

Animal Drug User Fee
Act (ADUFA) Public Meeting

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Animal Drug User Fee Act(ADUFA) Public Meeting

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M O R N I N G S E S S I O N

(9:17 a.m.)

*Opening, Welcome and Overview**by Jacqueline Farmer, Center for Veterinary Medicine, FDA*

MS. FARMER: Good morning. My name is Jacqueline Farmer. Thank you for joining us today. I'm sorry for the delay. I'm just going to go over a few housekeeping items before we get started. This meeting is being recorded and transcribed.

If you are making comments, we'll ask that you please go to the microphone in the center there. Or if you do have a presentation you've already given me, if you could come up to the lectern that would be really helpful. That way the transcriber will capture everything.

As soon as the transcript is available, it will be accessible at www.regulations.gov. They may be viewed at the divisions of Dockets Management at the Food and Drug Administration, or it will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. This information does appear in detail in the FR notice.

Restrooms are down the hall on the left past the elevators, and on the first floor, there is a deli on the hall on the -- down the hall on the left past the elevators. If you happen to make it up to the third floor without signing

in, there is a registration by the door. Please feel free to fill it out before you go if you didn't happen to do so upon your arrival.

With that, I'm going to turn it over to Dr. Dunham. Thank you.

DR. DUNHAM: Thank you very much.

FDA Remarks

by Dr. Bernadette Dunham, Director, Center for Veterinary Medicine, FDA

DR. DUNHAM: Good morning, and I'm the reason for the delay, so thank you for your patience. Every now and then, I really hit traffic snags and today was one of them. But thank you so much for coming. Can you hear me?

(Chorus of "No.")

DR. DUNHAM: No?

(Chorus of "Yes.")

DR. DUNHAM: Is it on?

MR. : It's on.

DR. DUNHAM: (Knocking sound.) Can you hear me now?

(No response.)

DR. DUNHAM: Bring it closer. Is that any better?

(Chorus of "Yes.")

DR. DUNHAM: Yes. Okay. So once again, I'm so sorry for the delay but I do appreciate everybody coming and for your patience. So with no further ado, I'll have a few comments to get us all started here, and my glasses. All

right.

Thank you again for being part of this very important public meeting regarding the reauthorization of the Animal Drug User Fee Program, otherwise known as ADUFA. As you may know, this program has been and continues to be important to both human and animal health.

ADUFA I and ADUFA II are ones you're very familiar with, but let me just recap very briefly. CVM has met all of its performance goals for both ADUFA I and ADUFA II.

ADUFA I, as you recall, focused on reducing the time to complete submissions to meet and exceed statutorily mandated timeframes.

ADUFA II focused on reducing the number of review cycles for critical submissions by instituting the End Amendment Review Process. An ADUFA program has enabled CVM to provide an efficient, predictable and timely evaluation of new animal drugs.

So why are we here today? Well, as you know, in Congress's wisdom and in their foresight they've outlined a very interactive and transparent process for the reauthorization of ADUFA, and we have followed that process.

We started the process back on November 7, 2011 with a kickoff public meeting. This was followed by negotiations with industry, and although the negotiations were not public, there were several touch points that provided opportunities

for all of us to stay involved in the process.

For example, we published the minutes of each negotiating session with the regulated industry on the FDA internet website. These minutes summarized any substantial proposals and any significant controversial or differences of opinion during the negotiations and their resolutions.

We kept the ADUFA public comment docket open during the entire process. (Background noise reduction.) That's quieter -- for any additional comments that you wanted to provide to us. Now we've met several times with our consumers and other stakeholders throughout this whole process, and I thank you very much for your engagement.

Once the proposed recommendations for ADUFA III were agreed to and ratified by FDA and the industry, and the clearance obtained from the Department of HHS and OMB, we published the recommendations in the Federal Register.

We intend to keep the docket open for 30 days from the date of issuance of the Fed Register seeking public comments. After consideration of such public reviews and comments from this meeting and the docket, we will revise any recommendations as necessary.

Finally, we anticipate this process concluding by mid-January of 2013 at such time that we intend to transmit the ADUFA III reauthorization package to Congress.

As we moved forward in ADUFA III, it was important

to keep the successes of ADUFA I and ADUFA II as we move forward to streamline the process, assure predictability and most importantly, to protect human and animal health.

It's at this point that I'm now going to turn the rest of the meeting over to Dr. Steven Vaughn and Roxanne Schweitzer. They're FDA co-chairs of the process to review the proposed recommendations, and then have your comments. So thank you very much for your patience.

by Dr. Steven Vaughn, Director, Office of New Animal Drug Evaluation,

Center for Veterinary Medicine, FDA

DR. VAUGHN: Thank you, Dr. Dunham. I am Steve Vaughn. I'm the Director of the Office of New Animal Drug Evaluation, and this is Roxanne Schweitzer, who is our Director of our Office of Management, and we're going to give you a presentation of the proposed recommendations for the reauthorization of ADUFA.

[Slide.]

DR. VAUGHN: So as Bernadette had said, we had -- in ADUFA I, we had a very successful five-year stint with the first initiation of the User Fee Program. We eliminated the backlog of pending submissions that we had built up at that time, and when we started the program.

We reduced our review times to statutory timeframes. We created a more predictable and streamlined process, and it added for us \$43 million and 72 FTEs for the program over

those 5 years.

We reauthorized ADUFA in ADUFA II that ran from Fiscal Year 2009 through this current year of Fiscal Year 2013. We reduced the number of second review cycles by a new process that was created called End-Review Amendments.

We developed our electronic submission capability, and we're now receiving over half of our electronic submissions now -- over half of our submissions are coming in electronically now, and that number is rising very rapidly.

We've added pre-approval foreign inspection goals to facilitate the timely inspection of foreign manufacturing facilities. We've increased the transparency by participating in 10 public workshops, 8 to date and the last 2 are going to be this spring as we complete this 5 year performance, and then we've increased the funding to \$98 million over 5 years.

[Slide.]

DR. VAUGHN: Just to give you a review of the performance goals more specifically, we have completed, over ADUFA I and II, 90 -- over 90 percent of the manufacturing supplements within 120 days, over 90 percent of the Administrative NADAs within 60 days.

For the non-administrative NADAs, we've done 90 percent within 180 days, and if an end-review amendment was requested and received within -- completed it within 345 days.

For Supplemental New Animal Drug Applications, the

non-manufacturing supplements, we did 90 percent within 120 days, over 90 percent within 345 days if there was an end-review amendment.

For INAD Data Submissions, these are the large data packages, we did over 90 percent within 180 days and 90 percent -- over 90 percent within 270 days if an ERA was requested and received.

For Protocol Submissions, they were completed over 90 percent within 50 days and over 90 percent in 60 to 80 days depending on when the ERA was received.

[Slide.]

DR. VAUGHN: We've exceeded all of our performance goals outlined in the Performance Goals Letter for all submission types, and the data represented eight years of ADUFA performance, both ADUFA I from 2004 to '08 and ADUFA II 2009 through '11.

[Slide.]

DR. VAUGHN: So the FDA goals for ADUFA reauthorization for us were the objectives that we went into the reauthorization process with these principles in mind. First, to sustain the fundamentals that drive public health outcomes, and those are to sustain the science of drug development, to improve the quality of evidence in submitted applications and to promote a more predictable and efficient review process.

We focused performance enhancements on increasing the quality and efficiency of the current program and maintaining public confidence.

We ensure timely reauthorization, ensure stakeholders' participation in the process and continue the sound financial footing that allows us to complete these other objectives.

[Slide.]

DR. VAUGHN: The reauthorization discussions yielded proposed recommendations in several areas, and I'm going to highlight some of those. Performance highlights included shorter review times for certain reactivations and resubmissions, shorter review times for microbial food safety hazard characterizations and a shorter review time for qualifying prior approval labeling supplements.

It also includes enhancing the exchange of scientific information. Both FDA and the industry agree on the need to submit information earlier in the development to enable the parties to reach agreement at a pre-submission conference or to begin review of a protocol.

FDA will provide increased flexibility for sponsors to submit scientific data or information concurrent with protocol review, and there are several process improvements for submitting dosage characterization data.

[Slide.]

DR. VAUGHN: In the area of chemistry, manufacturing and control enhancements, we'll be using 30-day CBEs. These are the type of submission known as changes being effected for resubmitted supplements. We'll be doing comparability protocols under INADs, and we'll have a two-phase CMC technical section review process.

We'll also be exploring the feasibility of some new areas that possibly will require some statutory revisions in the future. These include expanded use of our conditional approval provisions and to explore looking at modifying our current requirements that the use of multiple new animal drugs in the same medicated feed will be subject to an approved application.

Basically, this is addressing combinations and looking for a new approach to make it more cost effective for the approval of medicated feed combinations.

[Slide.]

DR. VAUGHN: So the reauthorization discussions then summarized the timeframes. The review goal timeframes are summarized here in this slide.

For a regular review for manufacturing supplements, we're looking still at 120 days, but we are adding the CBE-30 provision. It will enable some reactivations and resubmissions to be done then in 30 days.

The non-administrative NADAs will be going from 180

days to 135 days for reactivations. The non-manufactured Supplemental NADAs will be doing the same.

The INAD data submissions will be looking at 180 days for the regular review and then 60 days for reactivations/resubmissions. The INAD protocol submissions will have a regular review of 50 days and reactivations and resubmissions in 20 days.

Now what this is doing is honoring the timeframes that we used in the developed end-review amendment process but it provides flexibility for both the industry sponsors and for FDA to be able to make the process work better and give both parties the time they need to consider and develop responses to the initial review cycle, but it does sustain the same review times that we had in the end-review amendment for the most part.

Then, as far as Administrative NADAs, they'll still remain at 60 days. The Qualifying Label Supplements will be done. This is a new performance goal -- will be done in 60 days. The INAD Microbial Food Safety Hazard Characterization will be done in 100 days. This is similar to our review times for smaller data packages.

So with that, I'm going to turn it over to Roxanne Schweitzer.

*by Roxanne K. Schweitzer, Associate Director for Management,
Center for Veterinary Medicine, FDA*

DR. SCHWEITZER: I just wanted to clarify one thing. David Wardrop, for those of you that might be expecting him, is on the phone. He tried to fly in yesterday but unfortunately due to the fog, he was unable to land and was rerouted back home.

So he is the co-lead with Steve Vaughn on it, so I'm just here to fill in for him.

[Slide.]

DR. SCHWEITZER: So moving away from the performance, I'm going to now talk about the proposed recommendations for the revenue stream. We modified the inflation and the workload adjuster, we changed the revenue fee distribution and we added a new collection shortfall adjustment, and I'll walk you through those in the following slides.

[Slide.]

DR. SCHWEITZER: For our first one to walk through what the financial baseline would be for 2014. For 2014, the base revenue amount is \$21.6 million. We then have one-time IT funding of \$2 million for a total in 2014 of \$23.6.

For each year, 2015 to 2018, that base revenue amount of \$21.6 will be further adjusted for the new statutory provision for the inflation adjuster, which I'll walk through,

and may further be adjusted for the workload and/or new collection shortfall.

[Slide.]

DR. SCHWEITZER: The modified inflation adjuster provision, the new provision, accounts for changes in FDA's cost related to payroll compensation and benefits, as well as changes in the non-payroll costs, the CPIU, Consumer Price Index.

The formulation for that calculation is the latest three-year average change in the FDA payroll compensation and benefits multiplied by the three-year average change in the proportion of FDA's PC&B to total FDA costs. Then you add the latest three-year change in the CPI multiplied by the three-year average change in proportion of FDA non-payroll costs.

So that is the new inflation adjuster. We moved away from the fixed 5.9 that was in ADUFA II.

[Slide.]

DR. SCHWEITZER: Moving on to some further adjustments, the fee distribution. In ADUFA II, it was 25 percent for each of the 4 fee types. In order to increase the revenue stream's stability, reduce the application fee and minimize potential for collection shortfalls, we will now get 20 percent from applications, 27 percent from products, 27 from sponsors and 26 percent from establishments.

Another change is the modification to the workload adjuster. We have modified the base years for calculating it to ensure that it adequately captures changes in FDA's workload during ADUFA III. So instead of 1998 to 2002, it is now 2009 to 2013.

[Slide.]

DR. SCHWEITZER: Finally, the new collection shortfall language, and this was set in order for us to offset adjustment based on any collection shortfalls in previous years.

[Slide.]

DR. SCHWEITZER: Finally, we look forward to hearing your comments today, whether you share them here at the public meeting, via written comments or electronically, and the comment period is open through January 4th. Thanks.

DR. DUNHAM: Thank you very, very much.

MS. FARMER: Thank you. We're going to move on to the stakeholder remarks, and we're going to begin with Mr. Tyler J. Smith.

Stakeholder Groups' Remarks

by Tyler J. Smith, The Johns Hopkins Center for a Livable Future

MR. SMITH: Thank you, Director Dunham and others, for this meeting today. My name is Tyler Smith and I'm presenting today on behalf of the Johns Hopkins Center for a Livable Future.

I'm going to review the recommendations that we've been making for some time now for reauthorization of ADUFA III, but my focus today is actually on the question in my title.

Where is public health? These recommendations should be familiar to many of the people in the room who have followed the reauthorization process, certainly to those at CVM we've had the privilege of meeting with over the past year.

But despite the meetings we've held, despite the comments we've submitted, none of these recommendations were included in the draft recommendations released in the Federal Register earlier this month.

[Slide.]

MR. SMITH: So just some background, the Center for a Livable Future is an academic research center based at the Johns Hopkins Bloomberg School of Public Health. We study the complex interconnections among food systems, public health and the environment.

A key priority for us is ensuring that antimicrobial drugs are used responsibly in food animal production in order to slow the development of antimicrobial resistance, which is a major public health crisis.

[Slide.]

MR. SMITH: So just to review our recommendations

quickly. First, our recommendations have focused on the antimicrobial sales and distribution data reported under Section 105. We had three key recommendations for how we thought the statute should be changed during reauthorization.

First, collecting and reporting data by state or region. Right now, the national sales data we have are limited in what they can explain about local patterns of resistance and more local data would be appropriate for understanding those patterns.

Second, we ask that data be reported on all antimicrobial classes that are publicly reported regardless of the number of sponsors of drug products in those classes. So right now, we're unable to see any data for some of the most critical drugs in human medicine, including fluoroquinolones and streptogramins.

It's our contention that the public interest in knowing more about sales abused drugs far outweighs any private interest in protecting confidential business information.

Then finally, collecting and reporting feed mill data makes sense given the agency's acknowledgement that the use of antimicrobials in feed poses a qualitatively greater risk of selection for antimicrobial resistance than use by other routes.

[Slide.]

MR. SMITH: Now there are clear public health rationales for collecting additional data. First, the data we have right now are simply inadequate for understanding patterns of resistance that we see through surveillance systems like the National Antimicrobial Resistance Monitoring System, or NARMS.

The Government Accountability Office, in a report last year, found that the data collected under ADUFA specifically were inadequate for this purpose. Then when you compare what's collected in this country to what is collected overseas in countries like Denmark, where you can trace antimicrobial use to individual animals, you really see the inadequacy of the system we have and you see why we need more.

Then in addition to kind of long-term scientific goals of understanding patterns of resistance, there are more immediate goals of understanding the impact of FDA's voluntary approach to reducing misuse of antimicrobials in food animal production.

CLF, I have to say, along with many other public health groups, is very skeptical that Guidance 213, and the process it outlines, will successfully end the misuse of antimicrobials in food animal production.

We've expressed these concerns and the Deputy Commissioner for Foods, Michael Taylor, wrote an op-ed in *USA Today* where he asked us to trust, but verify, that the

approach was working.

Well unfortunately, we don't have sufficient data to verify that the approach is working. We need more and better data, and ADUFA is the primary vehicle for collecting data currently.

[Slide.]

MR. SMITH: So as Director Dunham noted earlier, there have been opportunities for public stakeholder involvement in the ADUFA reauthorization process. More than a year ago, a colleague of mine, Dr. Meghan Davis, presented the recommendations I reviewed earlier actually in this same room, and we also submitted those in writing as part of the comment period that was open then.

We then proceeded to meet with CVM privately over the course of the past year. CLF had at least three meetings, three meetings with CVM and then other groups such as Keep Antibiotics Working, the Pew Charitable Trusts, the American Academy of Pediatrics and others met with them, as well.

Despite those meetings, our recommendations were not only not included in the draft recommendations that CVM released but they were not even acknowledged, nor were our efforts otherwise.

So now we're at the kind of the next stage of the public input process. We have yet another public meeting where we are today. We have another comment period that's

open and CLF will submit comments but we are deeply skeptical that any of these opportunities will lead to meaningful progress on our recommendations.

Just to sum up, we've now -- we will have had seven meetings by the end of this process with CVM -- public health groups will. There will have been two comment periods. Despite all of that, there will have been zero public health enhancements to ADUFA.

[Slide.]

MR. SMITH: So this all stands in sharp contrast to how the agency operates on the human drug equivalent of ADUFA, or PDUFA, the Prescription Drug User Fee Act.

If you look at the stakeholder process around PDUFA V, which was reauthorized earlier this year, you can see not only were stakeholders more involved in the process but their priorities were addressed in the recommendations that the agency sent to Congress and the recommendations including key authorities that were explicitly aimed at improving drug safety.

But if you compare that to ADUFA and the draft recommendations that have been released so far, you see there was no acknowledgement of public stakeholder's priorities, let alone any inclusion of those priorities in the document, and there was no action whatsoever on antimicrobial sales data collection.

Now you have to ask, "Why?" These are very basic recommendations. We're asking for more data so we can better understand a public health crisis, and it seems increasingly clear to us that the answer is money.

[Slide.]

MR. SMITH: ADUFA is a key funding stream for the Center for Veterinary Medicine. It provides millions of dollars in user fees and revenue to the center, as Dr. Vaughn reviewed earlier.

I've prepared a table showing the annual user fee revenue collected under ADUFAs I and II for the five most recent years for which this information is available, and then also the amount of money that the center stands to gain under the first year of ADUFA III when it is reauthorized.

This is a conflict of interest because the regulator is dependent upon the regulated industry for its funding. The statute requires the agency to negotiate with the industry it regulates in order to secure additional funding.

The industry has said in minutes that were published on FDA's website that it does not believe additional data should be collected under ADUFA, and it has opposed the release of additional data that was collected under ADUFA.

So this conflict of interest pretty clearly explains FDA's inaction on basic public health recommendations.

[Slide.]

MR. SMITH: So just in conclusion, CLF is not opposed to reauthorization of ADUFA III, although certainly, in the long-term, a more appropriate funding source for a regulatory agency should be identified. However, right now, ADUFA is the only vehicle we have for antimicrobial sales data collection.

So for the time being, we support the reauthorization of ADUFA with enhancements to data collection. But we do note that it is quite discouraging that we presented basic public health recommendations, along with other groups, in seven meetings over the past year.

We've gone through two public comment periods, or rather, we've gone through one and we'll be submitting comments for the current public comment period soon. Yet despite all of that, the agency ignored our recommendations. Our efforts were not even acknowledged in the draft recommendations released earlier this month.

So for us, the next step is Congress. We are heartened by Representative Henry Waxman's leadership in introducing -- or rather announcing the Data Act to expand current antimicrobial sales collection requirements, and we look forward to helping him advance that legislation during the reauthorization process next year.

[Slide.]

MR. SMITH: Thank you for your time, and I've

included my contact information should any of you have any questions.

DR. DUNHAM: Thank you very much.

MS. FARMER: Next, we'll hear from Mr. Steven Roach.

Remarks by Patient and Consumer Advocates

by Steven Roach, Public Health Program Director,

Food Animal Concerns Trust on behalf of Keep Antibiotics Working

MR. ROACH: Hello. I'm Steven Roach, Public Health Program Director for Food Animal Concerns Trust. Today, I'm speaking on behalf of Keep Antibiotics Working. Keep Antibiotics Working is a coalition of health, consumer, patient, agricultural, environment, humane and other advocacy groups with more than 11 million supporters dedicated to eliminating a major cause of antibiotic resistance, the inappropriate use of antibiotics in food animals.

In addition to the 13 member groups of Keep Antibiotics Working, we coordinate our effort with a large number of other organizations, including other consumer advocacy groups, medical associations and public health associations.

We work with over 400 organizations that support greater action on antimicrobial use in food animals. All these groups are interested in ADUFA reauthorization process because of the role of food animal drugs in the spread of antimicrobial resistance.

Keep Antibiotics Working has serious concerns about how the FDA's dependence on ADUFA funds gives the regulated industry too much leverage in agency decision making. KAW believes the complete absence of any public stakeholder priorities in the FDA's proposed recommendations to Congress reflects this influence.

KAW asks that FDA, in making its final recommendations to Congress, include public stakeholder priorities, and warns that the failure to do so will further erode public support for the agency and puts the program, and subsequently the Center for Veterinary Medicine, at risk just as much as the threat that the regulated industry will walk away from negotiations.

Public law 110-316, ADUFA II, sets out the specific procedures that FDA must follow in developing and making its recommendations for ADUFA III to Congress. These procedures require FDA to consult with stakeholders other than the regulated industry.

ADUFA II requires FDA to consult with the following specific groups: scientific and academic experts, veterinary professionals, representatives of patient and consumer advocacy groups. In addition, FDA must consider the comments of members of the public.

ADUFA II requires that FDA take comment from these stakeholders at specific points. First, at prior public input

before beginning any negotiations with industry, including a public meeting, an open comment period, periodic consultation during industry negotiations, and finally, a public meeting and comment period once FDA has developed proposed recommendations. Today's meeting is a final public meeting required by Congress in the ADUFA reauthorization process.

Over the last year, starting with a meeting on November 7, 2011, non-industry stakeholders have repeatedly met with the FDA to provide specific suggestions for enhancements to the ADUFA program.

Yet the draft recommendations released by the FDA on December 5 include none of the priorities of the external stakeholders and fail to even acknowledge the considerable input received.

Stakeholder input has been considerable starting with the November 7, 2011 public meeting and comment period. Keep Antibiotics Working, representing patient and consumer advocacy groups, presented at the meeting and also submitted written comments. KAW made the following specific suggestions.

ADUFA III funds be directed to postmarketing safety reviews of antimicrobial drugs for which premarket reviews were not done.

ADUFA III, direct FDA to collect and publicly report antimicrobial use data from feed mills.

ADUFA III, direct FDA to provide more detail in public reports related to antimicrobial sales and distribution data collected as required by ADUFA II.

In addition, KAW recommended that ADUFA III set a date by which FDA must make public its reports on antimicrobial sales and distribution.

Other stakeholders, the American Veterinary Medicine Association representing veterinary professionals, Johns Hopkins University Center for a Livable Future, representing scientific and academic experts, and the Pew Charitable Trust, representing consumers and veterinarians, in oral and written comments recommended improvements in antimicrobial use, data collection and reporting.

FDA received a few other brief comments from non-industry stakeholders but they did not make specific suggestions for enhancements. Non-industry stakeholders continued to meet with the FDA during the period of industry negotiations.

KAW organized three meetings with the FDA that included the following stakeholders: the American Medical Association, Association of Professionals for Infection Control and Epidemiology, Center for Food Safety, Consumers Union, Infectious Disease Society of America, National Consumers League, Pew Charitable Trust, Michigan Antibiotic Resistance Reduction Coalition and the American Academy of

Pediatrics.

During these meetings, we restated our suggestions from the November meeting and in response the FDA's April unveiling of its voluntary plan to reduce inappropriate uses of antimicrobials in food animals, added a new request that ADUFA III direct FDA to report on numbers of submissions made by drug sponsors under FDA's voluntary plan.

KAW and the other stakeholders believe that this reporting is needed so that the public will be able to determine whether FDA's voluntary plan is working. In addition to these meetings organized by KAW, the Johns Hopkins University Center for a Livable Future also met twice with the FDA to urge the agency to include improved antimicrobial drug collection and reporting in ADUFA III.

Despite this considerable stakeholder input, FDA's draft recommendations to Congress do not include any of the priorities of the public stakeholders and do not even acknowledge the input provided.

Eleven non-industry stakeholder organizations provided comment to the FDA with all agreeing on the need for ADUFA III to direct FDA to improve antimicrobial use data collection and reporting.

Some of the requests, such as improved reporting on antimicrobial sales and distribution data or an agreement to provide information on submissions related to FDA's voluntary

plan on the withdrawal of inappropriate uses of antimicrobials in food animals would require almost no new resources from the Agency.

In fact, FDA provided much of the data requested on sales and distribution to a member of Congress on a one-time basis. During meetings with KAW, FDA repeatedly emphasized that it was reluctant to include these proposals because of concerns about industry opposition and the threat of lost revenue.

Given FDA's long refusal to collect data on antimicrobial use in food animals until required to do so by Congress in ADUFA II, KAW believes that FDA has shown itself incapable of taking on the task unless directed to do so by Congress.

KAW has serious misgivings about the impact of FDA's, and specifically the Center for Veterinary Medicine's, dependence on ADUFA funds. This, we believe, has given the regulated industry unreasonable influence over the center, which is reflected in FDA's failure to include any of the priorities of the public stakeholders in its recommendations to Congress.

Congress also clearly was aware of the potential for a funding program of this nature to distort the relationship between the regulators and the regulated industry so required FDA to receive input from a much broader range of

stakeholders.

FDA's failure to include or even acknowledge the input received from non-industry stakeholders erodes public support for the program and frankly, puts the program and the center at risk as much as the threat that the regulated industry will walk away from negotiations.

FDA has one last opportunity to change course before making its final recommendations to Congress, and we urge you to do so. As I have already described, FDA has repeatedly heard from Keep Antibiotics Working and other public stakeholders, so I will not restate our requests once again. Thank you.

DR. DUNHAM: Thank you very much.

MS. FARMER: We'll now hear from Dr. Elizabeth Wagstrom.

by Dr. Elizabeth Wagstrom, Chief Veterinarian,

National Pork Producers Council

DR. WAGSTROM: Thank you. I'm Dr. Liz Wagstrom. I'm Chief Veterinarian at the National Pork Producers Council. I've also served as a public health veterinarian within state public health agencies. So I feel like I understand public health from both animal agriculture, as well as human foodborne illness areas.

I'm pleased today though to offer these comments on behalf of the National Pork Producers Council. Pork

producers, about 67,000 of them throughout the United States, work hard to produce a safe, nutritious food product for the consuming public, both here and across the world.

As you know, ADUFA amends the Federal Food Drug and Cosmetic Act and authorizes FDA to collect fees from animal health companies to enable the Center for Veterinary Medicine to meet performance standards as outlined by Dr. Vaughn and others here.

The FDA and the animal health industry have negotiated a fee structure that will contribute in part to timely review of submissions. These submissions may be in regard to animal health products for companion animals, food animals or those considered minor species.

The products under review may be for things such as the treatment of parasites, the relief of pain or the treatment of disease among other things. It is important that ADUFA be reauthorized to enhance the health of all animals.

ADUFA should be reauthorized, as negotiated by the FDA and the animal health industry, without additional requirements or amendments. ADUFA should not become a vehicle for agendas about antibiotic use or animal agriculture.

The FDA already has a rigorous science based process in place for the review and approval of new antibiotics. Furthermore, FDA is taking steps to further restrict certain uses of currently approved antibiotics and ensuring that

veterinarians have oversight over antibiotic use.

ADUFA is a piece of legislation that is not just about antibiotics and not just about food animals. ADUFA is much broader than that and should be reauthorized as negotiated. Thank you.

DR. DUNHAM: Thank you very much.

MS. FARMER: We will now hear from Ms. Mallory Gaines.

by Mallory Gaines, National Cattleman's Beef Association

MS. GAINES: Hello. Mallory Gaines of the National Cattleman's Beef Association. The National Cattlemen's Beef Association appreciates the opportunity to offer public comments on the proposed recommendations for the reauthorization of the Animal Drug User Fee Act.

Our members are sincerely committed to raising healthy cattle and ensuring a safe food supply for consumers. An effective and efficient animal drug approval process is essential, to both the health and well-being of animals and to the overall public health.

We support the reauthorization of the ADUFA in order to provide resources for FDA Center of Veterinary Medicine to conduct timely evaluation of new drugs for safety and effectiveness without compromising the quality of the process.

Predictable and rapid review of new drug applications is important to multiple stakeholders. In past

discussions for reauthorization of ADUFA, some proposed amendments supported post-market activities as evaluations for antimicrobial resistance.

NCBA is concerned about the problem of antimicrobial resistance and believes that sound scientific principles should be applied to any evaluation of the possible contributing factors.

NCBA does not support using ADUFA reauthorization as a vehicle to authorize or fund post-market activities. New animal drug user fees should be utilized solely to support and facilitate the new animal drug approval process.

The current information collected in the ADUFA amendment Section 105, does not correlate with the actual antimicrobial drug use in food producing animals. The sales data provided by the drug sponsors cannot be further broken out into sales per species with any known degree of accuracy.

Evaluation and interpretation any antimicrobial use data, as well as identification of the objectives for the collection of such data, should precede data collection. Interpretation of antimicrobial use data needs to remain unbiased and accurately reflect scientific facts.

Additionally, any antimicrobial use data gathering system should not be overly burdensome to the end-user. NCBA advocates for the use of risk assessment to determine what data is most supportive of science-based decision-making.

In conclusion, we support the reauthorization of the Animal Drug User Fee Act. The science-based drug review process continues to be an effective method for determining the safety and efficacy of new veterinary drugs.

Currently, FDA-CVM is addressing the use of collection of antimicrobial use data in food producing animals through the regulatory process with review of comments from stakeholders collected in a recent Advanced Notice of Proposed Rule.

The path forward with this issue should continue in this context. As authorized by ADUFA, new animal drug user fees should be used to support the new animal drug approval process and not to facilitate additional post-market activities.

Thank you for your consideration of these comments of the National Cattlemen's Beef Association presented today. Thank you.

DR. DUNHAM: Thank you.

MS. FARMER: We'll now hear comments from Dr. Gail Hansen.

by Dr. Gail Hansen, Pew Campaign on Human Health and Industrial Farming

MS. GAINES: Good morning. I'm Gail Hansen. I'm with the Pew Charitable Trust, and I'd like to thank you, -- FDA, for allowing us to speak at this public meeting. I urge FDA to pursue these greatly needed improvements in animal drug

usage data collection via the authorization or reauthorization of ADUFA.

The agency and the public really need to better understand the role of antibiotics in the food animal agriculture and the impact on antibiotic resistance. As you know, 2008 Congress required the first ever collection and public reporting of sales and distribution of antibiotics intended for food animal use.

In 2010, the first data required to be collected was made available to the public to consumer groups and in public health groups. Last year, the second report was made available to the public and we're still waiting for the 2011 data to be released. We hope very soon.

In the ADUFA reauthorization, FDA should collect and report additional information for the public to inform the public health officials about additional risks posed by the non-therapeutic antibiotic use in livestock and in poultry.

I was amazed, I mean just amazed, that there was not even a mention of these public health additions in the last -- in the reauthorization of ADUFA, either in FDA's achievements in the last ADUFA or in their proposed future plans.

FDA did acknowledge in their recent guidance to industry in 209-213 that scientific evidence revealed that it's inappropriate to use antibiotics for production purposes and to make animals grow faster.

To ensure that industry doesn't sort of end-run FDA, these voluntary guidelines -- and end-run the voluntary guidelines and actually intends to curb the overuse of antibiotics, FDA must collect and report more detailed antibiotic sales data.

In fact, as mentioned by the Government Accountability Office, as a couple of other folks have mentioned, the report in 2011 found that while FDA proposed this voluntary strategy, they don't collect the data that's needed to measure the strategy's effectiveness.

The Government Accountability Office, or GAO, also recommended that FDA and USDA collect detailed data on antibiotic use and use this data to evaluate FDA's voluntary strategies, and FDA and USDA agreed. These were not new suggestions.

Similar recommendations were made by GAO both in 1999 and in 2004. ADUFA is the logical existing vehicle that we have right now to collect this information to protect human health. Currently with the authority that FDA has with ADUFA as it stands now, they could, and should, take bolder steps to communicate this drug's sales data.

FDA has now published, as I said, two summaries for public consumption but they really only talk about the total sales by broad drug classifications. So there's at least four enhancements that FDA could make within the existing ADUFA

authority and the information that it requires of sponsors.

First, reporting data, the summary data of quantity of drugs by road of administration, that's allowed under the current law and should be reported annually. In 2011, FDA provided that information for one year's worth of data in response to a direct request from Representative Slaughter from New York.

In that report, it revealed that about 89 percent of the antibiotics were given to feed animals -- food animals and their feed and water. The route of the administrative, we understand that's not a proxy for a reason for administration but it adds a piece of information to the puzzle.

Second, monthly summary sales data could be provided in an annual public report. FDA should publish these data in order to provide animal health scientists, veterinarians, public health officials more useful information on how trends and drug sales might relate to trends in antibiotic resistance, and antibiotic resistance both on the farm or all -- in the farm and bacteria in the meat and in the general human population.

Third, while Pew appreciates that FDA is currently required to protect business confidentiality by grouping classes of drugs manufactured by fewer than three sponsors, FDA could and should divide the not independently reported, or NIRs, category into drugs that are used in human medicine and

not used in human medicine.

Finally, with FDA's existing authority, information supplied by drug manufacturers should be submitted in a format that allows it to be easily merged with data from other FDA databases to allow for a more detailed data examination and analysis.

Then looking forward, FDA should request additional authority from Congress. Some members of Congress have already written to and told FDA that they're willing to work with the agency to actually do that.

FDA could certainly protect public health by seeking additional authority from the 113th Congress that's coming up to expand the mandate of the ADUFA amendments in this next reauthorization.

Specifically, Congress should allow FDA to collect and report the amount of each antibiotic class that's sold over the counter in the amount that's sold only by veterinary prescription or through the Veterinary Feed Directive.

This would help clarify the extent to which veterinarians are currently involved in the administration of drugs to food animals, and the extent to which producers acquire important human drugs by other means.

It would also provide information on how well the Voluntary Industry Guidelines are -- that are intended to curb sales for growth promotions are really working. So it gives

us a chance to verify, as was mentioned before.

Also, the FDA should recommend to Congress that the summary reports indicate the labeled routes of drug administration. This is important sort of given the agency's recognition that the risk to public health is greater when antibiotics are administered to whole flocks or whole herds, rather than to individual animals.

I recognize that these data are not equivalent to actual use data but they can begin to -- once again, they can begin to give us a better picture of what's going on. It would help the agency. It would help the producers. It would help veterinarians spot trends in potential over-alliance on drugs for some purposes.

Finally, FDA should build support in Congress for a system to track antibiotic animal drug usage such that the data can be used and compared to data from other surveillance programs on antibiotic resistance. This would simply follow the advice that the World Health Organization and the World Organization for Animal Health has already given.

Pew appreciates FDA's recognition of the problem of antibiotic resistance and the need for improved knowledge about food animal uses of antibiotics that often contribute to this problem.

However, more steps are needed to make the data that's collected and publicly reported usable and useful to

public and animal health professionals and officials to allow analysis of trends, to determine whether steps that are taken are adequate to reduce drug overuse and misuse and ultimately to look at antibiotic resistance that adversely affects us all. Thank you.

DR. DUNHAM: Thank you very much.

MS. FARMER: We'll now hear from Mr. David Edwards.

by Dr. David Edwards, Director for Animal Biotechnology,

Biotechnology Industry Organization

MR. EDWARDS: Good morning. BIO certainly appreciates the opportunity to comment today at this public forum. It's good to see a lot of public interaction with this process.

My name is Dr. David Edwards and I'm the Director for Animal Biotechnology at the Biotechnology Industry Organization. We represent over 1,100 member organizations that research, develop and produce innovative healthcare, agricultural, industrial and environmental technologies, including many of those reviewed by the U.S. Food and Drug Administration.

Although applications to be reviewed by the FDA are many times for new products, the application of technology to animal agriculture is not something that is new. It has allowed us to more efficiently and sustainably produce food and fiber for a growing population.

Innovations that are brought to the FDA for review by CVM promote public health and wellbeing through the utilization of animals as food, companions and research subjects for human health.

The reauthorization of ADUFA allows the FDA to continue collecting fees and enable the CVM to meet performance standards. These standards lead to more predictable timing for review of applications to CVM, which improves the availability of innovative products for farmers, veterinarians and researchers.

As this is the third time such fees will be authorized, the general principles expressed through ADUFA are sound and BIO appreciates the further improvements that are being made through the currently pending agreement.

The fees under ADUFA should act as an incentive to innovate by providing predictable timelines to get products through the approval process and should not be used as another barrier to the commercialization of these products.

The true goal of regulation should be as a science based process to evaluate safety and efficacy so that products can come to the marketplace efficiently and allowing producers and consumers to then determine their appeal.

BIO supports the science based review system, especially a system that provides predictable timelines. These characteristics allow for the continuation of research

that delivers the needed products that feeds the world growing population and keep it healthy. Interference or any unnecessary delay in the system only serves to stifle outcomes that would otherwise work towards these goals.

Scientists and farmers use a broad array of technologies to achieve a cleaner, safer and healthier food supply. The performance agreements in this ADUFA agreement will help facilitate this process and achieve these worthwhile goals.

Improvements to be realized through this ADUFA agreement will foster an improved review system that is more iterative in nature instead the application system being a black box through which information does not appear to flow.

The communications between a sponsor and CVM will not only lead to a better system but also result in better products for animal health, human health and human nutrition. BIO looks forward to the passage of these improvements to the ADUFA system and appreciates the opportunity to comment.

We will continue to strive for improved tools at BIO, such as applications of these biotechnologies to help heal, fuel and feed the world. Thank you very much.

DR. DUNHAM: Thank you very much.

MS. FARMER: We'll now hear from Ms. Susan Vaughn Grooters.

by Susan Vaughn Grooters, Center for Science and Public Interest

MS. VAUGHN GROOTERS: Good morning. On behalf of the Center for Science and the Public Interest, we appreciate the opportunity to offer comments on the reauthorization of the Animal Drug User Fee Act in the 113th Congress, or ADUFA III.

CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by 900,000 subscribers to its nutrition action health letter, and by foundation grants. CSPI accepts no food industry or government monetary support to carry out our work.

CSPI individually, and as part of the coalition of Keep Antibiotics Working, has worked extensively on the issue of antibiotic resistance stemming from the overuse of antibiotics in food animal production.

CSPI is deeply concerned with the public health implications of the rise of antibiotic resistant pathogens in the food supply and we have taken measures through foodborne illness outbreak analysis to highlight when cases, hospitalizations and deaths occur.

We are in the midst of a public health crisis. Steps taken by FDA to address this critical public health issue must be firm and authoritative. The actions outlined in the draft of December 5 in the Federal Register Notice are far

from sufficient.

Section 105 of the Animal Drug User Fee Act of 2008 required the first ever collection and public reporting of certain data regarding the sales and distribution of approved antimicrobial new animal drugs intended for use in food producing animals.

We commend FDA for seeking public comment on how to improve this data collection and reporting in order to improve monitoring of antibiotic use and the resulting public health threat.

However, we are here today to urge the FDA to pursue much more robust data collection. Public Health Law 110-316 ADUFA II sets out specific procedures that FDA must follow in developing and making its recommendations to Congress.

The procedures require FDA to consult with stakeholders other than regulated industry. ADUFA requires FDA to consult with the following specific groups: scientific and academic experts, veterinarian professionals, representatives of patient and consumer advocacy groups.

In addition, FDA must consider the comments of members of the public. ADUFA requires that FDA take comment from these stakeholders at specific points. First, the FDA has to have public input at the beginning of negotiations with the regulated industry, including a public meeting and through open comment period.

Secondly, FDA must gain insight through stakeholders through periodic consultation during the regulated industry's negotiations. Finally, a public meeting and comment period must be held once the FDA has developed proposed recommendations.

Here we are today. Over a year ago with a meeting commencing on November 7, non-industry stakeholders have repeatedly gone to organizational expenses to travel to the center and provide FDA specific suggestions for enhancements to ADUFA.

Dishearteningly, recommendations by the FDA released after a year's plus consultation include not one of the priorities of consumer stakeholders, and they fail to even acknowledge the considerable suggestions offered to the agency.

In the reauthorization of ADUFA III, we ask that collected fees be directed to postmarketing safety reviews of antimicrobial drugs for which premarket review was not done. We also urge that ADUFA III direct FDA to collect antimicrobial use data from feed mills, thus allowing species level data to be made public.

Finally, we ask that ADUFA III require FDA to provide more detail in public reports related to antimicrobial sales and distribution data collected, as required by ADUFA II.

Capturing and disseminating additional data is essential to measure the trends of antibiotic usage and to determine the effectiveness and impact of the agency's guidances in making certain that usage growth promotion is curbed and not just a shell game of hiding old practices behind new labels.

More granular data is needed. It is impossible for the agency to attempt to reign in usage without having a meaningful baseline and trend analysis on which to build policy.

Given that FDA's collected data on antimicrobial use in food animals was only included after being required to do so by Congress in ADUFA II in the 2010 report, it is not surprising that our previous recommendations are not included in the draft reauthorization request, but it is certainly disappointing.

FDA has chosen to pursue voluntary use for antibiotic use in food producing animals. CSPI remains skeptical of this approach and urges the agency to maintain a rigorous schedule of ensuring cooperation.

Robust data collection and the public dissemination of that data is one key avenue for ensuring that stakeholders are able to access both industry compliance and FDA's performance as a guiding agency behind reform.

Without public access to this information,

stakeholders remain in the dark about any potential progress.
Thank you.

DR. DUNHAM: Thank you.

MS. FARMER: We'll now hear from Dr. Richard
Carnevale.

Remarks by Regulated Industry

by Dr. Richard Carnevale, Vice President,

Animal Health Institute

DR. CARNEVALE: Good morning. I am Dr. Richard Carnevale, Vice President at the Animal Health Institute and I served as chief negotiator from the Animal Health Institute for the ADUFA III negotiations, along with a team of representatives from AHI member companies.

Thanks for the opportunity to comment on this agreement reached between AHI and FDA-CVM. We began negotiations in early March of this year. AHI went into the negotiations on ADUFA III with the goals of securing short-term performance improvements and some long-term program changes while trying to contain the increasing costs of the program by implementing sustainable fee levels.

Recent industry survey data has indicated that overall regulatory costs and time to approval have significantly increased over the last 10 years. While the agency has been dutifully meeting all of the ADUFA timeframes, the number of submitted new animal drug applications has been

declining resulting in a commensurate rapid yearly increase in individual fees for new animal drug applications and supplements.

The industry felt that any substantial increase in costs going forward could be another economic disincentive for companies to invest research dollars to develop new and innovative products that treat diseases in companion and food animals.

The majority of animal health products result in sales magnitudes less than those for human drugs and with virtually no prescription drug insurance to cover those veterinary drug costs.

Considering it can take up to 10 years and \$100 million to get a product approved, significantly increasing user fees only further limits industry interest in pursuing approvals particularly for smaller indications and smaller markets.

The negotiations between AHI and FDA were always professional, but as with most negotiations not without their disagreements. FDA understandably wanted to assure that the necessary resources will be available to meet any new and more demanding performance standards, while the industry wanted to make sure that sponsors are getting value for the fees they are being asked to pay.

After nearly five months of very hard work on both

sides an agreement was reached that both parties could be assured was based on the best available financial and human resource data.

The agency can be confident that the necessary resources would be there, particularly in the out years, while the industry could be assured that the increases in fees will be based on actual costs rather than worse case estimates, and that the review process can continue to be made more efficient.

The new financial agreement differs from the current ADUFA, as Roxanne mentioned, by applying a variable inflation or cost adjustor factor rather than the fixed cost adjustor that was applied for ADUFA II. This will assure FDA operating costs will be accurately calculated based on real time data with salaries, benefits and an adjusted consumer price index for the Washington, D.C. area.

On performance standards, all current timelines on first time sentinel submissions will be maintained. The new performance enhancements will help to shorten review time for second and subsequent submissions leading to faster completion of technical sections, and hopefully more rapid approval of safe and effective new animal drugs.

We were pleased that the agency has agreed to study in cooperation with stakeholder's specific processes that might be changed to enhance product availability such as

conditional approvals for major animal species.

One issue I would like to address that's gotten a lot of attention this morning is the matter of antimicrobial sales and distribution data.

In ADUFA II, AGDUFA I reauthorized in 2008, Congress included a new Section 105 of the Animal Drug User Fee Amendments to the FDNC Act requiring FDA to collect and report on antimicrobial distribution data from animal drug sponsors manufacturing antimicrobials for use in food producing animals.

These data are collected on a yearly basis, and the law specified the specific data that could be collected and reported. During the negotiations on ADUFA III, FDA and AHI did discuss concerns from stakeholders regarding the extent of antibacterial drug use through food producing animals.

FDA expressed a desire to have industry support the soliciting of input from all stakeholders and other government agencies on ways to improve the collection of usage data on, in particular, medically important antibiotics used in food animals.

AHI did state our general support for the further study of this issue so as to put animal antibiotic use into proper context, but we stressed that it should be independent of the ADUFA reauthorization.

The ADUFA agreement includes no new provision for

additional data collection but at about the same time we were concluding the agreement, FDA published the Advanced Notice of Proposed Rulemaking in July requesting stakeholder input on the collection and reporting of antibiotic sales and distribution data, as well as possible new methods for collecting information on actual use of antimicrobials in food animals.

The comment period, which was extended by 60 days, recently closed at the end of November. AHI and most other stakeholders have submitted extensive comments to this ANPR. We believe this is the process that is the most appropriate vehicle for dealing with the issue rather than through this animal drug fee user reauthorization.

Since I have the opportunity to talk about antibiotic use, I'd like to set the record straight on some serious misinformation that is being offered to the public about the ADUFA Section 105 data.

Contrary to what has been stated in at least two blogs I've read recently on the Huffington Post website, animal drug sponsors, for the majority of antibiotics used in food animals, do not know how much of a particular active ingredient is being sold for use in a particular food animal species or for what indication, and therefore does not report such information to FDA.

Antibiotics used in food animals are frequently

approved for multiple animal species and multiple indications. This is particularly the case with those drugs used in feed. Once the product leaves a manufacturer's premises, it may enter numerous distribution channels with actual final use simply not known by the company.

FDA is required to report quantities of active ingredients that have more than three sponsors in order to protect confidential information, as they do with any other data submitted to them by drug sponsors.

However, FDA's own report shows that the bulk of total sales, about 83 percent, are made up of four classes of compounds: tetracyclines, penicillins, macrolides and ionophores.

Ionophores, which amount to about 30 percent of the total, are not used in human medicine, as we know. FDA reports the amounts of the other classes of ingredients so the public knows exactly how much in sales each of these classes represents.

To be honest with you, the bulk of the antibiotic use is tetracyclines, as you can see from looking at the report. So FDA isn't really hiding any data that's been reported to them except for those individual drugs that are manufactured in most cases by a single sponsor.

However, this amounts to less than 20 percent of the total antibiotic sales in food animals and includes some

drugs, as was mentioned by a previous speaker -- one of the previous speakers, that are not used or not important to human medicine.

I also would like to note that AHI has voluntarily been reporting the same kind of antibiotic sales data for eight years prior to the federal collection requirement mandated in ADUFA. So there's really been no secret as to how much of these compounds are being sold and probably used in food animals.

It's also clear that the author of these blogs I mentioned before continue to misuse the information as provided in the FDA reports by quoting that 80 percent of all antibiotics are used in food animals.

They are well aware that FDA has warned about citing this statistic since it's not an accurate reflection of the actual use of antibiotics in animals in comparison to humans for numerous reasons, FDA discussed in a caution document they posted to their website.

So having said that, returning to the specific topic we're talking about today, AHI firmly supports the ADUFA III agreement and looks forward to working with members of Congress and their staff to secure reauthorization of the bill. Thank you for your time.

DR. DUNHAM: Thank you very much.

MS. FARMER: We'll now hear from Dr. Ashley

Peterson.

by Dr. Ashley Peterson, Vice President of Science and Regulatory Affairs,

National Chicken Council

DR. PETERSON: Good morning. My name is Dr. Ashley Peterson, Vice President of Science and Regulatory Affairs for the National Chicken Council. The National Chicken Council is the national non-profit trade association representing producers and processors that produce about 95 percent of the chickens in the United States, as well as a numerous allied members who support the industry.

We appreciate the opportunity to provide comment at today's meeting on ADUFA III. We also echo those comments that have been given by the National Pork Producers Council, the National Cattlemen's Beef Association, BIO and AHI.

Let me start by saying that the National Chicken Council supports science based statistically validated and a technically sound approach to antibiotic usage and data collection. We support a clean reauthorization of the user fee bill.

The National Chicken Council and other livestock trade associations continue to work with FDA's Center for Veterinarian Medicine on how to capture representative usage information, as demonstrated in the comments and cc's submitted to the recent ANPR titled "Antimicrobial Animal Drug Sales and Distribution Reporting."

We believe that CVM should continue to address this issue through the regulatory process so that all stakeholders are provided with the -- whoops. That was not part of my comment.

We believe that CVM should continue to address these issues through the regulatory process so that all stakeholders are provided with the same opportunity to deliver constructive input. Additionally, NCC believes that a common misconception is that the amount of antimicrobials used in livestock is directly correlated to antibiotic resistance patterns observed in human medicine.

As illustrated by the lack of effect on resistance in human *Campylobacter* cases observed after the withdrawal of Enrofloxacin from the poultry industry and Denmark's similar experience, a direct correlation is difficult to demonstrate.

The National Chicken Council also believes that there are a variety of issues and complications with collecting data at feed mills or requiring species-specific sales and distribution data from drug sponsors themselves.

We hope to continue to work with CVM to determine what the questions are that we are trying to answer, and secondly, to develop a logical and sound approach to answering those questions.

Finally, NCC supports the continued scientific research in this important topic area and protecting food

safety and promoting public health, as the chicken industry's number one priority. Thank you.

DR. DUNHAM: Thank you very much.

MS. FARMER: We'll now hear from Dr. Ashley Shelton Morgan.

Remarks by Veterinary Professionals

by Dr. Ashley Shelton Morgan, Assistant Director of Government Relations Division,

American Veterinary Medical Association

DR. MORGAN: Good morning. I am Ashley Morgan, Assistant Director with the American Veterinary Medical Association's Government Relations Division. I'm here on behalf of the AVMA, the largest veterinary medical association in the world.

The association is comprised of 82,500 members, which represents approximately 83 percent of the veterinarians in the United States. These are involved in a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The FDA Center for Veterinary Medicine's procurement of drug sponsor "user fees" and how those user fees are utilized are important to the AVMA and to the wider veterinary profession, considering the need for therapeutics in the myriad species and conditions veterinarians treat.

To help ensure adequate availability of veterinary

drugs, the AVMA supports increased Congressional funding of the FDA Center for Veterinary Medicine for the New Animal Drug Application approval process indexed to keep pace with cost increases.

I am here today to underscore that the AVMA supports user fees for new animal drug applications only if such fees are directed toward the expediting and review and approval process for animal drug products. We emphasize that the funding attained through this program should be targeted solely on the application process.

We also support the utilization of a science based risk-benefit approach that is balanced to ensure that the process for drug approvals is not overly burdensome, so that new drugs can continue to be developed, approved, and made commercially available for use.

The AVMA looks forward to continuing to be a part of discussions related to the re-authorization of ADUFA, particularly any components to the program that would be anticipated to specifically affect veterinary medicine. The AVMA appreciates the opportunity to provide feedback to the FDA today. Thank you.

DR. DUNHAM: Thank you very much.

MS. FARMER: We will now open the floor for remarks from the general public. If you would like to provide comment, please walk to the mike in the center aisle.

Public Comment Period

MR. DODEMAIDE: Good morning. My name is Dr. Robert Dodemaide. I work for Eco Animal Health, which is a British headquartered company with its U.S. office in Princeton, New Jersey.

Firstly, on the approval process, we started to get serious with our new animal drug I guess in 2005 and we got it our first approval in 2011. This was with a new chemical entity which had not been approved for either human or animal medicine prior, so we thought we did that -- we though we achieved that approval in pretty good time, in fact.

I'd like to thank really the CVM for the very professional way that they helped us get through this process. We had some pretty serious disagreements from time to time but on the whole, I think it was very beneficial the way CVM staff contacted us via email, via phone and tried very hard to help us through this process.

There's only four of us in the U.S. and about 30 odd in the U.K., so I think we -- for a very tiny company, I think we did extremely well with this new chemical entity for an antibiotic for use in food animals.

So I would urge CVM to continue the iterative procedures whereby they contact sponsors by telephone, by email in order to get a quick answer to a brief question or a small issue that needs to be resolved quickly.

I really did appreciate the industry's review amendment process, which is going to be changed with ADUFA III, but I thought that was a tremendous idea rather than getting an incomplete letter with another round of submissions and another 180-day review time.

So I think they have been very good improvements and I look forward to seeing ADUFA III implemented. I agree with previous speakers that ADUFA should really be directed towards the approval process rather than collecting post-approval distribution data.

I think there are other mechanisms that FDA has to collect that data. For example, our periodic reviews, which occurs six monthly for the first two years of approval, and then annually we're required to submit marketing data, and then there is a separate form which requires us to identify species indication and usage of the antibiotic in question.

So I think that sort of data is currently being provided to CVM. It's pretty well impossible for us to get down to the farm level because our manufacturing facility supplies drug to a national distributor, who then provides product to regional distributors, then local distributors, then it's used by prescription by an individual farmer.

For us to go through all of those layers of distribution to an individual farm, individual indication level would be impossible for us to do. It would require an

army of support staff, and a company of our size we simply could not afford to do that.

I think that just about concludes my comments so thank you again, Steve. I do appreciate the efforts of your review staff to help us through this process, and I look forward to ADUFA III being implemented.

DR. DUNHAM: Thank you very much. Anybody else?

(No response.)

DR. DUNHAM: I'm not seeing any other hands, so at this time I think I really do want to thank you very much for your critically important feedback as we enter the last stage of our process. Your support of this program is appreciated and necessary, as you are our key stakeholders.

So we at CVM want to extend a very sincere thank you for your coming today and participating in the ADUFA reauthorization public meeting. At this time, we will now close this portion of the program. Thank you very much.

MS. FARMER: Before we adjourn, we would like to remind you that there is still an open comment period if you would like to submit comments in writing or electronically. Thank you.

(Whereupon the meeting was adjourned at 10:34 a.m.)