with fewer than 10 full-time employees are exempt from reporting. In addition, EPA promulgated an alternate threshold for reporting at 40 CFR §372.27 that allows reporters to use a short reporting form (Form A) that includes significantly fewer reporting elements than the standard form (Form R). Although any reporting facility meeting the criteria may use the alternate threshold, this option was adopted in response to a petition from the Small Business Administration and may be particularly advantageous to small entities. Furthermore, EPA created a range reporting option for the Form R at 40 CFR §372.85 that allows releases or transfer of less than 1,000 pounds to be reported in one of three ranges (1 to 10 pounds, 11 to 499 pounds, or 500 to 999 pounds) rather than as a specific estimate. This option was adopted to provide burden reduction for small businesses.

- Information Gathering Rules Under Section 8(a) of the Toxic Substances Control Act - Under 40 CFR 704.3, a manufacturer or importer is generally not subject to reporting if its total annual sales, when combined with those of its parent company (if any), are less than $4 million; or if total annual sales are between $4 and $40 million and annual production or importation volume of the chemical substances, mixtures or categories is less than 45,400 kilograms (100,000 pounds).

- Pesticide Registration Activities under the Federal Insecticide, Fungicide, and Rodenticide Act – During the pesticide registration process, applicants may submit a "Formulator's Exemption Statement" (EPA Form 8570-27) to reduce the data submission burden for registration of a product that uses an EPA-registered pesticide product as the source of its active ingredient. This form exempts the applicant from furnishing the generic data that already were submitted by the company registering the source product. The Agency also has cataloged and computerized its pesticide database so that one can easily determine whether a particular study has been submitted, and by whom it was submitted. This identifies, by chemical and site(s), each item of data in the EPA files. As a result, applicants encounter little difficulty in identifying available data needed to support an application for registration.

- Risk and Technology Review - For the 2011 Petroleum Refinery Risk and Technology Review, EPA provided small refiners with additional time to provide survey responses recognizing the challenges some refiners would face in staffing up quickly to meet deadlines. They were further offered the option to submit handwritten responses or compact discs (CDs) via the mail, instead of required electronic reporting, which sometimes poses challenges for small businesses.

- Greenhouse Gas Reporting Program – The requirements of this program are not applicable to enterprises below a certain size, which exempts many small businesses. In addition, where feasible, the program provides additional flexibilities that benefit small businesses, including accommodating existing GHG emissions estimation and reporting methodologies and providing simplified methodological options and alternative methods to minimize reporting burden.

- Mobile Source Programs - Many mobile source regulations that affect the fuel, vehicle, engine, and equipment sectors contain special provisions and flexibilities for small businesses. Because small businesses may have limited IT resources, EPA designed program registration and compliance information systems to be user friendly and to accept a variety of reporting formats (e.g., web forms, Excel templates, and PDF forms) so companies do not have to purchase any special software.

- Universal Waste Management Program – EPA's Universal Waste Management Program for certain types of common hazardous waste has streamlined standards that already limit the number of information collections for all handlers. In addition, small quantity handlers of Universal Waste are exempt from submitting notifications of Universal Waste management. EPA also does not require small quantity handlers to keep records of their Universal Waste shipments.

- Resource Conservation and Recovery Act (RCRA) – Under RCRA, many very small and small quantity generators (VSQGs and SQGs) are owned by small entities. Both groups are provided flexibilities as they exempt from certain RCRA reporting requirements, such as completing the biennial report, submitting a contingency plan, and export reporting under tolling agreements. In addition, VSQGs are not required to ship hazardous waste using a RCRA manifest.

- Spill Prevention Control and Countermeasure (SPCC) - EPA made several regulatory modifications to reduce the burden of the SPCC requirements (40 CFR part 112) for facilities, including those that are small business. For example, EPA streamlined spill prevention requirements by creating tiered options to comply with the regulatory requirements for smaller oil storage facilities. This included removing the requirement for a Professional Engineer to certify the SPCC Plan and minimizing the number of requirements for a subset of facilities. For facilities, including small businesses, in the electrical sector, EPA provided an option for contingency planning in lieu of secondary containment to comply with the SPCC rule. EPA also reduced the SPCC regulatory burden for farms by providing exemptions for certain types of equipment and containers and by clarifying the definition of facility in the rule to provide flexibility in how a farmer determines whether regulatory requirements apply and to allow a farmer to self-certify the SPCC Plan.

- National Primary Drinking Water Regulations (NPDWRs) - NPDWRs, which are developed under the Safe Drinking Water Act, allow for less frequent monitoring and reporting requirements for small public water systems. For example, under the Lead and Copper Rule, small water systems are allowed to take fewer samples than larger systems. Water systems can also reduce or even eliminate monitoring for certain chemical contaminants if water systems meet certain conditions (i.e., a water system's recent history of no contaminant and/or reporting violations). EPA provides grants to technical assistance providers to support small water systems. State set-asides under the Drinking Water State Revolving Loan Fund can also be used to support small water systems.

- Clean Water Act Effluent Guidelines - Under the Clean Water Act, effluent guidelines, which are national Clean Water Act industrial wastewater discharge requirements, have reduced reporting requirements that help small businesses. The reduced requirement may involve allowing a facility to provide a certification of a certain operational practice, in lieu of collecting and analyzing wastewater samples. For example, when developing a rule that covered dental offices, which are overwhelmingly small businesses, EPA spent considerable effort to minimize reporting requirements. Rather than collecting and analyzing wastewater on an annual or semi-annual basis, which would otherwise be required as a minimum, the rule specifies a one-time submission of a certification that the dental practice is meeting the rule's requirements (e.g., the dental practice uses a dental amalgam separator).

In addition to offering reporting and recordkeeping flexibilities to small businesses, EPA also offers assistance to aid small businesses in complying with the regulations and requirements that affect them. This compliance assistance includes regulatory guidance, fact sheets, outreach materials, hotlines, help desks, webinars, and tutorials. Several examples of compliance assistance offered by EPA are discussed below.

- Multi-lingual Compliance Guides - EPA provided a compliance guide in English and Spanish for small entities that must comply with EPA's Toxic Substances Control Act (TSCA) Title IV Lead Renovation Repair and Painting Program regulations. EPA also provided compliance guides for small entities in different affected industries that must comply with EPA's TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products Program, with translations into several languages.

- Webinars/Video Tutorials - EPA hosted several webinars for small entities that must comply with EPA's TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products Program, and conducted several webinars for entities that must comply with EPA's TSCA Inventory Notification (Active – Inactive) Rule. EPA's Mobile Source program offers video tutorials to provide the regulated community with program registration, reporting and compliance assistance.

- Help Desk Support/Hotlines – Agency systems, such as those for EPA's Mobile Source Program, may offer help desk support, including toll free numbers and email boxes, that are fully staffed to ensure timely responses to inquiries.

In your testimony, you stated that EPA is using information technologies that would reduce paperwork burdens, such as reducing the average reporting time for the Toxics Release Inventory by 13% and a software system that would reduce reporting burdens related to public water systems by 23%. Please explain in more detail how these technologies will reduce reporting burdens on small businesses.

- Toxics Release Inventory (TRI) - TRI is an area where EPA is using information technologies to reduce burden by streamlining the information collection process. TRI has been a flagship for electronic reporting since 2002 and currently involves reporting by more than 20,000 companies annually. This year, EPA enhanced TRI's primary submission instrument, which is used by thousands of facilities to describe their toxic chemical inventories and document significant events (releases, transfers, disposals, etc.). These enhancements reduce average reporting time by 13% for each of the approximately 80,000 forms submitted annually. As part of this effort, EPA evaluated the reporting complexity and was able simplify the application, reducing the number of pages in the application from 193 to 85. Additional enhancements included new features, such as automated data quality checks and improved data upload and prior year data import functionality to help accelerate reporting from year to year. A simplified password resetting process also makes it quicker for companies

to respond. As a result, there is less need for help desk calls, which also results in less burden to end users and less time to complete reporting.

- Public Water Systems Supervision (PWSS) Program – Activities under the PWSS Program, which have record keeping and reporting requirements, are mandatory for compliance with 40 CFR parts 141 and 142. EPA and the states have agreed that burden associated with the PWSS program can be significantly reduced by hundreds of thousands of hours annually through electronic reporting of compliance data. EPA has promoted e-reporting through its September 2016 release of the Compliance Monitoring Data Portal (CMDP), a data tool that allows water systems and laboratories to report data directly to the state data system.

  Safe Drinking Water Information System (SDWIS) Prime is a centralized infrastructure technology system that will replace SDWIS State and other systems, which are hosted and operated separately by each primacy agency. Benefits of this transition to SDWIS Prime include improvements in program efficiency and data quality, greater public access to drinking water data, facilitation of electronic reporting, reductions in reporting burdens on laboratories and water utilities, reductions in data management burden for states, and ultimately, reduction in public health risk.

  Taken together, SDWIS Prime and CMDP will facilitate direct e-reporting, which will increase data accuracy and completeness while decreasing the reporting burden for primacy agencies, utilities and laboratories, the majority of which are small businesses. Primacy agencies can then make more informed decisions and focus their limited resources on public health problems. EPA is actively working with 27 primacy agencies to transition to use of the CMDP, with 4 already using CMDP for official compliance data reporting, and 8 states already using the test version of CMDP with laboratories and water systems. One primacy agency using the CMDP has already documented a 0.4% error rate in lab reporting after only one week using CMDP, compared to a 21% error rate before using CMDP, along with a reduction in primacy agency staff time, because the primacy agency staff no longer need to manage the error reports and data fixes. Instead, CMDP allows the labs to use data validation notifications to identify and fix their own errors, to certify the accuracy of the data, and to provide an electronic signature, all before submitting to the primacy agency. CMDP also has the potential to reduce lab reporting burden because the labs are less likely to resubmit the same sampling data twice. The potential burden reduction when all states utilize CMDP is 867,000 hours.

Representative Kelly

1. **How does EPA measure burden hours to calculate the estimate? How do you know your estimates are accurate?**

2. **How does EPA calculate the cost of an information collection request? How do you know your calculations are accurate?**

EPA has a lengthy and thorough process for developing, and then refining, its estimates for the hour (question 1) and cost (question 2) burden estimates associated with an information collection. Initial estimates are developed by EPA subject matter experts, often as part of the economic analysis step in the regulation development process. These calculations are usually informed by burden calculations in similar existing ICRs, technical literature and feedback from stakeholders, potential respondents, and state/local/tribal governments. Once these initial estimates have been developed, EPA solicits formal public feedback on the collection and the burden estimates. This is done twice, via two separate Federal Register Notices. The first Federal Register notice solicits public feedback on the initial estimates prepared by EPA. EPA gathers further public feedback by conducting one-on-one consultations with several potential respondents. As part of this solicitation for public feedback, EPA may provide a sample of the proposed collection instrument or survey for comment. After revising the initial estimates based on the public feedback, the second Federal Register notice solicits on public comment on the final estimates that are submitted to OMB for review. A summary of the public feedback received, and EPA's response to that feedback, is included in the ICR Supporting Statement. This process is followed both when the ICR is created and again every three years when the ICR is renewed. Listed below are specific examples of how EPA has implemented these practices.

- Estimating Paperwork Burdens Associated with Pesticide Data Requirements - In the case of pesticide data call-ins (DCI), EPA starts with the assumption that the administrative and technical-level paperwork activities comprise about 35 percent of the costs associated with a pesticide testing requirement. This methodology is based on using the average cost estimates for the specific studies requests in each DCI and is only applicable to DCI related data generation. Under this approach, EPA assumes that a more expensive study probably causes the respondent to incur more burden hours and costs than a less expensive study. The public, registrants, key stakeholders, and OMB developed this percentage from numerous sources of information including Agency expertise, consultation with industry, and repeated review of the Agency's information collection activities. To help calculate the burden, EPA maintains an archive of the basic Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) study cost estimates that were developed through surveys of independent testing laboratories, Agency economic analyses, and registrant comments during ICR renewal periods. To the extent possible, EPA uses multiple sources to provide test cost estimates, which are updated as needed.

- Pesticide Data Call-In (DCI) Response Burden Assessment Workshop - EPA held a DCI Response Burden Assessment Workshop with industry stakeholders in December 2013 as part of an effort to reassess its methodology for calculating respondent burdens in response to a DCI. EPA consulted with industry about Agency assumptions, the methodology used to estimate the burden, the hour

estimates for conducting information collection activities, and the accuracy and appropriate distribution of the labor rates. The Agency is using this data to update the 2007 burden methodology guidance document entitled "General Methodology Used to Estimate Paperwork Burden Hours and Costs by the Office of Pesticide Programs for Submission of Required Data/Information for Responding to a Data Call-In Notice." Industry participants included, but were not limited to, representatives from BASF, the Dow Chemical Company, the American Chemistry Council Biocides Panel, Steptoe and Johnson, LLP, Technology Sciences Group Inc., Monsanto, and SC Johnson. Meeting materials comments are part of the docket for the ICR renewal at: EPA-HQ-OPP-2016-0109.

- Consumer Confidence Report (CCR) Rule - The CCR Rule provides that each community water system (CWS) must "mail or otherwise directly deliver" one copy of the report to each customer. Each CWS must also make a "good faith effort" to reach consumers who do not receive water bills by using other means recommended by the primacy agency. A good faith effort to reach consumers should include a mix of appropriate methods including posting on the Internet, mailing to postal patrons in metropolitan areas, advertising the availability of the report in the news media, posting in public places, etc. Over the last 15 years, there has been a great increase in the communication tools available to CWSs to deliver CCRs to their customers. Specifically, electronic delivery of the CCR is an approach that can promote the open exchange of information between CWSs and consumers consistent with Congressional intent and the 1998 rule. The EPA interprets the existing rule language "mail or otherwise directly deliver" to allow a variety of forms of delivery of the CCR, including electronic delivery. During the development of an interpretive rulemaking, EPA worked with industry associations, who developed and implemented pilot tests to determine if regulatory options were feasible for the regulated community. We estimate that we were able to reduce $1,000,000 in compliance burden as a result of the move to electronic delivery for the Consumer Confidence Report Rule, which was revised using, in part, pilot studies together with responses from the regulated community.

3. **At our March hearing, one of the witnesses discussed strategies that agencies use to receive responses from the public on information collection requests. Once of those strategies was for agencies to use federal money to pay respondents for information. An example was a request from EPA where respondents were offered $50 to complete a survey. Is this a regular practice that EPA conducts?**

Offering an incentive to complete a survey is a practice that EPA uses, but only infrequently and only with nominal incentives. In determining whether to provide monetary incentives to survey respondents, EPA considers factors including the difficulty of finding the population of interest, the reporting burden on the respondents, past experience with similar populations, and the effect of increasing the survey response rate on the cost of conducting the survey and

on data quality. EPA identifies its survey methodologies, including use of incentives, in the ICR Supporting Statement Part B, which is subsequently reviewed by the Office and Management and Budget (OMB).

4. **Have there been concerns that paying respondents for information does not a produce a representative sample?**

EPA offers incentives to improve response rates in hard to reach populations, which helps to produce a representative sample. This is consistent with OMB guidance, which states that "[i]ncentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data...."[1] In any instance where EPA utilizes monetary incentives to help produce a more representative sample, the steps taken and the justification for them are explained in the ICR Supporting Statement Part B, which is made available for public comment via two separate Federal Register notices and reviewed by OMB during their ICR approval process.

5. **Should this Committee be concerned that agencies are resorting to paying people to give them information?**

Monetary incentives are only used in a highly-circumscribed set of circumstances and only in a limited manner that is closely defined by OMB guidance with the goal of improving the Agency's ability to effectively fulfill its mandates. EPA is able to obtain the vast majority of the information it needs to carry out its statutory obligations without having to use monetary incentives. When EPA proposes to use a monetary incentive for a certain information collection, that decision is documented in the ICR Supporting Statement Part B. Before approving any such collection, OMB will carefully review the submission to ensure the use of monetary incentives is merited.

Representative Bacon

1. **The PRA encourages agencies to consider whether conducting pilot tests of an information collection is feasible. Does EPA conduct pilot tests of its information collection requests? If so, can you point to an instance where you lessened the burden on small entities after a pilot test?**

When creating or renewing an ICR, EPA consults with a targeted group of stakeholders to test collection instruments, ensure that survey instruments are well designed, and confirm that burden estimates are accurate. All ICRs are then required to go through two rounds of public comment, which give the public an opportunity to comment on both the survey instrument and the projected public burden. The survey instrument is made available via the public docket during this time for stakeholders to review and test. All feedback on the survey

[1] Office of Management and Budget, Questions and Answers when Designing Surveys for Information Collections (January 2006, updated October 2016), (available at https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/pmc_survey_guidance_2006.pdf)

instrument is carefully considered and documented in the ICR Supporting Statement. Listed below are examples of specific instances when EPA employed pilot tests for our collections.

- Chemical Data Reporting (CDR) Reporting - EPA collects information once every four years about the production and use of chemicals under its Toxic Substances Control Act (TSCA) CDR rule. The rule requires that CDR data be reported electronically to EPA. Industry input on the 2012 CDR was used to identify improvements for subsequent reporting cycles to ease the burden on businesses, including small businesses. In the fall of 2015 EPA recruited business volunteers to beta-test the electronic reporting tool, and made changes in response to their input. In addition, after each reporting cycle, EPA evaluates the feedback received from respondents and identifies improvements to the reporting tool As a result EPA has improved usability of the reporting tool by improving the visibility of "OK" button and the clarity of text in certain drop-down screens. EPA also improved functionality to assist in better compliance with reporting obligations by adding additional text and explanations throughout the reporting tool to better explain reporting obligations, warnings, or other issues; changing specific error messages, such as for percent production volume and volume used on site; and improving functionality to "grey out" reporting blocks that are not applicable, based on the information that the submitter enters into the system. Further, EPA corrected basic functionality of the reporting tool, including correcting an initial colon that prepopulated a data field and a CBI checkbox that was enabled differently based on how the text field was populated; investigating methods to improve the chemical identification validation speed; correcting a problem with certain information getting updated in the PDF version of the entered data.

- Toxics Release Inventory Made Easy (TRI-Me) Submissions - When EPA first launched TRI-MEweb, the online software facilities use to complete and submit TRI reporting forms, the Agency pilot tested it with reporting facilities as part of the development process. TRI-MEweb eases burden on reporters by prepopulating fields, providing data validation, and generally supporting a facility as it completes a form. EPA also uses feedback from reporting facilities on TRI-MEweb to develop enhancements to the software for successive reporting years, Some of the changes that have resulted include incorporating the ability to update technical contact staff data, making the process of bypassing the use of the TRI-ME map to directly input a stream name where a facility is releasing chemicals easier to navigate, allowing facilities to use TRI-MEweb to notify EPA when they would not be reporting to TRI, improving the interface for editing a chemical release value on the Form R for prior years, improving communications associated with data quality error alerts, and proactively working with reporters on the status and completion of their submissions via automated email correspondence and reports.

2. **Your written testimony states that EPA will obtain information from other federal sources instead of the public when possible. How does EPA identify these federal sources?**

EPA uses a multi-pronged approach to discern whether its proposed and current collections are either unique and necessary or duplicative. EPA first searches all available sources – published and unpublished literature, databases, and all data available from EPA programs and offices and other federal entities – and considers all relevant information. Additionally, as part of EPA's regulatory development process, EPA convenes intra-agency workgroups that would identify any information already available within the Agency. Also part of the regulation development process is an interagency review, which allows other federal agencies to identify areas of duplication. During this time, EPA also works with the regulated entities to formulate the survey instruments to ensure that questions asked are relevant and accessible and, through that process, learns about information facilities have already submitted to other agencies or departments. If existing data are sufficient for the proper performance of EPA functions, EPA will not collect additional information. As an example, for the Spill Prevention Control and Countermeasure (SPCC) and Facility Response Plan (FRP) requirements in 40 CFR part 112 and the Risk Management Program requirements (40 CFR part 68), EPA allows facility owner/operators to reference information/records maintained for other regulatory agencies when meeting the EPA requirements. However, when existing information is not sufficient or was produced or obtained in a way that makes EPA doubt its validity, the Agency will determine whether information collection is necessary.

In addition to all of the efforts EPA undertakes to ensure there are not are not duplicative collections, the public is also given the opportunity to review the survey instrument and identify any potential duplications during the two public comment periods required when the ICR is created and again every three years when the ICR is renewed.

When appropriate, EPA also shares information it gathers so that other entities do not need to duplicate those efforts. For example, in some mobile-source programs, EPA shares data collected with co-regulators such as the California Air Resources Board (CARB) and the National Highway Traffic Safety Administration (NHTSA). This sharing is automated so that reporters do not have to submit the same information to multiple agencies. Described below are additional specific examples of the steps EPA takes to prevent duplicating collections of other federal agencies.

- Inventory of the Supply, Trade, and Use of Mercury under the Toxic Substances Control Act (TSCA) - The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), enacted on June 22, 2016, implemented reforms to TSCA. Among other changes to TSCA, the Lautenberg Act amended TSCA section 8(b) to require EPA to establish: (1) an inventory of mercury supply, use, and trade in the United States; and (2) reporting requirements applicable to any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process not later than June 22, 2018. In addition to using this information for the mercury inventory, this information would be used by the U.S. Government to assist in its implementation of the United Nations Minamata Convention on Mercury.

Prior to developing its initial inventory, EPA reviewed federal and state reports and databases, among other sources, in order to assemble a collection of available information on mercury, mercury-added products, and manufacturing processes involving mercury. In reviewing data obtained, the Agency found that its baseline of data lacked the specificity and level of detail required to develop a mercury inventory responsive to TSCA section 8(b)(10)(D) or to be useful to inform mercury use reduction efforts for both the public and private sectors.

TSCA section 8(b)(10)(D)(ii) directs the Agency to "coordinate the reporting . . . with the Interstate Mercury Education and Reduction Clearinghouse" (IMERC) to avoid duplication. Furthermore, TSCA section 8(a)(5)(a) states "[i]n carrying out [TSCA section 8], the Administrator shall, to the extent feasible . . . not require reporting which is unnecessary or duplicative." While developing this proposed rule, the Agency coordinated with IMERC and Northeast Waste Management Officials' Association to ensure that data collected in accordance with the proposed reporting requirements and existing IMERC reporting requirements would not be duplicative and that information collected would be shared to the greatest extent practicable. EPA also reviewed three other data collection systems applicable to supply, use, and trade of mercury (including mercury-added products and mercury used in manufacturing processes): the TSCA section 8(a) Chemical Data Reporting rule, the Toxics Release Inventory (TRI) program, and the U.S. International Trade Commission Interactive Trade DataWeb (USITC DataWeb). EPA tailored the proposed reporting requirements to such that submitters would automatically skip certain data fields if they self-identified as submitted Mercury information to IMERC or to the TSCA CDR.

- Framework Rules Implementing Toxic Substances Control Act (TSCA) Amendments - Prior to and during the prioritization and risk evaluation process, EPA engages and collaborates with partner federal agencies. TSCA specifically authorizes other federal agencies, at EPA's request, to: (1) make their services, personnel, and facilities available to the Agency, (2) provide information, data, estimates, and statistics to the Agency, and (3) grant EPA access to all information in its possession as the Agency may reasonably determine to be necessary for the administration of the Act. EPA expects to leverage relevant information collected by other agencies, e.g., information on occupational and consumer exposures, in evaluating the risks of chemicals under TSCA. In addition, if EPA obtains information under TSCA related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Agency, TSCA requires that the Agency make that information available to the relevant Federal agency or office of EPA.

- Greenhouse Gas Reporting Program - When developing this collection, extensive steps were taken to evaluate existing programs and data currently available to confirm that the program would not duplicate other information collections. The other programs and data sources reviewed included the methodologies used in the Greenhouse Gas Inventory of Emissions and Sinks, the U.S. Department of Energy's

Energy Information Administration's quarterly inspection reports from underground coal mines, and EPA's Acid Rain Program. Where opportunities were identified, the Greenhouse Gas Reporting Program leverages data reported to other agencies. For example, EPA allows underground coal mine reporters to use data reported to Mine Safety and Health Administration.

3. **When EPA is obtaining information from another agency such as the National Oceanic and Atmospheric Administration (NOAA), do the respondents who gave their information to NOAA know that EPA will also be using their information?**

The Coastal Zone Act Reauthorization Amendments (CZARA) requires states and territories with coastal zone management programs that have received approval under CZARA to develop and implement coastal nonpoint programs. CZARA establishes joint review and approval of the coastal nonpoint programs by NOAA and EPA.

Representative Norman

1. **How does EPA periodically review existing information collection requirements to determine whether the information collection is still necessary or should be changed or removed?**

EPA continually examines what Agency data collection efforts can be streamlined to reduce reporting and recordkeeping burden, particularly when the ICR or the underlying regulation are being reviewed. EPA is required to review each information collection at least every three years as part of the ICR renewal process mandated by the Paperwork Reduction Act. In addition, many rulemakings undergo to a periodic review, which is another opportunity to review information collection requirements. EPA takes these opportunities to review the existing regulatory and statutory requirements to ensure that the collection is necessary or to determine that the collection needs to be revised or ended.

In in addition to EPA's evaluation of information collections, stakeholders are also given the opportunity to provide input on EPA collections and their necessity as part of both the ICR development and renewal processes and the regulatory development process. EPA considers this input when determining if an information is still necessary. As part of the ICR renewal process, for example, EPA conducts consultations with a limited number of stakeholders, solicits new public feedback through Federal Register Notices, and certifies in the ICR Supporting Statement that a collection continues to meet a valid need that is properly authorized in law or regulation. The ICR Supporting Statement also discusses the need and use of the information collection. EPA takes care to design the regulatory reporting and recordkeeping requirements to minimize the burden of information collection and to maximize the utility of the collected information.

If it is determined that there is information that no longer needs to be collected, removing those elements from a collection may be done as part of the ICR renewal process, but more

often requires revising the underlying regulation. As part of ongoing burden reduction efforts, EPA is committed to eliminating reporting or recordkeeping requirements that are determined to be unnecessary. Described below are examples of when EPA reviewed existing collections to determine if changes needed to be made.

- Significant New Alternatives Program (SNAP) ICR Renewal - During the process of renewing the SNAP ICR, for example, the Office of Air and Radiation involved a group that was representative of the reporting universe in evaluating the Agency's burden/cost and asked them to broadly comment on the ICR as a whole. This comprehensive review of the information collected led to the elimination of certain information no longer considered necessary and changes to the formatting to improve clarity and reduce burden.

- Revisions to the Greenhouse Gas Reporting Rule - In recent rulemakings to revise the Greenhouse Gas Reporting Rule, EPA examined areas where data collections can be streamlined or otherwise reduced for reporters – focusing in particular on areas where data elements are no longer used for data analysis. As a result, a final rule revised the requirement for underground coal mines to make it easier to exit the program when a facility closes down. The Agency also revised the requirements for municipal solid waste landfills to eliminate requirements to report the surface area by cover type.

- National Primary Drinking Water Regulations (NPDWRs) – All NPDWRs under the Safe Drinking Water Act (Act) are reviewed and a determination is made as to whether to revise the regulation at least every six years. The review includes evaluating current health effects data, along with information on treatment, analytical methods, occurrence and exposure, to determine if a revision to the drinking water standard is appropriate to protect public health. Such revisions in the regulation could determine frequency of monitoring, reporting, and recordkeeping. During the last of these reviews there was a decrease of 344,195 hours in the total estimated respondent burden compared with the ICR previously approved by OMB at that time. The decrease was a result of removing burden associated with variances, exemptions and constructed conveyances to reflect no new activity in these categories; updating relevant baseline information for each rule with the most current and accurate information available; and updating burden to incorporate the results of consultation with stakeholders.

2. **Since EPA is responsible for many different laws and regulations, how does EPA keep track of its authority to collection information?**

EPA's ICR Program, established and headed by EPA's Chief Information Officer (CIO), is responsible for ensuring agency-wide compliance with and effective implementation of the information collection policies prescribed by the Paperwork Reduction Act. This program maintains an inventory of all proposed and ongoing collection of information and oversees

submission of Agency ICRs to OMB for review and approval. This inventory is maintained in an Agency-wide system that also assists in tracking, developing, reviewing and approving Agency ICRs. This system contains comprehensive information about every ICR package including data on its history of approvals, current expiration date, collection methodology and instruments, burden calculations, and statutory or regulatory authority. EPA also relies on the information available via OMB's ICR database (made publicly available via Reginfo.gov). Reports available via this database include an inventory of all Agency ICRs and their current expiration dates.

Representative Blum

1. **There are instances of information collection requests that are posted on the Office of Information and Regulatory Affairs (OIRA) that have hundreds or thousands of hourly burdens on respondents, but there are zero costs. Why are there instances where this is a large hourly burden to collect the information, but zero costs?**

   Per OMB guidance,[2] the costs submitted by federal agencies (which are recorded in OMB's ICR database and displayed publicly at Reginfo.gov) include capital and operation and maintenance (O&M) costs associated specifically with the collection, recordkeeping, or dissemination of the information cited in the ICR, but exclude labor costs. Additionally, that guidance instructs agencies to also exclude costs for investments or purchases made to achieve regulatory compliance with requirements not associated with the information collection, as part of customary and usual business or private practices, or that are already accounted for in the reported hourly burden. Because of those exclusions, EPA has several ICRs listed in Reginfo.gov as imposing hourly burden but no cost burden. While labor cost estimates are not directly entered in OMB's ICR database or displayed as a separate field on Reginfo.gov, they are included in ICR Supporting Statement.

Representative Knight

1. **What is EPA doing to address concerns that agencies are not utilizing more electronic forms and other paperwork requirements?**

   As part of the ICR process, EPA evaluates and decides whether the collection of information could involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitted electronic submission of responses. The ICR Supporting Statement includes explanation of the decision. Further, under the Government Paperwork Elimination Act, agencies are required to provide, where practicable, an electronic reporting option.

   In the last several years, EPA rolled out electronic reporting platforms as part of its E-Enterprise for the Environment Initiative and the last administration's Digital Government Strategy. In 2013, EPA established an Agency-wide policy on e-reporting that calls upon managers and staff to start with the default assumption that new regulatory reporting

[2] See ROCIS HOW TO Guide for Agency Users of the Information Collection Request (ICR) Module, dated September 1, 2017 (available at www.rocis.gov)

requirements will be satisfied electronically. Electronic reporting reduces burden for reporting and recordkeeping, improves data quality, and streamlines communication between the submitters and EPA.

Additionally, over the last decade, EPA, together with its State and tribal partners, has made considerable progress in converting paper-based reporting by industry to electronic reporting, leveraging EPA's electronic reporting gateway, the Central Data Exchange (CDX) and supporting partner-based efforts through the Exchange Network, the internet-based system used by state, tribal and territorial partners to securely share environmental and health information with one another. Currently, CDX, the application used by the EPA and stakeholders to manage electronically transmitted environmental data, supports electronic reporting for over 100,000 active industry users filing over two million transactions a year across over 120 EPA program data collections.

Efforts are ongoing to identify and address remaining legacy reporting processes in the Agency. This year, EPA conducted a baseline assessment across all EPA programs and identified roughly 60 environmental reporting activities that are still using paper forms and reports. While these are not all of the remaining paper-based reporting requirements, they represent reports that are burdensome to EPA in terms of volume and complexity, and most likely present challenges to industry and EPA partners as well. Using the information from this assessment, EPA identified several reports that may bring targeted efficiencies to both EPA, industry, and/or State or tribal partners relatively quickly. Some examples include: 1) automated notifications for submitters reporting chemical safety information under TSCA; 2) E-filing options for National Emissions Standards for Hazardous Air Pollutants; and 3) advancing work in automating of partner-to-partner transactions such as the electronic filing of State Implementation Plans for the air program. EPA will address such reporting processes as resources allow.

Additional initiatives to implement electronic reporting are described below.

- Electronic Data Submissions for Toxic Substances Control Act (TSCA) Programs - EPA uses electronic data submission for many of its programs including TSCA section 4 test data submissions, TSCA section 5 new chemical notices, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(b) Chemical Data Reporting (CDR), TSCA section 8(d) health and safety data reporting rules, TSCA section 8(e) notifications of substantial risk, TSCA Title VI submissions from accreditation bodies and third-party certifiers, and EPCRA section 313 reporting to the Toxics Release Inventory.

  The reporting application for CDR uses the registrant's company and submitter information to populate applicable data elements. The applications contain validations that inform users of the required vs. optional fields, required formats, and if there are any exceptions or regulatory requirements they should be aware of. For example, the CDR application lets a user know if their chemical is exempt from reporting, or if it falls under other specific regulations that may require different reporting

requirements. The CDR application also facilitates the use of XML and CSV file uploads to make the population of large amounts of data easier. Not only can new XML files be generated and uploaded, but the CDX copy of record contains an XML file of completed submissions that can be uploaded and edited to create a new submission. In addition, to comply with the Lautenberg Act requirement to provide substantiation, some of the new applications allow a user to copy substantiations from other forms within the submission, greatly reducing the amount of data entry that needs to be completed.

- Electronic Submission Options for EPA's Pesticide Program - EPA is taking steps towards offering a fully electronic submission option for the pesticide program using a web portal. For the past few years, applications for pesticide registration have been submitted electronically, including forms, studies, and draft product labeling. Applicants need not submit multiple electronic copies of any pieces of their applications. EPA created guidance for formatting and submission of registration information. See http://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications. EPA also clarified for pesticide applicants in PR Notice 2011-3 that the requirement to submit multiple copies of data is applicable only to paper submissions. Similarly, EPA interprets the requirement to submit five copies of draft labeling in 40 CFR 152.50(e) to apply only to applications made on paper. As electronic submissions are easily reproducible, EPA will accept electronic applications containing one copy of all the required elements. As a result, currently, EPA rarely receives paper copies of application materials. In September 2015, EPA opened the Pesticide Submission Portal (PSP) for pesticide applicant use. This web-based portal allows applicants to submit some of the basic application forms and information. To guide the public through the submission process, EPA has created a User guide, and other helpful information. See http://www.epa.gov/pesticide-registration/e-submission-resource-documents-assembly-electronic-packages-and-discs. The enhanced electronic submissions program accepts submissions for numerous regulatory actions; including, new pesticide active ingredients, amendments to registered pesticide products, experimental use permits, inert ingredient requests and petitions for food tolerances.

- Electronic Reporting Option for Pesticide Producing Establishments - On January 2, 2016, EPA launched a new voluntary electronic alternative to the decades-old process of registering and annual reporting for pesticide producing establishments using hard copy forms sent via regular mail to EPA. Under FIFRA Section 7, all active domestic and foreign pesticide producing establishments, regardless of whether or not the establishment produced or distributed a pesticide, active ingredient or device must submit to EPA an annual pesticide establishment report. With this new electronic Section Seven Tracking System (SSTS) pesticide producers can now enter annual production reports directly into the EPA database, helping to streamline annual reporting and potentially decrease annual agency burden by more than 50%. These reports are a critical means of tracking pesticides through commerce and knowing their origins. By providing more accurate and real-time information to Customs & Border Protection Agencies, SSTS will help to protect our borders and citizens from

illegal importations. SSTS will also benefit business owners, by saving the 14,910 registered pesticide establishments time and money; and allowing companies to bring new products to the market faster.

SSTS is housed on the EPA Central Data Exchange (CDX) and utilizes LexisNexis Identity Proofing to ensure protection of Confidential Business Information. LexisNexis also helps to reduce the burden on businesses which previously had to submit a letter to EPA on company letterhead every time their agent or company information changed, now they can submit this all electronically.

- National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule - EPA
  published the 2015 NPDES Electronic Reporting Rule, which modernizes Clean Water Act (CWA) reporting for municipalities, industries and other facilities. The rule replaces most paper-based NPDES reporting requirements with electronic reporting. Specifically, the rule requires regulated entities to report information electronically, instead of filing written paper reports. These reports include: Discharge Monitoring Reports (DMRs); Notices of Intent to discharge in compliance with a general permit; and other specified program reports. The rule also requires states and other regulatory authorities to share data electronically with EPA. The data that these regulatory authorities will share with EPA includes permit, compliance monitoring (e.g., inspection), violation determination, and enforcement action data.

- Greenhouse Gas Reporting Tool - All data collected for the Greenhouse Gas Reporting Program (GHGRP) is done electronically via the electronic Greenhouse Gas Reporting Tool (e-GGRT). The e-GGRT is a web-based reporting tool that leverages existing Agency systems and provides innovative real-time data quality feedback features to assist users and streamline data collection. Data that is expected to be consistent is carried over (pre-populated) from year-to-year by the tool to reduce burden on reporters, including small businesses. This includes facility identifier information, unit level identifier information and configurations. The program has also worked with states to address overlapping GHG data collection. For example, e-GGRT supports Washington State's greenhouse gas reporting program to reduce burden on reporters that are subject to both state and federal GHG data requirements. The program has also worked with EPA's voluntary methane program ICRs to leverage the e-GGRT platform to collect related data under EPA's Methane Challenge and Landfill Methane Outreach Programs, reducing burden on reporters who are both subject to the GHGRP and participants in those voluntary programs.

- Compliance and Emissions Data Reporting Interface (CEDRI) - Electronic information collection and data submission are strongly promoted across EPA's air programs. For stationary sources, EPA has developed the Compliance and Emissions Data Reporting Interface (CEDRI), which is located on the EPA's Central Data Exchange (CDX),. As part of this effort to facilitate electronic data submissions, the EPA developed and released the Electronic Reporting Tool (ERT), which stakeholders use to electronically create stationary source sampling test plans and

reports. The ERT creates a complete electronic report for submittal to the Agency by calculating test results from data that stakeholders provide. These combined developments are intended to reduce burden on all reporting entities, including small businesses. For example, the EPA modified CEDRI to accept ICR responses from affected sources in the Plywood and Wood Composite Products manufacturing sector, allowing them to voluntarily electronically submit ICR responses to EPA. The Agency is also working on a larger effort under its E-Enterprise for the Environment Initiative to consolidate reporting requirements common to a number of different air emissions collection programs into a single common electronic form which, once fully implemented, will significantly reduce burden on reporters.

- Safe Drinking Water Information System (SDWIS) Prime/Compliance Monitoring Data Portal - EPA is working with states to develop SDWIS Prime, which is a centralized infrastructure technology system that will replace the current data system used by most state programs. SDWIS Prime facilitates electronic reporting, which results in improvements in program efficiency and data quality, greater public access to drinking water data, facilitation of electronic reporting, reductions in reporting burdens on laboratories and large and small water utilities, reductions in data management burden for states, and ultimately, reduction in public health risk. In addition, EPA has developed the Compliance Monitoring Data Portal, which is an electronic reporting system for drinking water data. EPA is working with several states to transition to this electronic reporting tool. Some states, such as Utah, are already using the system. These two tools, together, will facilitate direct e-reporting, which will increase data accuracy and completeness while decreasing the reporting burden for primacy agencies, large and small utilities and laboratories. This will reduce the burden on both state programs and regulated water systems, as less time will be spent on correcting data errors.

2. **For the information that you collect electronically, what is EPA doing to protect small businesses' privacy and sensitive data?**

   Privacy and sensitive data collected from individuals filing on behalf of small businesses (typically the small business owner or operator) are protected under the Privacy Act and are used solely for the purposes of conducting transactions with the Agency. Both user identity and confidential information are encrypted with certified approaches and technology and are used for the sole purpose of the intended collection. Use and protection by EPA is also described in the applicable System of Record Notice and security plan, as well as EPA program system procedures for handling confidential business information.

3. **Your written testimony describes information technologies that EPA is using to streamline the information collection process. Could you explain in more detail what those technologies are and how they will reduce reporting burdens on small businesses?**

   EPA uses technologies and shared services to streamline the information collection process, enable electronic reporting and improve data quality. Electronic reporting reduces reporting burdens on small businesses by streamlining the reporting process, prepopulating data, reusing data for multiple purposes, improving data quality to minimize rework, streamlining

communications between respondents and providing access to help features such as online videos and tutorials. In addition, EPA's Central Data Exchange (CDX), the Agency's electronic reporting gateway, utilizes additional information technologies to further reduce burden on respondents, including allowing electronic signature as an alternative to conventional paper-based wet-ink signatures, consolidating electronic payments with real-time reporting, and providing self-serve password resets. EPA's shared services approach to CDX means it can be leveraged by its partners, including States and Tribes, so they do not have to develop their own services. Finally, based on EPA's commitment to streamlining information collection and reducing unnecessary burden, surveys are conducted continuously to identify opportunities to improve the user experience.

United States Department of the Interior

OFFICE OF THE SECRETARY
Washington, DC 20240

DEC - 1 2017

The Honorable Steve Chabot
Chairman
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Chairman Chabot:

Enclosed are responses prepared by the U.S. Fish and Wildlife Service to questions submitted following the Committee's October 11, 2017 oversight hearing on the Paperwork Reduction Act.

Thank you for the opportunity to provide this material to the Committee.

Sincerely,

Christopher P. Salotti
Legislative Counsel
Office of Congressional and Legislative Affairs

Enclosure

cc: The Honorable Nydia M. Velazquez
Ranking Member

QUESTIONS FOR THE RECORD
Submitted to Stephen Guertin, Deputy Director for Policy
U.S. Fish and Wildlife Service
"Evaluating the Paperwork Reduction Act Part II: Are Burdens Being Reduced?"
House Committee on Small Business
October 11, 2017

Chairman Chabot

1. What flexibilities does the Service provide to help small businesses comply with information collections?

Response: The U.S. Fish and Wildlife Service (Service) strives to reduce the information collection burden on the public, particularly small businesses, as much as possible. For example, we are actively working to automate our most frequently used permit applications via the Service's new ePermits System. We are modernizing the permit process from the current Adobe PDF form to a new streamlined electronic forms process, which will enhance the user experience and simplify the process for permit applicants. Once this new process is in place, the amount of time necessary for an applicant to apply for a permit will be drastically reduced. The Service also plans on eliminating the necessity for physical mail-in applications, thus reducing costs as well. With this modernized process, an applicant will be able to track and get notifications on the status of their application as it moves along the process.

In addition to targeted improvements in our permit processes, the Service also provides small businesses and other parties the opportunity to seek special accommodations related to our information collections. All information collection instruments administered by the Service include the contact information for the Service's Information Collection Clearance Officer (ICCO). This information is included to solicit feedback regarding our burden estimates and other aspects of the information collection on an ongoing basis. Although we are unaware of any specific requests from small businesses for assistance with complying with Service collections of information, we are committed to working with the requestor to determine the appropriate accommodation to ease any burden. If the requested accommodations are outside the scope of the approved information collection, the Service's ICCO will work with the program to revise the information collection for approval by OMB, if appropriate.

2. In your testimony, you stated that the Service reported to the Office of Management and Budget's Office on Information and Regulatory Affairs (OMB-OIRA) for its 2017 Information Collection Budget that the Service had a decrease of 24,863 burden hours and a decrease of $497,080 in annual costs. What steps did the Service take to create this decrease in burden hours and costs? How can this be applied to other agencies to reduce their paperwork burdens on small businesses?

Response: The reductions reported to OMB in the 2017 Information Collection Budget were the result of a thorough review of existing information collections that allowed for the elimination of unnecessary reporting requirements; changes in burden estimates due to decreased submissions;

and the discontinuation of completed information collections that were no longer needed. Examples of collections discontinued by the Service include:

- Monitoring of the Peregrine falcons, closed following the species' recovery and delisting under the Endangered Species Act;
- Reporting requirements for the Coastal Impact Assistance Program, which no longer issues financial assistance awards; and,
- Surveying of residents' attitudes on jaguar conservation, which is now completed.

The Service remains keenly aware of the need to monitor information collections affecting small businesses. Our ICCO works with the relevant programs to identify appropriate actions to minimize the burden placed upon small businesses. The Service's ICCO also works closely with agency rulemaking staff to thoroughly analyze all documents to determine whether or not information collection is included, changed, discontinued, and/or relocated within the regulations, or if they include new information collections requiring OMB approval. The close coordination between the ICCO and agency rulemaking staff has helped the Service to continuously review and update many of our collections of information. Other agencies would likely benefit from the same level of collaboration between their ICCO and rulemaking staff.

Representative Kelly

1. How does the Service measure burden hours to calculate the estimate? How do you know your estimates are accurate?

Response: The Service's ICCO works with Service programs to review actual submission statistics for the previous 12-24 months to develop a sound understanding of the anticipated number of respondents and responses for the renewal period. If appropriate, we adjust the burden estimates to account for any unusual events, pending rulemaking actions, or anticipated changes in statutory requirements.

The Service endeavors to validate our time burden estimates through targeted outreach to individuals familiar with the collections of information. The targeted outreach solicits feedback on:

- The necessity and practical utility of the information collection;
- Estimate of the time required to comply with the information collection;
- Any suggestions to enhance the quality, utility, and clarity of the information collection; and,
- Ideas to minimize the burden on respondents.

Based on the feedback from targeted outreach, the Service has: revised our burden estimates, as appropriate; consolidated similar information collection instruments to streamline compliance; and, automated processes to reduce burden time on respondents whenever possible.

2. How does the Service calculate the cost of an information collection request? How do you know your calculations are accurate?

Response: The Service's ICCO works with Service programs to review actual submission statistics for the previous 12-24 months to develop a sound understanding of the anticipated number of respondents and responses for the renewal period. If appropriate, we adjust the burden estimates to account for any unusual events, pending rulemaking actions, or anticipated changes in statutory requirements.

When calculating the dollar value of the "annualized labor hours burden" estimates for information collections, the Service uses the most recently published Bureau of Labor Statistics "Employer Costs for Employee Compensation". As appropriate, we use more specific labor cost tables when dealing with significantly higher or lower paid respondents in industries such as oil and gas (higher) or international manufacturing (lower).

The Service calculates the "non-hour cost burden" estimates associated with permit application fees and other allowable costs using data from the previous 12-24 month period, as well as data from the targeted outreach process.

Representative Bacon

1. The PRA encourages agencies to consider whether conducting pilot tests of an information collection is feasible. Does the Service conduct pilot tests of its information collection requests? If so, can you point to an instance where you lessened the burden on small entities after a pilot test?

Response: The Service has not recently conducted any pilot tests of its information collection requirements.

2. How often does the Service work with other agencies such as EPA or the National Oceanic and Atmospheric Administration (NOAA) to see whether there is any overlap in paperwork requirements from other agencies?

Response: The Service strives to prevent duplicative and overlapping information requirements in several ways. First and foremost, we rely on the expert knowledge of our program staff. Program staff work closely with their counterparts in other agencies (e.g., EPA and NOAA) and can identify, and eliminate, potential duplicative information collections under laws that we have split jurisdiction with another agency.

When seeking OMB-approval for new collections of information, the Service's ICCO first reviews existing approvals published on OMB's website to make sure that we are not duplicating the information collection requirements of other agencies. We also use government-wide common forms, when applicable. The ICCO also works closely with her counterparts at other agencies and actively participates in the Council of Agency PRA Officers (CAPRA) to share information and identify potential duplication. CAPRA consists of federal agency/departmental level PRA Officers who ensure compliance with the Paperwork Reduction Act.

The Service details efforts to identify and eliminate duplication in the supporting statement for all of our information collections.

Representative Norman

1. How does the Service periodically review existing information collection requirements to determine whether the information collection is still necessary or should be changed or removed?

Response: The Service's ICCO thoroughly reviews all rulemaking actions to provide an ongoing analysis of existing information collections to determine if they are still accurate and necessary. Additionally, the Service's ICCO initiates reviews of all collections approximately 9 months in advance of the collection renewal to determine whether the collection is still necessary and, if so, whether any requirement has changed or is no longer necessary. If appropriate, the ICCO works with the Service program to submit a request to OMB to revise or discontinue collections with changed or unnecessary requirements.

2. Since the Service is responsible for many different laws and regulations, how does the Service keep track of its authority to collect information?

Response: The Service's programs and rulemaking staff immediately notify the ICCO of any changes to Service authorities that affect existing collections of information or necessitate a new collection of information. The ICCO works closely with the appropriate program to determine the impact of such changes on collections to determine what action, if any, is deemed necessary.

3. In your testimony, you mentioned that the Service is taking steps to streamline the NEPA (National Environmental Protection Act) process. Can you explain in more detail what those steps are?

Response: The Service is working with the Department of the Interior (Department) to implement Secretarial Order 3355 on Streamlining National Environmental Policy Act (NEPA) Reviews and Implementation of Executive Order 13807, "Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects". One of the primary directives of the Secretarial Order is to ensure timely completion of Environmental Impact Statements (EIS) by setting a target of one year from the issuance of the Notice of Intent to prepare an EIS to the completion of the Final EIS. The Secretarial Order also instructs bureaus to reduce paperwork and streamline the NEPA process by setting a page limit of 150 pages for EISs, or 300 pages for unusually complex projects. The Service is also considering other actions to streamline the NEPA process such as: developing tools such as Environmental Assessment templates to provide a consistent and streamlined approach to NEPA analysis and preparation; conducting a review of Categorical Exclusions to identify those needing updates and opportunities for the development of new Categorical Exclusions; and promoting the use of programmatic NEPA analyses to streamline routine actions.

4. We learned in a hearing in September that the NEPA process can take many years to complete. How does your agency plan to make sure NEPA decisions are made in one year?

Response: The Secretarial Order instructs bureaus to implement improvements, identify impediments, and recommend actions to streamline the NEPA review process. Some of the actions the Service is exploring include providing staff with training and tools such as templates, streamlining the document-approval process, and promoting early engagement by Service staff in NEPA reviews, especially for priority projects.

Representative Blum

1. There are instances of information collection requests that are posted on the Office of Information and Regulatory Affairs (OIRA) that have hundreds or thousands of hourly burdens on respondents, but there are zero costs. Why are there instances where there is a large hourly burden to collect information, but zero costs?

Response: The Regulatory Information Service Center & OIRA Consolidated Information System (ROCIS) only captures "non-hour cost burden" estimates associated with information collections, not "annualized labor cost burden" estimates associated with information collections. The Service reports annualized labor cost burdens to OMB in the Supporting Statement "A", but OMB does not track that data through ROCIS.

When applicable, the Service does report "non-hour cost burden" estimates in ROCIS. These cost burden estimates take into account costs associated with generating, maintaining, and disclosing or providing the information (including filing fees paid for form processing, permit/application fees, etc.). Several of the Service's information collections have no associated non-hour cost; thus, the dollar amount reported through the ROCIS platform will be zero.

Representative Knight

1. What is your agency doing to address concerns that agencies are not utilizing more electronic forms and other paperwork requirements?

Response: Through the use of online platforms, the public can quickly and easily conduct business with the Service that was previously more time consuming. The Service has endeavored to make processes easier for the public, as well as to make our operations more efficient, by making forms available electronically through our website. The Service has nearly 200 forms available to the public online, ranging from the "Horseshoe Crab Tagging Release Form" to the "Oil and Gas Operations Special Use Permit Application".

Another example of the Service's use of online platforms is the recently launched electronic version of the Federal Duck Stamp that allows users to buy stamps online through participating state licensing systems. A printed receipt, available immediately, is valid for 45 days, during which time a physical duck stamp is mailed. There currently are 23 states that participate in the e-stamp program. The stamp represents the permit required by the Migratory Bird Treaty Act of 1918 to hunt waterfowl and is required to be carried by every waterfowl hunter who is more than 15 years old.

2. For the information that you collect electronically, what is your agency doing to protect small businesses' privacy and sensitive data?

Response: The information that is collected through public-facing electronic forms is stored and protected within the DOI/FWS network on the relevant systems. Depending upon where the data is stored, it is generally secured with access level control (permissions); is encrypted while in transit; and can be further protected within associated databases. Once the information is collected and stored within the Service system, the data is only accessible to Service employees unless specified and approved for public consumption.

Chairman Chabot

Q1. What flexibilities does DOL provide to help small businesses comply with information collections?

A1. The Department's discretion is largely dependent on the requirements in the underlying statute however, DOL provides flexibilities when appropriate. When implementing information collections, the program agencies strive to implement collections in a way that minimizes the burden for all businesses, including small employers.

In addition, all DOL program agencies that administer worker protection programs publish compliance assistance materials on specific topics which are available through the agency website. DOL also provides toll-free numbers that any member of the public, including small businesses, may call to receive guidance or answers to their questions.

As mentioned in the testimony, the DOL's Employment Law Guide describes the major statutes and regulations administered by the Department that affect businesses and employees. In addition, DOL's Employment Laws Assistance for Workers and Small Businesses (elaws) Program includes more than 30 interactive e-tools that provide easy-to-understand information about DOL laws and regulations. These resources are available to help employees, employers, and the general public comply with the law. Elaws is available at www.dol.gov/elaws.

Q2. Last year, the Department of Labor proposed substantially revising an employer reporting requirement for health insurance and retirement plans and proposed removing the small business exemption (fewer than 100 employees). The goal of the Paperwork Reduction Act is to reduce the reporting burden, but the DOL's Paperwork Reduction Act Statement regarding the Form 5500 estimated expanding the reporting requirement would impact 2.97 million filers, costing $668 million dollars and 1.52 million hours to comply. Some of this revision may have to do with contracting with a third party administrator's new IT system. Does the Department of Labor plan on finalizing this regulation that would significantly impact a substantial number of small businesses? What are the plans for this revision?

A2. The Employee Benefits Security Administration (EBSA) received 200 public comments and one petition with 102 submissions/signatures in response to the proposal to revise the Form 5500. EBSA is reviewing the comments and has not made any decisions regarding finalizing the revisions as proposed.

Representative Kelly

***Q1.* How does DOL measure burden hours to calculate the estimate? How do you know your estimates are accurate?**

A1. Most DOL programs use a combination of internal subject matter experts (SMEs) and public engagement to help ensure the accuracy of time burden estimates. Initial time burden estimates are determined by program SMEs who are familiar with what a respondent will need to do to respond to the collection. Pursuant to OMB guidance, these estimates are discussed in the public record for each information collection request, most specifically in responding to item 12 in the supporting statement used to justify the request. OCIO reviews and clears each request before submitting it to OMB for final approval. Part of this review is the quality and transparency of the estimates, including sources used to calculate the burden.

Furthermore, consistent with PRA requirements, DOL PRA *Federal Register* notices specifically invite public comments that evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used. DOL outreach events also provide members of the public an opportunity to comment on specific issues and have sometimes led to a program reevaluating an estimate. Finally, the instruments (e.g., forms and circulars) DOL uses to collect information provide specific points of contact for suggestions on how to simplify the collection process or to leave general feedback. DOL uses this public input to reduce respondent burden, while not materially reducing employee protections. These strategies allow small businesses to provide their views on both the burden estimates and how to reduce paperwork burden both at an early stage before the collection is fielded and on an ongoing basis thereafter.

***Q2.* How does DOL calculate the cost of an information collection request? How do you know your calculations are accurate?**

A2. Most DOL programs use a combination of internal subject matter experts (SMEs) and public engagement to help ensure the accuracy of other costs burden estimates. Other costs are defined as those not related to time.

Initial burden estimates are determined by program SMEs who are familiar with what a respondent will need to do to respond to the collection. Pursuant to OMB guidance applicable to all agencies, these estimates are discussed in the public record for each information collection request, most specifically in responding to item 13 in the supporting statement used to justify the request. OCIO reviews and clears each request before submitting it to OMB for final approval. Part of this review is the quality and transparency of the estimates, including sources used to calculate the burden. While these requirements on agencies and opportunities for public engagement have long been part of Federal efforts to reduce paperwork burden, DOL has taken special care in recent years to ensure cost burden estimates are comprehensive.

Furthermore, consistent with PRA requirements, DOL PRA *Federal Register* notices specifically invite public comments that evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used. DOL outreach events also provide members of the public an opportunity to comment on specific issues and have sometimes led to a program reevaluating an estimate. Finally, the instruments (e.g., forms and circulars) DOL uses to collect information provide specific points of contact for suggestions on how to simplify the collection process or to leave general feedback. DOL uses this public input to reduce respondent burden, while not materially reducing employee protections. These strategies allow small businesses to provide their views on both the burden estimates and how to reduce paperwork burden both at an early stage before the collection is fielded and on an ongoing basis thereafter.

***Q3.* Your written testimony states that the time burden for DOL's information collection requests has remained virtually unchanged from what it was 12 years ago. How have the costs changed?**

A3. Out of pocket cost burdens have increased by $3.5 billion since 2005, an increase of over 150 percent. About 25 percent of this increase is attributable to inflation, according to BLS figures. New legislation also drives changes to cost burdens imposed by information collections. New legislation accounts for approximately $0.65 billion of the dollar cost increase.

Representative Bacon

Q1. The PRA encourages agencies to consider whether conducting pilot tests of an information collection is feasible. Does your agency conduct pilot tests of its information collection requests? If so, can you point to an instance where you lessened the burden on small entities after a pilot test?

A1. DOL agencies perform pilot tests when a program finds the exercise will be appropriate. Testing can be a useful resource to refine what is being asked of respondents and lead to greater efficiencies should a pilot be expanded. In addition to pilot tests, the Bureau of Labor Statistics (BLS) has a special clearance for other types of testing such as cognitive testing, which relies on an intensive, one-on-one interview with a small number of typical respondents to ensure that questions are written as clearly and concisely as possible to reduce burden. Even in cases where there is no pilot testing of an instrument, DOL programs will employ a type of usability testing where a person familiar with the program but unfamiliar with the form will complete it and provide feedback.

Representative Norman

Q1. How does DOL periodically review existing information collection requirements to determine whether the information collection is still necessary or should be changed or removed?

A1. DOL recognizes the importance of reviewing information collection requirements to ensure the data being collected is necessary. When identifying opportunities to reduce paperwork burden, it is often the individual program agencies that are able to recognize what information is necessary and what may no longer be needed. In addition to reviews by program agencies, the DOL periodically reviews its inventory of information collections for duplicative, outdated, unnecessary, or inconsistent requirements. The Department employs multiple strategies in this regard. For example, in conjunction with the OMB data call for the Information Collection Budget (ICB), OCIO asks each DOL program agency to review their information collections and identify initiatives they will undertake within the next year to reduce burden.

If an agency identifies a better or more practical way to collect information, OCIO will work with the program to implement it consistent with statutory requirements. One example of a burden reduction initiative is Occupational Safety and Health Administration (OSHA) Standards Improvement Project series designed to remove or revise duplicative, unnecessary, and inconsistent safety and health standards. OSHA is in the middle of the fourth iteration of this effort and expects to decrease public burden by more than 100,000 hours.

Finally, the PRA mandates each agency obtain approval for each information collection at least every three years. Importantly, this requirement ensures that even minor collections are subject to periodic reviews.

Q2. Since DOL is responsible for many different laws and regulations, how does DOL keep track of its authority to collect information?

A2. In accordance with OMB guidance applicable to all agencies, each information collection request submitted to OMB includes a justification statement consisting of 18 questions[1] to support the collection. The justification statement covers a variety of topics—including, the need and uses for the collection, efforts to reduce burden through information technology, potential to use other sources for the information, burdens the collection will impose on both the public and the Federal Government, and efforts to reduce burden (particularly on small businesses or other small entities).

The first item to be addressed in the justification statement is the agency's need for the collection, including legal and administrative requirements that necessitate the collection. The agency must also identify the appropriate section of each statute and regulation mandating or authorizing the collection. Program agency responses are reviewed by the Office of the Solicitor of Labor when appropriate and always by OCIO staff. DOL includes this information in the *Federal Register* notices when information collection requests are sent to OMB for final approval.

Representative Blum

Q1. There are instances of information collection requests that are posted on the Office of Information and Regulatory Affairs (OIRA) that have hundreds or thousands of hourly burdens on respondents, but there are zero costs. Why are there instances where there is a large hourly burden to collect information, but zero costs?

A1. OMB guidance applicable to all agencies dictates that respondent burdens must be identified as either time or monetary costs, such as purchasing equipment specifically to respond to the Federal information collection or engaging an outside attorney or accountant to help prepare the response.[2] In accordance with longstanding OMB guidance, a federal agency would not count the monetary value of a respondent's time as an out of pocket cost, because this would double count the burden. Consequently, it is possible for an information collection that solely involves staff time to not register as a monetary cost.

In addition, in accordance with regulations codified at 5 CFR 1320.3(b)(2), an agency would exclude financial resources needed to comply with a collection of information if those resources would be incurred in the course of normal or routine activities (e.g., compiling and maintaining business records). Consequently, there may be financial costs associated with recordkeeping that might entail no burden, because maintaining the records is customary; however, reporting the information to an agency would entail burden.

Q2. Because DOL's regulations impact all industries, how does DOL make sure that small businesses across all industries are heard when it comes to paperwork requirements?

A2. DOL provides several opportunities for small businesses to give feedback on ways to minimize paperwork burdens. In addition to the response to Representative Norman's first question, the Small Business Regulatory Enforcement Fairness Act (SBREFA) assists small businesses with understanding and complying with regulations. Among other actions under SBREFA, the Occupational Safety and Health Administration (OSHA) involves small businesses in the development of some proposed rules through Small Business Advocacy Review Panels. In addition, when a DOL program agency anticipates that particular groups may be especially interested in providing feedback on a particular information collection, the agency may alert stakeholders that a comment period is open.

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[1] Information collection requests employing statistical methods have an additional supporting statement addressing those unique issues.

[2] See *ROCIS How To Guide for Agency Users of Information Collection Request (ICR) Module* at 40,

Q3. What kinds of outreach activities does DOL do to reach small businesses of all different types of industries, especially in rural places like in the state of Iowa?

A3. In addition to the outreach activities discussed in the response to Chairman Chabot's first question, DOL programs have local offices throughout the country. These offices engage in outreach activities, many of which are directed towards small businesses. For example, DOL program agencies often will send a representative to speak to a local trade association on how to comply with a particular set of requirements. These events also provide attendees a chance to ask questions or provide other feedback.

Q4. Does DOL find that different industries have a different burden or higher costs for the same information collection? How does DOL account for these differences?

A4. When an information collection applies to employers generally, DOL agencies will normally calculate burden estimates based on the average time and cost it takes a typical respondent to answer the collection, regardless of specific issues for any particular industry; consequently, both highs and lows are generally discounted. A program agency may discuss burden ranges as part of the explanation for calculating the average respondent burden. For example, an agency will adjust burden estimates for information collections directed at financial services industries that typically engage outside counsel more than relying on staff attorneys employed by the firm. If an information collection results in a greater burden for a particular industry or if a collection generally applicable to all employers would not be appropriate for a particular industry or sector, a program agency may consider unique factors or extenuating circumstances and could consider alternative requirements. As previously mentioned, in both PRA *Federal Register* notices for each individual collection, DOL specifically asks for public comments on the accuracy of its burden estimates and how those estimates might be improved.

Representative Knight

Q1. What is DOL doing to address concerns that agencies are not utilizing more electronic forms and other paperwork requirements?

A1. DOL utilizes electronic forms when they are practicable, and over 90 percent of DOL information collections that include forms make them available electronically. Just one example of an electronic filing success story is the EBSA's Form 5500, the Annual Return/Report of Employee Benefit Plan. The Form 5500 electronic filing requirement has significantly reduced annual reporting burden (from 1,948,529 burden hours and $663,870,000 in other costs for 2006, before electronic filing, to 585,765 burden hours and $244,094,600 in other costs today).

DOL periodically reviews all "paper only" forms to see if new opportunities for an electronic option might exist. In some cases, DOL phases in the use of electronic forms to allow business to incorporate their usage over time. DOL considers the cost, benefits, practical utility, and available resources in ongoing efforts to increase the use of electronic forms. DOL has many instances where programs use a hybrid approach that allows both electronic and paper filing options. DOL has historically recognized that requiring only electronic submissions can pose unique challenges to certain entities, particularly small businesses in areas with limited Internet connectivity. In accordance with OMB guidance applicable to all Federal agencies, DOL programs address the use of automated, electronic, mechanical, or other information technology options in the supporting statement used to justify each information collection.

Q2. For the information that you collect electronically, what is DOL doing to protect small businesses' privacy and sensitive data?

A1. DOL systems contain a wide variety of sensitive information. Protecting and securing sensitive electronic data is of the utmost importance to the Department. Departmental policies dictate that any information sharing or change to information collection practices must be reviewed to assess the security impact and mitigate any vulnerability.[3] DOL employs several strategies to protect small businesses private and sensitive data an agency may have. These include:

- Ongoing review and aggregation of reports on the quarterly plans of action and milestones to mitigate security weaknesses, eGovernment evaluations, and annual review of Departmental security programs.
- Annual security awareness training and other activities throughout the year to reinforce the IT security knowledge of DOL employees.
- Maintaining a computer security incident response capability to address incidents across the Department. The DOL Computer Security Incident Response Capability functions in dual modes—proactive and reactive. DOL proactively monitors federal and commercial computer incident response and homeland security groups (e.g., US-CERT) to determine potential threats to DOL systems and newly discovered vulnerabilities in DOL systems and applications. OCIO then notifies the security officers at each component agency, and, as required, collects feedback on the mitigation of new vulnerabilities and threats.
- Integrating information security into the DOL Enterprise Architecture; System Development Life Cycle Management and Manual; and IT planning, management, and the Capital Planning and Investment Control processes.
- Participating in several government-wide initiatives to share lessons learned and to ensure compliance with the objectives of EGovernment on the President's Management Agenda. These activities include, but are not limited to:
  - Promote use of the Internet, other information technologies, and interagency collaboration in providing E-Government services, to provide increased opportunities for citizen participation in Government
  - Improve the Government's ability to achieve agency missions and program performance goals;
  - Reduce costs and burdens for businesses and other Government entities;
  - Make the Federal Government more transparent and accountable; and
  - Provide better access to Government information and services in a manner consistent with laws regarding protection of personal privacy, national security, records retention, and access for persons with disabilities, as well as other relevant laws.

In addition, DOL takes appropriate steps to protect sensitive business information when it is requested from DOL files under the Freedom of Information Act (FOIA). More specifically, DOL provides businesses an opportunity to identify whether information that might be responsive should be redacted because it involves trade secrets and privileged or confidential commercial or financial data.

Q3. When DOL requests information from businesses that will be available to the public, what does DOL do to ensure that small businesses' sensitive data does not put them at a competitive disadvantage by disclosing this sensitive information?

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[3] See DOL IT Security Web site.

A3. As mentioned in the response to Representative Knight's second question, DOL takes appropriate steps to protect sensitive business information when it is requested from DOL files under FOIA. In accordance with Department of Justice Guidance, DOL provides businesses an opportunity to identify whether information that might be responsive should be redacted because it involves trade secrets and privileged or confidential commercial or financial data.[4]

With respect to grants, DOL is committed to conducting a transparent award process and publicizing information about program outcomes. Posting successful grant applications on public websites is a means of promoting and sharing innovative ideas. DOL publishes proposal abstracts on the internet. DOL also publishes a redacted version of awardees' technical proposals required by funding opportunities. Except as specifically disclosed in the Funding Opportunity Announcement, no attachment to a technical is published. Even when published, technical proposals and abstracts are not published until after the cooperative agreements are awarded. In addition, information about cooperative agreement progress and results may also be made publicly available. DOL recognizes that grant applications sometimes contain information that an applicant may consider proprietary or business confidential information, or may contain personally identifiable information. In order to ensure that proprietary or confidential business information or personally identifiable information is properly protected from disclosure, applicants whose technical proposals will be posted are asked to submit a redacted version of the proposal, with any proprietary or confidential business information and personally identifiable information redacted. All non-public information about the applicant's and consortium members' staff (if applicable) should be removed as well.

[4] See *Department of Justice Guide to the Freedom of Information Act* at 306.

The Honorable Steve Chabot
Chairman
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515-6315

FEB 20 2018

Dear Chairman Chabot:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 11, 2017, hearing before the Committee on Small Business, entitled "Evaluating the Paperwork Reduction Act Part II: Are Burdens Being Reduced?" This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John M. Martin
Principal Associate Commissioner
for Legislative Affairs

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We have restated your questions in bold, followed by our responses.

Chairman Chabot

1. **What flexibilities does FDA provide to help small businesses comply with information collections?**

FDA employs seminars, workshops, educational conferences, informational materials, email, and a toll-free telephone number to assist small businesses with compliance. FDA also provides access to regional small business advisors, as well as administrative and scientific support services, to assist businesses in providing timely and accurate responses to information requests.

2. **Your written testimony discusses many different ways that FDA collects information from the public. Are there certain methods that FDA finds are more effective in collecting information from small businesses in particular?**

FDA has not found particular methods to be more effective in collecting information from small businesses specifically. In general, FDA uses the same methods to collect information from both large and small businesses. We try to be innovative and efficient in our information collections to encourage a high response rate from firms of all sizes.

Representative Kelly

1. **How does FDA measure burden hours to calculate the estimate? How do you know your estimates are accurate?**

See answer to Question 2, below.

2. **How does FDA calculate the cost of an information collection request? How do you know your calculations are accurate?**

Burden hours are estimated by FDA program offices or economics staff, depending on the nature of the collection and experience with similar collections, using HHS guidelines for estimating the burden.

FDA economics staff estimates costs, using the estimates of the hours required provided by the program office.

Although these are estimates, the Agency takes steps to increase confidence in their accuracy by including a narrative of our basis for each burden estimate in the Federal Register notices where we invite public comments on our burden estimates. Also, the supporting statement in the information collection package submitted to OMB for approval describes the methods used to estimate burden.

Representative Bacon

1. **The PRA encourages agencies to consider whether conducting pilot tests of an information collection is feasible. Does FDA conduct pilot tests of its information collection requests? If so, can you point to an instance where you lessened the burden on small entities after a pilot test?**

The public has the opportunity to test run forms via the "draft form" submitted to OMB and made available in the electronic docket for the collection of information on the *regulations.gov* website.

Representative Norman

1. **How does FDA periodically review existing information collection requirements to determine whether the information collection is still necessary or should be changed or removed?**

All information collections are authorized by OMB for a maximum of three years. To ensure that existing collections of information are reauthorized before OMB approval expires, we begin the process of reauthorizing the collection after two years, at which time the existing information collection is evaluated.

2. **Since FDA is responsible for many different laws and regulations, how does FDA keep track of its authority to collect information?**

FDA determines its authority on a case by case basis, by consulting the statutes it administers and authority cited in currently approved collections.

Representative Blum

1. **There are instances of information collection requests that are posted on the Office of Information and Regulatory Affairs (OIRA) that have hundreds or thousands of hourly burdens on respondents, but there are zero costs. Why are there instances where there is a large hourly burden to collect information, but zero costs?**

We believe you may be referring to costs listed in the RISC[1] and OIRA Consolidated Information System (ROCIS). There are two areas in which FDA must calculate costs for responding or complying with a request or requirement for information: 1) capital, start-up, and operating and maintenance costs; and 2) labor and overhead costs. The labor and overhead costs are included in the information submitted to OMB but are not entered into the ROCIS database. Capital, start-up, and operating and maintenance costs are entered into the ROCIS database. Consequently, when we estimate that complying with the information collection request should not cause the public to incur capital, start-up, operating or maintenance costs, the ROCIS report will show the "cost" as zero. However, this number does not reflect the labor and overhead costs, which, again, are reported on the supporting statement submitted to OMB.

[1] Regulatory Information Service Center

2. **In your written testimony, you talk about information that may be collected through guidance documents. How often do new information collections come from guidance rather than regulations?**

We estimate that nearly 20 percent of FDA's approved collections of information are found in guidance. Other approved collections of information are found in regulations or in other documents or formats such as forms, surveys or focus groups.

Representative Knight

1. **What is FDA doing to address concerns that agencies are not utilizing more electronic forms and other paperwork requirements?**

FDA is making progress in offering respondents an electronic option to submit information, and encourages respondents to use electronic submission when available. And FDA is making a major investment in IT that will improve the experience for our customers, including by the increased use of electronic filing.

2. **For the information that you collect electronically, what is FDA doing to protect small businesses' privacy and sensitive data?**

Last year the U.S. Government Accountability Office recommended several cybersecurity measures FDA should take to safeguard industry and public health data at risk. FDA has implemented all of the program recommendations and addressed nearly all of the technical weaknesses, and we are committed to addressing every potential weakness that was identified.

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