

FDA Roundtable on Consumer Protection

Comments of Richard R. Wood, Executive Director
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I thank you for this opportunity to respond to Dr. Sundlof's presentation. I am Richard Wood, the Executive Director of Food Animal Concerns Trust or FACT. FACT advocates for farm management systems that promote the safety of meat milk and eggs. We currently have about 30,000 individual supporters nationwide. We also sponsor a demonstration egg farming system on 12 farms in Pennsylvania, with a Salmonella enteritidis control program on our farms since 1991, and we are now working with hog farmers in the Midwest. FACT has been involved in many of the CVM activities over the years. I will comment on two areas at the Center – its work related to antibiotic resistance and BSE.

We applaud the Center for Veterinary Medicine for making antimicrobial resistance its top priority. In our view a benchmark for giving this concern greater priority for CVM came in a Guidance Document that has not received much attention in itself, but signaled a significant turning point in terms of CVM's relationship to public health. Guidance Document 78 was finalized one year ago today. It acknowledges that the use of antimicrobial drugs in food animals selects for resistant bacteria, that if transferred to humans can have an adverse effect on human health. The Guidance Document requires that applications for new antibiotics intended for food animals must assess the potential human health impacts of the drug. This requirement in itself is a consumer protection action.

The most recent and best example of CVM action in behalf of public health is illustrated in its proposal to ban fluoroquinolones from use with poultry in light of recent sharp increases in resistance to fluoroquinolones in *Campylobacter* bacteria. *Campylobacter* is the most common cause of gastrointestinal illness acquired through food in the United States. Physicians have used fluoroquinolones as an essential treatment for foodborne disease since 1986, but fluoroquinolone resistant bacteria were rare until after 1995, when FDA approved the use of these drugs in drinking water for poultry. By 1998, the CDC found that over 13% of the foodborne *Campylobacter* bacteria infecting people were resistant to fluoroquinolones. Last year resistance rose to nearly 18%, an increase linked to fluoroquinolone use in poultry.

On behalf of a consortium of consumer and public health groups, I thank Dr. Sundlof, the Center for Veterinary Medicine and the FDA for initiating the notice. We now call on the FDA for speedy action in implementing its ban. The "proof of this pudding" lies in the FDA's timely Summary Judgement.

Other CVM examples of implementing the Guidance Document 78 are more difficult to identify from a consumer and public health perspective. The Framework Document was introduced soon after the Guidance Document was drafted. The Framework, if adopted by the Agency, can be a useful tool for future approvals. It would also provide the context around which consumers and other stakeholders could review and respond to FDA antimicrobial decisions, using the same set of assumptions and criteria employed by the Agency.

Unfortunately this Framework is still not in place.

Hopefully the January meeting on thresholds will bring us closer to its implementation in some form.

Now moving to the other end of the spectrum, in our view the most glaring failure of the Center for Veterinary Medicine to protect human health is in allowing the continued use of non-therapeutic antibiotics in food animals. We trust that the virginiamycin risk assessment is a first step in addressing this issue. And yet we are still waiting for a response to a petition filed on March 3, 1999 by consumer and public health groups, and by leading physicians. The petition requests that the Commissioner rescind approvals for subtherapeutic antibiotic uses in livestock that impacts human therapies. Lead sponsors from consumer groups are the Center for Science in the Public Interest, Environmental Defense, Public Citizen's Health Research Group, Union of Concerned Scientists, and FACT. Many of these same groups supported the \$3 million dollars appropriated to CVM its FY 2001 antibiotic resistance work. FACT was pleased to learn that the Center apparently intends to use these funds to target several approved animal drugs for a safety review, followed by possible withdrawal from the market.

There is no question about the FDA's authority to withdraw a drug from the market. But if CVM needs a "framework" for action on its prior approvals of non-therapeutic antibiotics, we encourage FDA's support of legislation similar to that introduced in the last session of Congress by Sherrod Brown. This legislation directs that essential antibiotic drugs are not to be used in livestock unless there is a reasonable certainty of no harm to human health (Guidance Document 78). The legislation clearly provides FDA with the statutory authority to act, and gives both the FDA and the industry a time-line for such a review.

Finally, we call for the public disclosure of antibiotic sales information. Health officials have indicated that a major obstacle in assessing the link between animal drug use and rising resistance is the lack of data on how extensively antibiotics are used in food production. One has to only look at the debate around fluoroquinolones and poultry, where on the one hand health officials are finding resistant *Campylobacter* in broilers at the supermarkets, and yet the poultry industry is saying they are not using the drug all that extensively. How much Baytril is being used on poultry farms? How many doses are being administered per hen? Regarding subtherapeutic drugs, licensed feed mills report the pounds of feed sold, but how much active ingredient is in the feed? It is time for the industry to stop playing shell games when it comes to their food animal use of antibiotics impacting human health. CVM must require the reporting of specific sales data that should also be made available to the health community and to the public.

The public has at least two important functions when it comes to defining how antibiotics are to be used with animals. First, consumer representatives should be at the table along with the scientists and other stakeholders to define the criteria by which an antibiotic is approved. For example, should resistance testing be a part of the approval process? What kinds of provisions are in place if resistance were to occur? Second, consumer representatives should be at the table to help identify the threshold for antibiotic resistance. At what point of resistance is an antibiotic to be considered a threat to public health?

FACT is also concerned about any steps taken to “expedite” the animal drug approval process. Once a drug is approved it is rarely removed from the marketplace by FDA action, and that process can take years to accomplish. The approval process must not be truncated for expediency’s sake. Both animal and public health may suffer in the long run and it may lead to unhealthy animals producing unwholesome food.

I have been at FACT since 1995. In these few years I have heard CVM officials on two occasions lift up a concern of great importance to consumers as “CVM’s top priority.” Today we heard that antibiotic resistance is CVM’s top priority, and as I have stated, FACT welcomes this emphasis. The other recent occasion for CVM setting a top priority, followed the adoption of the rule to prevent the occurrence of BSE (Bovine Spongiform Encephalopathy) in U. S. cattle. At that time the Center vowed to implement an intensive inspection process of feed mills and rendering plants. Many steps have been taken by CVM in that regard. Most notably I understand that over 9,000 inspections of feed mills, cattle producers and renderers have been completed over the last couple of years. I remember taking part in a teleconference designed to train feed-mill operators in this regulation. But a recent GAO study has found that more needs to be done.

The GAO reported that in these inspections, the FDA found over 18% of the firms surveyed, were not aware of the regulation that was adopted in 1997, including 11% of the renderers. (So much for the teleconference.) 28% of all those surveyed did not label their products with the required cautionary statements that the feed should not be fed to ruminants. 20% of the firms did not have a system in place to prevent co-mingling of ruminant feed materials.

Further enforcement steps must be taken by CVM as soon as possible. It is time to move beyond education and warning letters to enforcement actions. I understand that a rule addressing animal feed is being drafted, but there is no time-line for it being published or even discussed with stakeholders.

At the same time, the science around BSE continues to emerge. Careful attention needs to be paid to the 8 new BSE cases in Britain, where the spread of the disease may possibly be linked to cow blood in cattle feed, a protein source that is allowed in feed for U.S. ruminants.

In conclusion, we will soon see a change in the Administration. Significant building blocks to protect public health have been put into place over the last few years by CVM. The next Administration must cement those blocks together so that CVM can fully respond to both animal and human health. As these steps take place, it is our hope that consumers are involved in the building process all along the way. In our view, the greater the involvement, the better the final structure. Thank you.